

FOR PROFESSIONALS



**Cochlear**<sup>®</sup>

Hear now. And always

# Cochlear<sup>™</sup> Nucleus<sup>®</sup> System **Reliability Report**

**Volume 21 | December 2022**

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

# 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<sup>1</sup>, the reporting principles outlined in the European Consensus Statement on Cochlear Implant Failures and Explantations<sup>2</sup> and ANSI/AAMI CI86 – Cochlear implant systems: Requirements for safety, functional verification, labeling and reliability reporting.<sup>3</sup>

We are proud to present this latest report on the reliability of our implants and sound processors, including our new Nucleus 8 Sound Processor.

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

# 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*<sup>1</sup>, the reporting principles outlined in the *European Consensus Statement on Cochlear Implant Failures and Explantations*<sup>2</sup> and expert recommendations from the *International Classification of Reliability for Implanted Cochlear Implant Receiver Stimulators*.<sup>4</sup> 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*<sup>3</sup>, please visit [www.cochlear.com/reliability](http://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*.<sup>3</sup>

For the latest sound processor reliability data, please visit [www.cochlear.com/reliability](http://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*.<sup>1</sup> 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.

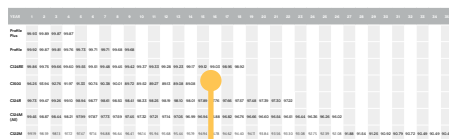
### More people choose Cochlear than any other implant brand

Number of registered implants - 31 December 2022

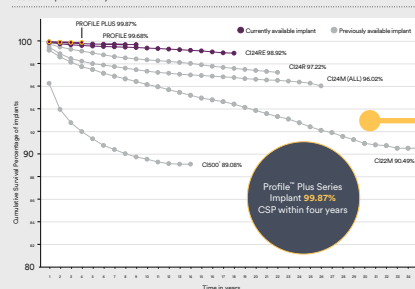
DEVICE	ADULTS	CHILDREN	COMBINED
Profile™ Plus	46,137	26,044	72,181
Profile™	54,279	52,884	107,163
CI24RE	83,102	131,450	214,552
CI500	15,388	14,507	29,895
CI24R	18,705	34,855	53,560
CI24M (All)	7,773	11,750	19,523
CI2EM	9,670	7,991	17,661

Over 500,000 registered Nucleus™ implants worldwide

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



### Nucleus™ Implant Reliability



Profile™ Plus Series Implant 99.83% CSP within four years

\* Voluntarily recalled in September 2015. 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.<sup>2</sup>

\* 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

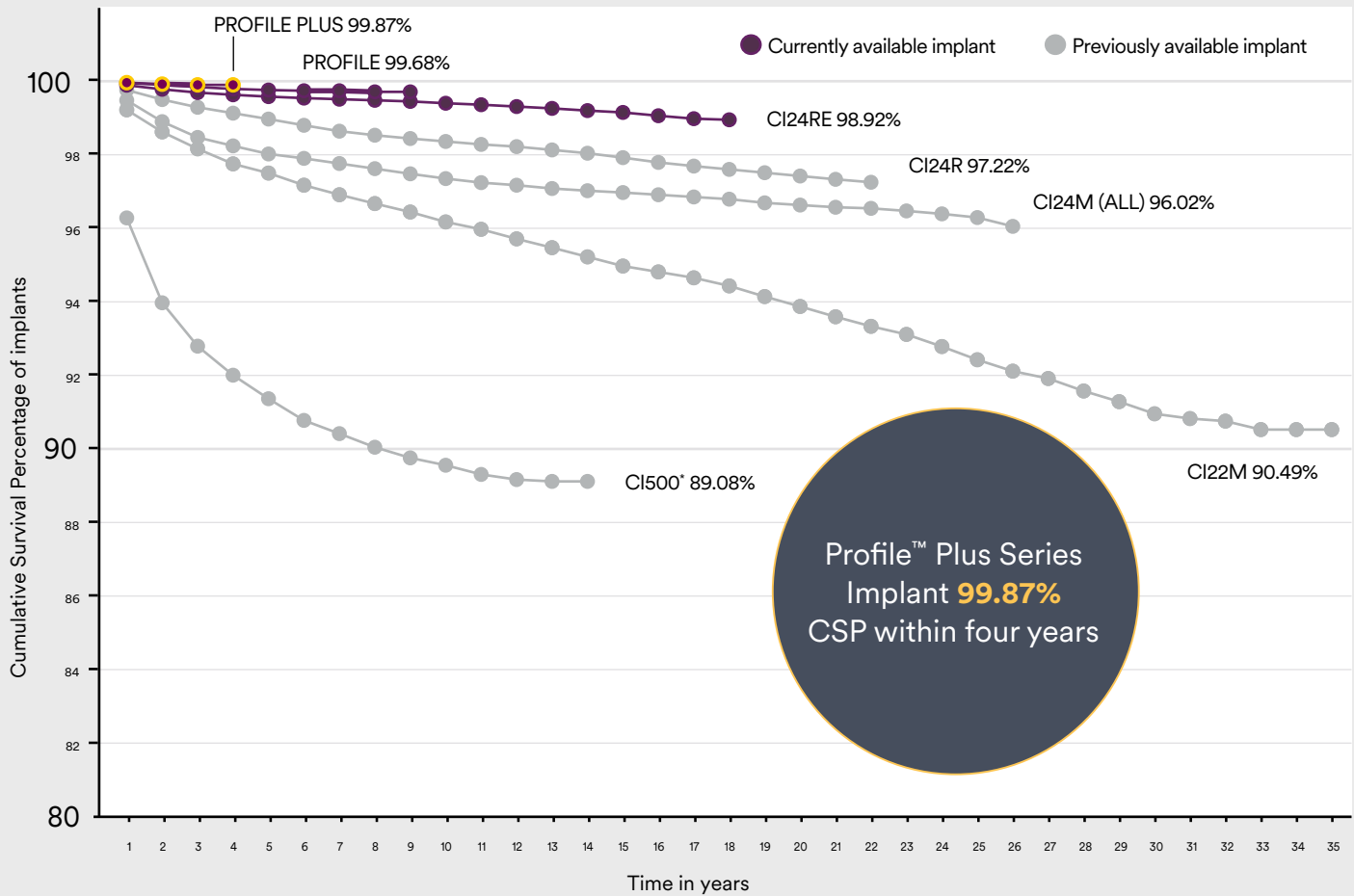
DEVICE	ADULTS	CHILDREN	COMBINED
Profile™ Plus	46,137	26,044	72,181
Profile™	54,279	52,884	107,163
CI24RE	83,102	131,450	214,552
CI500	15,388	14,507	29,895
CI24R	18,705	34,855	53,560
CI24M (All)	7,773	11,750	19,523
CI22M	9,670	7,991	17,661

