Reliability Report 2023

In accordance with the European and International Consensus on Cochlear Implant Failures and Explantations, and the ANSI/AAMI CI86 Standard

September 2023

oticon MEDICAL

About Oticon Medical

Oticon Medical offers cochlear implant solutions and bone anchored hearing systems for different patient groups with hearing loss. All of our solutions are specialized to meet the needs of those who face the hardest hearing challenges.

The choice to have a cochlear implant is a choice for life, which is why the reliability of the CI system you choose is of the utmost importance.

The report presents the reliability data for the Neuro Zti implant and the Neuro 2 Sound Processor, key components of the Neuro System from Oticon Medical.

The Neuro CI System is registered in more than 60 countries including the US, where FDA approval was obtained in 2021.

Cedric Briand

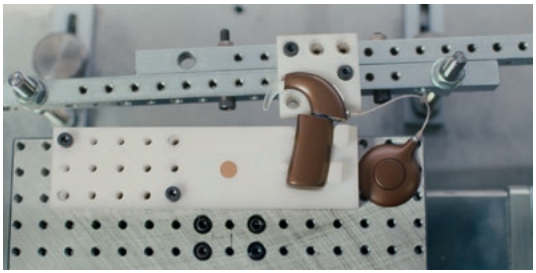
General Manager

Numerous tests performed to ensure high reliability

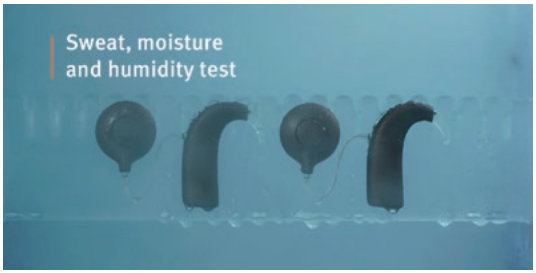
Cochlear implants help thousands of people worldwide, every day of every year. Every CI user needs to be able to rely on their device's performance, no matter what situation or environment they find themselves in products live up to the highest quality standards, in compliance with hundreds of international requirements.

To simulate patient's active lives, cochlear implants systems undergo hundreds of different tests. These tests include shock resistance, bending, stretching, exposure to extreme temperature and humidity conditions. These tests are performed thousands of times on the implant and the sound processor and also on all accessories and spare parts. For instance, one of these tests evaluates the number of times the battery compartment of the sound processor can be removed and replaced and still remain safe and usable. The requirements state the device must support it over 6,000 times.

Implant impact test



Sound processor battery compartment test – 6,000 cycles



Sound processor sweat, moisture and humidity test

How this report has been made

All cochlear implant manufacturers are required to report any implant or sound processor failures no matter where in the world they are.

This report is compliant with the reporting methodologies, procedures and guidelines recommended by the following standards and publications, which represent the state of the art when reporting the reliability of cochlear implants :

- International Standard : ISO 5841-2 Implants for Surgery — Cardiac Pacemakers — Part 2: Reporting of Clinical Performance of Populations of Pulse Generators or Leads. International Organization for Standardization (2000/2014) [1].
- European Consensus Statement on Cochlear Implant Failures and Explantations [Editorial]. Otology & Neurotology, Vol. 26, No. 6:1097–1099 © 2005, Otology & Neurotology, Inc. [2]
- International Classification of Reliability for Implanted Cochlear Implant Receiver Stimulators. Otology & Neurotology, Vol. 31, No. 8: 1190-1193 © 2010, Otology & Neurotology, Inc. [3]
- American National Standard : ANSI/AAMI CI86:2017. Cochlear Implant Systems: Requirements for Safety, Functional Verification, Labeling and Reliability Reporting. American National Standards Institute. [4]

Firstly, Part 1 of this report will present reliability data in accordance with the principles described in the European Consensus Statement on Cochlear Implant Failures and Explantations and in the International Classification of Reliability for Implanted Cochlear Implant Receiver Stimulators.

Then, Part 2 of this report will show reliability data in accordance with the guidelines outlined in the ANSI/AAMI CI86:2017 standard.

It should be noted that both the ANSI/AAMI CI86:2017 and the publications in Otology & Neurotology from the European and International Consensus Groups refer to principles adapted from the ISO standard 5841-2, originally designed for reporting reliability of cardiac pacemakers, pulse generators, or leads.

Reliability Part 1:

European and International consensus framework

Neuro Zti

96.83%

Average CSP after 8 years

Including accident-related issues
combining EVO and Classic

Neuro 2

0.7% FCRR

Average FCRR over 24 months

Implant reliability

Introduction

In accordance with the European and International Consensus on Cochlear Implant Failures and Explantations, the approach recommended to report clinically relevant reliability data is the Cumulative Survival Percentage (CSP), which is presented in the following page.

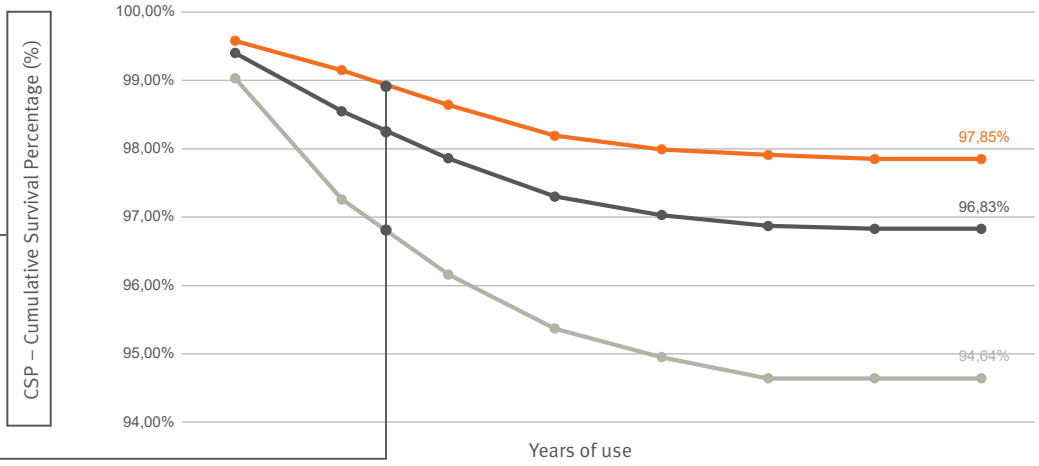
How to read this report

CSP – Cumulative Survival Percentage

Cumulative percentage of functioning devices over a given period of time after implantation*

95% confidence interval

The CSP curves report the 95% confidence interval to indicate the statistics' accuracy as required by the European and International Consensus on Cochlear Implant Failures and Explantations



	1 year	2 years	3 years	4 years	5 years	6 years	7 years	8 years	CI
Combined adults & children	99,40%	98,55%	97,86%	97,30%	97,03%	96,87%	96,83%	96,83%	0,74
Adults (+18y)	99.58%	99,15%	98,64%	98,19%	97,99%	97,91%	97,85%	97,85%	0,52
Children (-18y)	99,03%	97,26%	96,16%	95,37%	94,95%	94,64%	94,64%	94,64%	1,24

Curves

3 CSP curves are reported – one for adults, one for children (below 18 years old) and one combined – all including accident-related issues.

Detailed CSP

Detailed CSP are given for each year after implantation

**Device survival time begins with closure of the wound.*

Neuro Zti implant

It has the smallest surgical footprint[5] thanks to its unique rigid structure[5] made of zirconia and titanium. This enables it to absorb the high impacts encountered in daily life.

Neuro Zti also features a unique screw fixation system[5] that aims at making the implant stable without the need for bone bed drilling, saving precious time in the operating room[5].

Thanks to the unique loudness coding in duration and the OM pulse shape, the focused stimulation strategy has been developed to deliver precise stimulation and clear sound in a way that respects the natural physiology of the auditory system.

In addition, Neuro Zti has received the CE mark for extended MRI compatibility*. Thanks to a unique combination of an innovative magnet and a unique fixation system, the Neuro Zti MRI 3T is able to withstand MRI scans up to 3T with the magnet in place.

