Cochlear®
Hear now. And always

Cochlear™ Nucleus® System

Reliability Report

Volume 21 | December 2022

Reporting to European Consensus Statement, International Classification of Reliability, ANSI/AAMI CI86 Standard and ISO 5841-2.

Bec, Cochlear Nucleus System recipient

Kasper, Cochlear Nucleus System recipient

A message from our CEO

When choosing a cochlear implant manufacturer, the reassurance of high quality products that support a lifetime of hearing is key.

And in choosing a product that is made by Cochlear, you can feel confident that it is the result of our world-class manufacturing process and meets stringent, internationally recognised standards.

As the global leader in implantable hearing, with more than 700,000 devices provided, we take our responsibility to report on the reliability of our products very seriously. This is why we report with full transparency, in accordance with International Standard ISO 5841-2[1], the reporting principles outlined in the European Consensus Statement on Cochlear Implant Failures and Explantations[2] and ANSI/AAMI CI86 – Cochlear implant systems: Requirements for safety, functional verification, labeling and reliability reporting.[3]

We are proud to present this latest report on the reliability of our implants and sound processors, including our new Nucleus 8 Sound Processor: the world's smallest and lightest behind-the-ear sound processor.[4]

We look forward to continuing to work with our partners in the hearing health industry and supporting the important role that they play in delivering a lifetime of hearing outcomes to their patients.

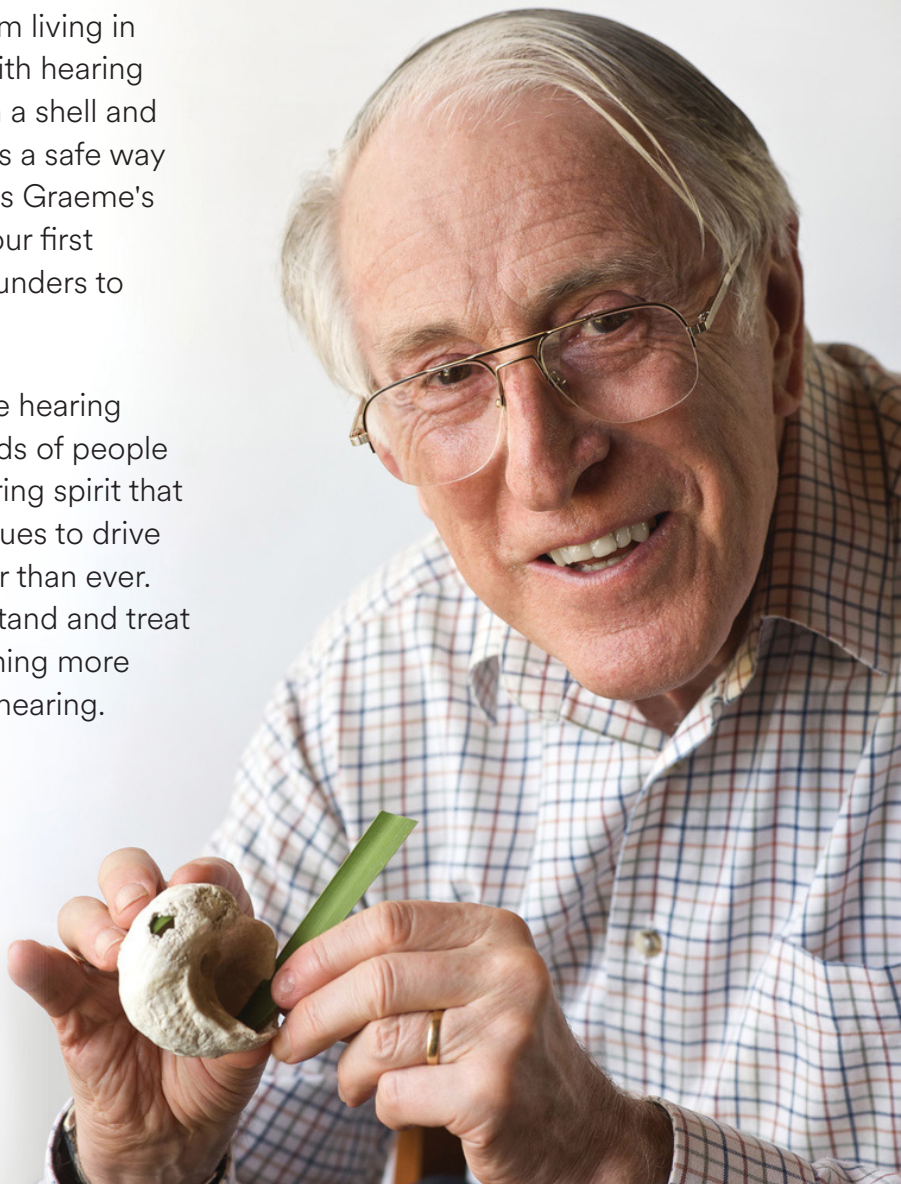
Dig Howitt
CEO & President

Proven over time

For 40 years Cochlear has been bringing people all over the globe into the world of sound.

Graeme Clark, an Australian ear surgeon, saw first-hand the isolation and frustration that comes from living in a world of silence as his father struggled with hearing difficulties. On holiday in 1977, fiddling with a shell and a blade of grass, Graeme realised there was a safe way to insert electrodes into the inner ear. It was Graeme's determination to help others that realised our first implantable solution, reconnecting Rod Saunders to hearing and bringing music into his life.

Today, Cochlear is the leader in implantable hearing solutions, connecting hundreds of thousands of people globally to a life full of hearing. The pioneering spirit that started Cochlear all those years ago continues to drive us forward and our commitment is stronger than ever. We're transforming the way people understand and treat hearing loss, and we're committed to reaching more people to provide support for a lifetime of hearing.



Professor Graeme Clark

About this report

This report provides reliability data for the internal (cochlear implant) and external (sound processor) components of our Nucleus® Systems.

Implant reliability data

The implant data in this report is based on the reporting methodology recommended by *International Standard ISO 5841-2*[1], the reporting principles outlined in the *European Consensus Statement on Cochlear Implant Failures and Explantations*[2] and expert recommendations from the *International Classification of Reliability for Implanted Cochlear Implant Receiver Stimulators*.[5] This report meets the requirements for cochlear implant reliability reporting outlined in these standards.

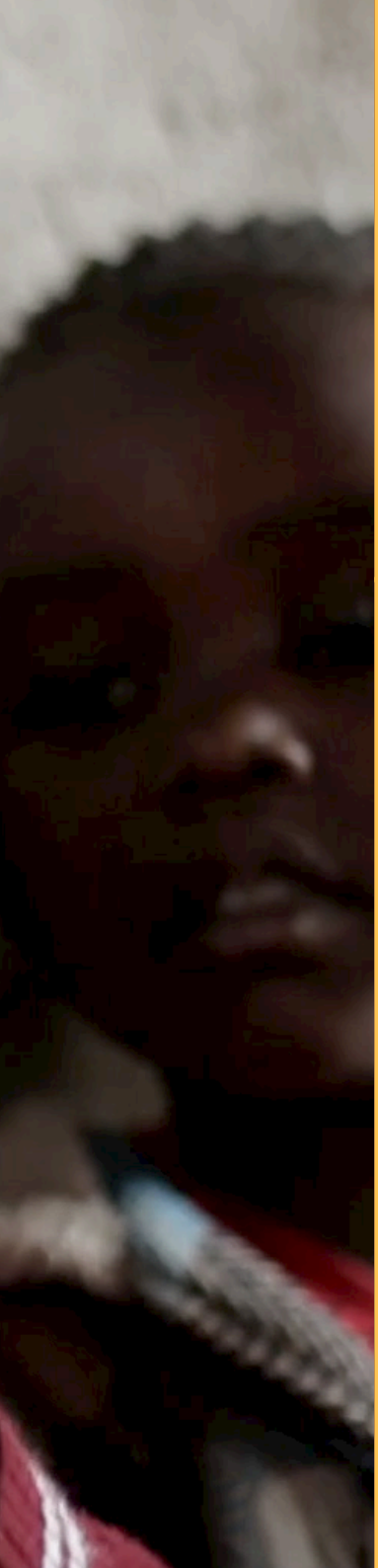
For implant reliability data which meets the reporting standards and methodology recommended by *ANSI/AAMI CI86 – Cochlear implant systems: Requirements for safety, functional verification, labeling and reliability reporting*[3], please visit www.cochlear.com/reliability.

Sound processor reliability data

The sound processor data in this report meets the reporting standards and methodology recommended by *ANSI/AAMI CI86 – Cochlear implant systems: Requirements for safety, functional verification, labeling and reliability reporting*.[3]

For the latest sound processor reliability data, please visit www.cochlear.com/reliability.

Jayso Leiyan, Cochlear Nucleus System recipient



Implant reliability

Compliance with implant reliability reporting standards

In 2005, the major European cochlear implant centres, global regulatory authorities and device manufacturers developed the *European Consensus Statement on Cochlear Implant Failures and Explantations*[2]. The consensus statement outlines how device failures and reliability should be reported, and the seven principles of best practice reporting.

In 2017 a new cochlear implant industry standard was published by the Association for the Advancement of Medical Instrumentation (AAMI) in conjunction with the American National Standards Institute (ANSI). The *ANSI/AAMI CI86 Standard*[3] outlines requirements for the reporting of implant reliability data.

Cochlear's implants are the most reliable[6] in the industry

CONSENSUS STATEMENT PRINCIPLES

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 International Standard ISO 5841-2.[1]

Manufacturers' 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.

Reports of CSR should give complete historical data of a given device, describing any technical modifications (which can be integrated into historical data by starting at time 0).

The complete data set of the 'mother' product should always be supplied when presenting data on subsequent device modifications.**

A new device can be attributed when there has been a change in either the case and/or the electrodes and/or the electronics and has been labelled by its own CE mark.

The CSR should be split into data for adults and for children and 95% confidence intervals (80% or 90% if the population is below 1,000 units) should be provided.

Device survival time starts to count with closure of the wound intraoperatively.

ANSI/AAMI CI86 STANDARD REQUIREMENTS

Manufacturers shall analyse returned product and report on the reliability of the product and mechanisms of failure.

* CSR is identical to Cumulative Survival Percentage (CSP).
** 'Mother' data refers to all data collected for a particular model of implant including all modifications to that model.

