

FOR PROFESSIONALS



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 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 5841-2¹, the reporting principles outlined in the European Consensus Statement on Cochlear Implant Failures and Explantations² 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.

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*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*.⁴ 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.

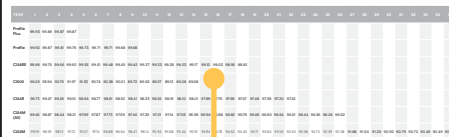
More people choose Cochlear than any other implant brand

Over 500,000 registered Nucleus® implants worldwide

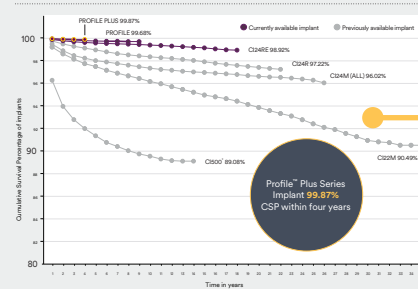
Number of registered implants - 31 December 2022

| DEVICE | ADULTS | CHILDREN | COMBINED |
|---------------|--------|----------|----------|
| Profile™ Plus | 46,137 | 26,044 | 72,181 |
| Profile™ | 54,279 | 52,884 | 107,163 |
| CID4RE | 83,102 | 131,450 | 214,552 |
| CIS90 | 15,388 | 14,507 | 29,895 |
| CID4R | 18,705 | 34,855 | 53,560 |
| CID4M (All) | 7,773 | 11,750 | 19,523 |
| CID2M | 9,670 | 7,991 | 17,661 |

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.

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

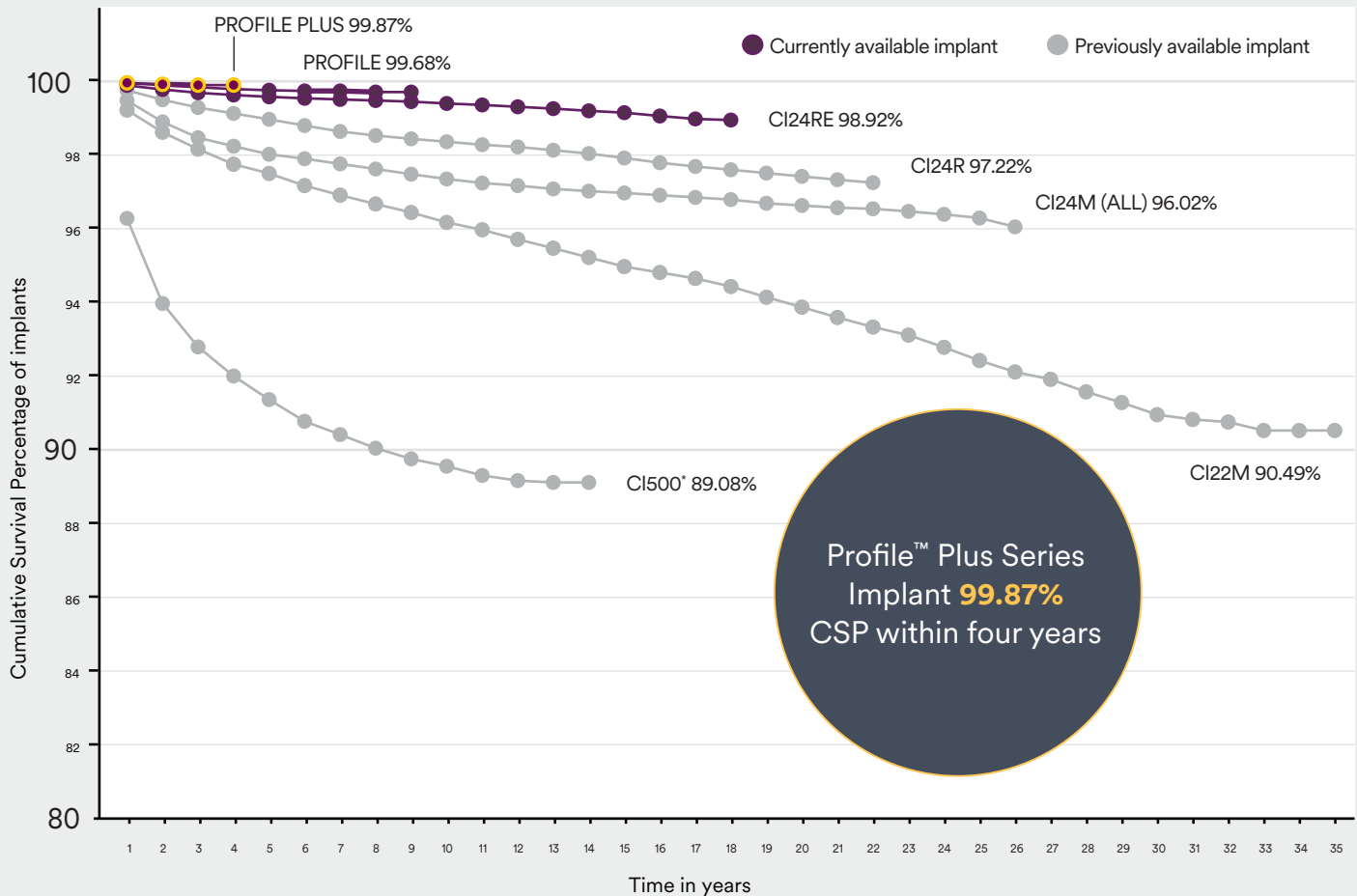
Number of registered implants – 31 December 2022