On October 14th, 2021, Oticon Medical voluntarily withdrew non-implanted Neuro Zti CI implants from circulation due to the identification of a number of devices exhibiting a loss of hermeticity. The issue was attributed to a limited number of devices from specific batches. Customers and regulators have been notified about this Voluntary Field Corrective Action (VFCA #211014) on 14-Oct-2021.

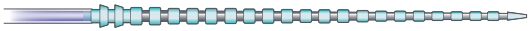
The root cause of this hermeticity issue was identified and corrective and preventive actions have been implemented. The Neuro Zti implant was cleared for re-entry to market by regulatory authorities in May 2022. Reliability data are presented separately for non-VFCA and VFCA device populations, providing the healthcare community with clinically relevant, patient-specific device performance.

**Subject to local availability according to local regulatory standards*

Electrode arrays

The Neuro Zti cochlear implant features two kinds of electrode arrays – Classic and EVO – both composed of 20 platinum iridium full-band electrodes.

The CLASSIC electrode array has a stiff profile proving greater insertion forces to support some compromised cochlear patency insertions.



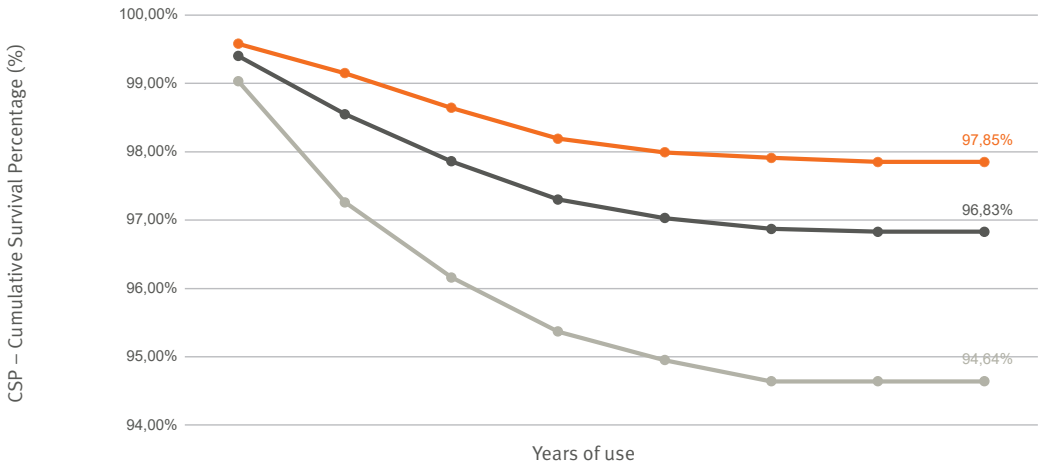
Neuro Zti CLA

The EVO electrode array has been designed for soft surgery[6,7] and is mainly used for normal cochleas insertions, also when surgeons want to preserve fragile cochlea's structure, and reduce the risk of trauma.[6,7,8]

Neuro Zti EVO

Neuro Zti – Classic & EVO (VFCA excluded)

The following tables and chart display reliability data for all implanted Neuro Zti, excluding the batches impacted by the Voluntary Field Corrective Action (VFCA).



	1 year	2 years	3 years	4 years	5 years	6 years	7 years	8 years	CI
Combined adults & children	99,40%	98,55%	97,86%	97,30%	97,03%	96,87%	96,83%	96,83%	0,74
Adults (+18y)	99.58%	99,15%	98,64%	98,19%	97,99%	97,91%	97,85%	97,85%	0,52
Children (-18y)	99,03%	97,26%	96,16%	95,37%	94,95%	94,64%	94,64%	94,64%	1,24

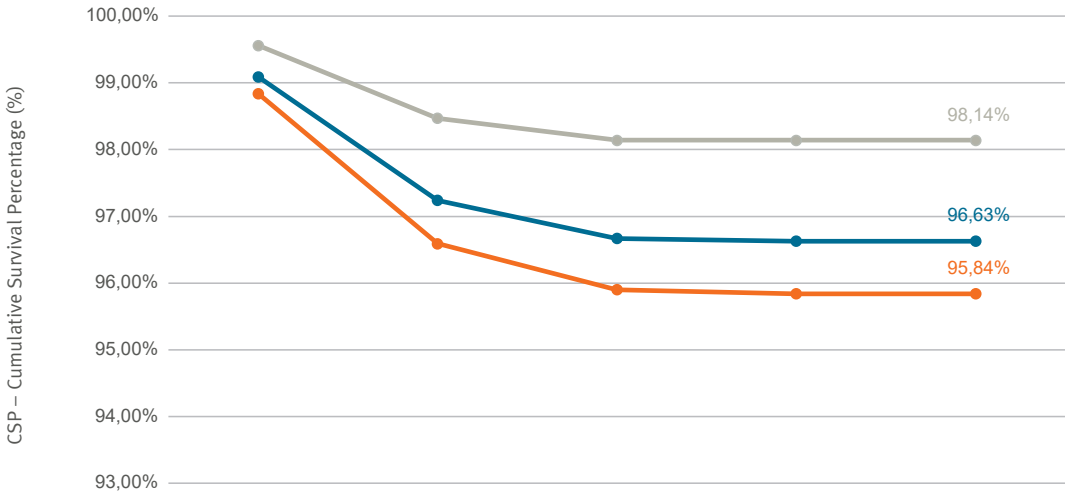
2015
First implantation
96.83%

Including accident-related issues

Data as of June 30th 2023

Neuro Zti – Classic & EVO (VFCA only)

The following tables and chart display reliability data ONLY for implanted Neuro Zti impacted by the Voluntary Field Corrective Action (VFCA).



	1 year	2 years	3 years	4 years	5 years	CI
Combined adults & children	99,09%	97,24%	96,67%	96,63%	96,63%	1,18
Adults (+18y)	98,84%	96.59%	95,90%	95,84%	95,84%	1,43
Children (-18y)	99,56%	98,47%	98,14%	98,14%	98,14%	0,68

2015

First implantation

96.63%

Including accident-related issues

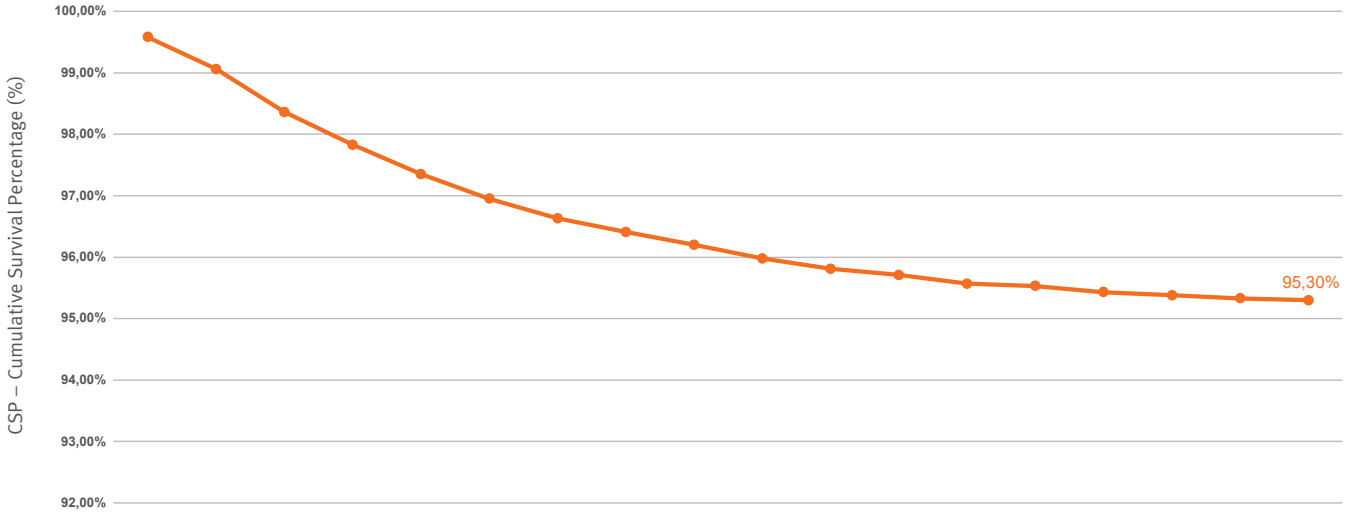
Data as of June 30th 2023

Digisonic SP implant

In 2005, the Digisonic® SP implant revolutionized the cochlear implant market thanks to its unique monobloc design with the magnet and the receiver in a single unit. The implant's structure, combined with an exclusive screw fixation system, removes the need to drill a bone bed during surgery.