COCHLEAR REPORTING PRACTICE	COCHLEAR COMPLIANCE	MED-EL COMPLIANCE[7]	ADVANCED BIONICS COMPLIANCE[8]	OTICON MEDICAL COMPLIANCE[9,10]
All device failures are reported to the competent authority. Cochlear uses the calculation procedures of ISO 5841-2.[1] All device failure modes are included, including failures due to external impact.	✓	✗ Sample size not included	✓	✗ Sample size not included
The source of data is Cochlear's global complaints handling database. Sample size and time period are specified with each report.	✓	✗ Sample size not included	✓	✗ Sample size not included
All models and all versions of each model are included in reports. Descriptions of any significant technical modfications are given.	✓	✗ COMBI 40+ not included	✓	✗ Pre-2006 devices not included
Reports aggregate the reliability of all devices (pre- and post-modification). If the post-modification is significantly different, post-modification is reported separately from the aggregate of all devices.	✓	✓	✓	✓
A new device is attributed when there has been a change in either the case and/or the electrodes and/ or the electronics and has been labelled by its own CE mark. Market practice is that all cochlear implants are labeled by one CE mark per authority.	✓	✓	✓	✓
Reports show separate data for adults and children. This Nucleus Reliability Report contains reliability data with 95% confidence intervals, in compliance with the consensus statement.[4]	✓	✓	✓	✓
Device survival time begins with closure of the wound.	✓	✓	✓	✓

COCHLEAR REPORTING PRACTICE				
Cochlear provides implant data in compliance with the requirements for reliability reporting at www.cochear.com	✓	✗	✓	✓

Why implant reliability matters

Longevity is an important factor when choosing an implant, especially if you are choosing for a child. High implant reliability can mean greater recipient satisfaction and less risk of additional surgery. When considering a cochlear implant, you should have access to the latest data on short and long term reliability, including success and failure rates for both adults and children.

What is Cumulative Survival Percentage (CSP)?

CSP is the metric used in this report to measure implant reliability. CSP provides information regarding the reliability of each make and model of implant over time.

CSP tells you the cumulative percentage of functioning implants over a given time period. For example, a CSP of 99% after five years means the chance of obtaining continued benefit from the cochlear implant, as described for its intended use, is 99% after five years. Put another way, the implant is 99% reliable within five years.

Calculation of CSP

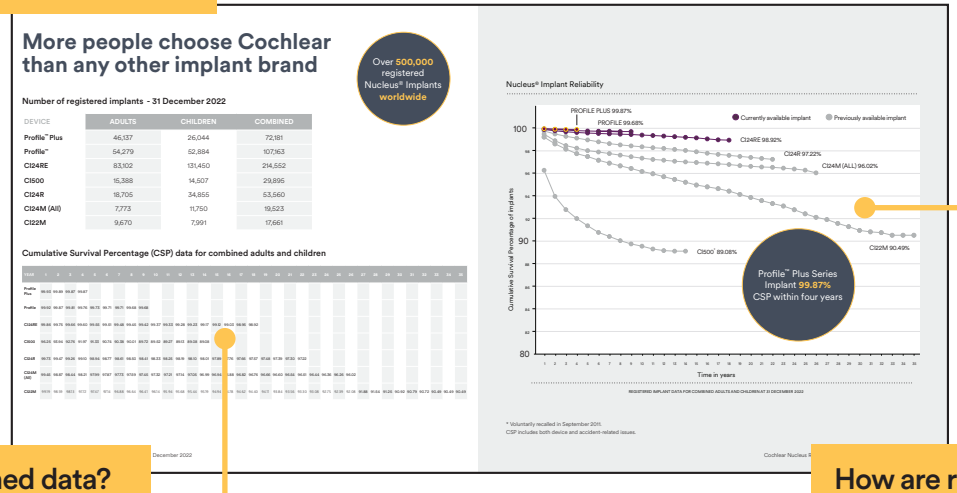
In this report, CSP includes both device and accident-related issues.

The reliability calculations used in this report are in accordance with the *International Standard ISO 5841-2.*[1] They are probability calculations, which use a modified actuarial analysis estimator. This data estimates the probability of survival within a period of time and is represented as CSP.

How are the results shown?

What data is in this report?

The data in this report covers the entire life of implant models and registered implants* worldwide.



More people choose Cochlear than any other implant brand

Over **500,000** registered Nucleus® Implants **worldwide**

Number of registered implants - 31 December 2022

DEVICE	ADULTS	CHILDREN	COMBINED
Profile™ Plus	46,137	26,044	72,181
Profile™	54,279	52,884	107,163
CI24RE	83,102	131,460	214,562
CI500	15,388	14,507	29,895
CI24R	18,705	34,855	53,560
CI24M (All)	7,773	11,750	19,523
CI22M	9,670	7,991	17,661

Cumulative Survival Percentage (CSP) data for combined adults and children

Nucleus® Implant Reliability

What is combined data?

Combined data is the cumulative survival percentage of both adult and children populations combined.

How are results shown?

Results for adults and children are shown separately with 95% confidence intervals (I) as stipulated by the European Consensus Statement.[2]

* An implant is registered with Cochlear when the recipient/clinic/hospital submits the registration of the implanted device. Implant registrations often lag behind surgery dates.

More people choose Cochlear than any other implant brand

Over **500,000** registered Nucleus® Implants **worldwide**

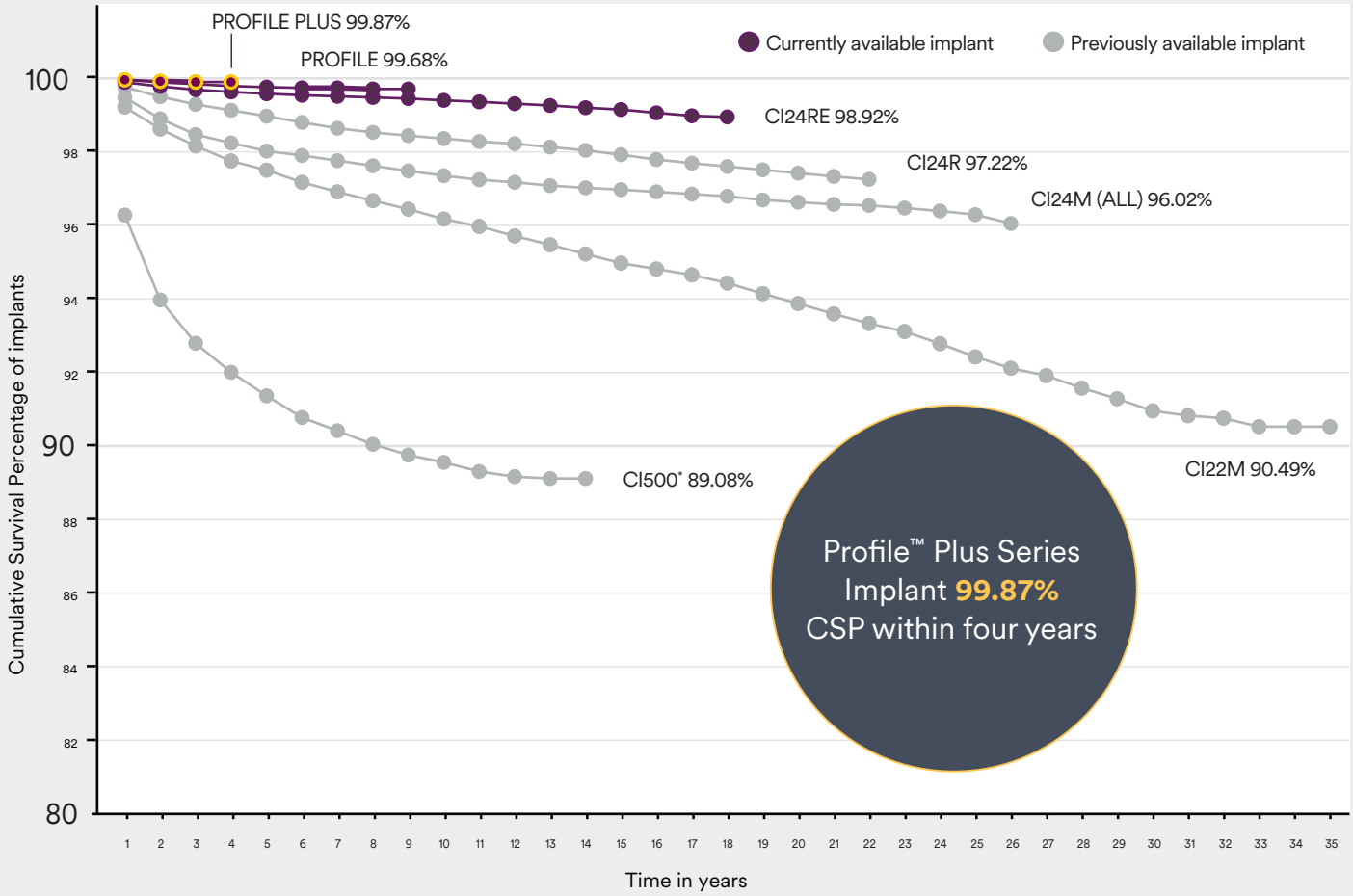
Number of registered implants – 31 December 2022

DEVICE	ADULTS	CHILDREN	COMBINED
Profile™ Plus	46,137	26,044	72,181
Profile™	54,279	52,884	107,163
CI24RE	83,102	131,450	214,552
CI500	15,388	14,507	29,895
CI24R	18,705	34,855	53,560
CI24M (All)	7,773	11,750	19,523
CI22M	9,670	7,991	17,661

Cumulative Survival Percentage (CSP) data for combined adults and children

YEAR	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35
Profile Plus	99.93	99.89	99.87	99.87																															
Profile	99.92	99.87	99.81	99.76	99.73	99.71	99.71	99.68	99.68																										
CI24RE	99.86	99.75	99.66	99.60	99.55	99.51	99.48	99.45	99.42	99.37	99.33	99.28	99.23	99.17	99.12	99.03	98.95	98.92																	
CI500	96.25	93.94	92.76	91.97	91.33	90.74	90.38	90.01	89.72	89.52	89.27	89.13	89.08	89.08																					
CI24R	99.73	99.47	99.26	99.10	98.94	98.77	98.61	98.50	98.41	98.33	98.25	98.19	98.10	98.01	97.89	97.76	97.66	97.57	97.48	97.39	97.30	97.22													
CI24M (All)	99.45	98.87	98.44	98.21	97.99	97.87	97.73	97.59	97.45	97.32	97.21	97.14	97.05	96.99	96.94	96.88	96.82	96.76	96.66	96.60	96.54	96.51	96.44	96.36	96.26	96.02									
CI22M	99.19	98.59	98.13	97.72	97.47	97.14	96.88	96.64	96.41	96.14	95.94	95.68	95.44	95.19	94.94	94.78	94.62	94.40	94.11	93.84	93.56	93.30	93.08	92.75	92.39	92.08	91.88	91.54	91.25	90.92	90.79	90.72	90.49	90.49	90.49

Nucleus® Implant Reliability



REGISTERED IMPLANT DATA FOR COMBINED ADULTS AND CHILDREN AT 31 DECEMBER 2022

* Voluntarily recalled in September 2011.
CSP includes both device and accident-related issues.

