



Cochlear®

Hear now. And always

Cochlear™ Nucleus® System **Reliability Report**

Volume 22 | December 2023

Reporting to European Consensus Statement,
International Classification of Reliability,
ANSI/AAMI C186 Standard and ISO 5841-2.

A message from our CEO

At Cochlear, we have a steadfast commitment to excellence. This means a dedication to quality, reliability and continued technological innovation across all of our products, giving you peace of mind when making the decision to choose a cochlear implant.

As the industry leader, we are also focused on improving hearing outcomes for you and your loved ones over the long term. We deliver cutting-edge technology in our products today, and we also actively embrace emerging technology to ensure our products lead the way tomorrow. This provides reassurance that our products and services available today are developed to adapt to future technology and support a lifetime of hearing.

Our promise to our customers extends beyond innovation. Commitment to excellence also means being transparent about reporting data on the reliability of our products.

For this reason, Cochlear publishes two reliability reports to provide easy access to the most up to date data which meets all industry-recognised cochlear implant reliability reporting requirements.

We are proud to deliver to you our latest reliability data.



Dig Howitt
CEO & President

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.

Implant reliability

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.

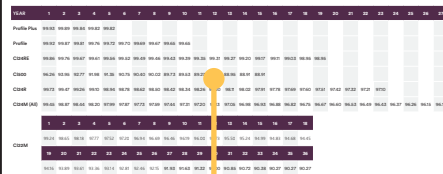
More people choose Cochlear than any other implant brand

Over 550,000 registered Nucleus® implants worldwide

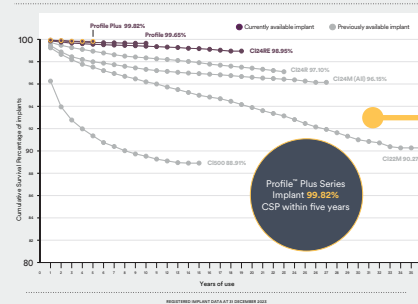
Number of registered implants – 31 December 2023

DEVICE	ADULTS	CHILDREN	COMBINED
Profile® Plus	66,900	36,045	102,935
Profile™	66,352	69,592	135,944
CID4RE	83,827	135,794	219,621
CIS90	15,388	14,507	29,895
CID4R	18,705	34,855	53,560
CID4M (All)	7,773	11,750	19,523
CID2M	9,870	7,591	17,461

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



Nucleus® Implant Reliability - combined Adults & Children



* CIS90 series was voluntarily recalled in September 2021. CSP includes both device and accident-related issues.

Cochlear Nucleus®

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 (CI) 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 **550,000** registered Nucleus® Implants **worldwide**

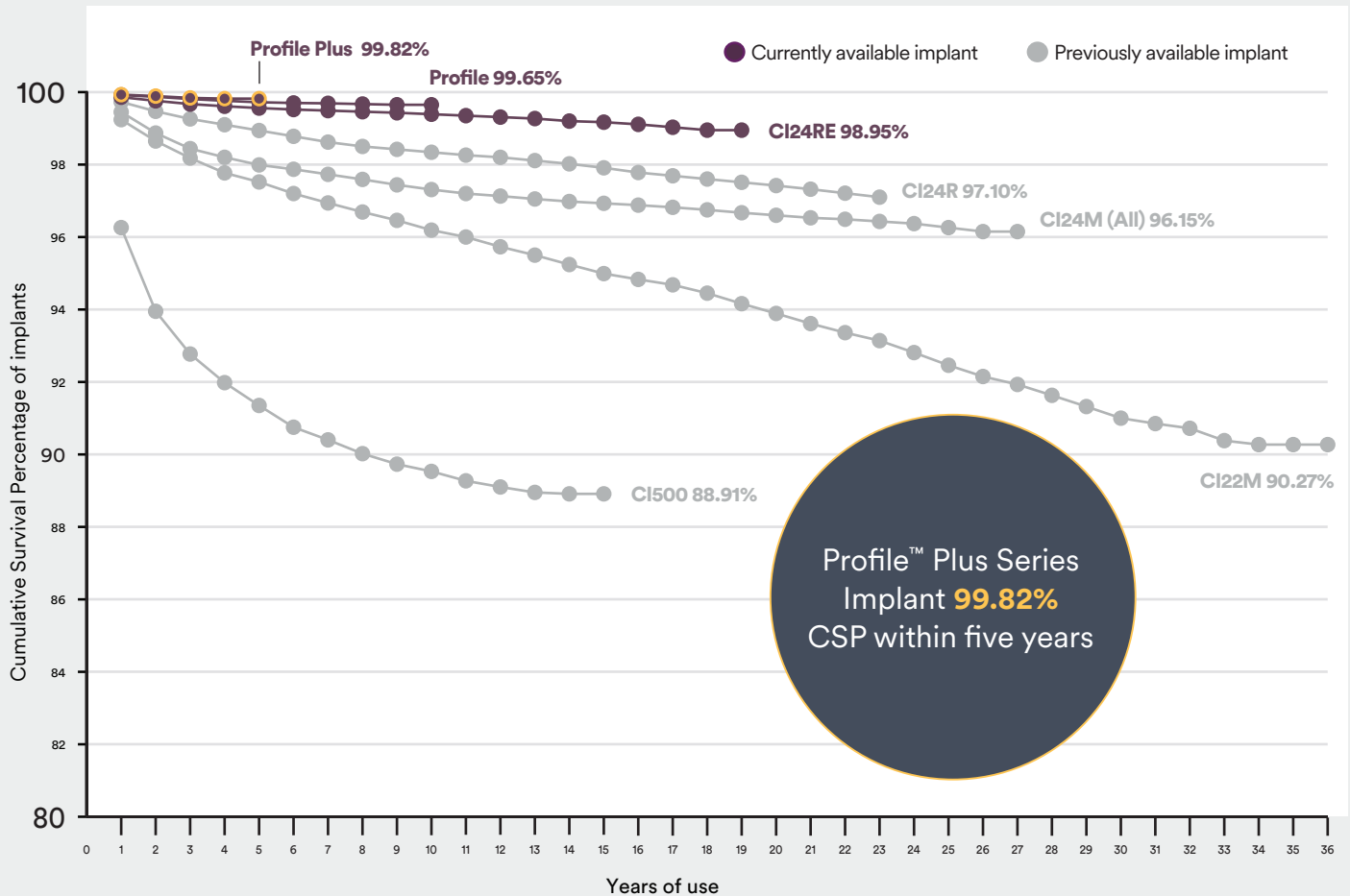
Number of registered implants – 31 December 2023