| 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

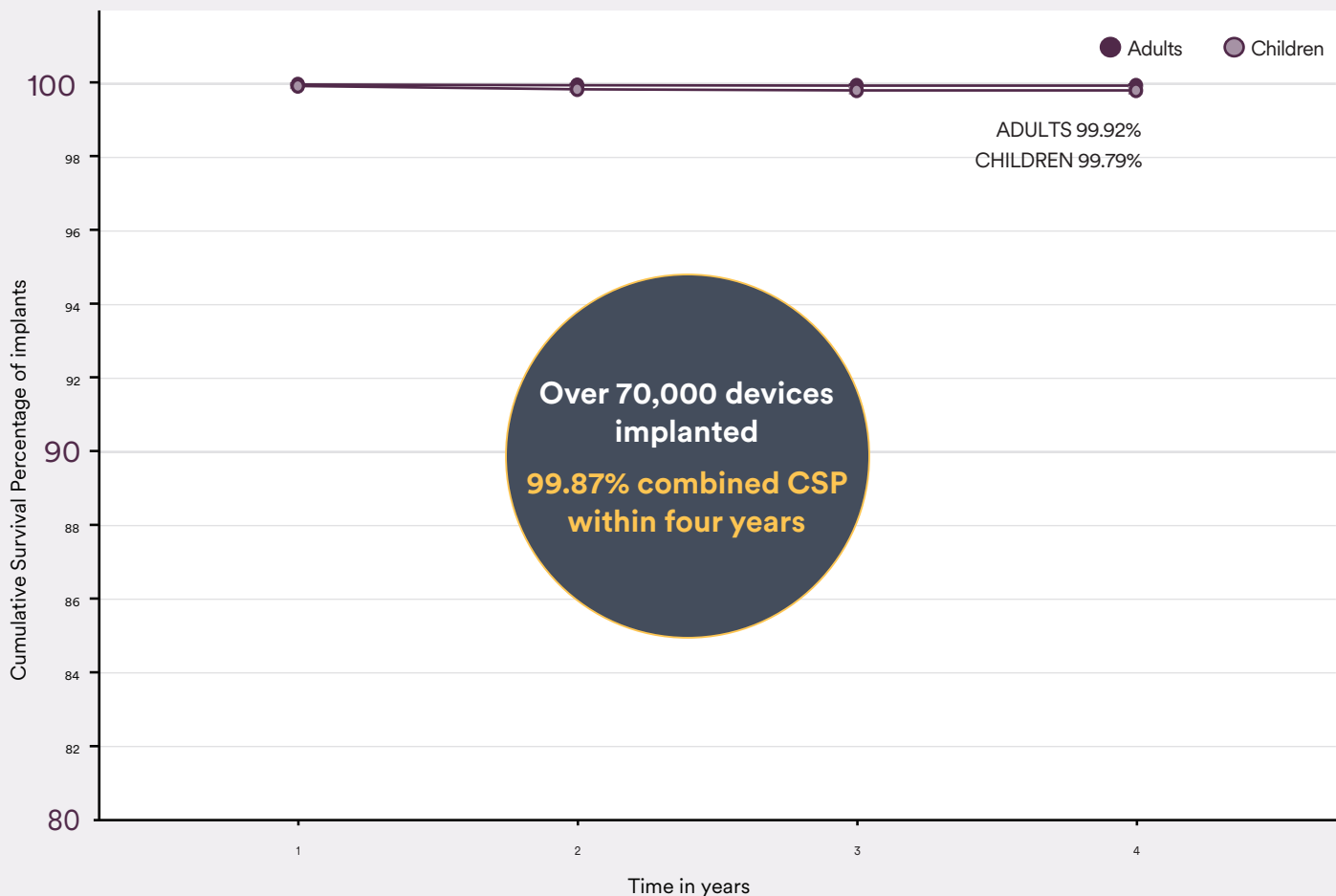
| YEAR | 1 | 2 | 3 | 4 |
|----------|-------|-------|-------|-------|
| Adults | 99.95 | 99.93 | 99.92 | 99.92 |
| Children | 99.91 | 99.82 | 99.79 | 99.79 |
| Combined | 99.93 | 99.89 | 99.87 | 99.87 |