Nucleus® Profile™ Plus Series Implant

Number of registered Profile™ Plus Series Implants – 31 December 2022

ADULTS	CHILDREN	COMBINED
46,137	26,044	72,181

Cochlear's latest implant, the Profile Plus Series, builds on the industry-leading thinness[11] of the Profile Series Implant and provides access to MRI at 1.5 Tesla and 3.0 Tesla without the need to remove the internal magnet.

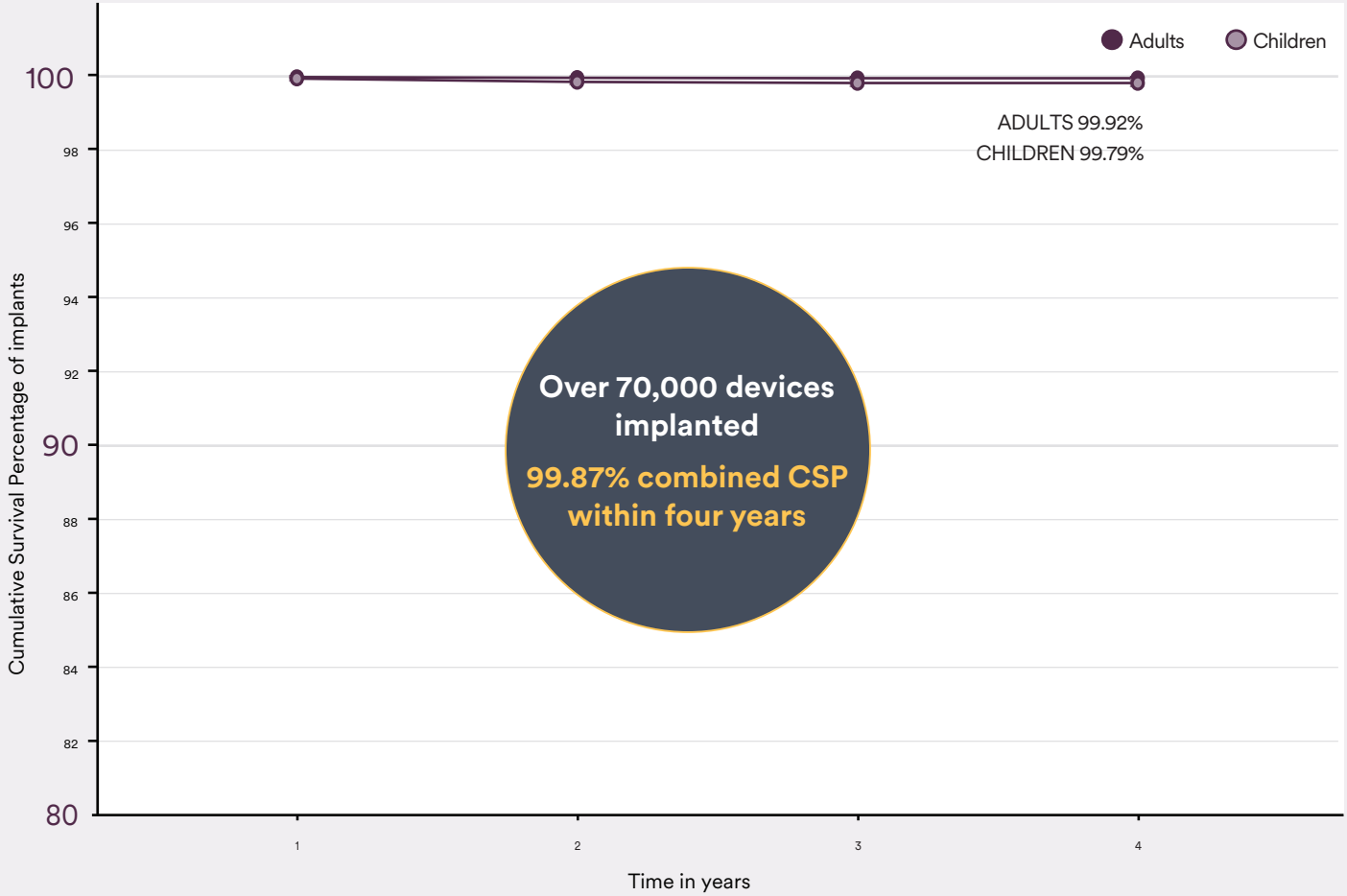
Commercially released in 2019, the Profile Plus Series Implant has delivered a combined Cumulative Survival Percentage of 99.87% within four years.

Profile Plus Series Implant Cumulative Survival Percentage

YEAR	1	2	3	4
Adults	99.95	99.93	99.92	99.92
Children	99.91	99.82	99.79	99.79
Combined	99.93	99.89	99.87	99.87

Cochlear Nucleus Profile Plus Implant with Slim Modiolar Electrode (CI632)

Profile™ Plus Series Implant Reliability



REGISTERED IMPLANT DATA FOR COMBINED ADULTS AND CHILDREN AT 31 DECEMBER 2022

Confidence intervals smaller than 0.1% may not be clearly visible in the graphs.
CSP includes both device and accident-related issues.

Nucleus Profile Series Implant

Number of registered Profile Series Implants – 31 December 2022

ADULTS	CHILDREN	COMBINED
54,279	52,884	107,163

At only 3.9 mm, the Profile Series Implant was commercially released in 2014 as the thinnest cochlear implant in the world.[11]

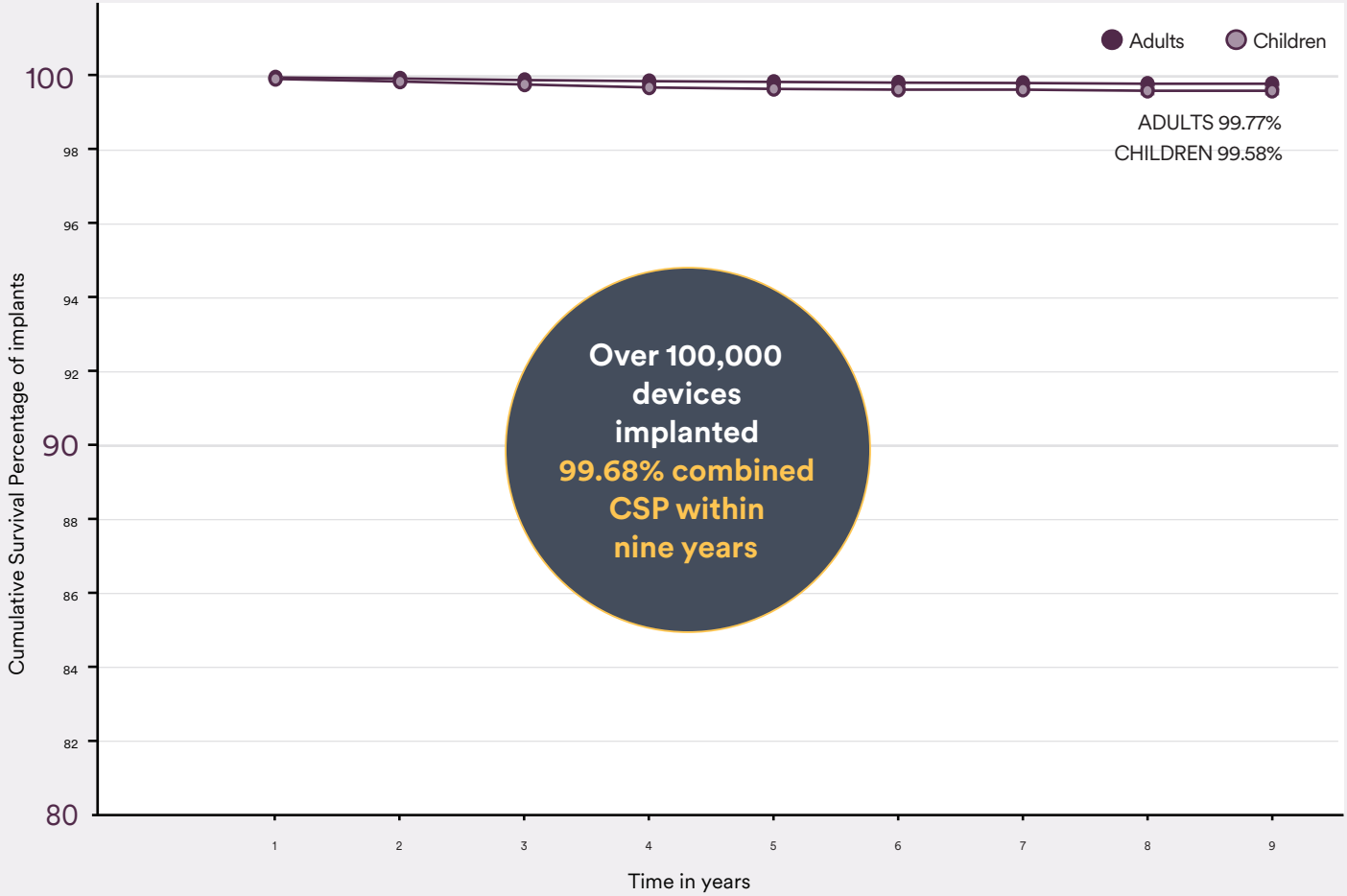
The Profile Series Implant sets the standard in implant reliability with a 99.68% combined Cumulative Survival Percentage within nine years.

Profile Series Implant Cumulative Survival Percentage

YEAR	1	2	3	4	5	6	7	8	9
Adults	99.94	99.91	99.87	99.84	99.82	99.80	99.79	99.77	99.77
Children	99.90	99.83	99.75	99.67	99.63	99.61	99.61	99.58	99.58
Combined	99.92	99.87	99.81	99.76	99.73	99.71	99.71	99.68	99.68

Cochlear Nucleus Profile Implant with Slim Modiolar Electrode (CI532)

Profile™ Series Implant Reliability



REGISTERED IMPLANT DATA FOR COMBINED ADULTS AND CHILDREN AT 31 DECEMBER 2022

Confidence intervals smaller than 0.1% may not be clearly visible in the graphs.
CSP includes both device and accident-related issues.