The Digisonic SP range has been discontinued in 2020. In accordance with the European consensus, Oticon Medical keeps on reporting its reliability over time.

Digisonic SP



	1 year	2 years	3 years	4 years	5 years	6 years	7 years	8 years	9 years	10 years	11 years	12 years	13 years	14 years	15 years	16 years	17 years	18 years
Combined adults & children	99,58%	99,06%	98,36%	97,83%	97,35%	96,95%	96,63%	96,41%	96,20%	95,98%	95,81%	95,71%	95,57%	95,53%	95,43%	95,38%	95,33%	95,30%

2006
First implantation
95.30%

Including accident-related issues

Data as of June 30th 2023

Sound processor reliability

Introduction

As for sound processors, we calculate the Failed Component Return Rate (FCRR) to describe their reliability, in accordance with the ANSI/AAMI CI86 standard. The manufacturer tests sound processors that have been returned to determine if they are working and, if not, why they failed.

I started noticing some sounds straight away. At first it was the sound of drawers being closed and cars in the street, then I started being able to hear the sound of my children's voices."

Mette, Denmark, cochlear implant user

How to read the sound processor data

Failed Component Return Rate (FCRR): percentage of the total number of original non-implantable components sold which are returned as failed devices each month.

Electronic failure

A functional failure of the electronics or the electronic assembly.

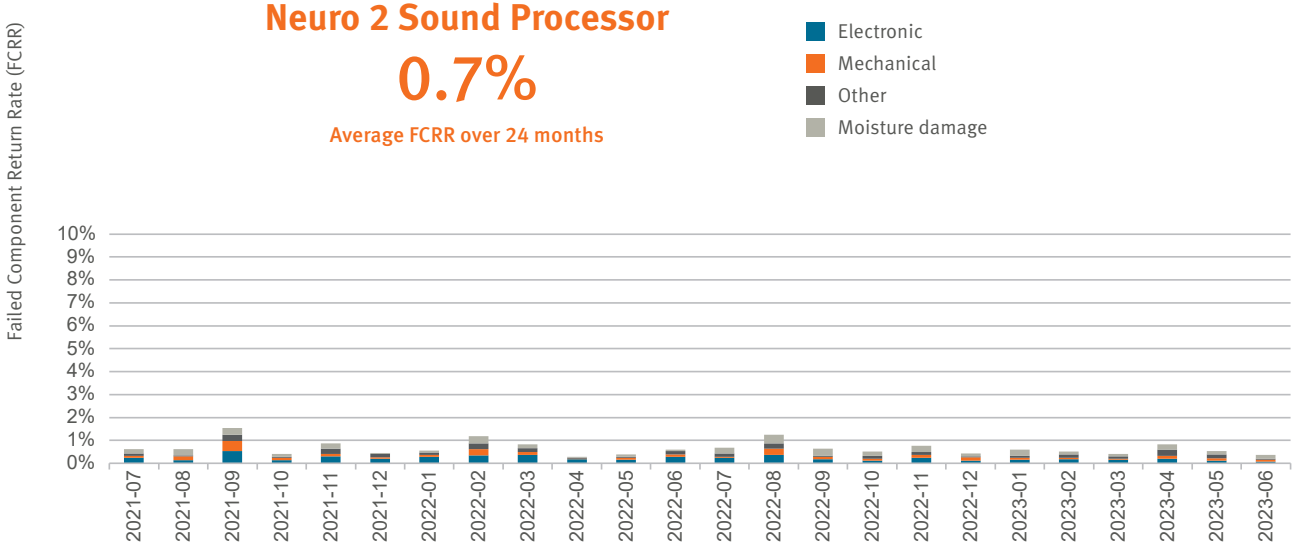
Other/unknown failure

Failures that don't fit in the other categories (e.g. firmware failures).

Neuro 2 Sound Processor

0.7%

Average FCRR over 24 months



Mechanical failure

A functional failure resulting from physical damage caused by mechanical stress, chemical exposure, or ultraviolet (UV) exposure that is a result of normal use.

Moisture damage failure

A functional failure that is a result of moisture ingress. This category excludes corrosion and other similar damage unless it results in a functional failure.

The Neuro 2 sound processor was commercialized in 2018. It is sweeping up prizes in the cochlear implant industry due to its groundbreaking design.

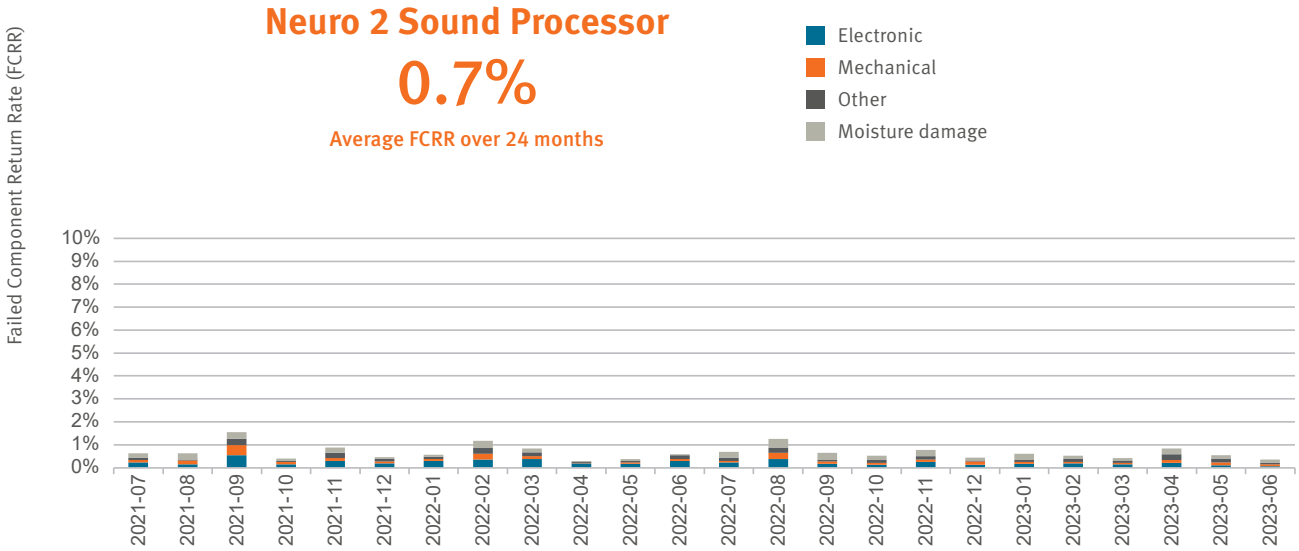
All cochlear implant systems can help users understand speech in quiet conditions. It's the noisy environments that remain the biggest challenge. Built on the Inium Sense chip platform from Oticon, the Neuro 2 sound processor features key technologies that capture sound details, efficiently remove noise and are clinically proven to improve speech understanding in noisy conditions.[9, 10]

Neuro 2 Sound Processor

Neuro 2 Sound Processor – Failed Component Return Rate

Fail Mode	July 21	Aug 21	Sep 21	Oct 21	Nov 21	Dec 21	Jan 22	Feb 22	Mar 22	Apr 22	May 22	Jun 22
Electronic	0.2%	0.1%	0.5%	0.2%	0.3%	0.2%	0.3%	0.4%	0.4%	0.2%	0.2%	0.3%
Fault Free*	0.2%	0.1%	0.4%	0.1%	0.3%	0.3%	0.3%	0.4%	0.4%	0.1%	0.1%	0.2%
Mechanical	0.1%	0.2%	0.4%	0.1%	0.1%	0.1%	0.1%	0.3%	0.1%	0.0%	0.1%	0.1%
Moisture damage	0.2%	0.3%	0.3%	0.1%	0.2%	0.1%	0.1%	0.3%	0.2%	0.0%	0.1%	0.0%
Other	0.1%	0.0%	0.3%	0.0%	0.2%	0.1%	0.1%	0.3%	0.2%	0.0%	0.1%	0.2%