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

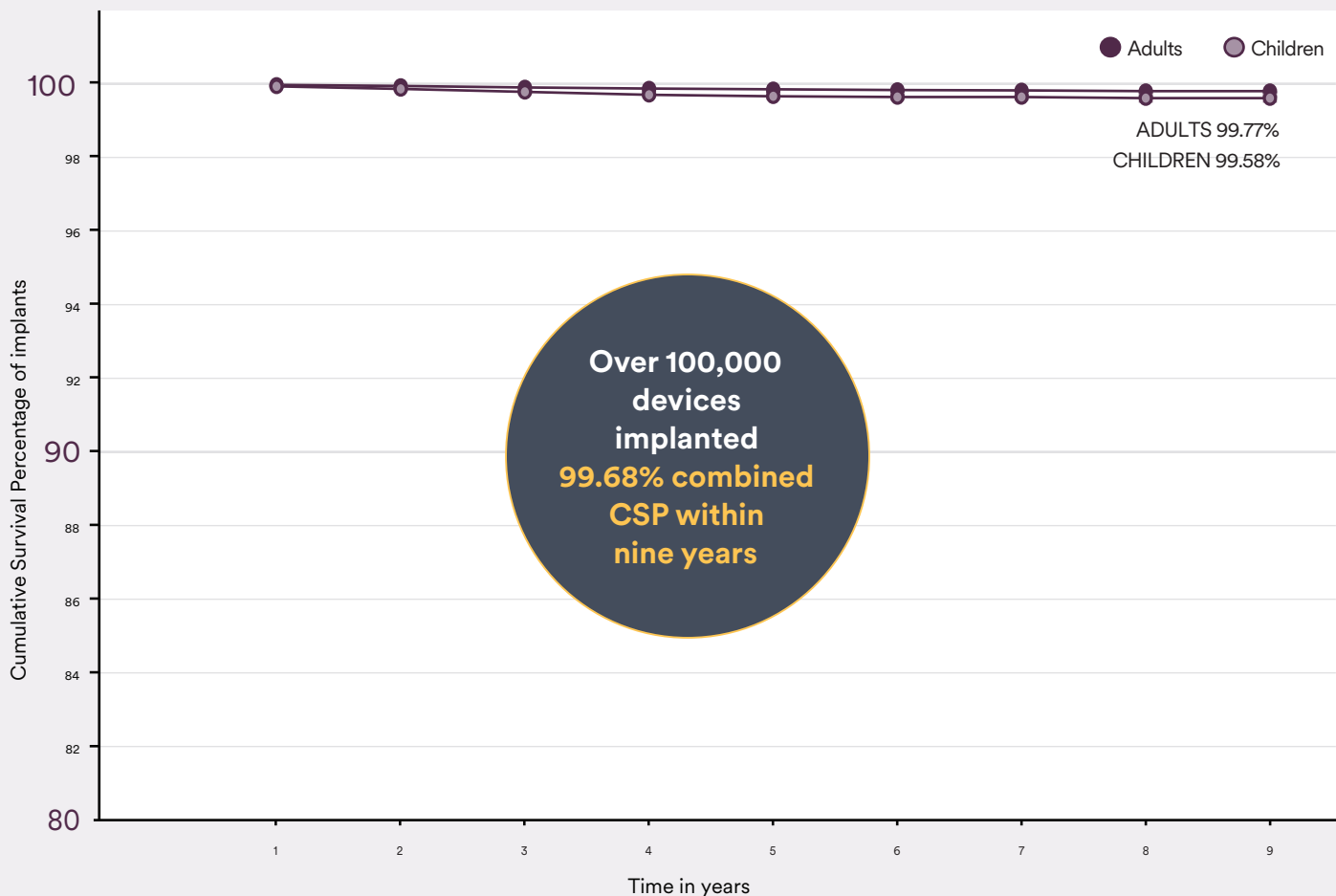
| YEAR | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
|----------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| Adults | 99.94 | 99.91 | 99.87 | 99.84 | 99.82 | 99.80 | 99.79 | 99.77 | 99.77 |
| Children | 99.90 | 99.83 | 99.75 | 99.67 | 99.63 | 99.61 | 99.61 | 99.58 | 99.58 |
| Combined | 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