DEVICE	ADULTS	CHILDREN	COMBINED
Profile™ Plus	66,190	36,045	102,235
Profile™	56,352	59,592	115,944
CI24RE	83,827	135,794	219,621
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
Profile Plus	99.93	99.89	99.84	99.82	99.82																						
Profile	99.92	99.87	99.81	99.76	99.72	99.70	99.69	99.67	99.65	99.65																	
CI24RE	99.86	99.76	99.67	99.61	99.56	99.52	99.49	99.46	99.43	99.39	99.35	99.31	99.27	99.20	99.17	99.11	99.03	98.95	98.95								
CI500	96.26	93.95	92.77	91.98	91.35	90.75	90.40	90.02	89.73	89.53	89.27	89.10	88.95	88.91	88.91												
CI24R	99.73	99.47	99.26	99.10	98.94	98.78	98.62	98.50	98.42	98.34	98.26	98.20	98.11	98.02	97.91	97.78	97.69	97.60	97.51	97.42	97.32	97.21	97.10				
CI24M (All)	99.45	98.87	98.44	98.20	97.99	97.87	97.73	97.59	97.44	97.31	97.20	97.13	97.05	96.98	96.93	96.88	96.82	96.75	96.67	96.60	96.53	96.49	96.43	96.37	96.26	96.15	96.15
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18									
CI22M	99.24	98.65	98.18	97.77	97.52	97.20	96.94	96.69	96.46	96.19	96.00	95.73	95.50	95.24	94.99	94.83	94.68	94.45									
	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36									
CI22M	94.16	93.89	93.61	93.36	93.14	92.81	92.46	92.15	91.93	91.63	91.32	91.00	90.85	90.72	90.38	90.27	90.27	90.27									

Nucleus® Implant Reliability - combined Adults & Children



REGISTERED IMPLANT DATA AT 31 DECEMBER 2023

* CI500 series was 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 2023

ADULTS	CHILDREN	COMBINED
66,190	36,045	102,235



Profile Plus Series Implant Cumulative Survival Percentage

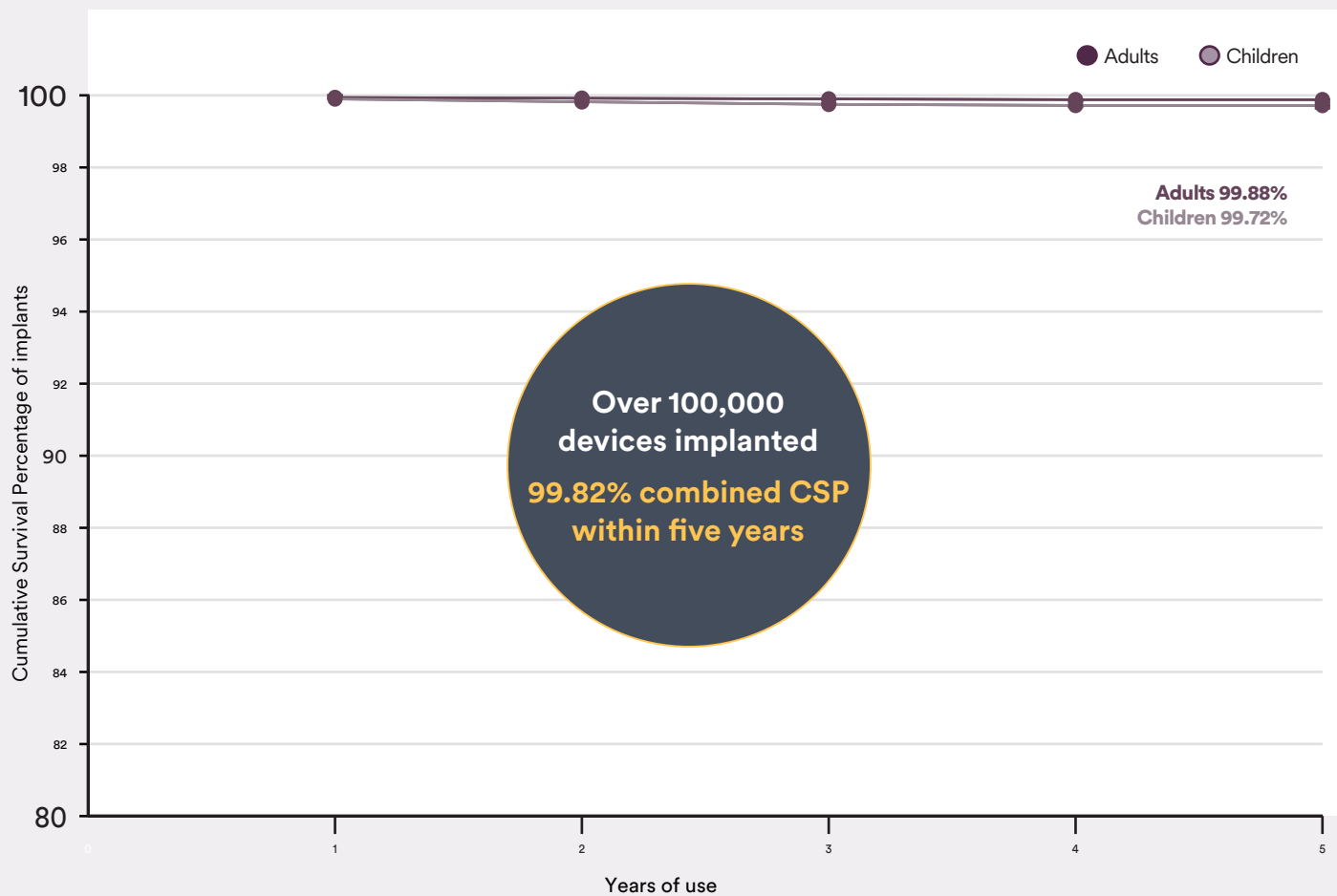
YEAR	1	2	3	4	5
Combined	99.93	99.89	99.84	99.82	99.82
Adults	99.94	99.92	99.90	99.88	99.88
Children	99.90	99.82	99.75	99.72	99.72