## 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



## Profile Plus Series Implant Cumulative Survival Percentage

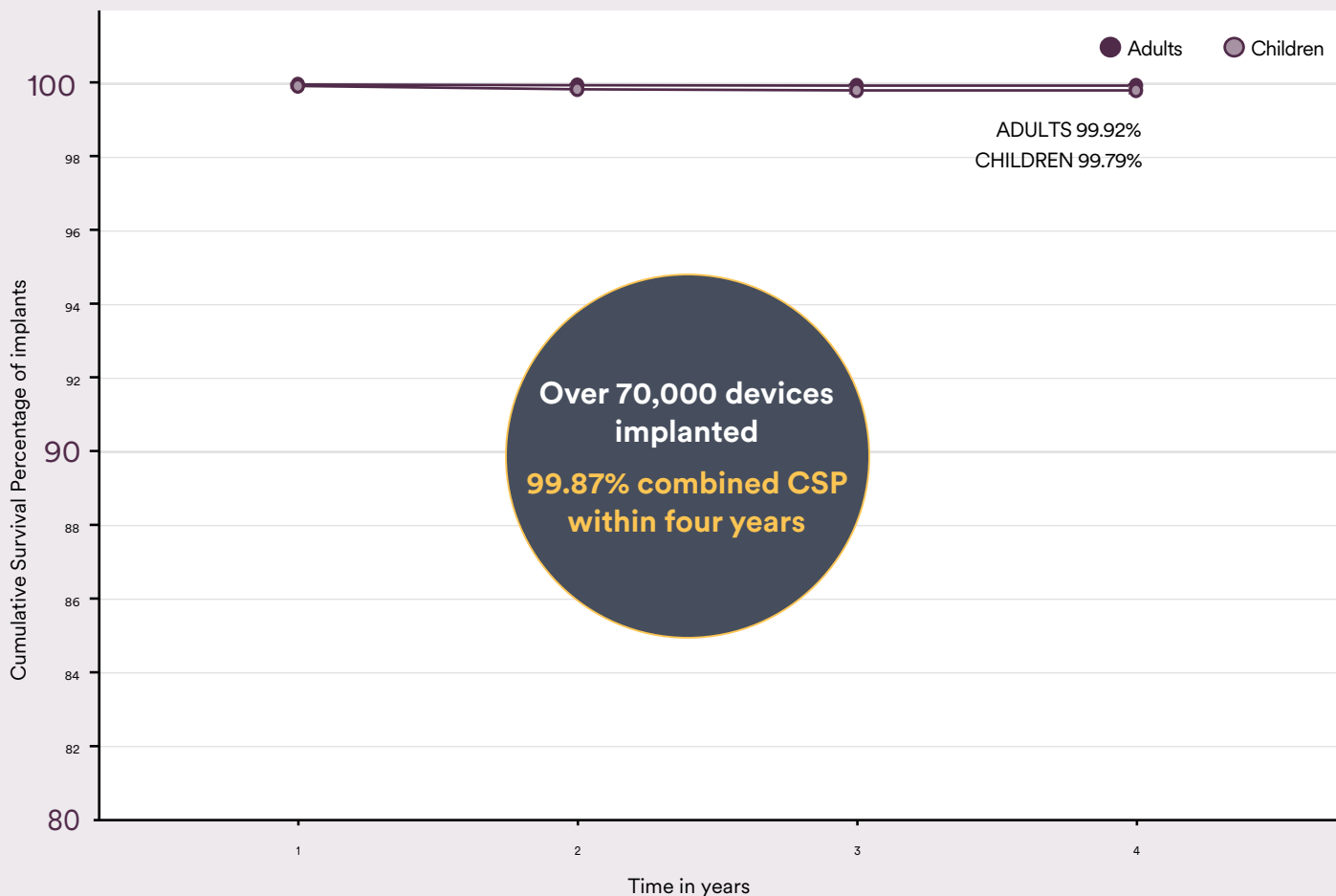
YEAR	1	2	3	4
Adults	99.95	99.93	99.92	99.92
Children	99.91	99.82	99.79	99.79
Combined	99.93	99.89	99.87	99.87

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



3.9 mm

## 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



## Profile Series Implant Cumulative Survival Percentage

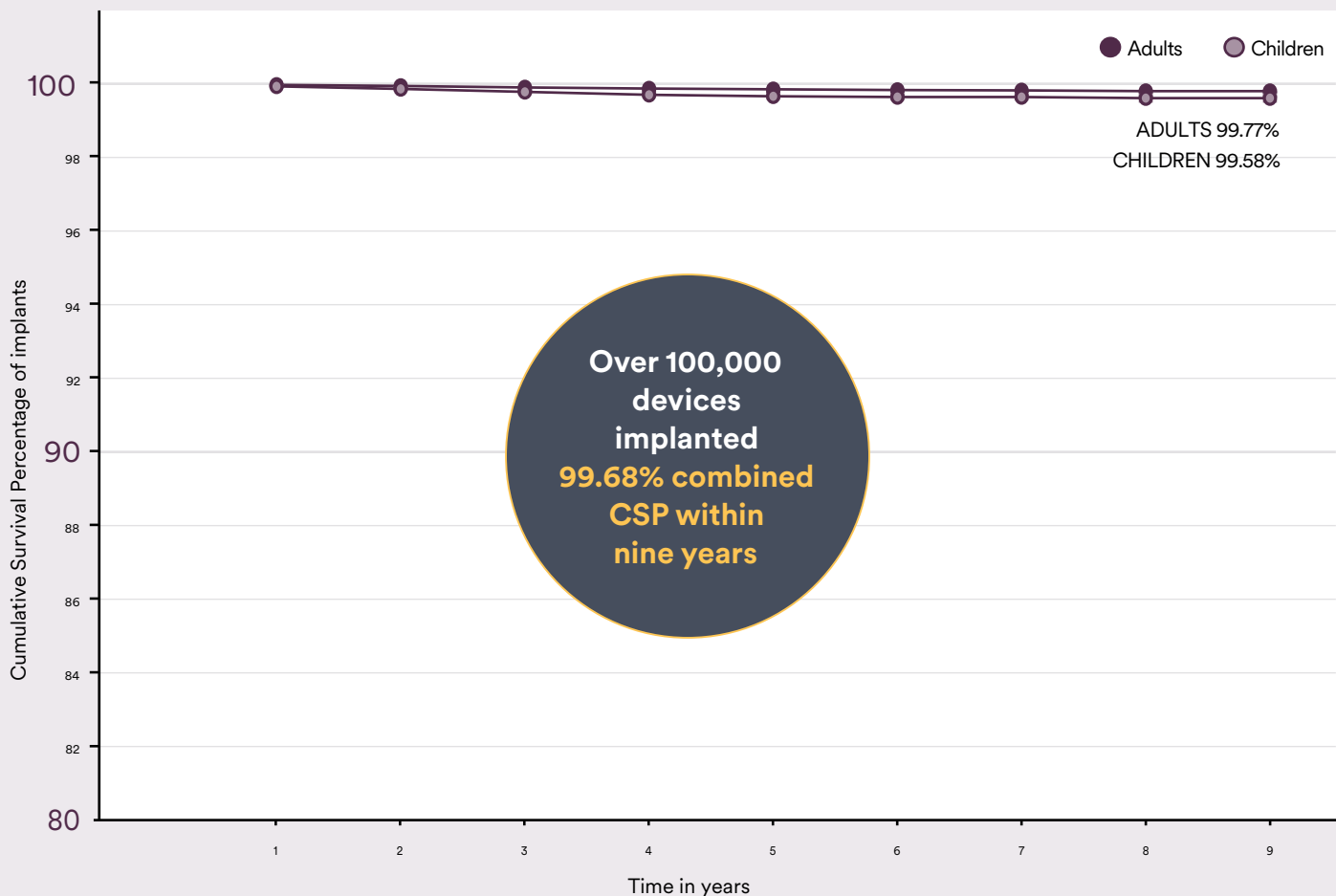
YEAR	1	2	3	4	5	6	7	8	9
Adults	99.94	99.91	99.87	99.84	99.82	99.80	99.79	99.77	99.77
Children	99.90	99.83	99.75	99.67	99.63	99.61	99.61	99.58	99.58
Combined	99.92	99.87	99.81	99.76	99.73	99.71	99.71	99.68	99.68