Fail Mode	July 22	Aug 22	Sep 22	Oct 22	Nov 22	Dec 22	Jan 23	Feb 23	Mar 23	Apr 23	May 23	Jun 23
Electronic	0.2%	0.4%	0.2%	0.1%	0.2%	0.1%	0.2%	0.2%	0.2%	0.2%	0.1%	0.1%
Fault Free*	0.3%	0.4%	0.2%	0.2%	0.3%	0.3%	0.3%	0.3%	0.1%	0.2%	0.3%	0.2%
Mechanical	0.1%	0.3%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.0%	0.1%	0.1%	0.1%
Moisture damage	0.3%	0.4%	0.3%	0.2%	0.3%	0.1%	0.3%	0.1%	0.1%	0.2%	0.1%	0.2%
Other	0.1%	0.2%	0.1%	0.1%	0.1%	0.0%	0.1%	0.2%	0.1%	0.3%	0.2%	0.1%



** Fault-free fail mode is a returned device that is found to be fully functional. The device condition might reflect normal wear and tear, such as minor mechanical damage (including scratches, cracks, and discoloration), corrosion, and/or moisture damage that did not result in a functional failure.*

References

1. International Standard : ISO 5841-2 Implants for Surgery — Cardiac Pacemakers — Part 2: Reporting of Clinical Performance of Populations of Pulse Generators or Leads. International Organization for Standardization (2000/2014).
2. European Consensus Statement on Cochlear Implant Failures and Explantations [Editorial]. Otology & Neurotology, Vol. 26, No. 6:1097–1099 © 2005, Otology & Neurotology, Inc.
3. International Classification of Reliability for Implanted Cochlear Implant Receiver Stimulators. Otology & Neurotology, Vol. 31, No. 8: 1190-1193 © 2010, Otology & Neurotology, Inc.
4. American National Standard : ANSI/AAMI CI86:2017. Cochlear Implant Systems: Requirements for Safety, Functional Verification, Labeling and Reliability Reporting. American National Standards Institute.
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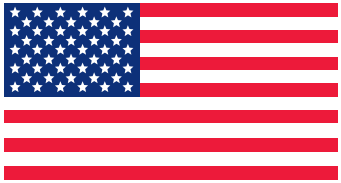
7. Martins et al., Evaluation of intracochlear trauma caused by insertion of cochlear implant electrode arrays through different quadrants of the round window, Biomed Res Int, 2015.
8. Wanna GB, O'Connell BP, Francis DO, Gifford RH, Hunter JB, Holder JT, Bennett ML, Rivas A, Labadie RF, Haynes DS., Predictive factors for short- and long-term hearing preservation in cochlear implantation with conventional-length electrodes. Laryngoscope. 2017 Jun 22. doi: 10.1002/lary.26714. [Epub ahead of print].
9. Segovia-Martinez M, Gnansia D & Hoen M. (2016). Coordinated Adaptive Processing in the Neuro Cochlear Implant System. Oticon Medical White Paper (M80293)
10. Langner F, Gnansia D, Hoen M, Büchner A, & Nogueira W (2017). Effect of dynamic range in different stages of signal processing in Cochlear Implant listeners on speech. ENT World Congress, IFOS 2017, June 24-28th, Paris, France.

I'm much more relaxed now during conversations since I got my Neuro CI. I simply get much more out of it without the extra effort"

Kim, Denmark, cochlear implant user

Part 2 Reliability:

ANSI/AAMI CI86:2017 standard



Neuro Zti

3.17%

Average CRP after 8 years

Neuro 2

0.7% FCRR

Average FCRR over 24 months

Implant reliability

Introduction

In accordance with the ANSI/AAMI CI86 – Cochlear implant systems: Requirements for safety, functional verification, labeling and reliability reporting.

The guidelines approved in 2017 through this standard require manufacturers to provide information to the public about the percentage of implanted devices that have been removed following implantation. This number is the cumulative removal percentage (CRP). It is important to track device reliability information over time because cochlear implants typically remain implanted for years. It is also important to track the reasons for removal when devices are replaced.

How to read the implant data

Medical reason

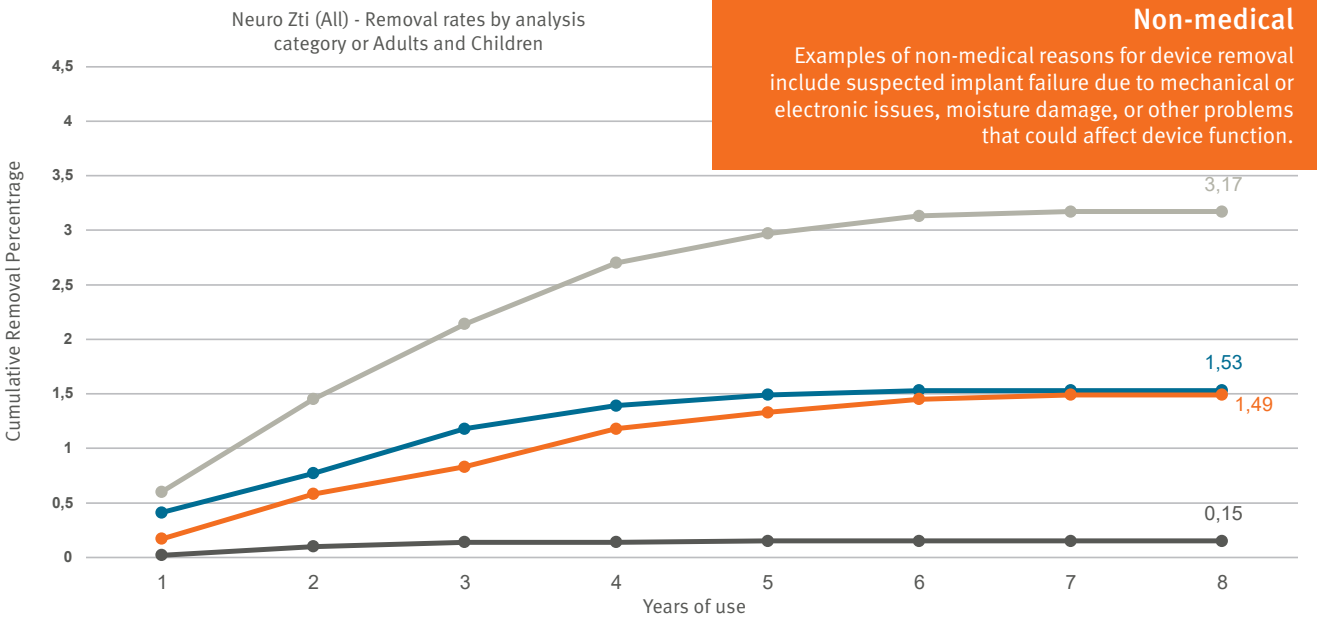
Examples of medical reasons for device removal include infection, rejection of the device due to allergy, or improper positioning of the internal device.

Inconclusive reason

Occasionally, manufacturer testing of the device indicates no fault found with the device, despite a reason for removal.

Non-medical

Examples of non-medical reasons for device removal include suspected implant failure due to mechanical or electronic issues, moisture damage, or other problems that could affect device function.



	1 year	2 years	3 years	4 years	5 years	6 years	7 years	8 years
Medical related	0,41%	0.77%	1.18%	1.39%	1.49%	1.53%	1.53%	1.53%
Device failure	0,17%	0.58%	0.83%	1.18%	1.33%	1.45%	1.49%	1.49%
Inconclusive	0.02%	0.10%	0.14%	0.14%	0.15%	0.15%	0.15%	0.15%
All categories	0.60%	1.45%	2.14%	2.70%	2.97%	3.13%	3.17%	3.17%

CRP – Cumulative Removal Percentage

Percentage of the total number of removed devices compared to the total number of implanted devices of the same model.