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



3.9 mm

Profile™ Plus Implant Reliability - Adults & Children



REGISTERED IMPLANT DATA AT 31 DECEMBER 2023

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 2023

ADULTS	CHILDREN	COMBINED
56,352	59,592	115,944



Profile Series Implant Cumulative Survival Percentage

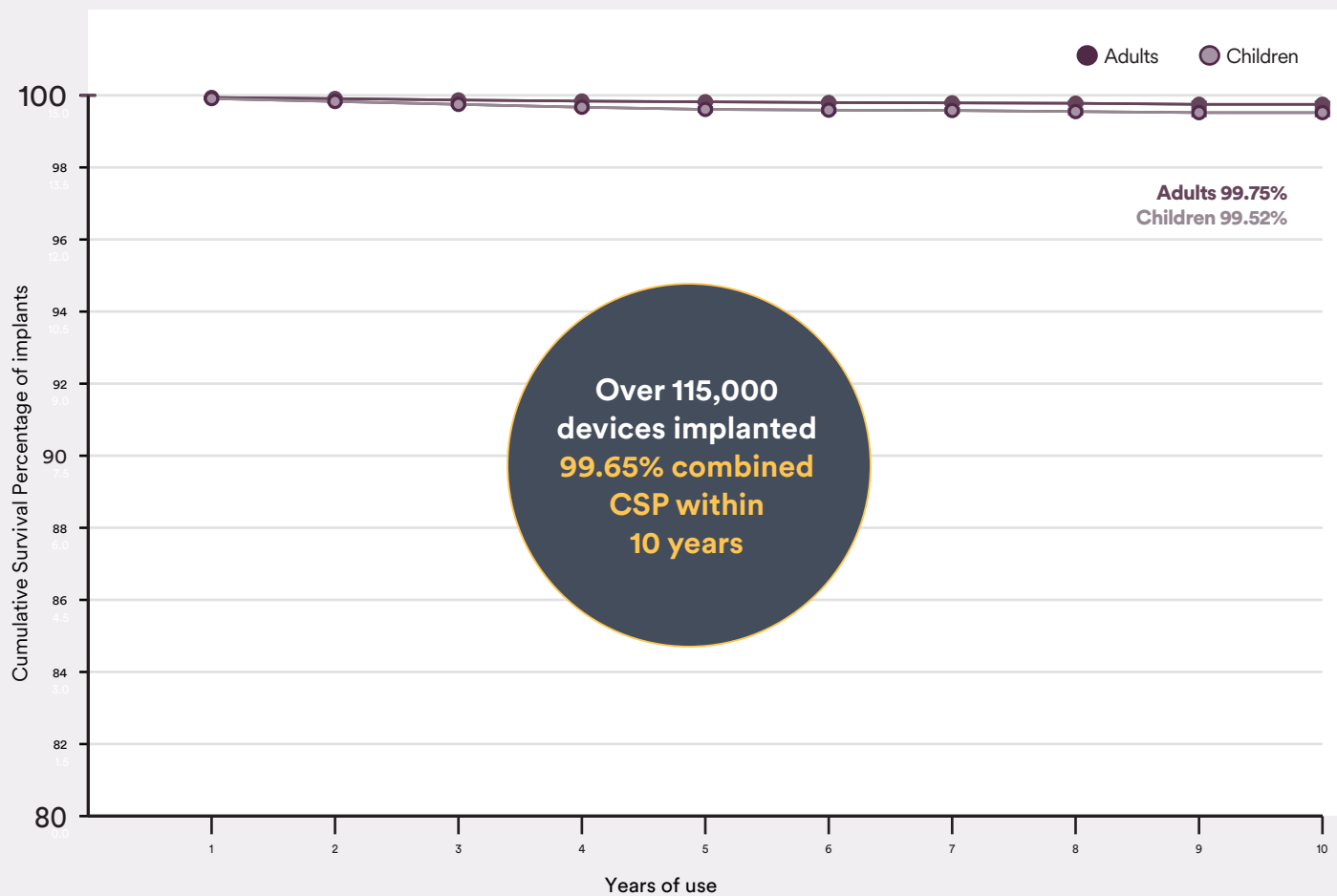
YEAR	1	2	3	4	5	6	7	8	9	10
Combined	99.92	99.87	99.81	99.76	99.72	99.70	99.69	99.67	99.65	99.65
Adults	99.94	99.91	99.87	99.84	99.82	99.80	99.79	99.78	99.75	99.75
Children	99.91	99.83	99.75	99.67	99.61	99.59	99.58	99.55	99.52	99.52

Cochlear Nucleus Profile Implant with Slim Modiolar Electrode (CI532)



3.9 mm

Profile™ Series Implant Reliability - combined Adults & Children



REGISTERED IMPLANT DATA AT 31 DECEMBER 2023

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 2023

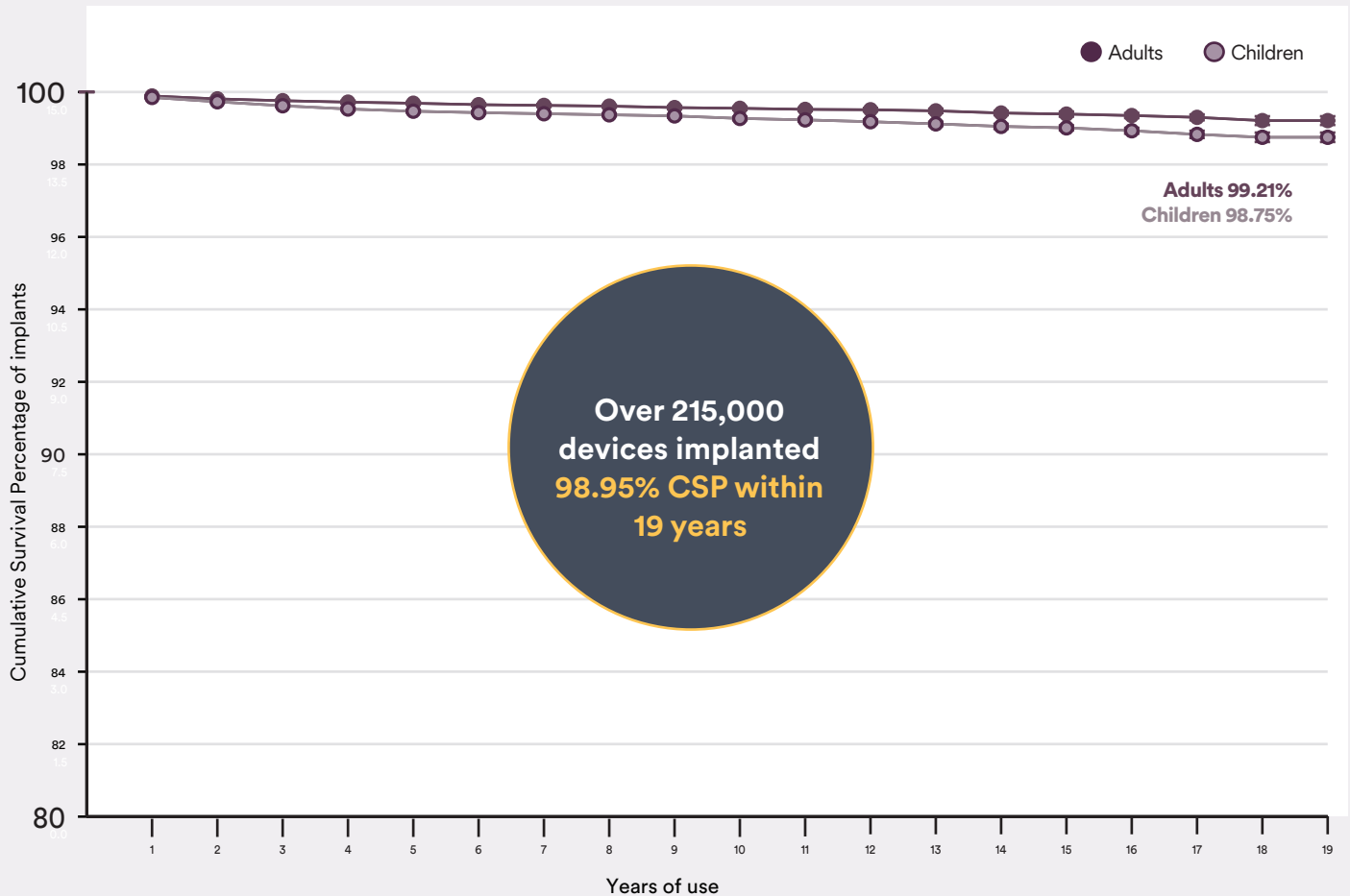
ADULTS	CHILDREN	COMBINED
83,827	135,794	219,621



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	19
Combined	99.86	99.76	99.67	99.61	99.56	99.52	99.49	99.46	99.43	99.39	99.35	99.31	99.27	99.20	99.17	99.11	99.03	98.95	98.95
Adults	99.89	99.81	99.76	99.72	99.69	99.65	99.63	99.61	99.57	99.55	99.52	99.51	99.48	99.42	99.39	99.35	99.30	99.21	99.21
Children	99.85	99.73	99.62	99.53	99.47	99.43	99.40	99.37	99.34	99.27	99.23	99.18	99.12	99.05	99.01	98.93	98.83	98.75	98.75