Cochlear Nucleus Profile Implant with Slim Modiolar Electrode (CI532)



3.9 mm

## 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

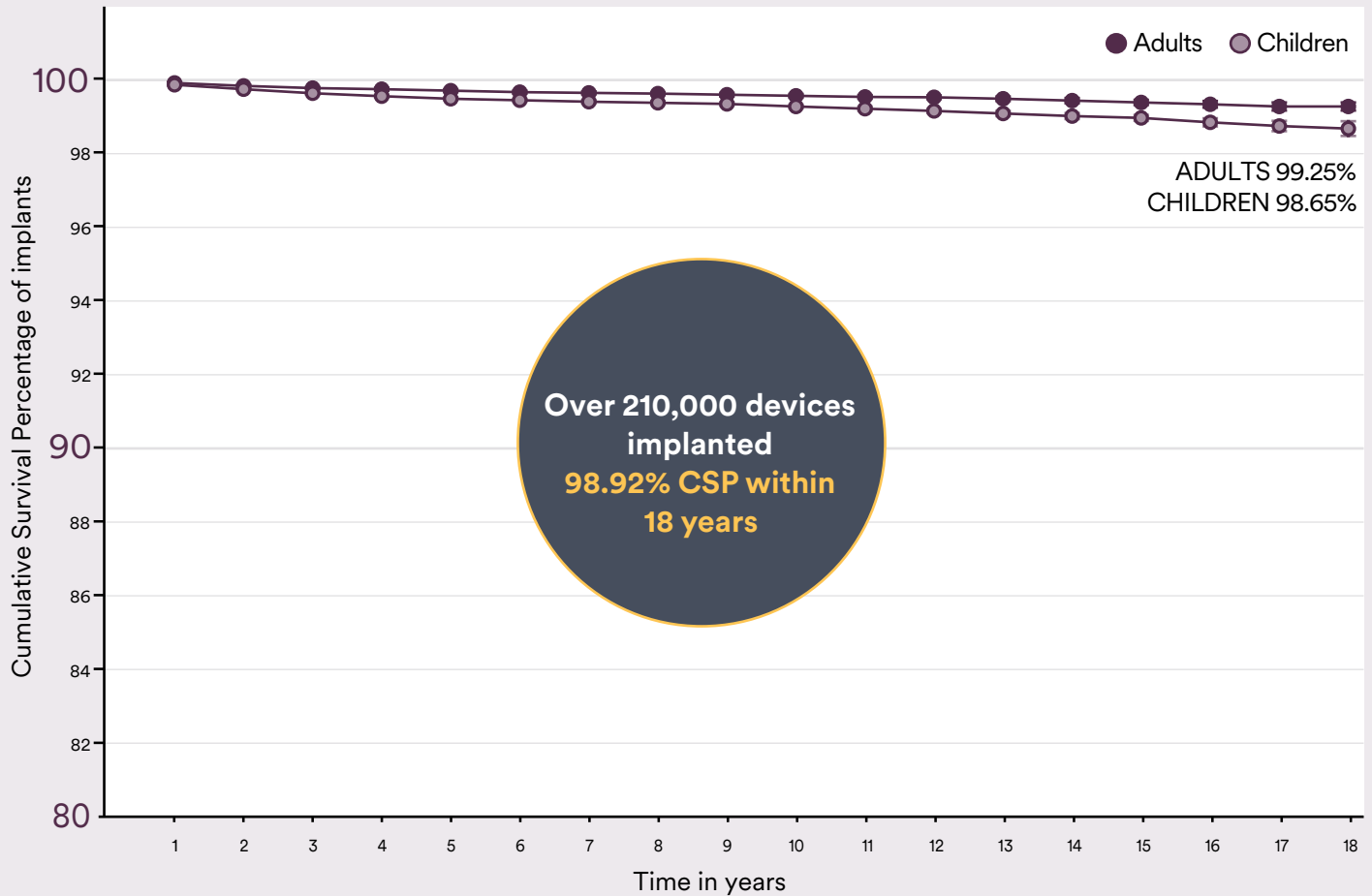
ADULTS	CHILDREN	COMBINED
83,102	131,450	214,552



## 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
<b>Adults</b>	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
<b>Children</b>	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
<b>Combined</b>	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