Age-related CRP

3 CRP data are reported – one for adults, one for children (below 10 years old) and one combined. Age-related differences may affect the CRP. Typically, children younger than 10 years of age have a higher chance of activity-related damage to the device.

Note: data and graphs on this page are for example only.

Neuro Zti implant

The Neuro Zti cochlear implant commercialized in 2015 is the result of more than 25 years' experience in cochlear implant development, manufacturing know-how and material science expertise.

Reliability data are presented separately for non-VFCA and VFCA device populations, providing the healthcare community with clinically relevant, patient-specific device performance.

Neuro Zti implant (VFCA excluded)

The following tables and chart display reliability data for all implanted Neuro Zti, excluding the batches impacted by the Voluntary Field Corrective Action (VFCA).

Group	Adults			
Subcategory	Medical related	Device failure	Inconclusive	Total
Years	CRP	CRP	CRP	CRP
Y1	0.28	0.11	0.03	0.42
Y2	0.51	0.31	0.03	0.85
Y3	0.88	0.42	0.06	1.36
Y4	1.13	0.62	0.06	1.81
Y5	1.22	0.71	0.08	2.01
Y6	1.22	0.79	0.08	2.09
Y7	1.22	0.85	0.08	2.15
Y8	1.22	0.85	0.08	2.15
[CI_low ; CI_up]	[0.98 ; 1.46]	[0.67 ; 1.03]	[0.07 ; 0.10]	[1.63 ; 2.67]

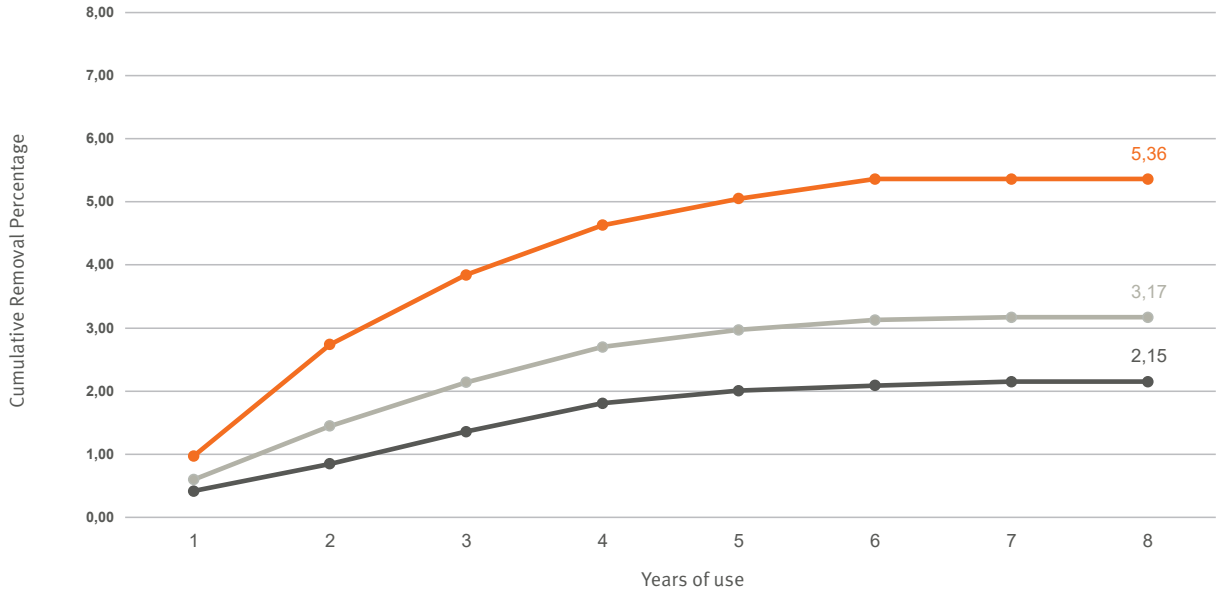
Group	Children			
Subcategory	Medical related	Device failure	Inconclusive	Total
Years	CRP	CRP	CRP	CRP
Y1	0.67	0.30	0.00	0.97
Y2	1.34	1.16	0.24	2.74
Y3	1.83	1.71	0.30	3.84
Y4	1.95	2.38	0.30	4.63
Y5	2.07	2.68	0.30	5.05
Y6	2.19	2.86	0.30	5.36
Y7	2.19	2.86	0.30	5.36
Y8	2.19	2.86	0.30	5.36
[CI_low ; CI_up]	[1.84 ; 2.54]	[2.24 ; 3.48]	[0.22 ; 0.39]	[4.12 ; 6.60]

Group	Combined Adults and Children			
Subcategory	Medical related	Device failure	Inconclusive	Total
Years	CRP	CRP	CRP	CRP
Y1	0.41	0.17	0.02	0.60
Y2	0.77	0.58	0.10	1.45
Y3	1.18	0.83	0.14	2.14
Y4	1.39	1.18	0.14	2.70
Y5	1.49	1.33	0.15	2.97
Y6	1.53	1.45	0.15	3.13
Y7	1.53	1.49	0.15	3.17
Y8	1.53	1.49	0.15	3.17
[CI_low ; CI_up]	[1.25 ; 1.80]	[1.17 ; 1.80]	[0.12 ; 0.19]	[2.42 ; 3.91]

Note: CI_up and CI_down are 95% Confidence Limits.

Neuro Zti implant (VFCA excluded)

Neuro Zti removal rates for all analysis categories and patient populations

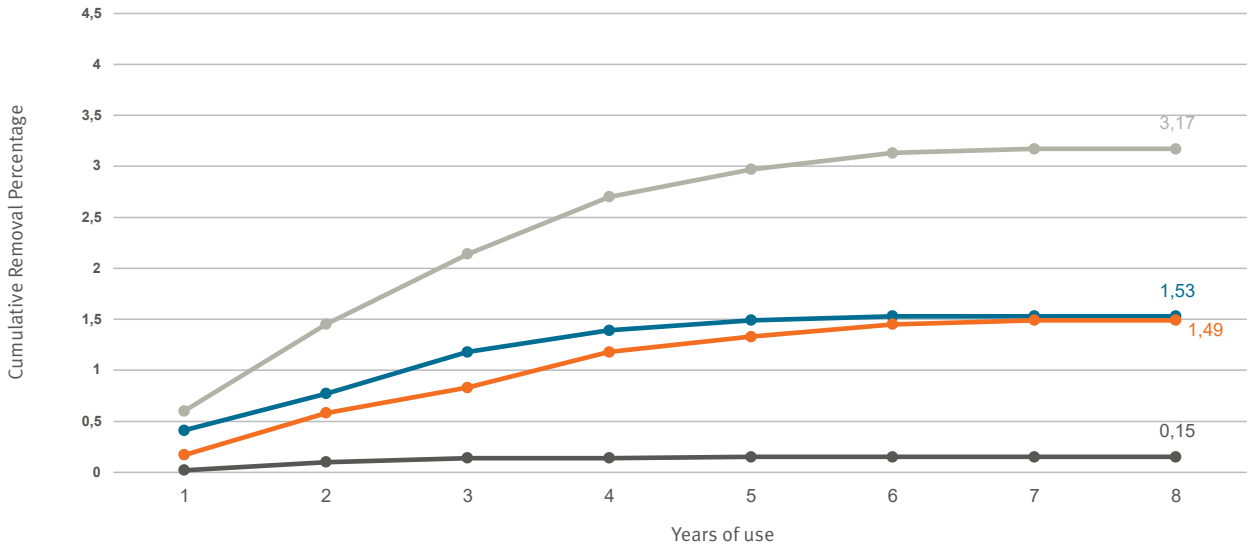


	1 year	2 years	3 years	4 years	5 years	6 years	7 years	8 years
Combined adults & children	0.60%	1.45%	2.14%	2.70%	2.97%	3.13%	3.17%	3.17%
Adults (≥10y)	0.42%	0.85%	1.36%	1.81%	2.01%	2.09%	2.15%	2.15%
Children (<10y)	0.97%	2.74%	3.84%	4.63%	5.05%	5.36%	5.36%	5.36%

data as of June 30th 2023

Neuro Zti implant (VFCA excluded)