CI24RE Series Implant Reliability - Adults & Children



REGISTERED IMPLANT DATA AT 31 DECEMBER 2023

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

Previously available implants

Nucleus® CI500 Series Implant



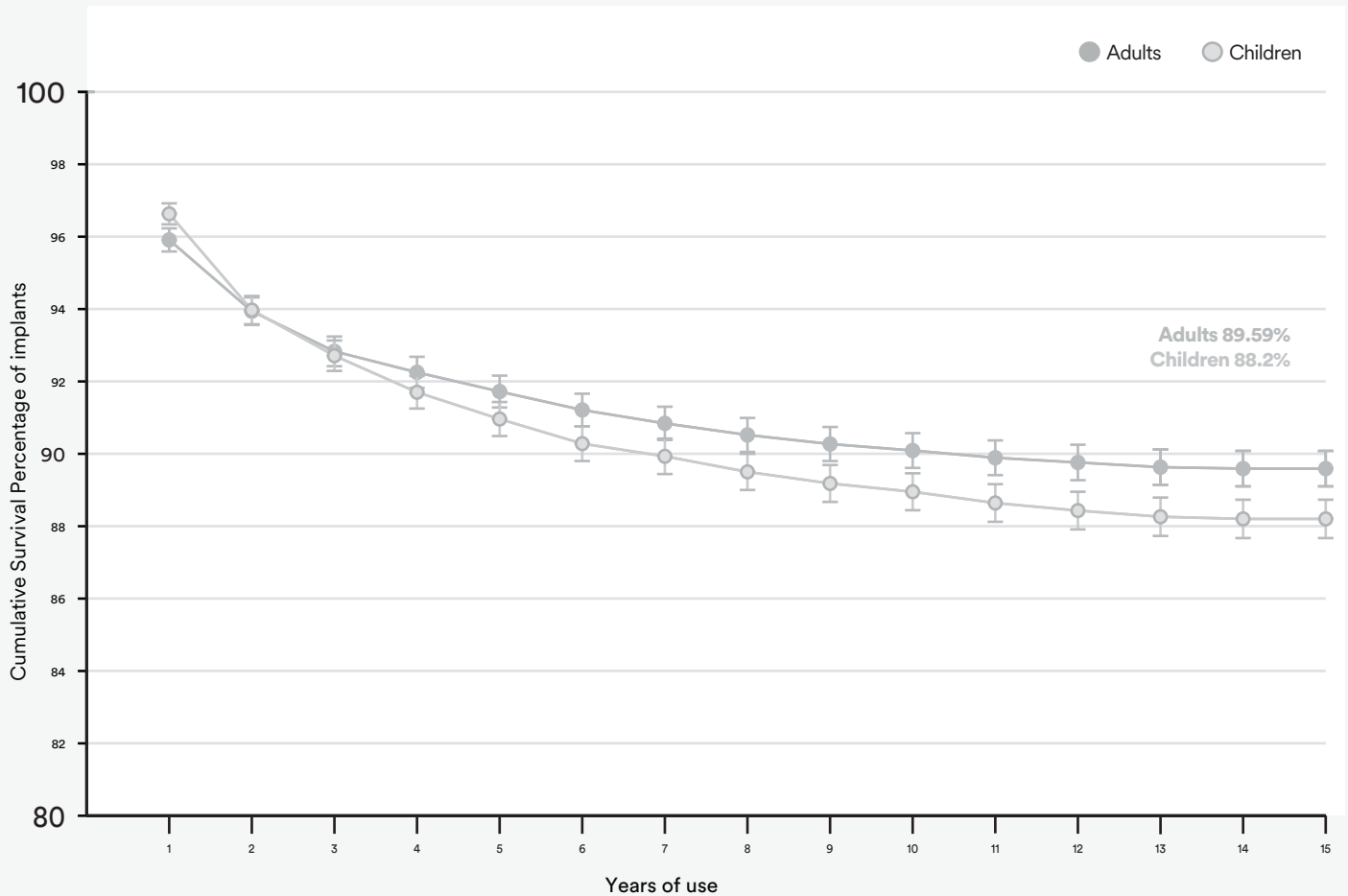
Number of registered CI500 Series Implants – 31 December 2023

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

CI500 Series Implant Cumulative Survival Percentage

YEAR	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Combined	96.26	93.95	92.77	91.98	91.35	90.75	90.40	90.02	89.73	89.53	89.27	89.10	88.95	88.91	88.91
Adults	95.91	93.94	92.83	92.25	91.72	91.21	90.84	90.52	90.27	90.09	89.89	89.76	89.63	89.59	89.59
Children	96.63	93.97	92.71	91.70	90.96	90.28	89.93	89.50	89.18	88.95	88.64	88.43	88.26	88.20	88.20

CI500 Series Implant Reliability - Adults & Children



REGISTERED IMPLANT DATA AT 31 DECEMBER 2023

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 2023

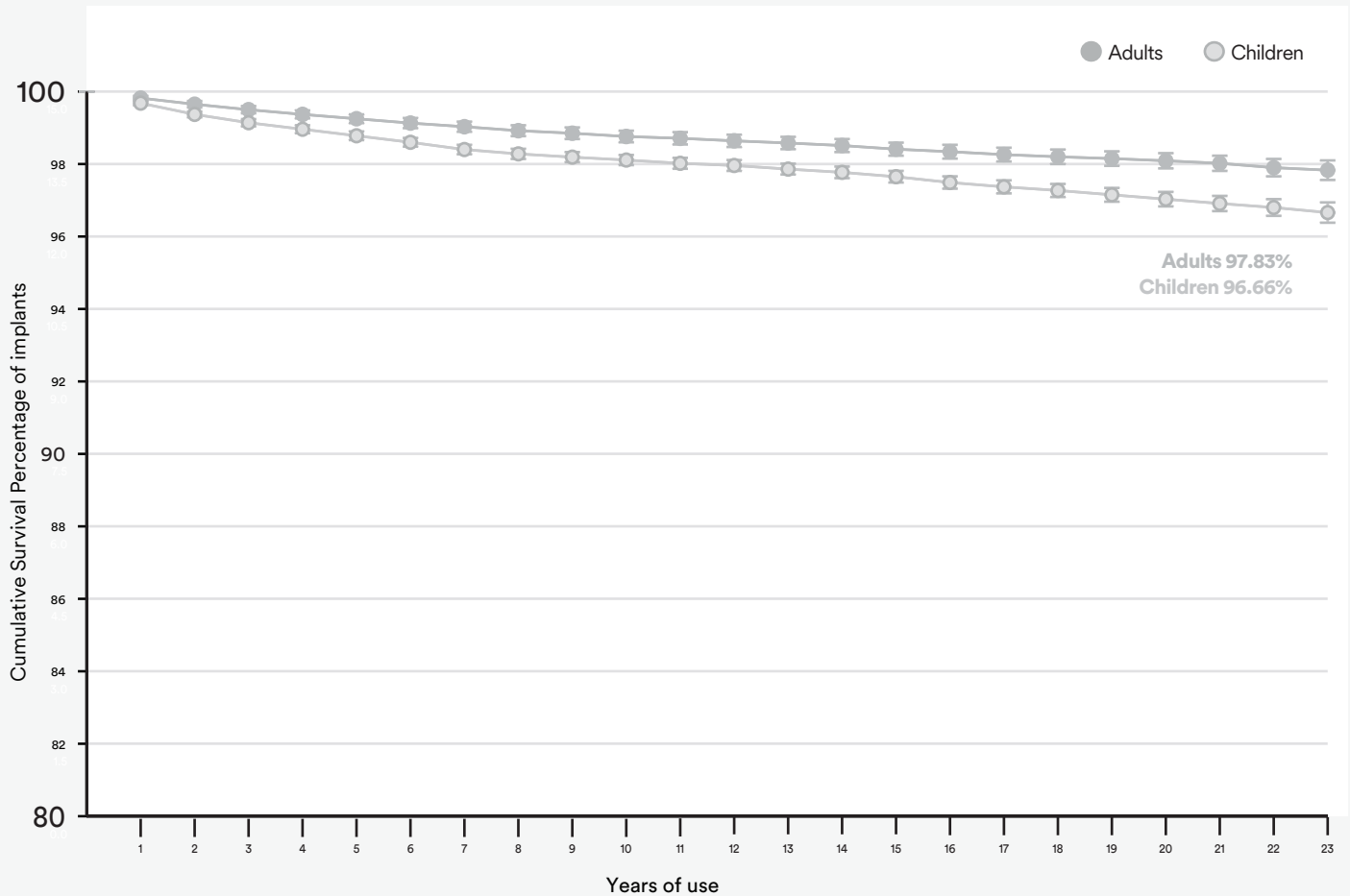
ADULTS	CHILDREN	COMBINED
18,705	34,855	53,560