## 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.





# Previously available implants

# Nucleus® CI500 Series Implant



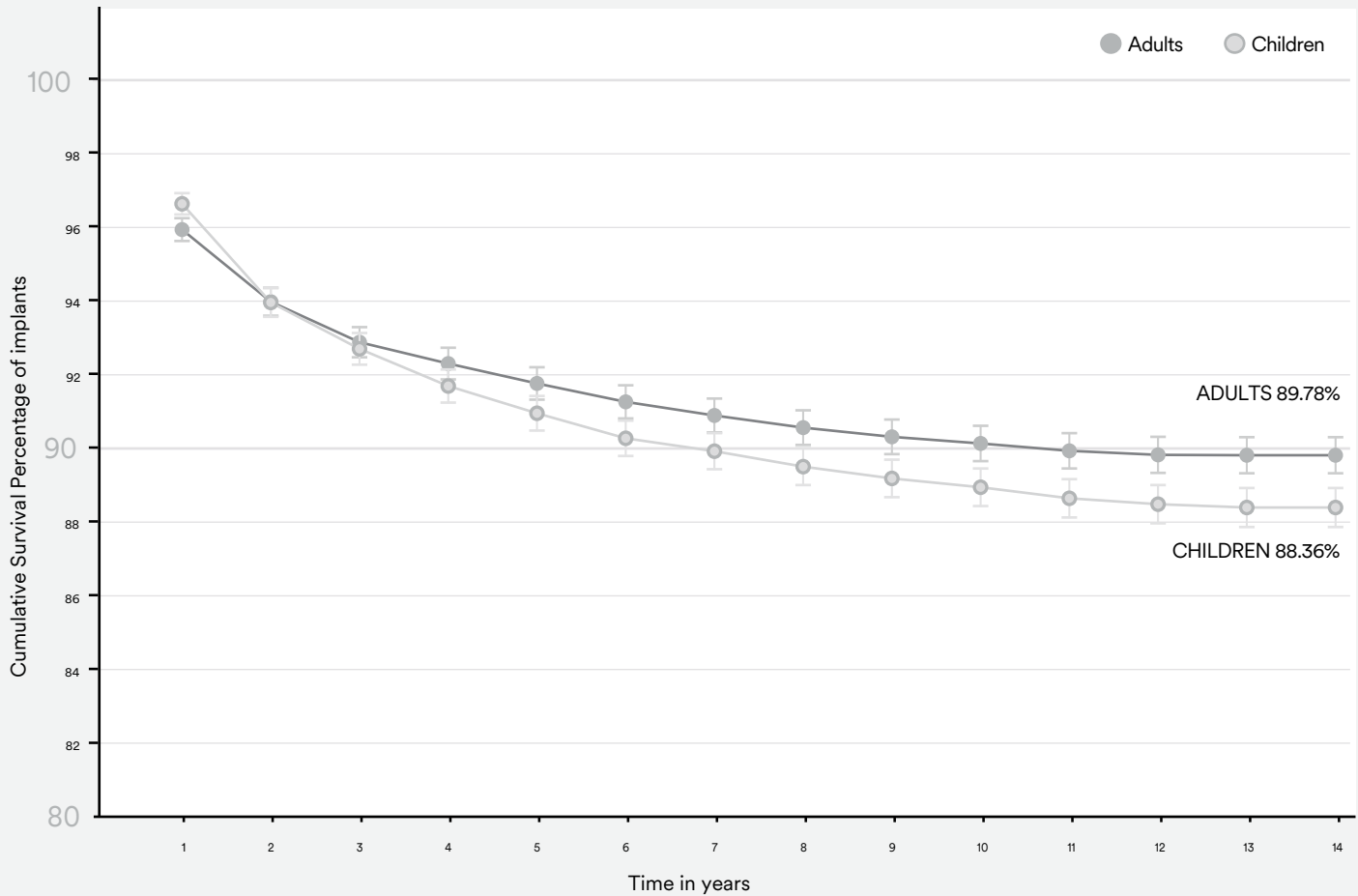
## Number of registered CI500 Series Implants – 31 December 2022

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

## CI500 Series Implant Cumulative Survival Percentage

YEAR	1	2	3	4	5	6	7	8	9	10	11	12	13	14
<b>Adults</b>	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
<b>Children</b>	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
<b>Combined</b>	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

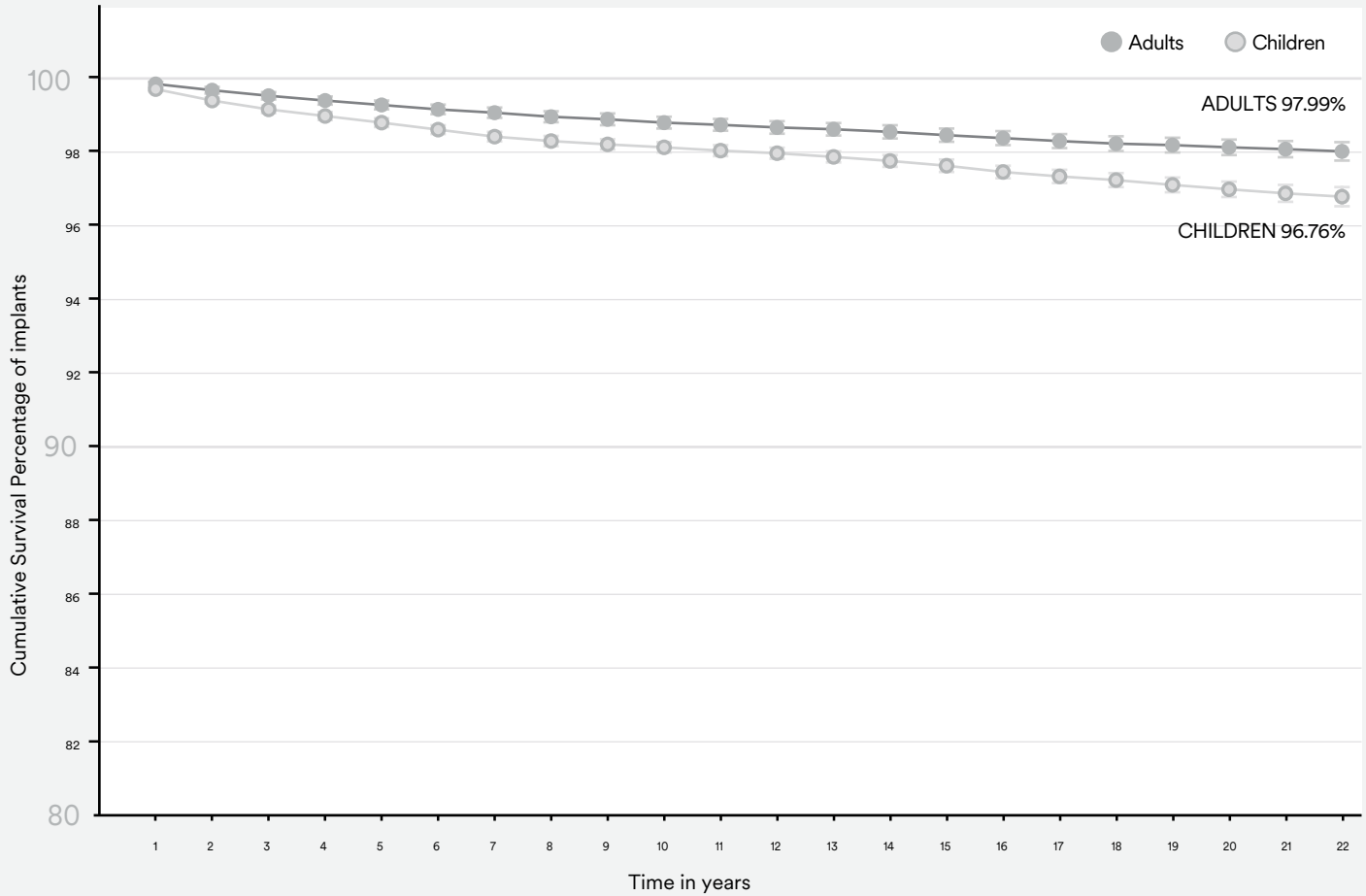
ADULTS	CHILDREN	COMBINED
18,705	34,855	53,560