Nucleus CI24RE Series Implant

Number of registered CI24RE Series Implants – 31 December 2022

ADULTS	CHILDREN	COMBINED
83,102	131,450	214,552

The CI24RE Series is the world's most widely used cochlear implant.*

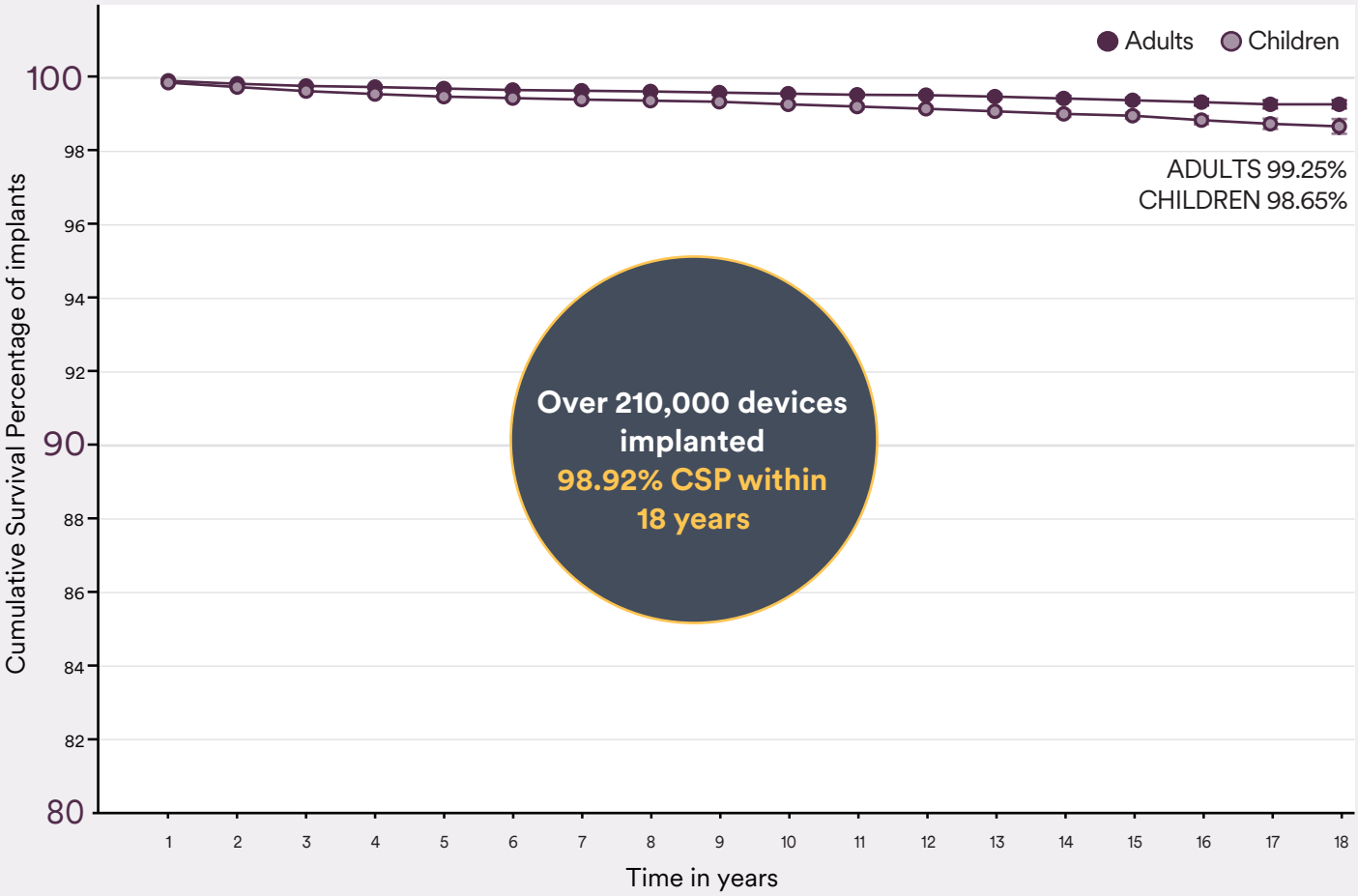
Released in 2005, it has a 98.92% combined Cumulative Survival Percentage within 18 years.

CI24RE Series Implant Cumulative Survival Percentage

YEAR	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Adults	99.89	99.81	99.75	99.72	99.68	99.64	99.62	99.60	99.57	99.54	99.51	99.50	99.46	99.41	99.36	99.31	99.25	99.25
Children	99.84	99.72	99.61	99.53	99.46	99.42	99.38	99.35	99.32	99.25	99.19	99.13	99.06	98.99	98.94	98.82	98.72	98.65
Combined	99.86	99.75	99.66	99.60	99.55	99.51	99.48	99.45	99.42	99.37	99.33	99.28	99.23	99.17	99.12	99.03	98.95	98.92

* Based on available data[7-9]. MED-EL and Oticon Medical do not report number of registered cochlear implants.

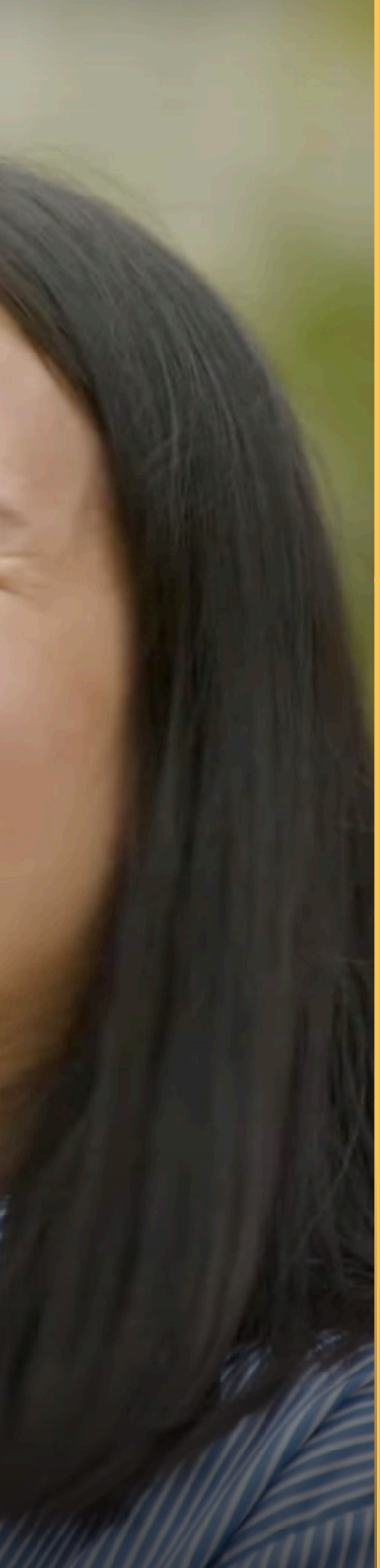
CI24RE Series Implant Reliability



REGISTERED IMPLANT DATA FOR ADULTS AND CHILDREN AT 31 DECEMBER 2022

Confidence intervals smaller than 0.1% may not be clearly visible in the graphs.
CSP includes both device and accident-related issues.

Ticha., Cochlear Nucleus System recipient



Previously available implants

Nucleus® CI500 Series Implant

Number of registered CI500 Series Implants – 31 December 2022

ADULTS	CHILDREN	COMBINED
15,388	14,507	29,895

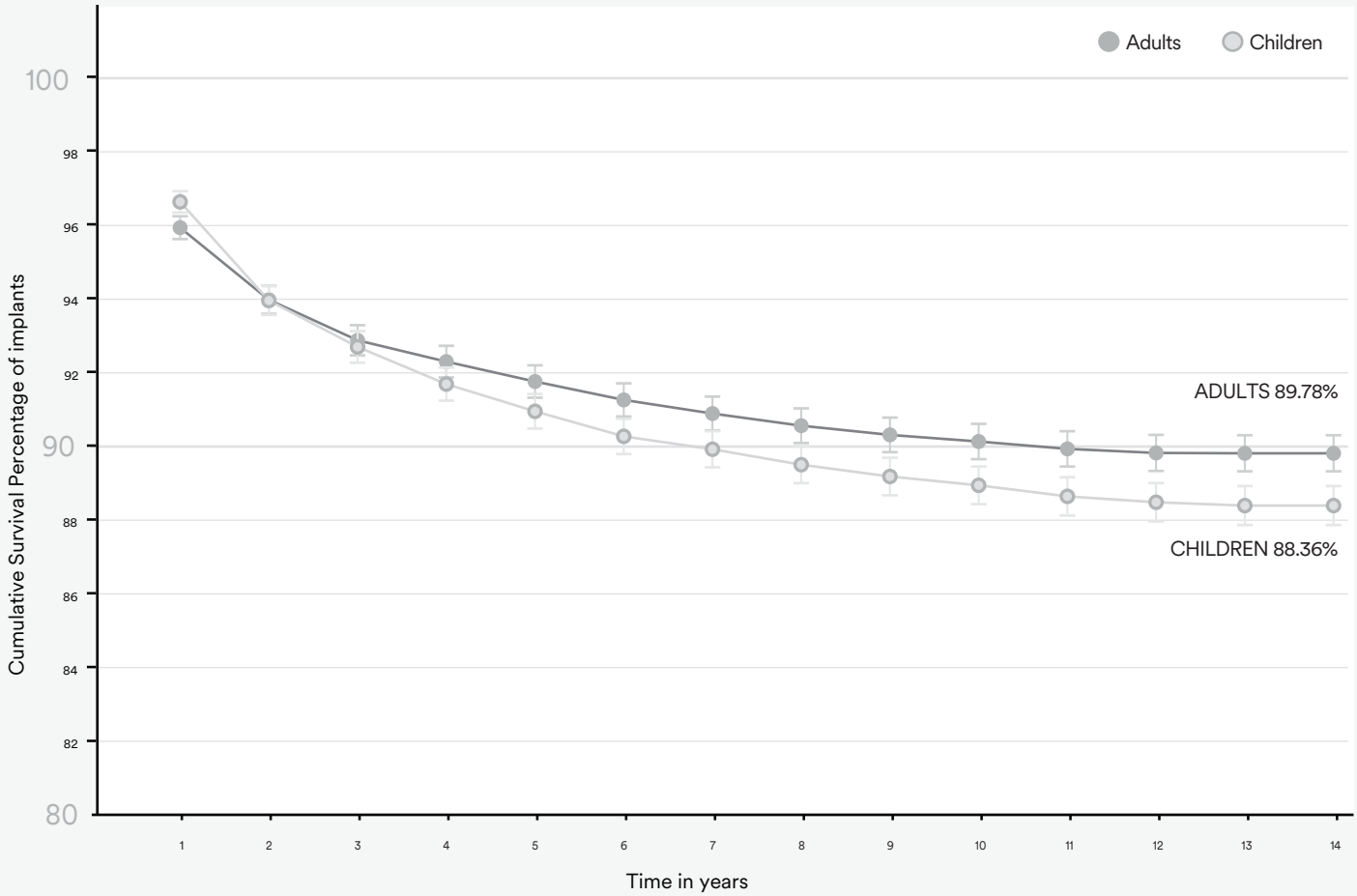
Released in 2009, the CI500 Series has a combined Cumulative Survival Percentage of 89.08% within 14 years.