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	23
Combined	99.73	99.47	99.26	99.10	98.94	98.78	98.62	98.50	98.42	98.34	98.26	98.20	98.11	98.02	97.91	97.78	97.69	97.60	97.51	97.42	97.32	97.21	97.10
Adults	99.82	99.65	99.50	99.37	99.25	99.13	99.03	98.92	98.85	98.76	98.71	98.64	98.58	98.51	98.41	98.34	98.26	98.20	98.15	98.09	98.02	97.90	97.83
Children	99.68	99.37	99.14	98.96	98.78	98.60	98.40	98.28	98.19	98.11	98.02	97.96	97.86	97.77	97.65	97.49	97.37	97.27	97.15	97.03	96.91	96.80	96.66

CI24R Series Implant Reliability - Adults & Children



REGISTERED IMPLANT DATA AT 31 DECEMBER 2023

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 2023

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



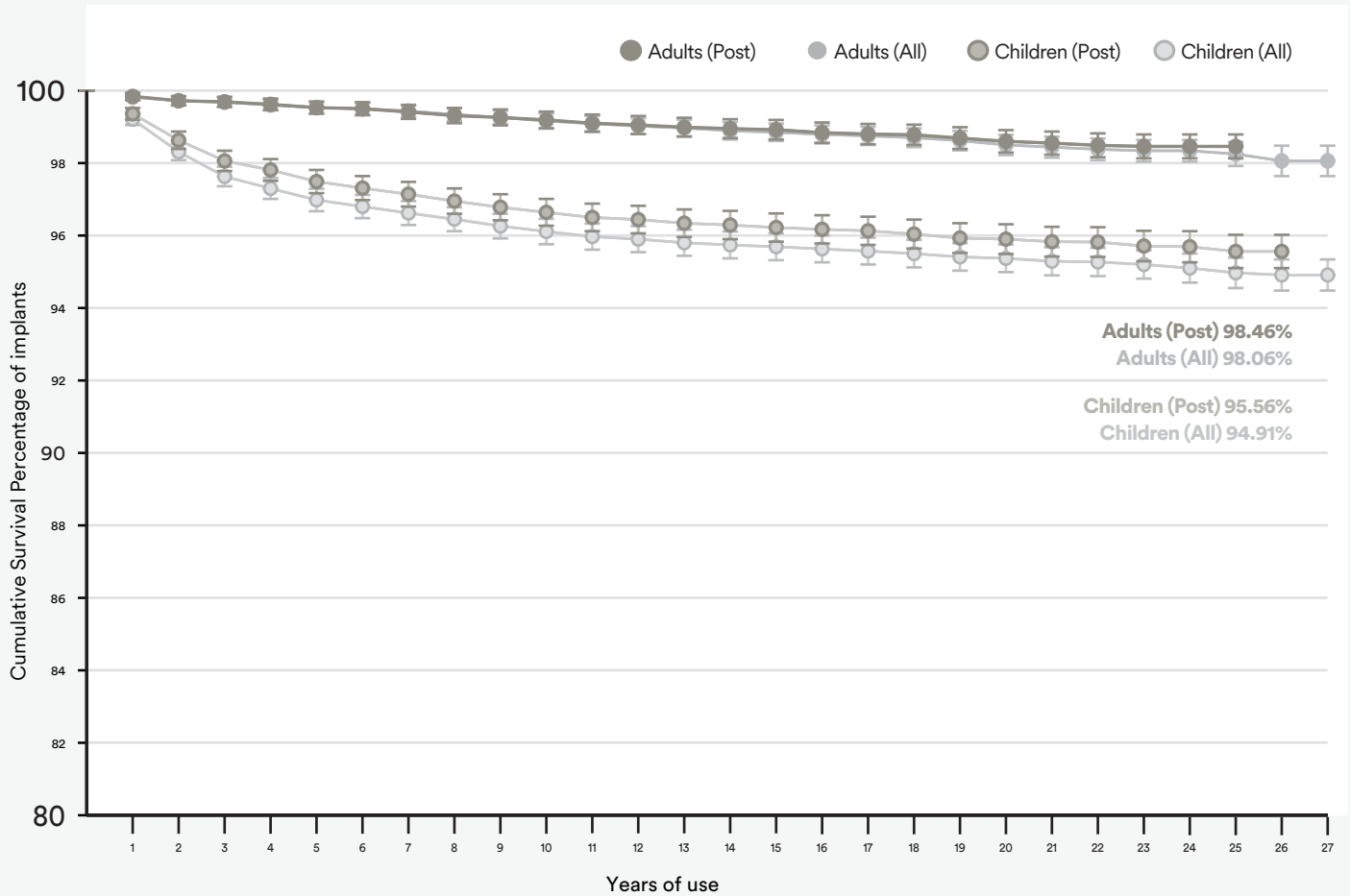
CI24M Implant Cumulative Survival Percentage