## 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
<b>Adults</b>	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
<b>Children</b>	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
<b>Combined</b>	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



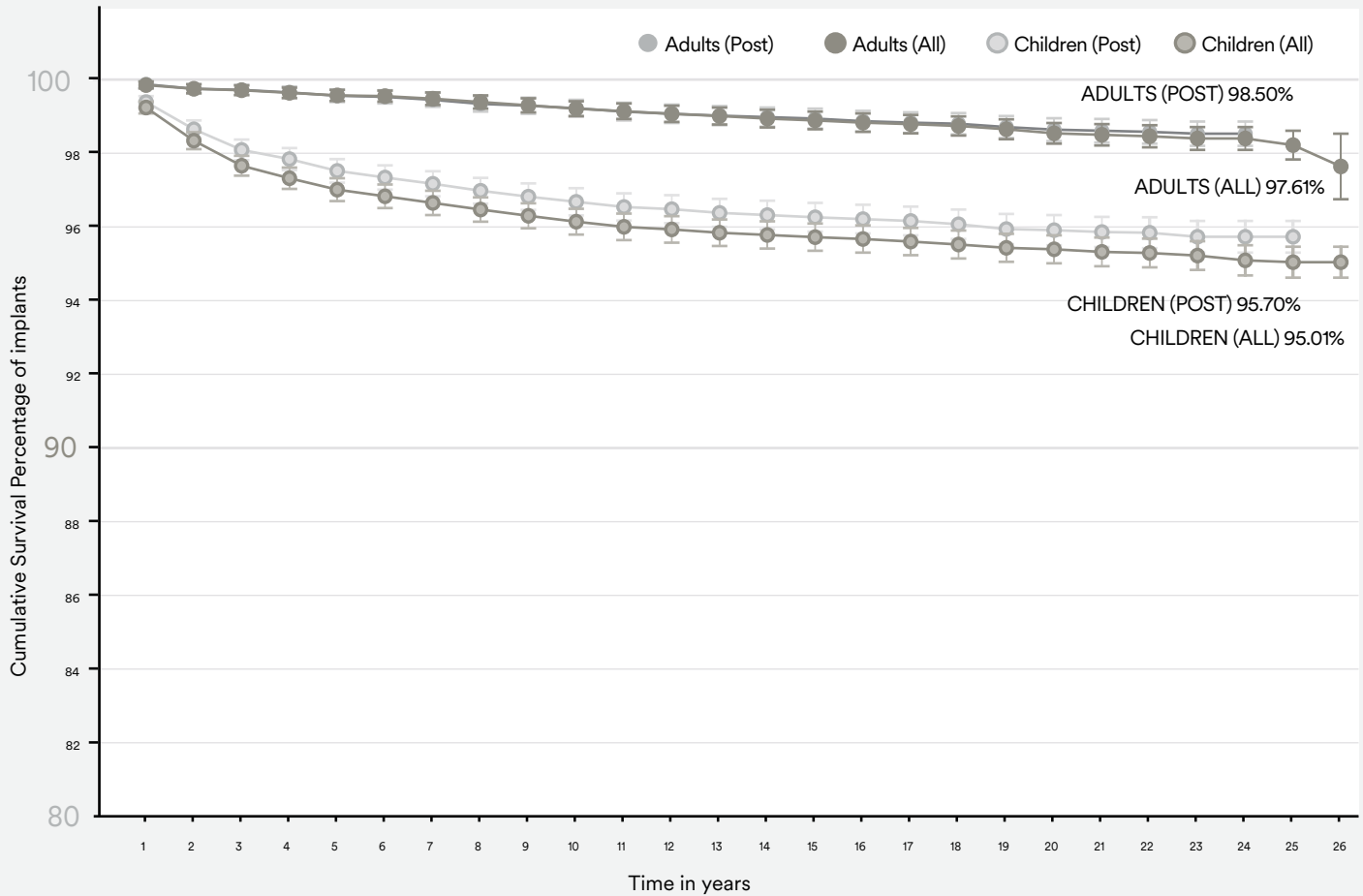
## CI24M Implant Cumulative Survival Percentage

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
<b>Adults (All)</b>	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
<b>Children (All)</b>	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
<b>Combined (All)</b>	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
<b>Adults (Post**)</b>	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	#	#
<b>Children (Post**)</b>	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	#
<b>Combined (Post**)</b>	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.<sup>1</sup>