The CI500 Series was voluntarily recalled in September 2011.

CI500 Series Implant Cumulative Survival Percentage

YEAR	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Adults	95.91	93.95	92.85	92.27	91.73	91.23	90.86	90.53	90.28	90.10	89.90	89.79	89.78	89.78
Children	96.61	93.93	92.67	91.66	90.92	90.24	89.89	89.47	89.15	88.91	88.61	88.45	88.36	88.36
Combined	96.25	93.94	92.76	91.97	91.33	90.74	90.38	90.01	89.72	89.52	89.27	89.13	89.08	89.08

CI500 Series Implant Reliability



REGISTERED IMPLANT DATA FOR ADULTS AND CHILDREN AT 31 DECEMBER 2022

Confidence intervals smaller than 0.1% may not be clearly visible in the graphs.
CSP includes both device and accident-related issues.

Nucleus CI24R Implant

Number of registered CI24R Implants – 31 December 2022

ADULTS	CHILDREN	COMBINED
18,705	34,855	53,560

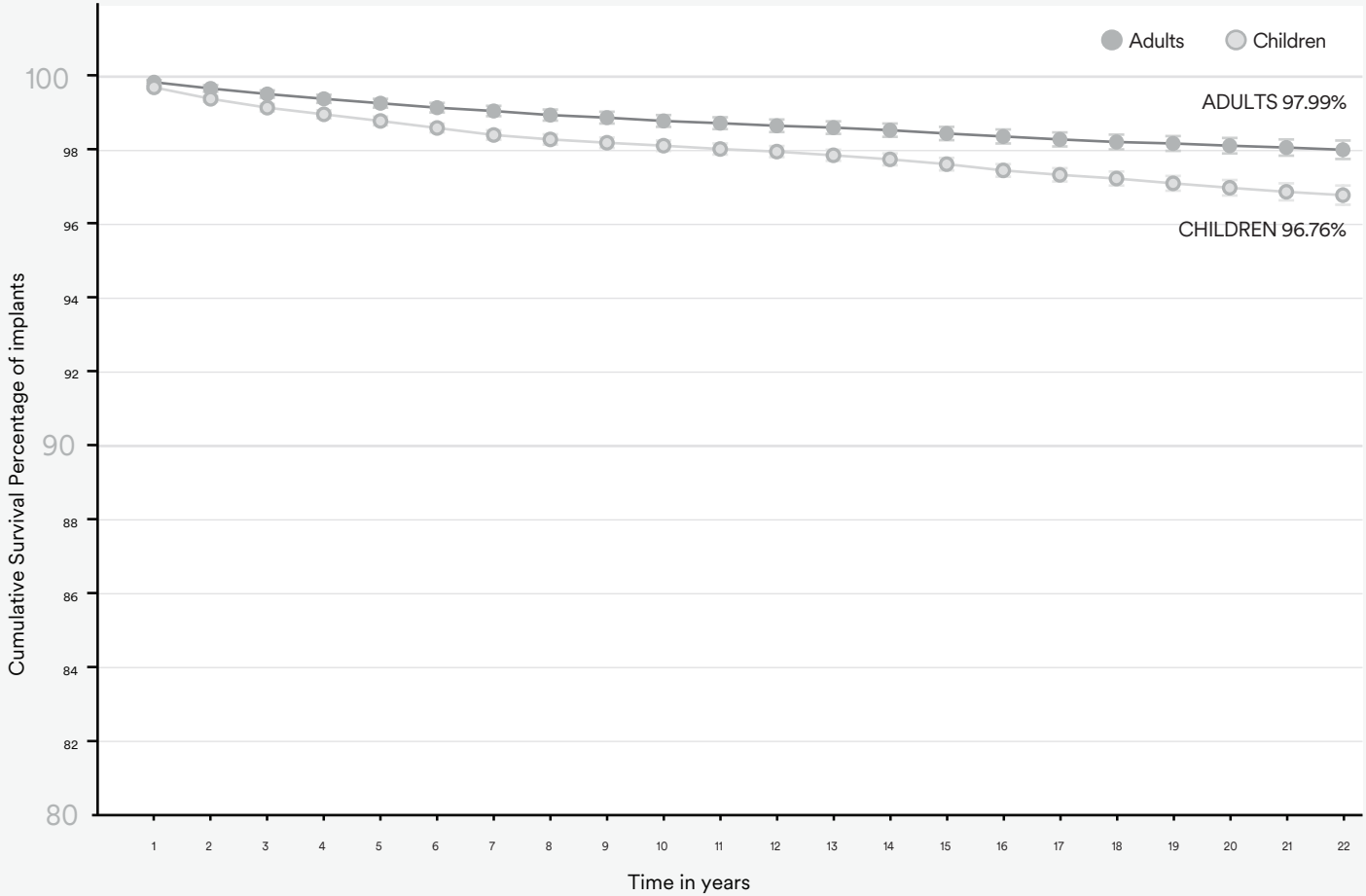
The CI24R Implant was released in 2000 with perimodiolar (Contour Advance®) and straight electrodes.

Within 22 years, the CI24R Implant has a combined Cumulative Survival Percentage of 97.22%.

CI24R Implant Cumulative Survival Percentage

YEAR	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22
Adults	99.82	99.65	99.50	99.37	99.25	99.13	99.04	98.93	98.86	98.77	98.71	98.64	98.59	98.52	98.43	98.35	98.27	98.20	98.16	98.10	98.05	97.99
Children	99.68	99.37	99.13	98.95	98.77	98.58	98.39	98.27	98.18	98.10	98.01	97.94	97.84	97.73	97.60	97.43	97.31	97.21	97.08	96.96	96.85	96.76
Combined	99.73	99.47	99.26	99.10	98.94	98.77	98.61	98.50	98.41	98.33	98.25	98.19	98.10	98.01	97.89	97.76	97.66	97.57	97.48	97.39	97.30	97.22

CI24R Implant Reliability



REGISTERED IMPLANT DATA FOR ADULTS AND CHILDREN AT 31 DECEMBER 2022

Confidence intervals smaller than 0.1% may not be clearly visible in the graphs.
CSP includes both device and accident-related issues.

Nucleus CI24M Implant

Number of registered CI24M Implants – 31 December 2022

	ADULTS	CHILDREN	COMBINED
ALL	7,773	11,750	19,523
POST**	6,071	9,225	15,296

Released in 1997, the CI24M Implant was the world's first cochlear implant with a removable magnet for MRI compatibility.

Within 26 years, the CI24M Implant has a combined Cumulative Survival Percentage of 96.02%.

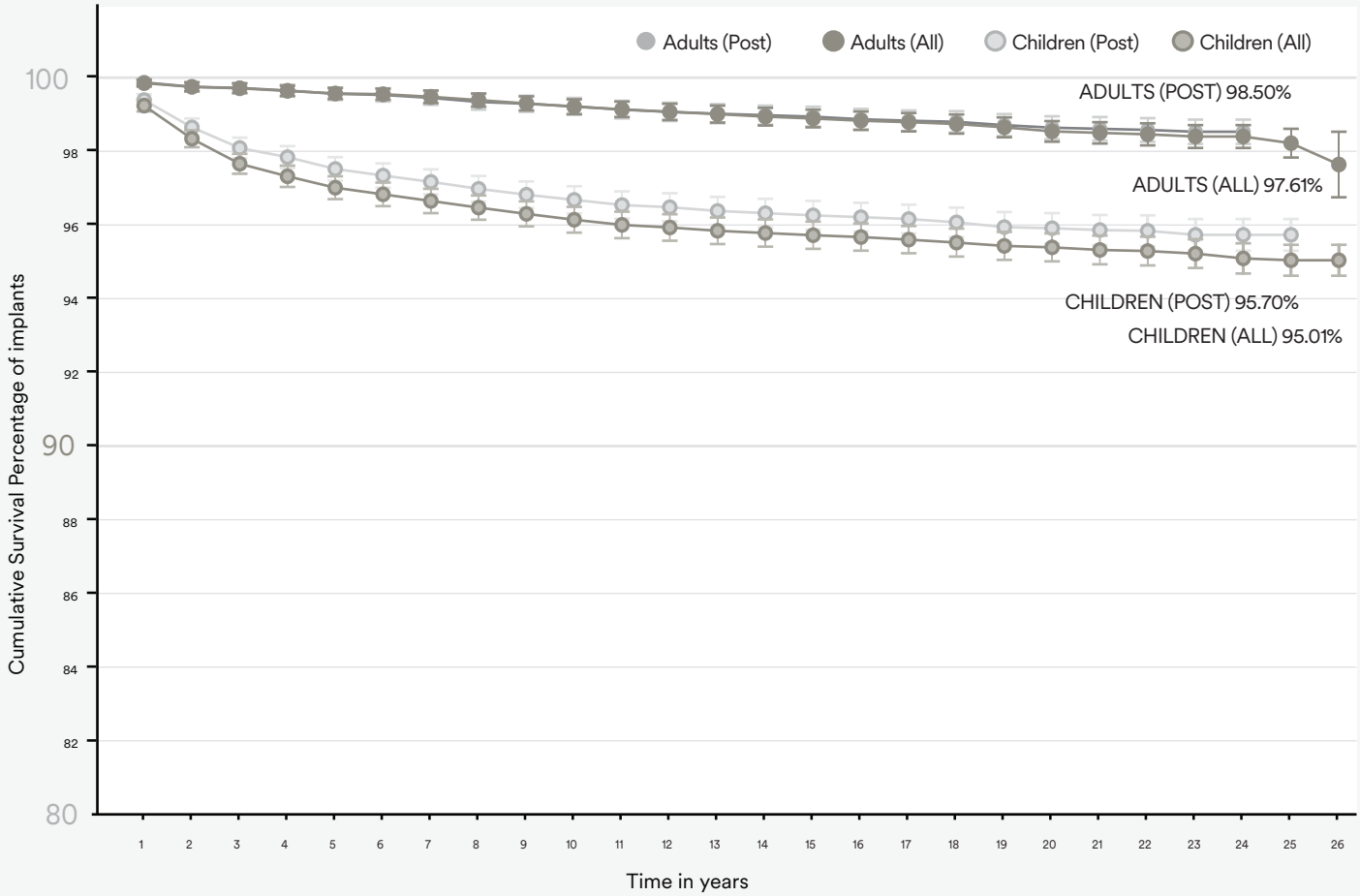
CI24M Implant Cumulative Survival Percentage