Neuro Zti removal rates by analysis category for adults and children



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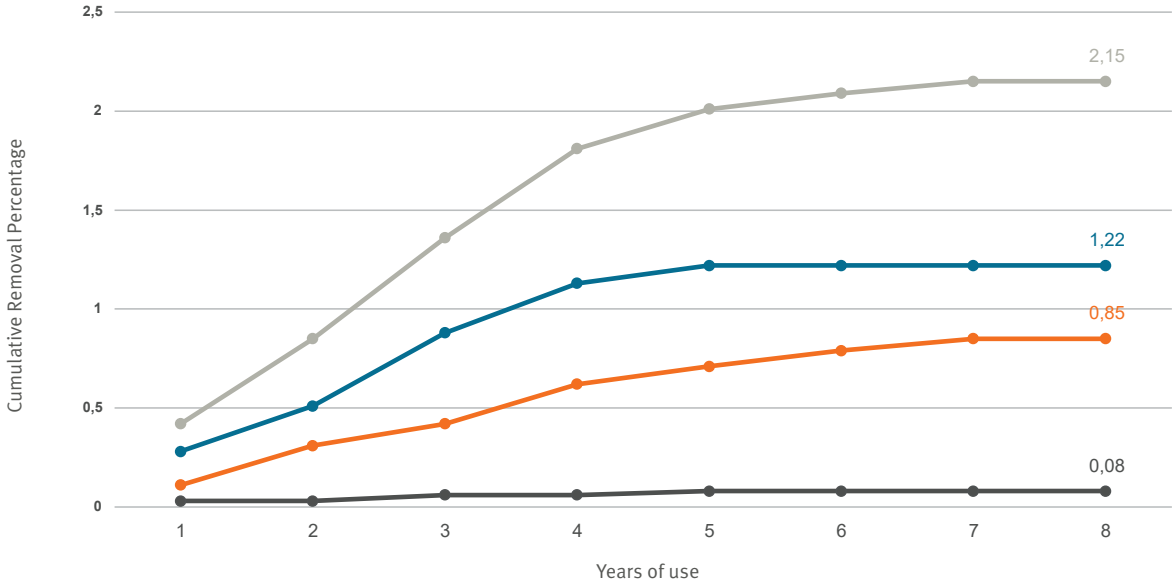
Medical related	0.41%	0.77%	1.18%	1.39%	1.49%	1.53%	1.53%	1.53%
Device failure	0.17%	0.58%	0.83%	1.18%	1.33%	1.45%	1.49%	1.49%
Inconclusive	0.02%	0.10%	0.14%	0.14%	0.15%	0.15%	0.15%	0.15%
All categories	0.60%	1.45%	2.14%	2.70%	2.97%	3.13%	3.17%	3.17%

data as of June 30th 2023

Neuro Zti implant (VFCA excluded)

Neuro Zti removal rates by analysis category for adults

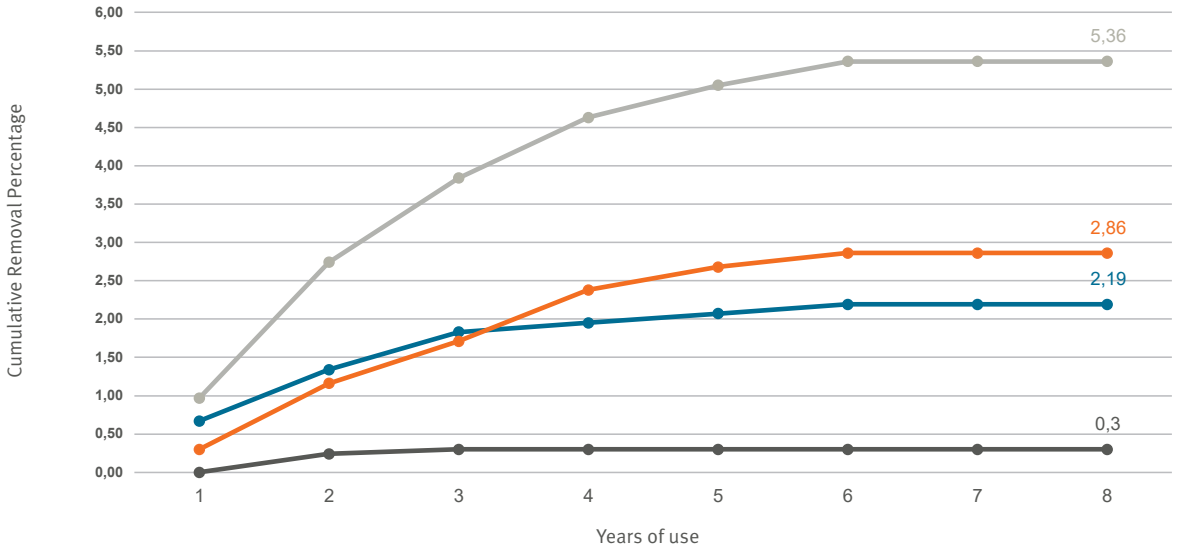


	1 year	2 years	3 years	4 years	5 years	6 years	7 years	8 years
Medical related	0.28%	0.51%	0.88%	1.13%	1.22%	1.22%	1.22%	1.22%
Device failure	0.11%	0.31%	0.42%	0.62%	0.71%	0.79%	0.85%	0.85%
Inconclusive	0.03%	0.03%	0.06%	0.06%	0.08%	0.08%	0.08%	0.08%
All categories	0.42%	0.85%	1.36%	1.81%	2.01%	2.09%	2.15%	2.15%

data as of June 30th 2023

Neuro Zti implant (VFCA excluded)

Neuro Zti removal rates by analysis category for children (<10 years old)



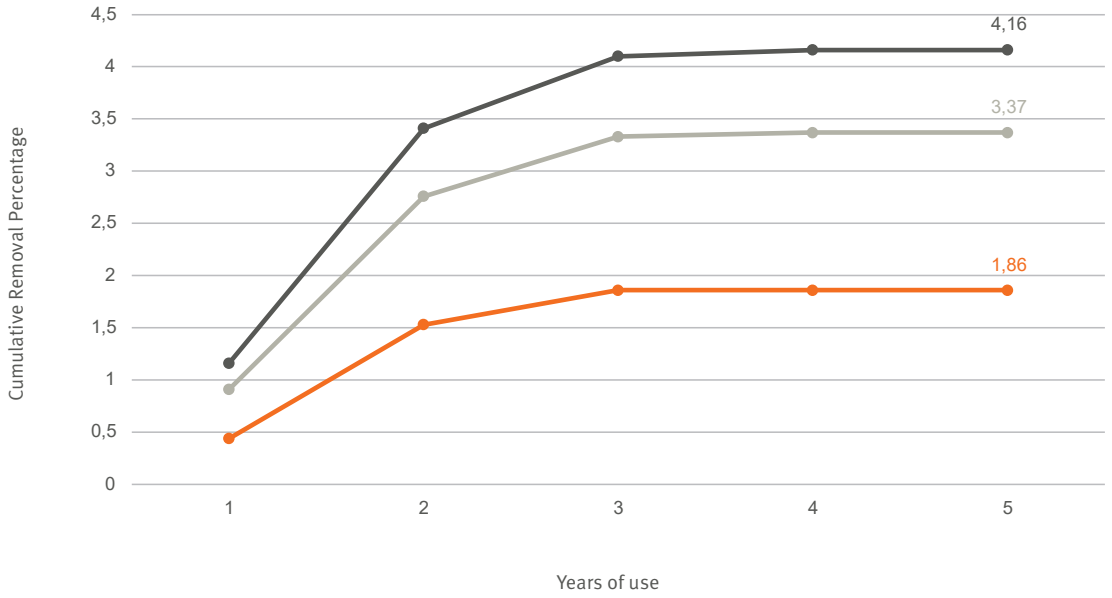
	1 year	2 years	3 years	4 years	5 years	6 years	7 years	8 years
Medical related	0.67%	1.34%	1.83%	1.95%	2.07%	2.19%	2.19%	2.19%
Device failure	0.30%	1.16%	1.71%	2.38%	2.68%	2.86%	2.86%	2.86%
Inconclusive	0.00%	0.24%	0.30%	0.30%	0.30%	0.30%	0.30%	0.30%
All categories	0.97%	2.74%	3.84%	4.63%	5.05%	5.36%	5.36%	5.36%

data as of June 30th 2023

Neuro Zti implant (VFCA only)

Neuro Zti removal rates for all analysis categories and patient populations

The following tables and chart display reliability data ONLY for implanted Neuro Zti impacted by the Voluntary Field Corrective Action (VFCA).