## 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



## CI22M Implant Cumulative Survival Percentage

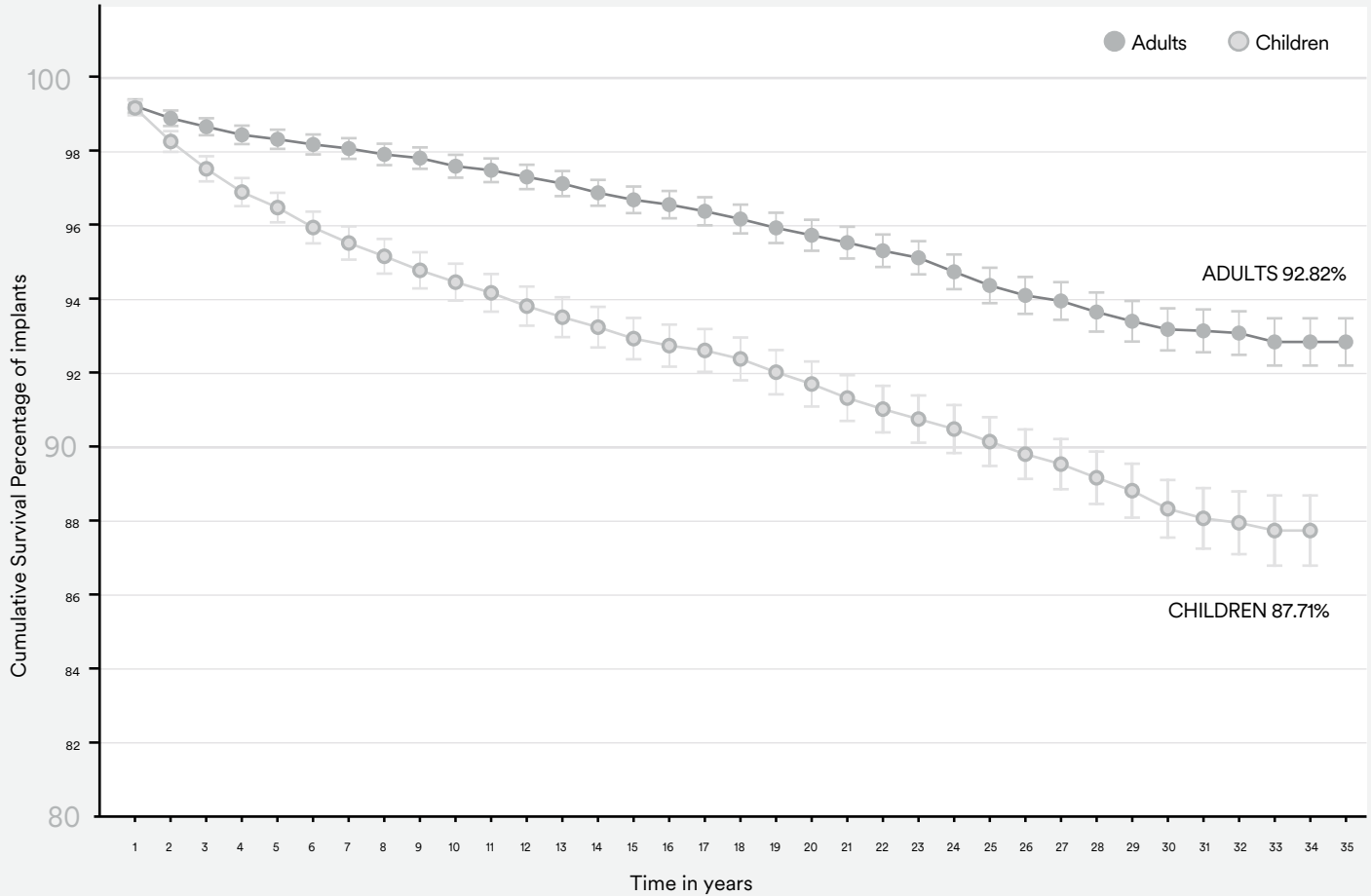
YEAR	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
<b>Adults</b>	99.21	98.88	98.65	98.43	98.31	98.17	98.06	97.90	97.80	97.58	97.47	97.29	97.11	96.86	96.67	96.54	96.36
<b>Children</b>	99.16	98.25	97.51	96.88	96.46	95.92	95.50	95.14	94.76	94.44	94.15	93.79	93.49	93.22	92.91	92.72	92.59
<b>Combined</b>	99.19	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
<b>Adults</b>	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
<b>Children</b>	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	#
<b>Combined</b>	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.<sup>1</sup>



## 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.



# 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.

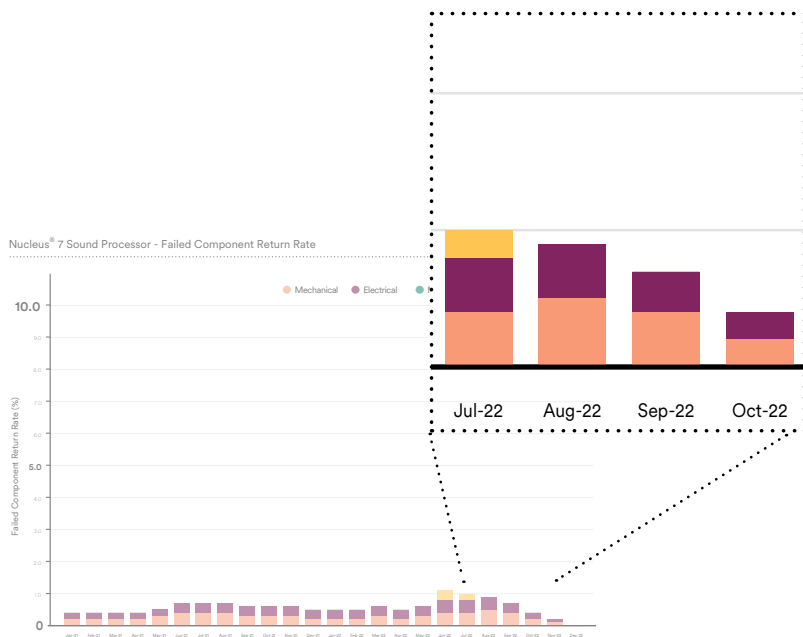
## What is Failed Component Return Rate (FCRR)?

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 discoloration), 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
<b>Mechanical</b>	0.2%	0.2%	0.2%	0.2%	0.3%	0.4%	0.4%	0.4%	0.3%	0.3%	0.2%	0.1%
<b>Electrical</b>	0.2%	0.2%	0.2%	0.2%	0.2%	0.3%	0.3%	0.3%	0.3%	0.3%	0.2%	0.1%
<b>Moisture</b>	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
<b>Other</b>	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
<b>Fault-Free</b>	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<sup>®</sup> 8 Sound Processor



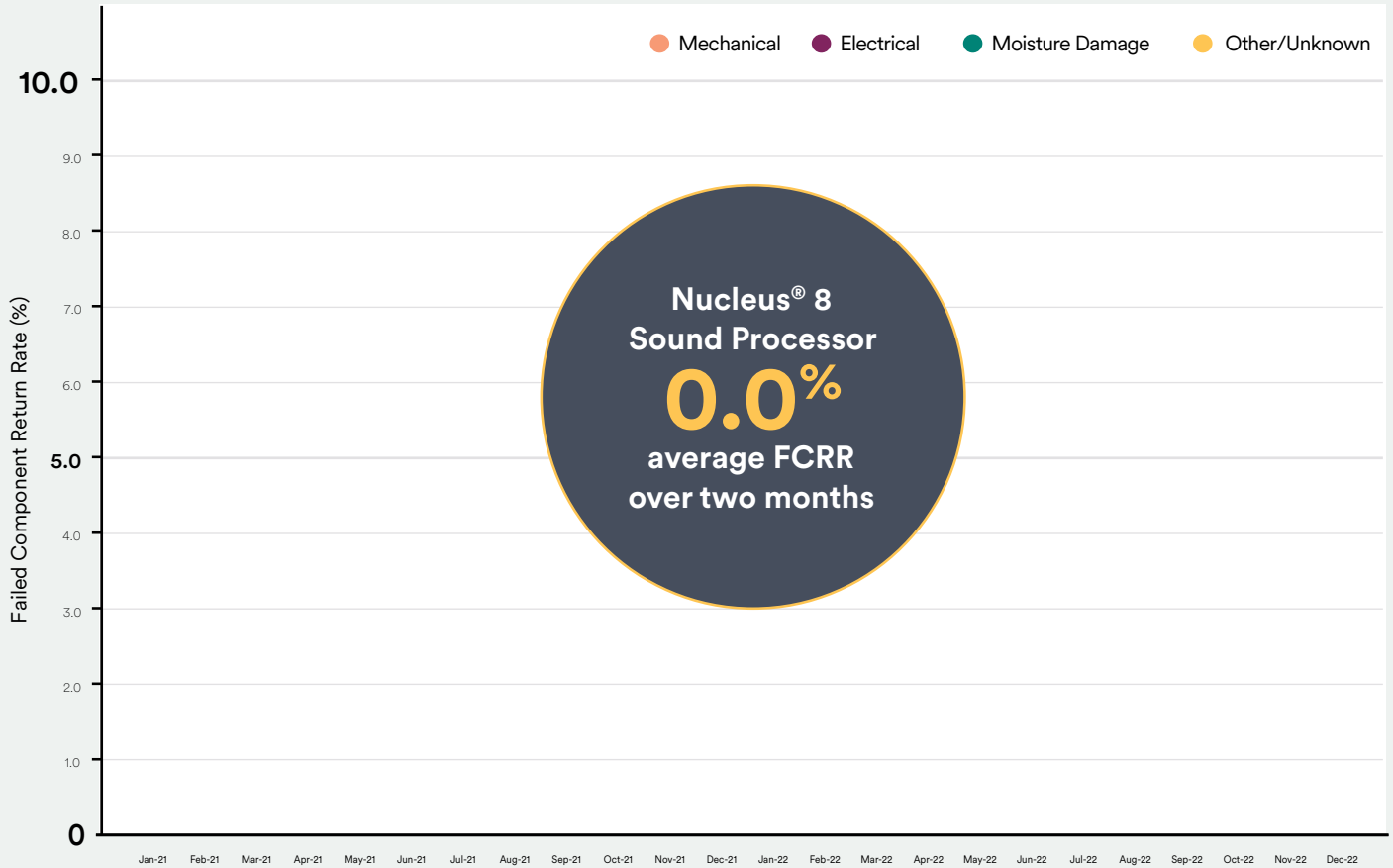
## Nucleus 8 Sound Processor – Failed Component Return Rate