YEAR	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26
Adults (All)	99.82	99.72	99.68	99.61	99.54	99.52	99.45	99.36	99.27	99.18	99.11	99.04	98.98	98.91	98.86	98.80	98.76	98.71	98.62	98.51	98.47	98.43	98.37	98.37	98.19	97.61
Children (All)	99.21	98.31	97.63	97.29	96.98	96.80	96.62	96.44	96.27	96.11	95.97	95.90	95.81	95.75	95.69	95.64	95.57	95.49	95.40	95.36	95.29	95.26	95.19	95.06	95.01	95.01
Combined (All)	99.45	98.87	98.44	98.21	97.99	97.87	97.73	97.59	97.45	97.32	97.21	97.14	97.05	96.99	96.94	96.88	96.82	96.76	96.66	96.60	96.54	96.51	96.44	96.36	96.26	96.02
Adults (Post)**	99.84	99.72	99.69	99.62	99.53	99.50	99.42	99.31	99.26	99.19	99.10	99.04	98.99	98.95	98.91	98.84	98.80	98.77	98.68	98.61	98.58	98.55	98.50	98.50	#	#
Children (Post)**	99.36	98.62	98.06	97.81	97.49	97.31	97.14	96.95	96.79	96.65	96.51	96.45	96.35	96.29	96.23	96.18	96.13	96.04	95.91	95.88	95.83	95.81	95.70	95.70	95.70	#
Combined (Post)**	99.55	99.06	98.70	98.52	98.29	98.17	98.03	97.88	97.76	97.65	97.52	97.47	97.39	97.34	97.28	97.22	97.18	97.11	97.00	96.95	96.90	96.88	96.80	96.80	96.80	#

** 'Post' refers to the addition of a structural support component to improve impact strength.

Individual populations are less than the minimum required for a valid calculation.[1]

CI24M Implant Reliability



REGISTERED IMPLANT DATA FOR ADULTS AND CHILDREN AT 31 DECEMBER 2022

Confidence intervals smaller than 0.1% may not be clearly visible in the graphs.
CSP includes both device and accident-related issues.

Nucleus CI22M Implant

Number of registered CI22M Implants – 31 December 2022

ADULTS	CHILDREN	COMBINED
9,670	7,991	17,661

Released in 1985, the CI22M Implant was the first commercially available multi-channel cochlear implant in the world.

Within 35 years, the CI22M Implant has a combined Cumulative Survival Percentage of 90.49%.

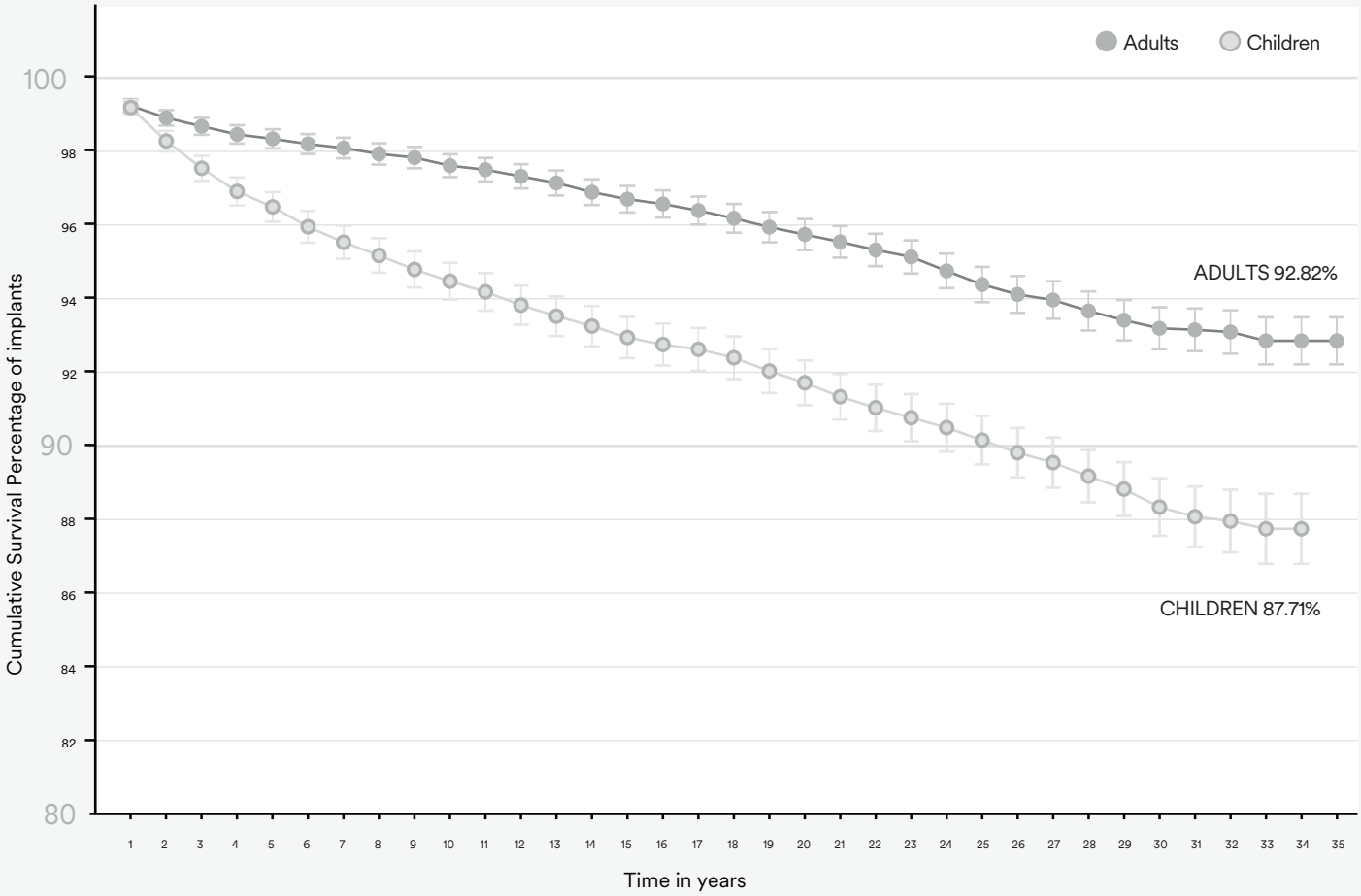
CI22M Implant Cumulative Survival Percentage

YEAR	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
Adults	99.21	98.88	98.65	98.43	98.31	98.17	98.06	97.90	97.80	97.58	97.47	97.29	97.11	96.86	96.67	96.54	96.36
Children	99.16	98.25	97.51	96.88	96.46	95.92	95.50	95.14	94.76	94.44	94.15	93.79	93.49	93.22	92.91	92.72	92.59
Combined	99.19	98.59	98.13	97.72	97.47	97.14	96.88	96.64	96.41	96.14	95.94	95.68	95.44	95.19	94.94	94.78	94.62

YEAR	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35
Adults	96.15	95.91	95.71	95.51	95.29	95.10	94.72	94.35	94.08	93.93	93.63	93.38	93.16	93.12	93.06	92.82	92.82	92.82
Children	92.36	92.00	91.68	91.30	91.00	90.73	90.46	90.12	89.78	89.51	89.14	88.79	88.30	88.04	87.92	87.71	87.71	#
Combined	94.40	94.11	93.84	93.56	93.30	93.08	92.75	92.39	92.08	91.88	91.54	91.25	90.92	90.79	90.72	90.49	90.49	90.49

Individual populations are less than the minimum required for a valid calculation.[1]

CI22M Implant Reliability



REGISTERED IMPLANT DATA FOR ADULTS AND CHILDREN AT 31 DECEMBER 2022

Confidence intervals smaller than 0.1% may not be clearly visible in the graphs.
CSP includes both device and accident-related issues.

Bernie, Cochlear Nucleus System recipient

Sound processor reliability

Why sound processor reliability matters

The reliability of a cochlear implant system depends not only on the implant, but also on the sound processor. Sound processors, an externally worn device, are typically used for a number of years, so high reliability enables ongoing access to a consistent hearing experience.

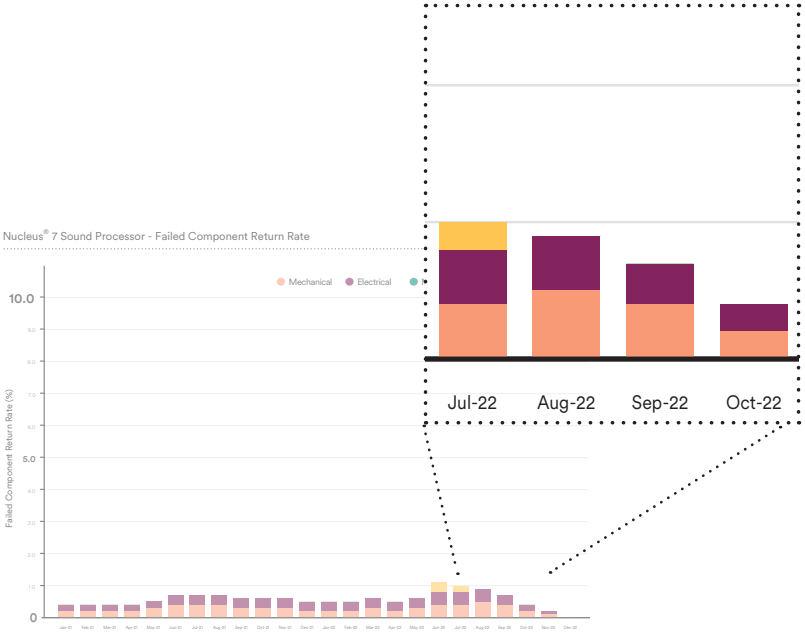
What is Failed Component Return Rate (FCRR)?

Failed Component Return Rate (FCRR) is the metric used in this report to measure sound processor reliability. FCRR provides information regarding the reliability of each make and model of sound processor.

Cochlear tests sound processors that have been returned to determine if they are working and, if not, why they failed. The FCRR is a percentage which represents the total number of failed processors received within a month compared to the total number of the same processor sold by the end of that month.

For example, if 20 faulty sound processors are returned in a month and 10,000 of the same sound processors have been sold as at the end of the month, the FCRR is 0.2%.

How are the results shown?



What is 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.

What is electrical failure?