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	27
Combined (All)	99.45	98.87	98.44	98.20	97.99	97.87	97.73	97.59	97.44	97.31	97.20	97.13	97.05	96.98	96.93	96.88	96.82	96.75	96.67	96.60	96.53	96.49	96.43	96.37	96.26	96.15	96.15
Adults (All)	99.82	99.72	99.68	99.60	99.53	99.50	99.44	99.34	99.26	99.16	99.09	99.02	98.97	98.89	98.85	98.79	98.75	98.70	98.62	98.50	98.44	98.38	98.34	98.34	98.25	98.06	98.06
Children (All)	99.21	98.31	97.63	97.30	96.98	96.80	96.62	96.45	96.26	96.11	95.97	95.90	95.80	95.74	95.69	95.63	95.57	95.50	95.41	95.37	95.29	95.27	95.20	95.10	94.97	94.91	94.91
Combined (Post**)	99.55	99.06	98.70	98.52	98.29	98.17	98.03	97.88	97.75	97.64	97.52	97.46	97.38	97.33	97.28	97.22	97.17	97.11	97.01	96.96	96.90	96.86	96.79	96.77	96.69	96.69	#
Adults (Post**)	99.84	99.72	99.69	99.62	99.53	99.50	99.41	99.31	99.26	99.19	99.10	99.05	98.99	98.95	98.92	98.84	98.80	98.78	98.69	98.60	98.55	98.49	98.46	98.46	98.46	#	#
Children (Post**)	99.36	98.63	98.06	97.81	97.49	97.31	97.14	96.95	96.78	96.64	96.50	96.44	96.34	96.29	96.22	96.17	96.13	96.04	95.93	95.90	95.83	95.82	95.71	95.69	95.56	95.56	#

** '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 Series Implant Reliability - Adults & Children



REGISTERED IMPLANT DATA AT 31 DECEMBER 2023

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 2023

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

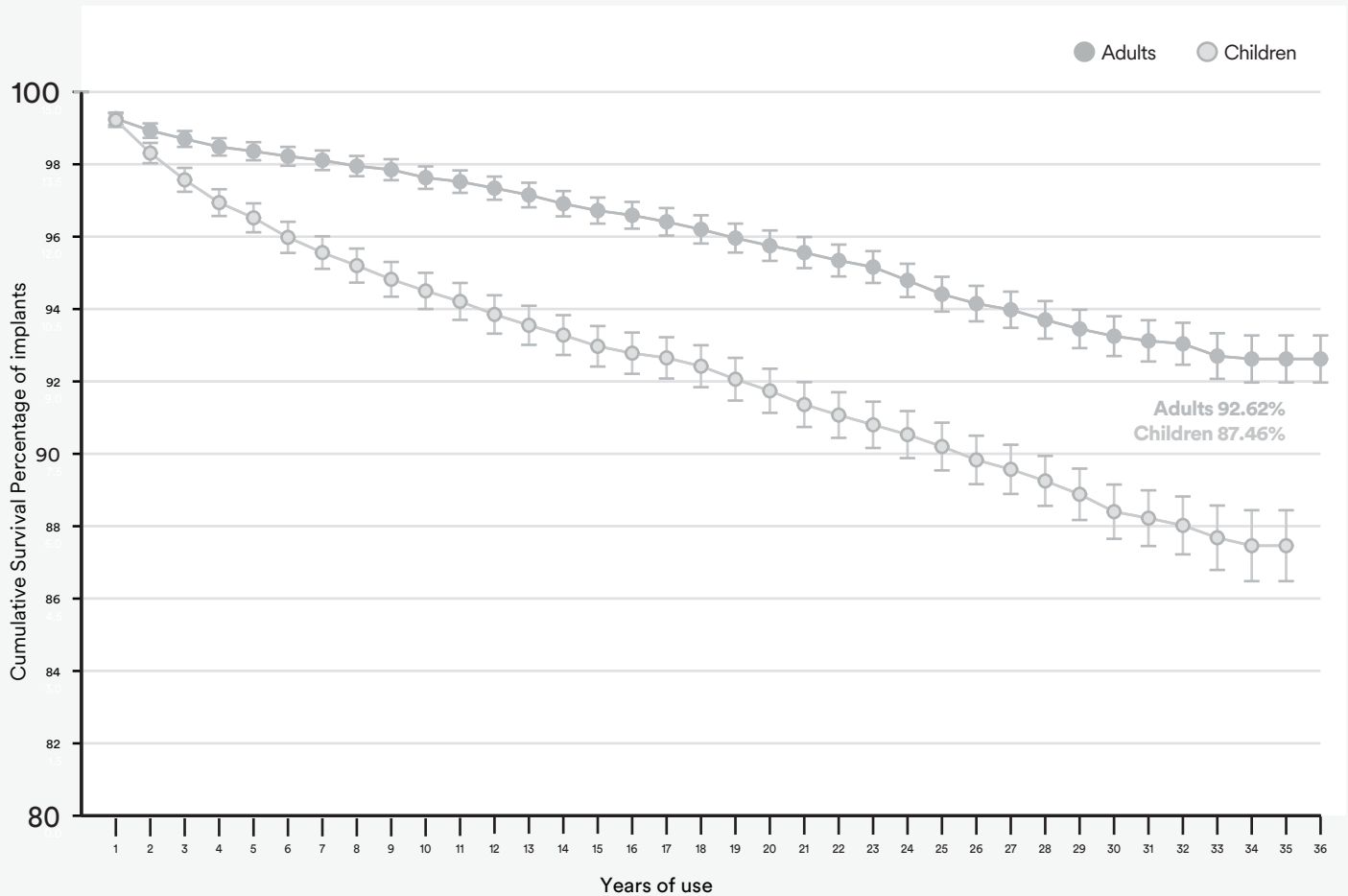
CI22M Implant Cumulative Survival Percentage

YEAR	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Combined	99.24	98.65	98.18	97.77	97.52	97.20	96.94	96.69	96.46	96.19	96.00	95.73	95.50	95.24	94.99	94.83	94.68	94.45
Adults	99.26	98.93	98.70	98.48	98.36	98.22	98.11	97.95	97.85	97.63	97.52	97.34	97.15	96.91	96.72	96.59	96.41	96.20
Children	99.22	98.31	97.57	96.94	96.52	95.98	95.56	95.20	94.82	94.50	94.21	93.85	93.55	93.28	92.97	92.78	92.65	92.42

YEAR	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36
Combined	94.16	93.89	93.61	93.36	93.14	92.81	92.46	92.15	91.93	91.63	91.32	91.00	90.85	90.72	90.38	90.27	90.27	90.27
Adults	95.96	95.75	95.56	95.34	95.16	94.79	94.41	94.15	93.98	93.70	93.45	93.25	93.12	93.04	92.70	92.62	92.62	92.62
Children	92.06	91.74	91.36	91.07	90.80	90.53	90.20	89.83	89.57	89.25	88.88	88.40	88.22	88.02	87.68	87.46	87.46	#