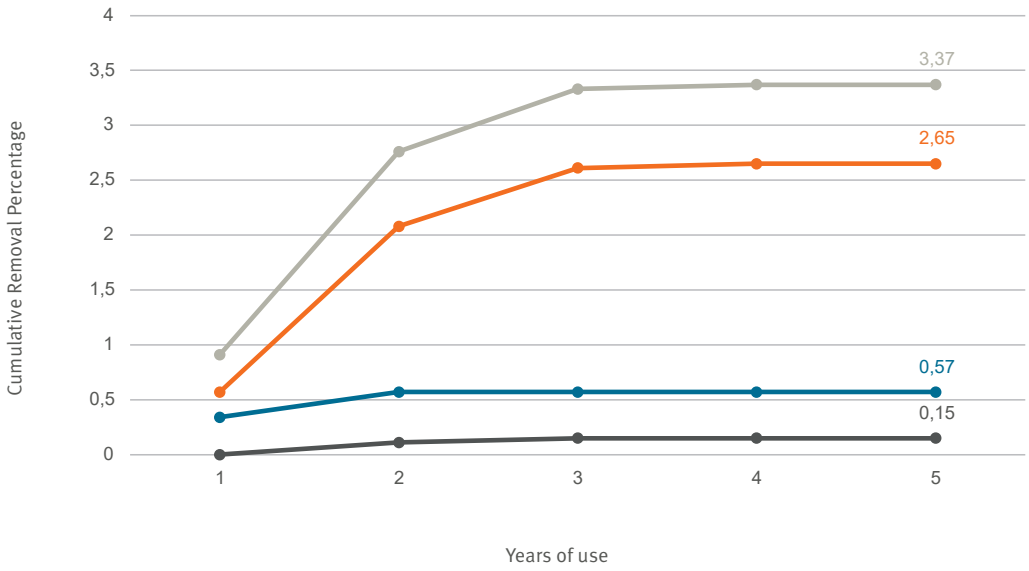


	1 year	2 years	3 years	4 years	5 years
Combined adults & children	0,91%	2,76%	3,33%	3,37%	3,37%
Adults (+18y)	1,16%	3,41%	4,10%	4,16%	4,16%
Children (-18y)	0,44%	1,53%	1,86%	1,86%	1,86%

data as of June 30th 2023

Neuro Zti implant (VFCA only)

Neuro Zti removal rates by analysis category for adults and children

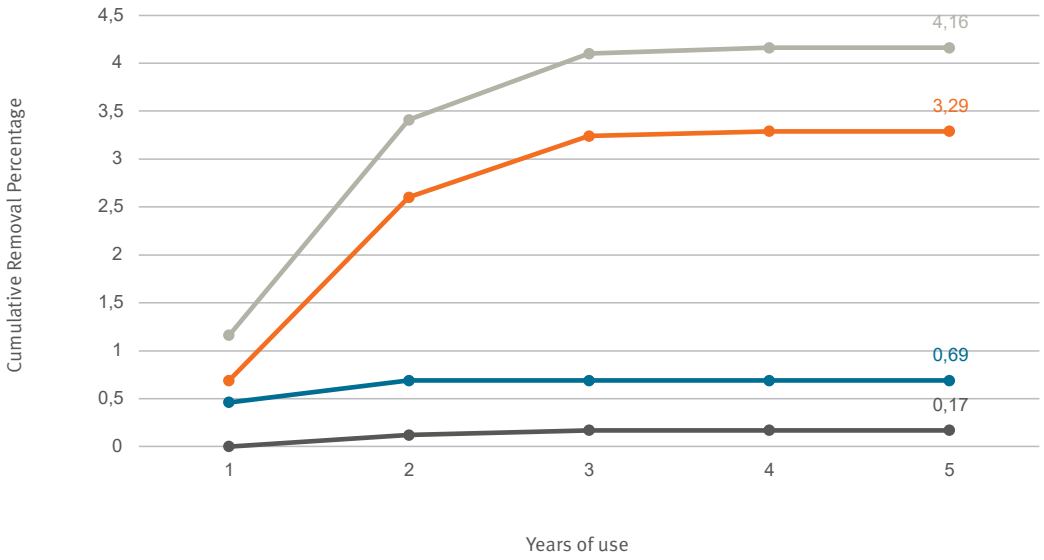


	1 year	2 years	3 years	4 years	5 years
Medical related	0,34%	0,57%	0,57%	0,57%	0,57%
Device failure	0,57%	2,08%	2,61%	2,65%	2,65%
Inconclusive	0,00%	0,11%	0,15%	0,15%	0.15%
All categories	0,91%	2,76%	3,33%	3,37%	3,37%

data as of June 30th 2023

Neuro Zti implant (VFCA only)

Neuro Zti removal rates by analysis category for adults

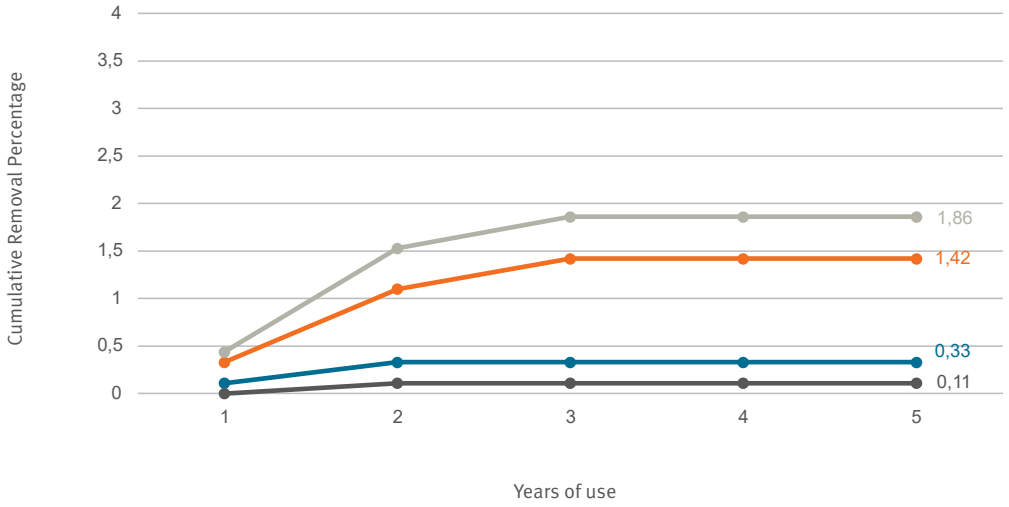


	1 year	2 years	3 years	4 years	5 years
Medical related	0.46%	0.69%	0.69%	0.69%	0.69%
Device failure	0.69%	2.60%	3.24%	3.29%	3.29%
Inconclusive	0.00%	0.12%	0.17%	0.17%	0.17%
All categories	1.16%	3.41%	4.10%	4.16%	4.16%

data as of June 30th 2023

Neuro Zti implant (VFCA only)

Neuro Zti removal rates by analysis category for children (<10 years old)



	1 year	2 years	3 years	4 years	5 years
Medical related	0.11%	0.33%	0.33%	0.33%	0.33%
Device failure	0.33%	1.10%	1.42%	1.42%	1.42%
Inconclusive	0.00%	0.11%	0.11%	0.11%	0.11%
All categories	0.44%	1.53%	1.86%	1.86%	1.86%

data as of June 30th 2023

Sound processor reliability

As for sound processors, we calculate the Failed Component Return Rate (FCRR) to describe their reliability, in accordance with the ANSI/AAMI CI86 standard. The manufacturer tests sound processors that have been returned to determine if they are working and, if not, why they failed.