A functional failure of the electronics or the electronic assembly.

What is 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.

What is other/unknown failure?

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

What is Fault-Free data?

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

Fail mode	Jan-22	Feb-22	Mar-22	Apr-22	May-22	Jun-22	Jul-22	Aug-22	Sep-22	Oct-22	Nov-22	Dec-22
Mechanical	0.2%	0.2%	0.2%	0.2%	0.3%	0.4%	0.4%	0.4%	0.3%	0.3%	0.2%	0.1%
Electrical	0.2%	0.2%	0.2%	0.2%	0.2%	0.3%	0.3%	0.3%	0.3%	0.3%	0.2%	0.1%
Moisture	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Other	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Fault-Free	0.2%	0.2%	0.2%	0.2%	0.2%	0.3%	0.3%	0.2%	0.2%	0.2%	0.2%	0.1%

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

Nucleus® 8 Sound Processor

Released in 2022, the Nucleus® 8 Sound Processor is the world's smallest and lightest behind-the-ear sound processor, and the first cochlear implant sound processor that's ready for Bluetooth LE Audio technology.*

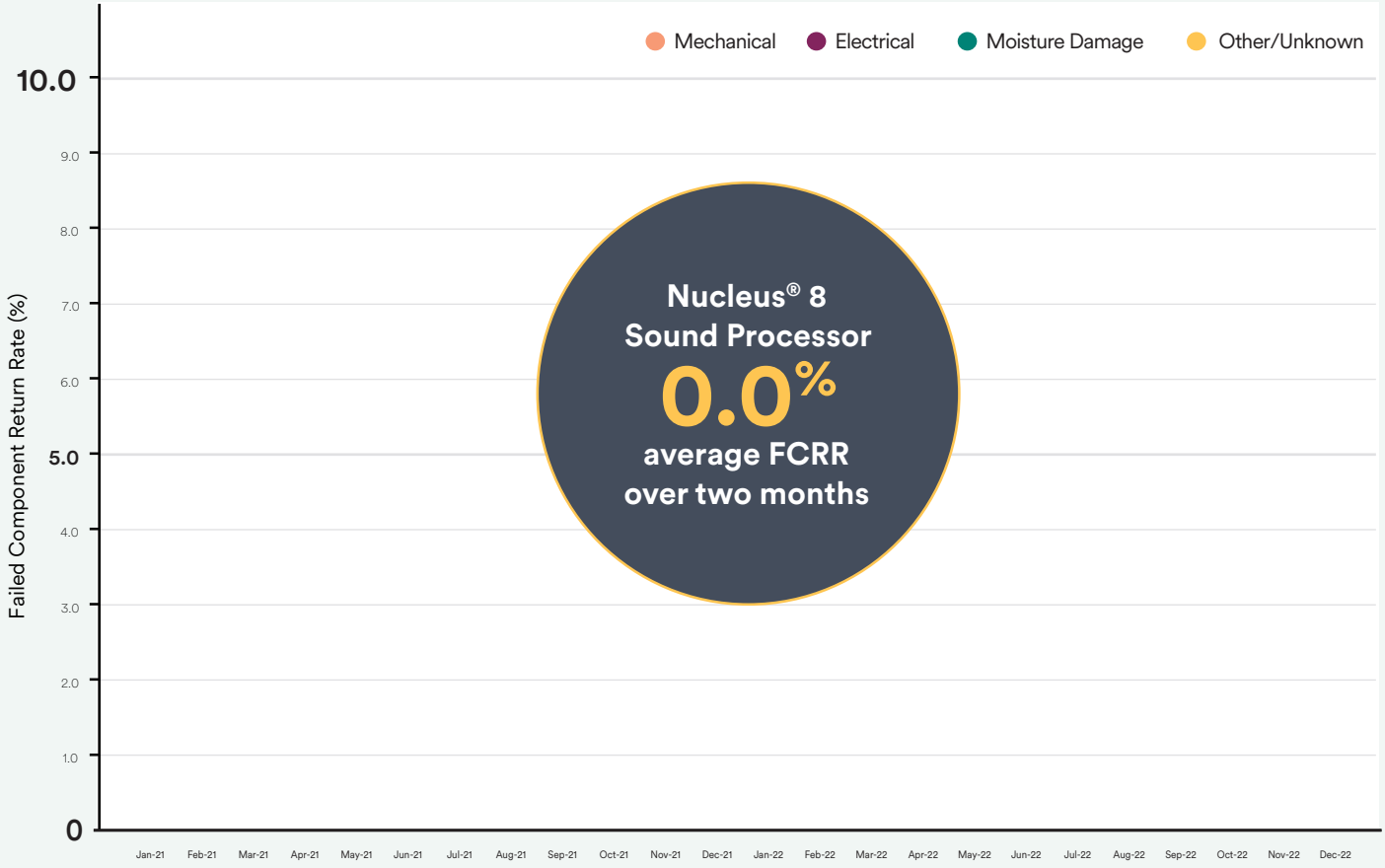
Nucleus 8 Sound Processor – Failed Component Return Rate

Fail mode	Jan-21	Feb-21	Mar-21	Apr-21	May-21	Jun-21	Jul-21	Aug-21	Sep-21	Oct-21	Nov-21	Dec-21
Mechanical	-	-	-	-	-	-	-	-	-	-	-	-
Electrical	-	-	-	-	-	-	-	-	-	-	-	-
Moisture	-	-	-	-	-	-	-	-	-	-	-	-
Other	-	-	-	-	-	-	-	-	-	-	-	-
Fault-Free	-	-	-	-	-	-	-	-	-	-	-	-

Fail mode	Jan-22	Feb-22	Mar-22	Apr-22	May-22	Jun-22	Jul-22	Aug-22	Sep-22	Oct-22	Nov-22	Dec-22
Mechanical	-	-	-	-	-	-	-	-	-	-	0.0%	0.0%
Electrical	-	-	-	-	-	-	-	-	-	-	0.0%	0.0%
Moisture	-	-	-	-	-	-	-	-	-	-	0.0%	0.0%
Other	-	-	-	-	-	-	-	-	-	-	0.0%	0.0%
Fault-Free	-	-	-	-	-	-	-	-	-	-	0.0%	0.0%

* When the technology becomes available for the Cochlear Nucleus 8 Sound Processor, a firmware update to your sound processor will allow you to connect to Bluetooth LE Audio compatible devices.

Nucleus® 8 Sound Processor - Failed Component Return Rate



Nucleus Kanso® 2 Sound Processor

Released in 2020, the Nucleus® Kanso® 2 Sound Processor combines our latest connectivity* features and a simple and durable all-in-one design in the smallest and lightest rechargeable off-the-ear sound processor.[4]

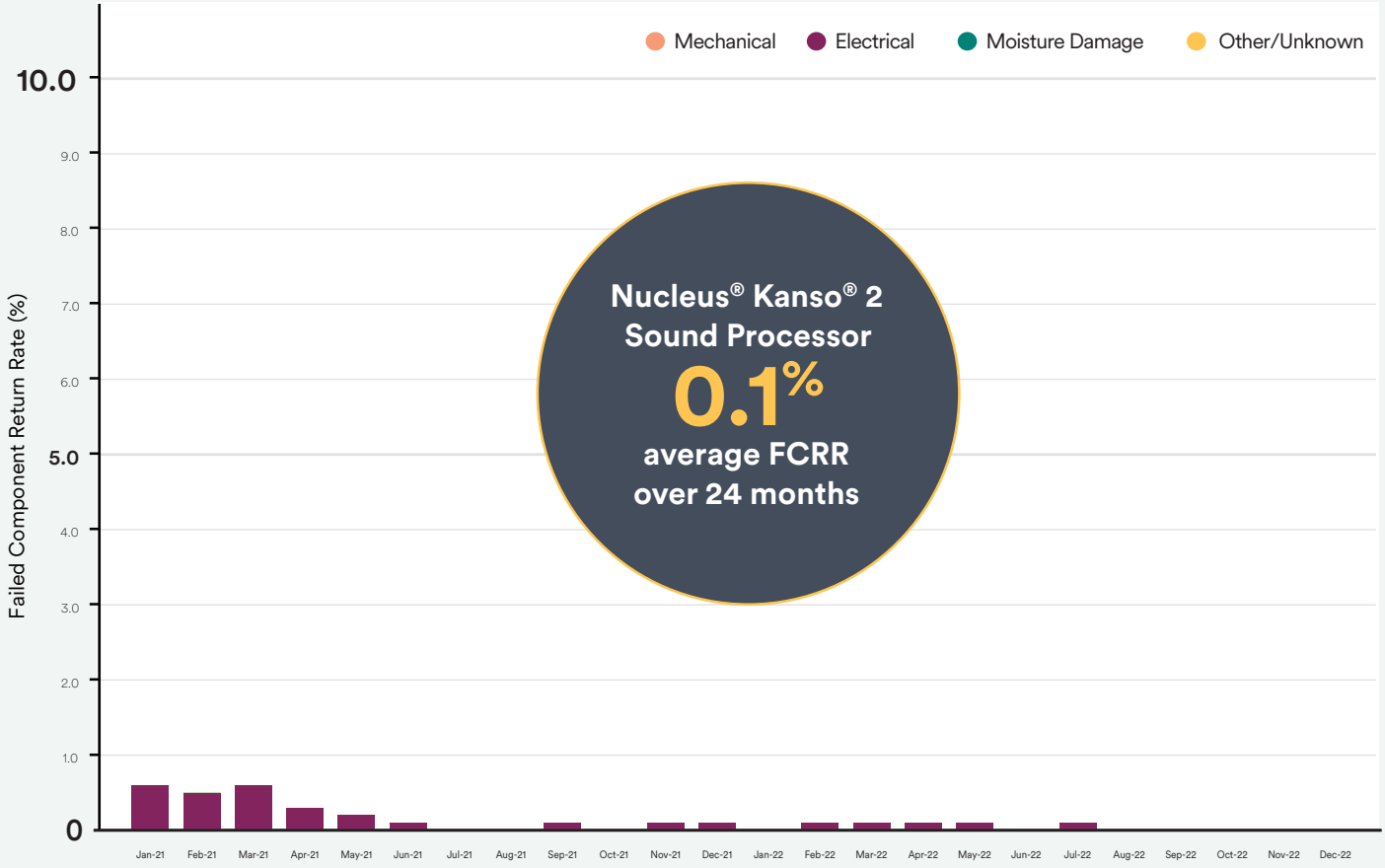
Nucleus Kanso 2 Sound Processor – Failed Component Return Rate

Fail mode	Jan-21	Feb-21	Mar-21	Apr-21	May-21	Jun-21	Jul-21	Aug-21	Sep-21	Oct-21	Nov-21	Dec-21
Mechanical	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Electrical	0.6%	0.5%	0.6%	0.3%	0.2%	0.1%	0.0%	0.0%	0.1%	0.0%	0.1%	0.1%
Moisture	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Other	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Fault-Free	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Fail mode	Jan-22	Feb-22	Mar-22	Apr-22	May-22	Jun-22	Jul-22	Aug-22	Sep-22	Oct-22	Nov-22	Dec-22
Mechanical	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Electrical	0.0%	0.1%	0.1%	0.1%	0.1%	0.0%	0.1%	0.0%	0.0%	0.0%	0.0%	0.0%
Moisture	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Other	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Fault-Free	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

* The Cochlear Kanso 2 Sound Processor is compatible with Apple and Android™ devices. For compatibility information visit www.cochlear.com/compatibility.