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

CI22M Series Implant Reliability - Adults & Children



REGISTERED IMPLANT DATA AT 31 DECEMBER 2023

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

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%

Nucleus[®] 8 Sound Processor

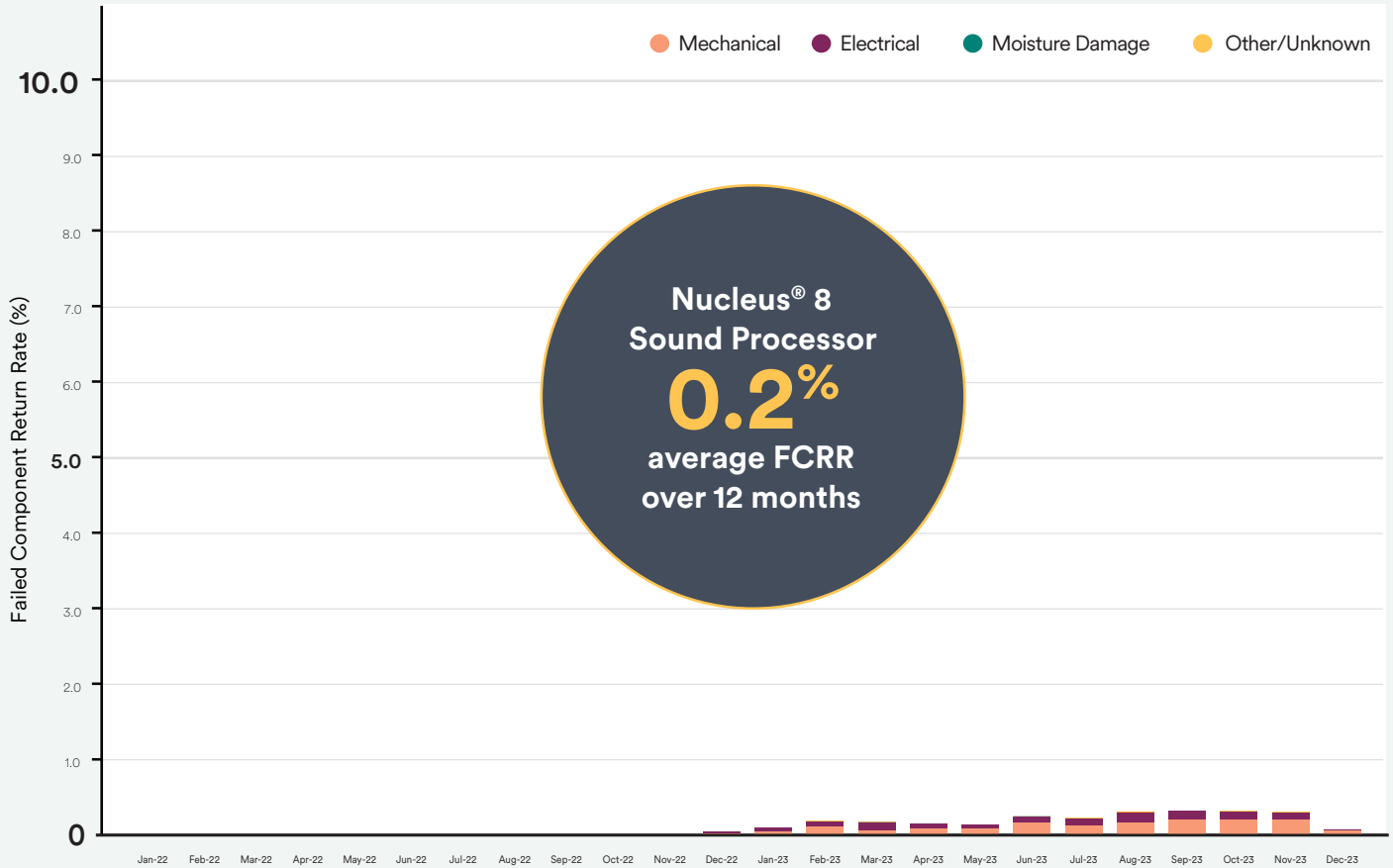


Nucleus 8 Sound Processor - Failed Component Return Rate

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%

Fail mode	Jan-23	Feb-23	Mar-23	Apr-23	May-23	Jun-23	Jul-23	Aug-23	Sep-23	Oct-23	Nov-23	Dec-23
Mechanical	0.1%	0.1%	0.1%	0.1%	0.1%	0.2%	0.1%	0.2%	0.2%	0.2%	0.2%	0.1%
Electrical	0.0%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	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%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Fault-Free	0.0%	0.0%	0.1%	0.0%	0.1%	0.1%	0.1%	0.1%	0.2%	0.1%	0.1%	0.0%

Nucleus® 8 Sound Processor - Failed Component Return Rate



Nucleus Kanso[®] 2 Sound Processor

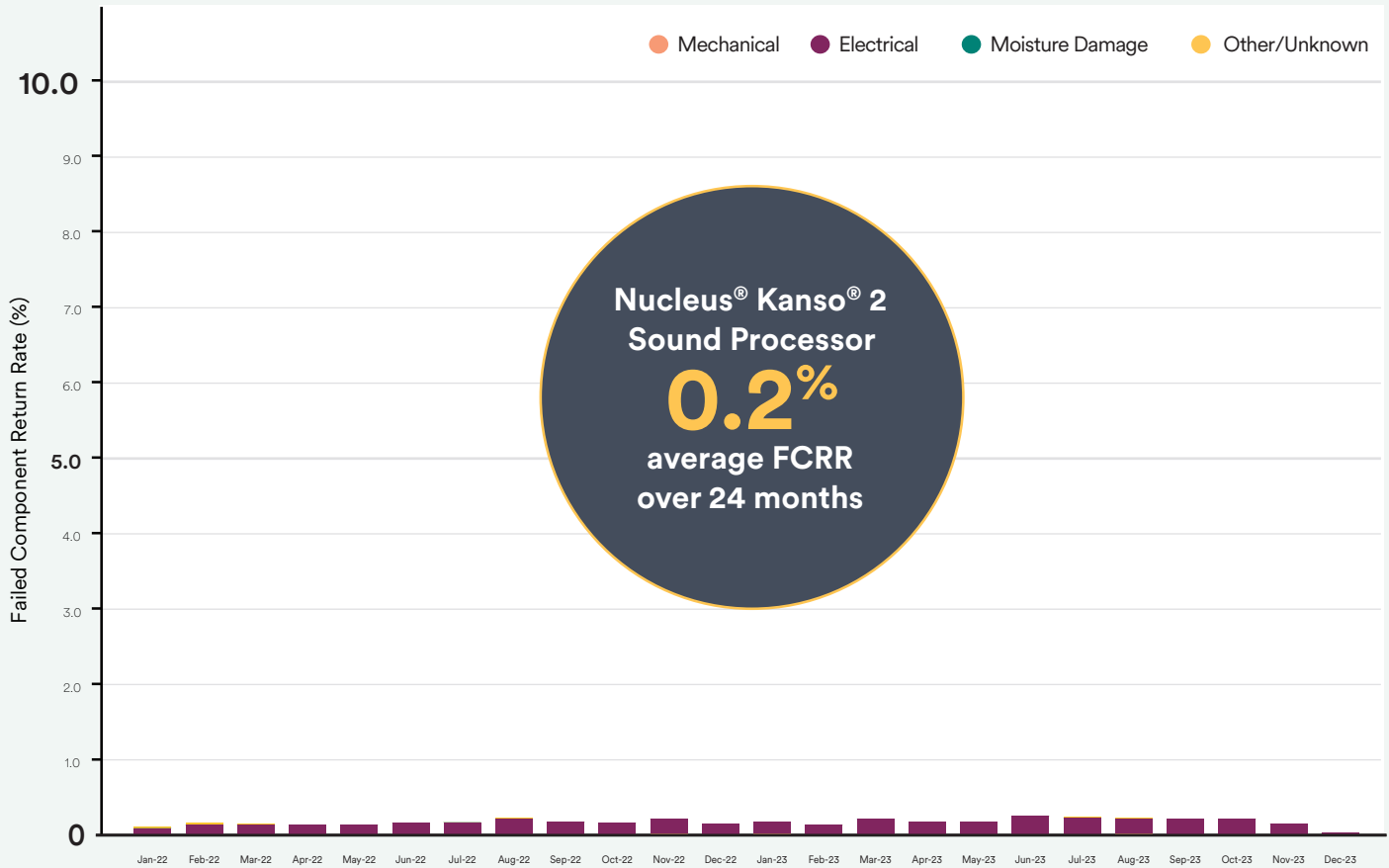


Nucleus Kanso 2 Sound Processor - Failed Component Return Rate

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	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.2%	0.2%	0.2%	0.2%	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	0.0%	0.0%	0.0%	0.0%	0.0%	0.1%	0.1%	0.1%	0.1%	0.2%	0.1%	0.1%