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%

## Nucleus® 8 Sound Processor - Failed Component Return Rate

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# Nucleus Kanso<sup>®</sup> 2 Sound Processor



## Nucleus Kanso 2 Sound Processor – Failed Component Return Rate

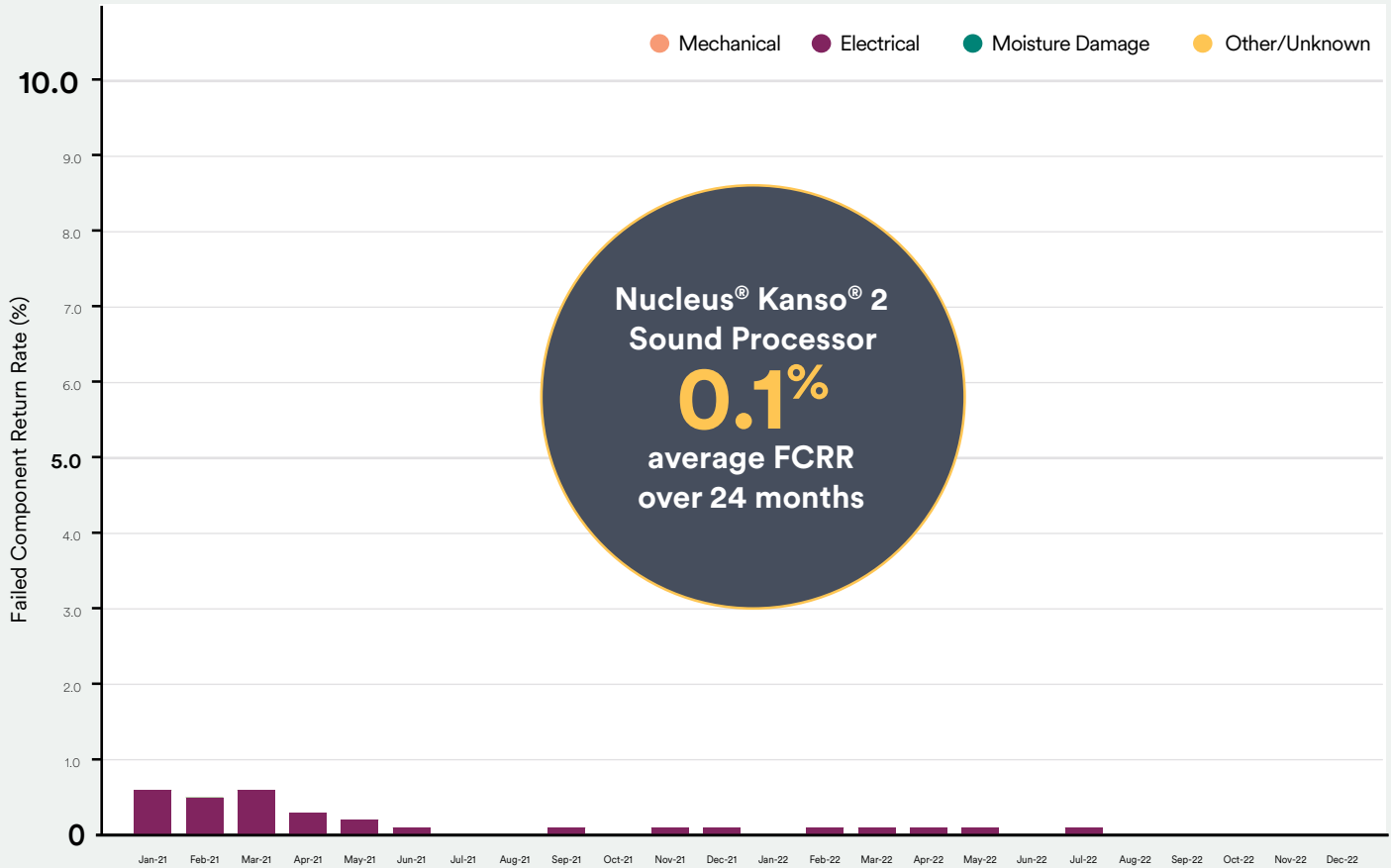
Fail mode	Jan-21	Feb-21	Mar-21	Apr-21	May-21	Jun-21	Jul-21	Aug-21	Sep-21	Oct-21	Nov-21	Dec-21
<b>Mechanical</b>	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
<b>Electrical</b>	0.6%	0.5%	0.6%	0.3%	0.2%	0.1%	0.0%	0.0%	0.1%	0.0%	0.1%	0.1%
<b>Moisture</b>	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%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



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

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# Nucleus<sup>®</sup> 7 Sound Processor