Nucleus® Kanso® 2 Sound Processor - Failed Component Return Rate



Nucleus® 7 Sound Processor

Released in 2017, the Nucleus® 7 Sound Processor is a behind-the-ear sound processor that delivers world-first connectivity and control directly from a compatible smartphone.*

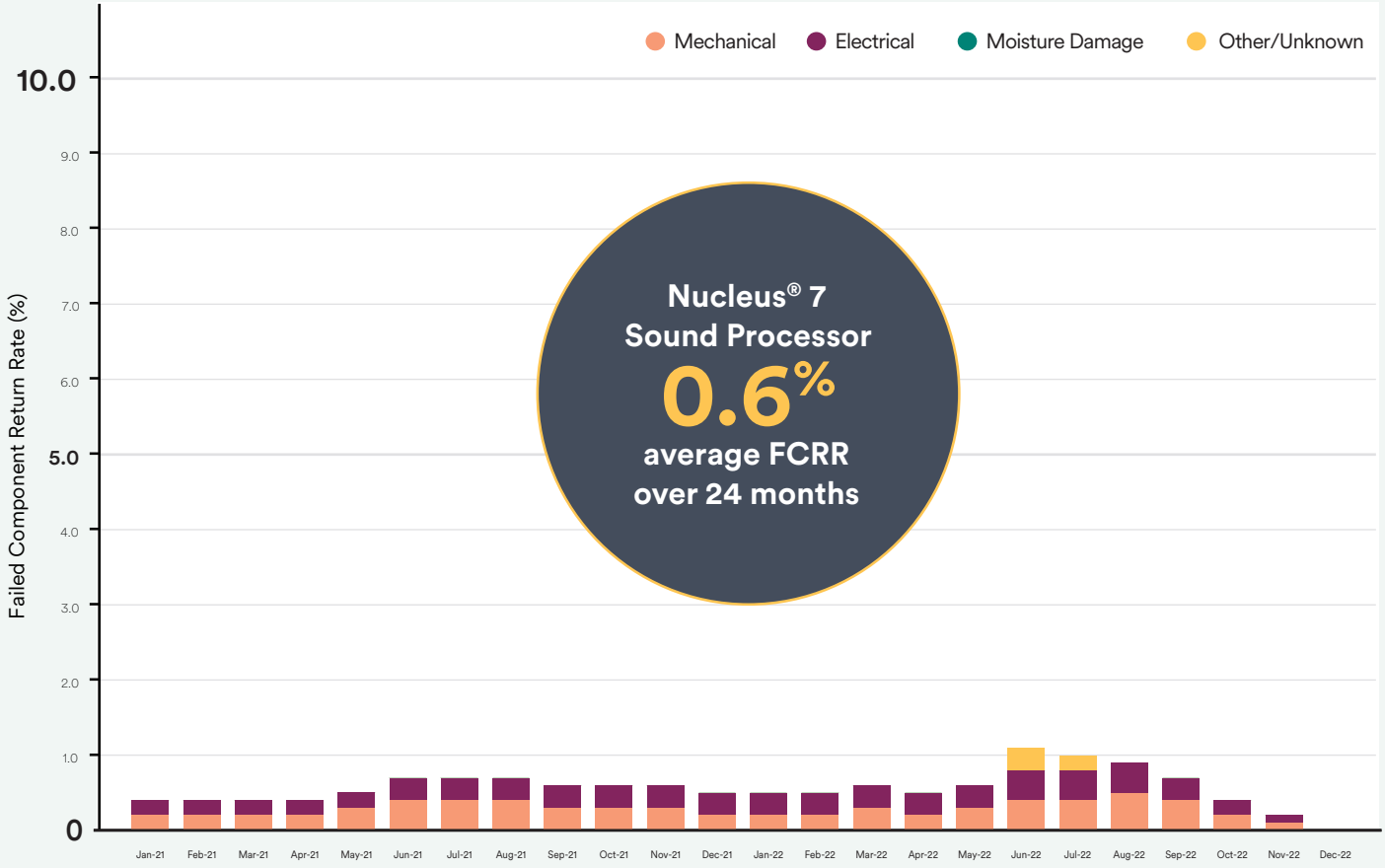
Nucleus 7 Sound Processor – Failed Component Return Rate

Fail mode	Jan-21	Feb-21	Mar-21	Apr-21	May-21	Jun-21	Jul-21	Aug-21	Sep-21	Oct-21	Nov-21	Dec-21
Mechanical	0.2%	0.2%	0.2%	0.2%	0.3%	0.4%	0.4%	0.4%	0.3%	0.3%	0.3%	0.2%
Electrical	0.2%	0.2%	0.2%	0.2%	0.2%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%
Moisture	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Other	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Fault-Free	0.2%	0.2%	0.2%	0.1%	0.1%	0.2%	0.2%	0.2%	0.2%	0.2%	0.1%	0.1%

Fail mode	Jan-22	Feb-22	Mar-22	Apr-22	May-22	Jun-22	Jul-22	Aug-22	Sep-22	Oct-22	Nov-22	Dec-22
Mechanical	0.2%	0.2%	0.3%	0.2%	0.3%	0.4%	0.4%	0.5%	0.4%	0.2%	0.1%	0.0%
Electrical	0.3%	0.3%	0.3%	0.3%	0.3%	0.4%	0.4%	0.4%	0.3%	0.2%	0.1%	0.0%
Moisture	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Other	0.0%	0.0%	0.0%	0.0%	0.0%	0.3%	0.2%	0.0%	0.0%	0.0%	0.0%	0.0%
Fault-Free	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.0%	0.0%

* The Cochlear Nucleus 7 Sound Processor is compatible with Apple and Android™ devices.
For compatibility information visit www.cochlear.com/compatibility.

Nucleus® 7 Sound Processor - Failed Component Return Rate



Appendix

GRAPHICAL REPRESENTATION OF IMPLANT DATA

Each implant graph represents a type of device based on the receiver/stimulator portion.

RECEIVER/ STIMULATOR	IMPLANTS*
Profile™ Plus Series	Cochlear™ Nucleus® Profile™ Plus with Contour Advance® Electrode (CI612) Cochlear Nucleus Profile Plus with Slim Straight Electrode (CI622) Cochlear Nucleus Profile Plus with Slim Modiolar Electrode (CI632) Cochlear Nucleus Profile Plus with Slim 20 Electrode (CI624)
Profile Series	Cochlear Nucleus Profile with Contour Advance Electrode (CI512) Cochlear Nucleus Profile with Slim Straight Electrode (CI522) Cochlear Nucleus Profile with Slim Modiolar Electrode (CI532) Cochlear Nucleus Profile Auditory Brainstem Implant (ABI541)
CI24RE Series	Nucleus Freedom® with Contour Advance Electrode Nucleus Freedom with Straight Electrode Cochlear Nucleus CI422 Cochlear Implant Cochlear Hybrid™ L24 Cochlear Implant
CI500 Series	Cochlear Nucleus CI512 Cochlear Implant Cochlear Nucleus CI513 Cochlear Implant Cochlear Nucleus CI551 Double Array Cochlear Implant Cochlear Nucleus ABI541 Auditory Brainstem Implant
CI24R	Nucleus 24 with Contour Advance Electrode Nucleus 24 with Contour® Electrode Nucleus 24k with Straight Electrode
CI24M	Nucleus 24 with Straight Electrode Nucleus 24 with Double Array Nucleus 24 Auditory Brainstem Implant [ABI]
CI22M	Nucleus 22

* Implant availability varies by market.

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. Geneva (Switzerland): International Organization for Standardization.
2. European Consensus Statement on Cochlear Implant Failures and Explantations. Otol Neurotol. 2005 Nov;26(6):1097-9.
3. ANSI/AAMI CI86. Cochlear implant systems: Requirements for safety, functional verification,. (2017). Arlington, VA: American National Standards Institute.
4. Cochlear Limited D1190805 Processor Size Comparison. 2022, May.
5. Battmer RD, Backous DD, Balkany TJ, Briggs RJ, Gantz BJ, van Hasselt A, et al. International Classification of Reliability for Implanted Cochlear Implant Receiver Stimulators. Otol Neurotol. 2010 Oct;31(8):1190-3.
6. Based on implant generations released within a comparable period with 5+ years of CSP data.
7. Cochlear Implant Reliability | MED-EL [Internet]. Medel.com. 2023 [cited 1 March 2023]. Available from: http://www.medel.com/hearing-solutions/cochlear-implants/reliability
8. Advanced Bionics Reliability Report December 2022. 028-Q048-02 Rev B. Advanced Bionics AG and affiliates. Data valid as of 1 October 2022.
9. Oticon Medical Reliability Report 2021. In accordance with European and Global Consensus on Cochlear Implant Failures and Explantations, ANSI/AAMI CI86 Standard. 224811UK - version B / 2021.09. Data valid as of 30 June 2021.
10. Oticon Medical Reliability Report 2021. According to ANSI/AAMI CI86 Standard. 224812US - version B / 2021.10. Data valid as of 30 June 2021.
11. Compared to all currently available receiver stimulators available from Cochlear and other cochlear implant manufacturers. Based on published device specification information.

Hear now. And always

Cochlear is dedicated to helping people with moderate to profound hearing loss experience a world full of hearing. As the global leader in implantable hearing solutions, we have provided more than 700,000 devices and helped people of all ages to hear and connect with life's opportunities.

We aim to give people the best lifelong hearing experience and access to next generation technologies. We collaborate with leading clinical, research and support networks to advance hearing science and improve care.

That’s why more people choose Cochlear than any other hearing implant company.

Cochlear Ltd (ABN 96 002 618 073) 1 University Avenue, Macquarie University, NSW 2109, Australia T: +61 2 9428 6555 F: +61 2 9428 6352

www.cochlear.com