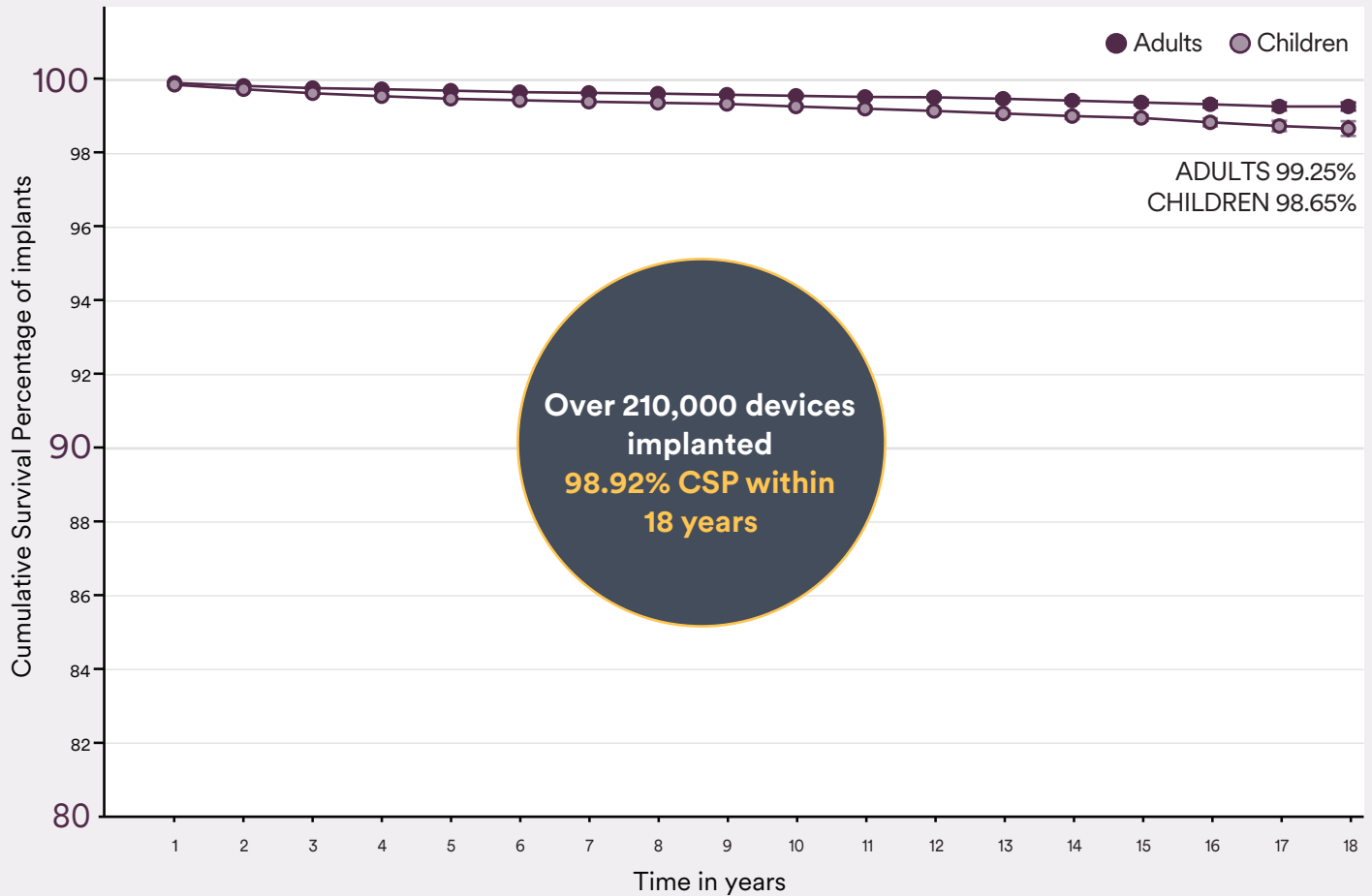
| ADULTS | CHILDREN | COMBINED |
|--------|----------|----------|
| 83,102 | 131,450 | 214,552 |