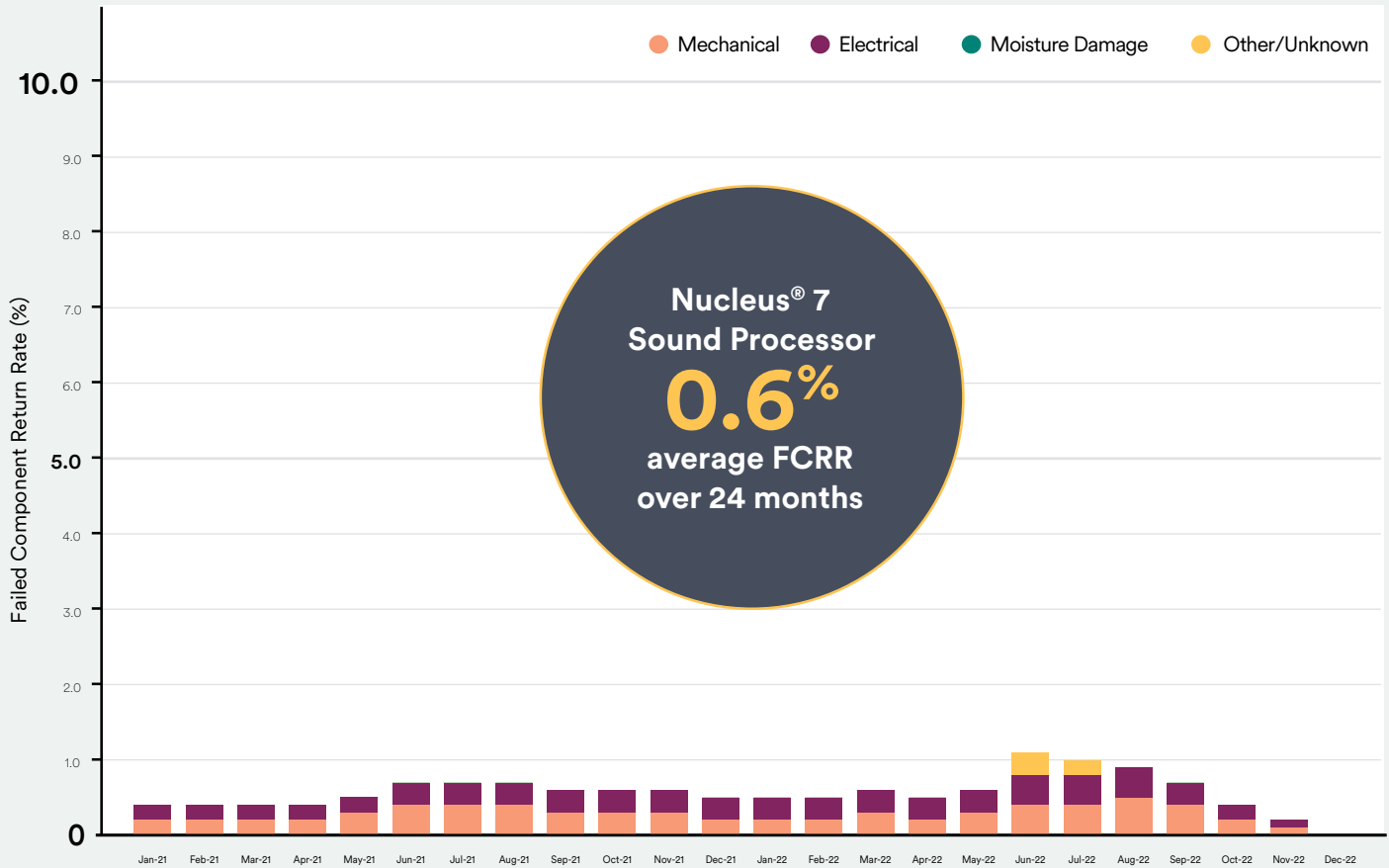


## Nucleus 7 Sound Processor – Failed Component Return Rate

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
<b>Mechanical</b>	0.2%	0.2%	0.2%	0.2%	0.3%	0.4%	0.4%	0.4%	0.3%	0.3%	0.3%	0.2%
<b>Electrical</b>	0.2%	0.2%	0.2%	0.2%	0.2%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%
<b>Moisture</b>	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
<b>Other</b>	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
<b>Fault-Free</b>	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
<b>Mechanical</b>	0.2%	0.2%	0.3%	0.2%	0.3%	0.4%	0.4%	0.5%	0.4%	0.2%	0.1%	0.0%
<b>Electrical</b>	0.3%	0.3%	0.3%	0.3%	0.3%	0.4%	0.4%	0.4%	0.3%	0.2%	0.1%	0.0%
<b>Moisture</b>	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
<b>Other</b>	0.0%	0.0%	0.0%	0.0%	0.0%	0.3%	0.2%	0.0%	0.0%	0.0%	0.0%	0.0%
<b>Fault-Free</b>	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.0%	0.0%

## Nucleus<sup>®</sup> 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*
<b>Profile™ Plus Series</b>	<ul style="list-style-type: none"> <li>Cochlear™ Nucleus® Profile™ Plus with Contour Advance® Electrode (CI612)</li> <li>Cochlear Nucleus Profile Plus with Slim Straight Electrode (CI622)</li> <li>Cochlear Nucleus Profile Plus with Slim Modiolar Electrode (CI632)</li> <li>Cochlear Nucleus Profile Plus with Slim 20 Electrode (CI624)</li> </ul>
<b>Profile Series</b>	<ul style="list-style-type: none"> <li>Cochlear Nucleus Profile with Contour Advance Electrode (CI512)</li> <li>Cochlear Nucleus Profile with Slim Straight Electrode (CI522)</li> <li>Cochlear Nucleus Profile with Slim Modiolar Electrode (CI532)</li> <li>Cochlear Nucleus Profile Auditory Brainstem Implant (ABI541)</li> </ul>
<b>CI24RE Series</b>	<ul style="list-style-type: none"> <li>Nucleus Freedom® with Contour Advance Electrode</li> <li>Nucleus Freedom with Straight Electrode</li> <li>Cochlear Nucleus CI422 Cochlear Implant</li> <li>Cochlear Hybrid™ L24 Cochlear Implant</li> </ul>
<b>CI500 Series</b>	<ul style="list-style-type: none"> <li>Cochlear Nucleus CI512 Cochlear Implant</li> <li>Cochlear Nucleus CI513 Cochlear Implant</li> <li>Cochlear Nucleus CI551 Double Array Cochlear Implant</li> <li>Cochlear Nucleus ABI541 Auditory Brainstem Implant</li> </ul>
<b>CI24R</b>	<ul style="list-style-type: none"> <li>Nucleus 24 with Contour Advance Electrode</li> <li>Nucleus 24 with Contour® Electrode</li> <li>Nucleus 24k with Straight Electrode</li> </ul>
<b>CI24M</b>	<ul style="list-style-type: none"> <li>Nucleus 24 with Straight Electrode</li> <li>Nucleus 24 with Double Array</li> <li>Nucleus 24 Auditory Brainstem Implant [ABI]</li> </ul>
<b>CI22M</b>	<ul style="list-style-type: none"> <li>Nucleus 22</li> </ul>

\* 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.

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