Fail mode	Jan-23	Feb-23	Mar-23	Apr-23	May-23	Jun-23	Jul-23	Aug-23	Sep-23	Oct-23	Nov-23	Dec-23
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	0.2%	0.1%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	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%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Fault-Free	0.1%	0.1%	0.2%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.0%

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



Nucleus[®] 7 Sound Processor

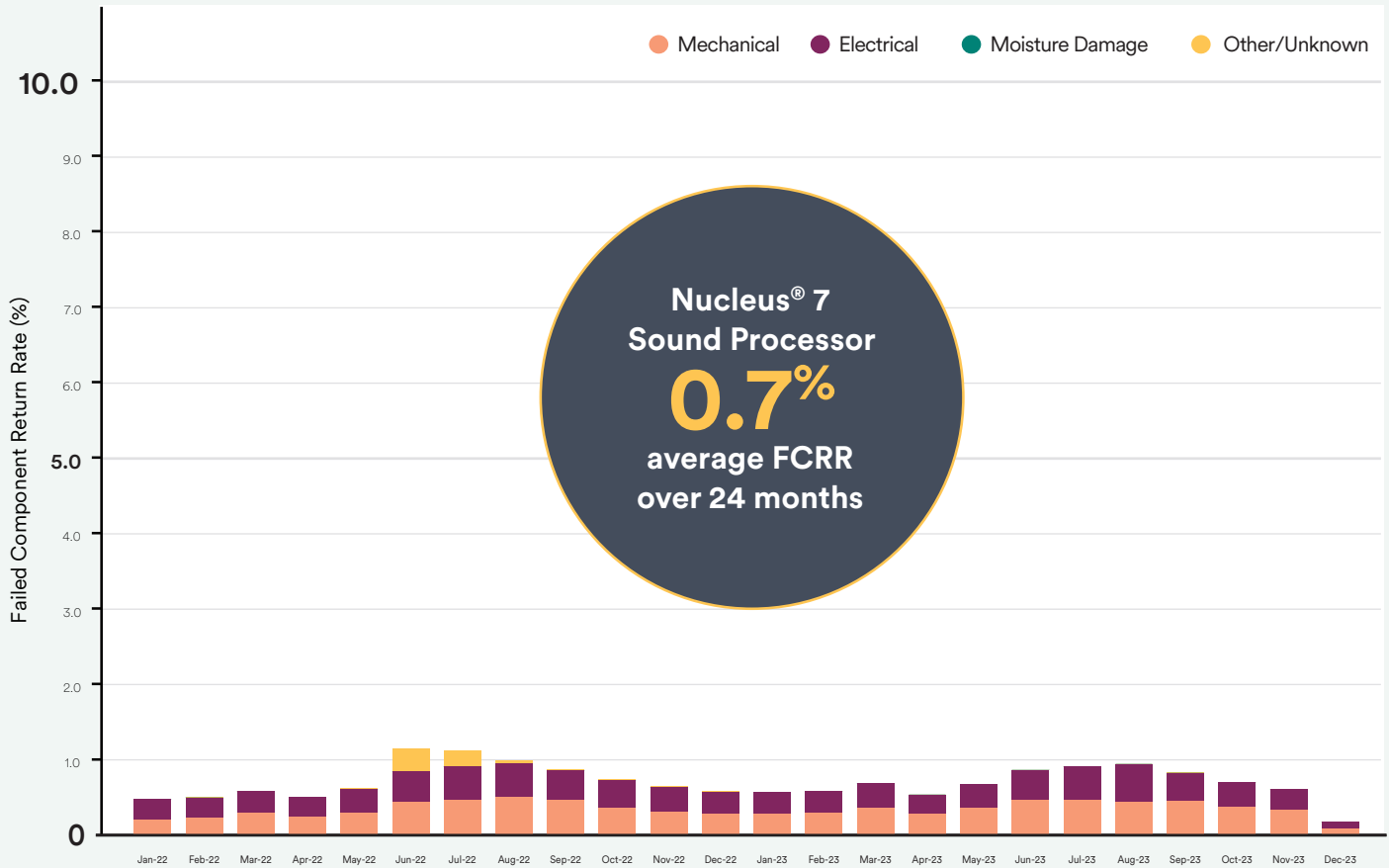


Nucleus 7 Sound Processor - Failed Component Return Rate

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%	0.5%	0.5%	0.5%	0.4%	0.3%	0.3%
Electrical	0.3%	0.3%	0.3%	0.3%	0.3%	0.4%	0.4%	0.4%	0.4%	0.4%	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%	0.3%	0.2%	0.0%	0.0%	0.0%	0.0%	0.0%
Fault-Free	0.1%	0.1%	0.1%	0.1%	0.1%	0.2%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%

Fail mode	Jan-23	Feb-23	Mar-23	Apr-23	May-23	Jun-23	Jul-23	Aug-23	Sep-23	Oct-23	Nov-23	Dec-23
Mechanical	0.3%	0.3%	0.4%	0.3%	0.4%	0.5%	0.5%	0.4%	0.5%	0.4%	0.3%	0.1%
Electrical	0.3%	0.3%	0.3%	0.3%	0.3%	0.4%	0.4%	0.5%	0.4%	0.3%	0.3%	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	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.0%	0.0%	0.0%

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. 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.

Notes

A series of horizontal dotted lines for taking notes.

Notes

A series of 25 horizontal dotted lines for taking notes.

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 750,000 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

Please seek advice from your health professional about treatments for hearing loss. Outcomes may vary, and your health professional will advise you about the factors which could affect your outcome. Always follow the directions for use. Not all products are available in all countries. Please contact your local Cochlear representative for product information.

In Australia, Cochlear™ Nucleus® Implant systems are intended for the treatment of moderately severe to profound hearing loss. For Cochlear™ Nucleus® Systems: This product is not available for purchase by the general public. For information on funding and reimbursement please contact your healthcare professional.

ACE, Advance Off-Stylet, AOS, Ardium, AutoNRT, Autosensitivity, Baha, Baha SoftWear, BCDrive, Beam, Bring Back the Beat, Button, Carina, Cochlear, 科利耳, コクレア, 코클리어, Cochlear SoftWear, Contour, コントゥア, Contour Advance, Custom Sound, DermaLock, Freedom, Hear now. And always, Hugfit, Human Design, Hybrid, Invisible Hearing, Kanso, LowPro, MET, MP3000, myCochlear, mySmartSound, NRT, Nucleus, Osia, Outcome Focused Fitting, Off-Stylet, Piezo Power, Profile, Slimline, SmartSound, Softip, SoundArc, True Wireless, the elliptical logo, Vistafix, Whisper, WindShield and Xidium are either trademarks or registered trademarks of the Cochlear group of companies.

The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by Cochlear Limited is under license.

© Cochlear Limited 2024. D2182827 V3 2024-04