I started noticing some sounds straight away. At first it was the sound of drawers being closed and cars in the street, then I started being able to hear the sound of my children's voices."

Mette, Denmark, cochlear implant user

How to read the sound processor data

Failed Component Return Rate (FCRR): percentage of the total number of original non-implantable components sold which are returned as failed devices each month.

Electronic failure

A functional failure of the electronics or the electronic assembly.

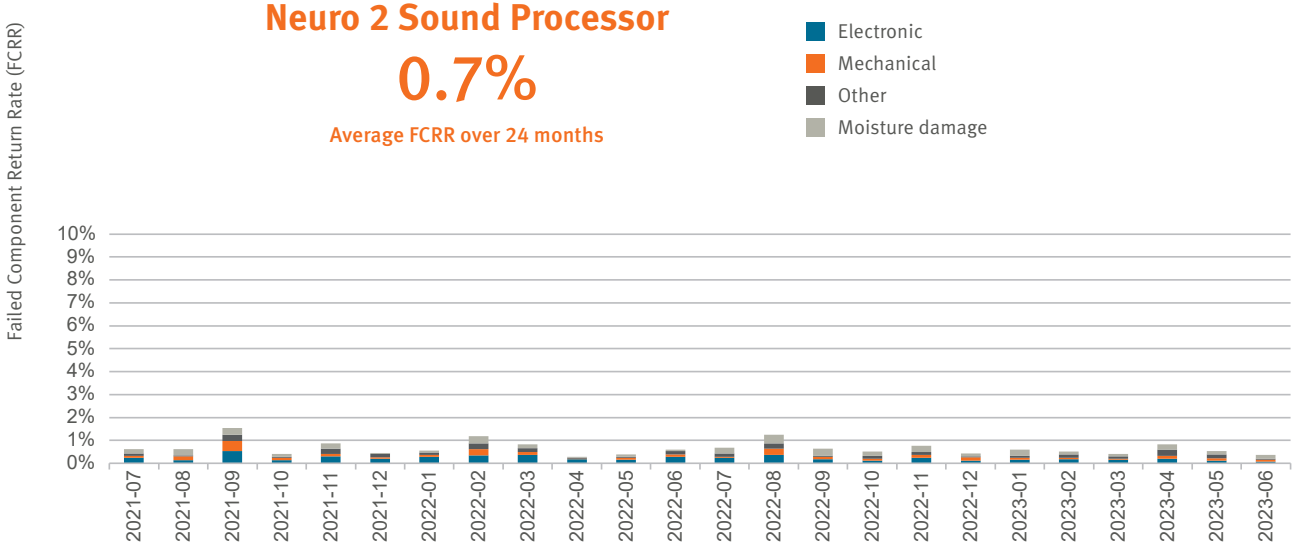
Other/unknown failure

Failures that don't fit in the other categories (e.g. firmware failures).

Neuro 2 Sound Processor

0.7%

Average FCRR over 24 months



Mechanical failure

A functional failure resulting from physical damage caused by mechanical stress, chemical exposure, or ultraviolet (UV) exposure that is a result of normal use.

Moisture damage failure

A functional failure that is a result of moisture ingress. This category excludes corrosion and other similar damage unless it results in a functional failure.

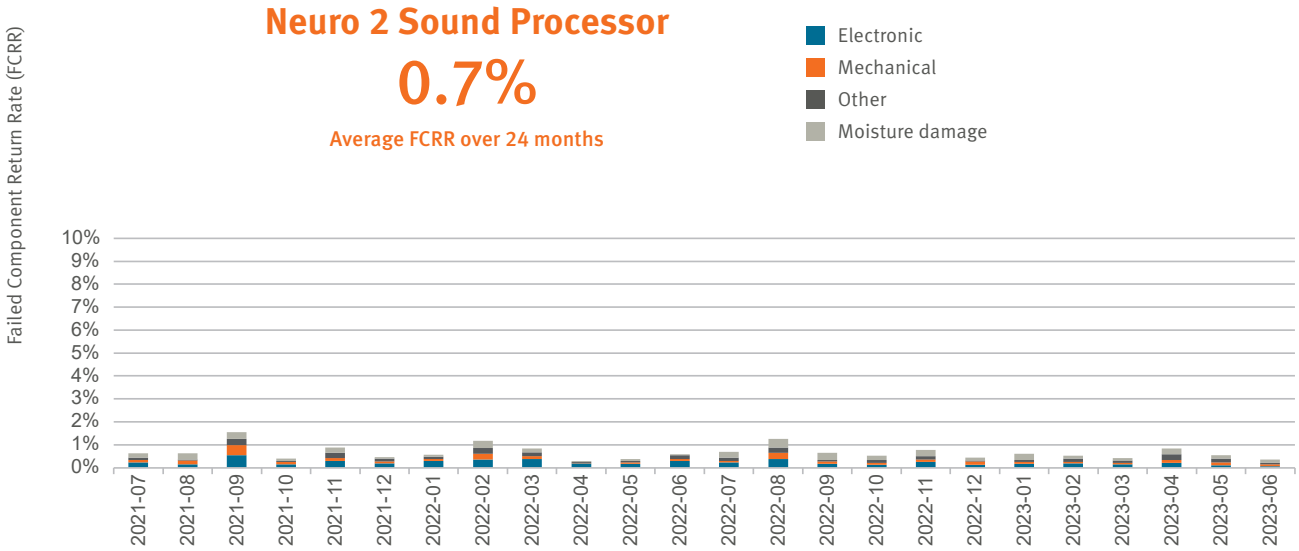
The Neuro 2 sound processor was commercialized in 2018. It is sweeping up prizes in the cochlear implant industry due to its groundbreaking design.

Neuro 2 Sound Processor

Neuro 2 Sound Processor – Failed Component Return Rate

Fail Mode	July 21	Aug 21	Sep 21	Oct 21	Nov 21	Dec 21	Jan 22	Feb 22	Mar 22	Apr 22	May 22	Jun 22
Electronic	0.2%	0.1%	0.5%	0.2%	0.3%	0.2%	0.3%	0.4%	0.4%	0.2%	0.2%	0.3%
Fault Free*	0.2%	0.1%	0.4%	0.1%	0.3%	0.3%	0.3%	0.4%	0.4%	0.1%	0.1%	0.2%
Mechanical	0.1%	0.2%	0.4%	0.1%	0.1%	0.1%	0.1%	0.3%	0.1%	0.0%	0.1%	0.1%
Moisture damage	0.2%	0.3%	0.3%	0.1%	0.2%	0.1%	0.1%	0.3%	0.2%	0.0%	0.1%	0.0%
Other	0.1%	0.0%	0.3%	0.0%	0.2%	0.1%	0.1%	0.3%	0.2%	0.0%	0.1%	0.2%

Fail Mode	July 22	Aug 22	Sep 22	Oct 22	Nov 22	Dec 22	Jan 23	Feb 23	Mar 23	Apr 23	May 23	Jun 23
Electronic	0.2%	0.4%	0.2%	0.1%	0.2%	0.1%	0.2%	0.2%	0.2%	0.2%	0.1%	0.1%
Fault Free*	0.3%	0.4%	0.2%	0.2%	0.3%	0.3%	0.3%	0.3%	0.1%	0.2%	0.3%	0.2%
Mechanical	0.1%	0.3%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.0%	0.1%	0.1%	0.1%
Moisture damage	0.3%	0.4%	0.3%	0.2%	0.3%	0.1%	0.3%	0.1%	0.1%	0.2%	0.1%	0.2%
Other	0.1%	0.2%	0.1%	0.1%	0.1%	0.0%	0.1%	0.2%	0.1%	0.3%	0.2%	0.1%



** Fault-free fail mode is a returned device that is found to be fully functional. The device condition might reflect normal wear and tear, such as minor mechanical damage (including scratches, cracks, and discoloration), corrosion, and/or moisture damage that did not result in a functional failure.*

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