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 |
|-----------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| 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 |

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



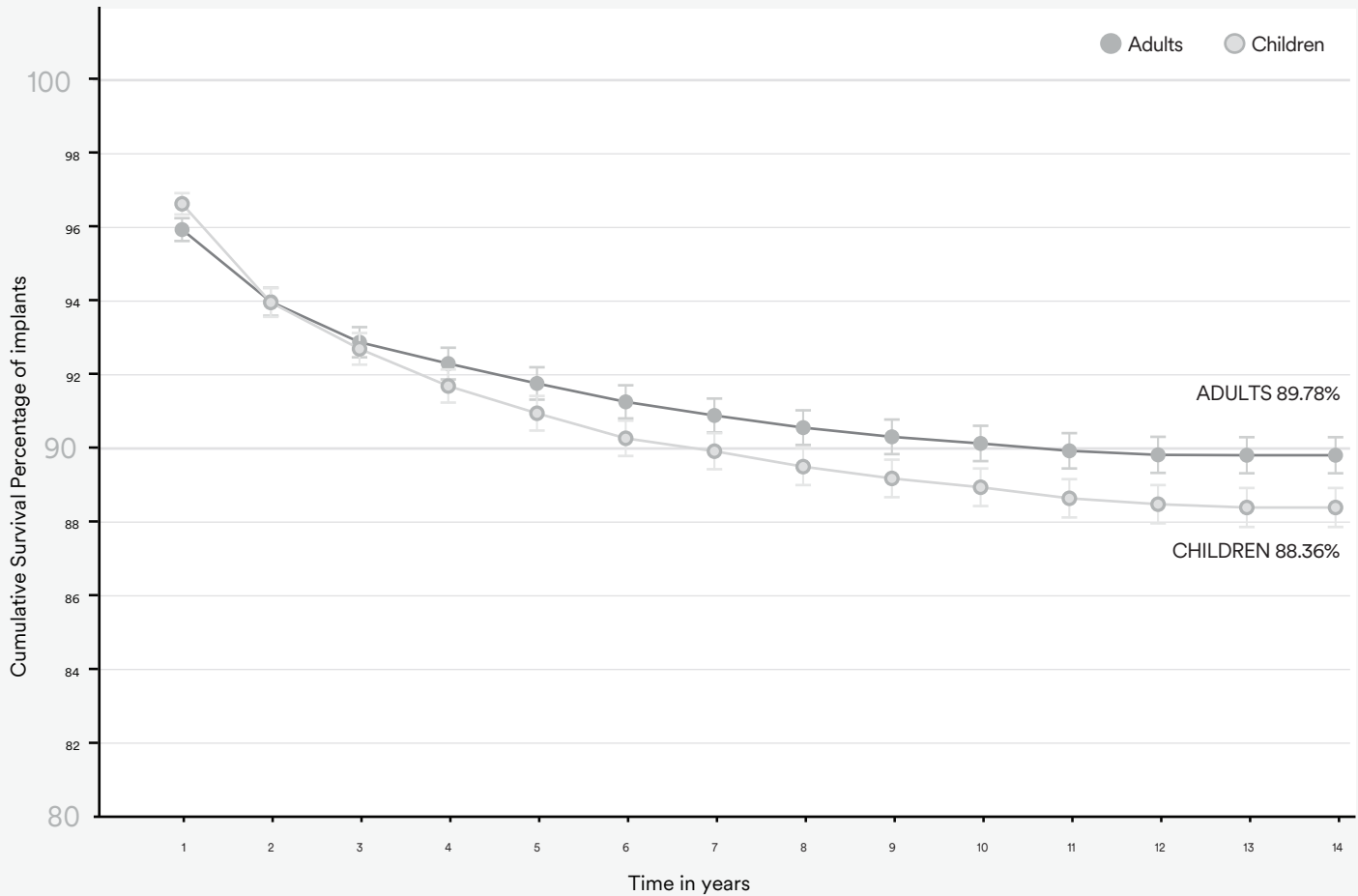
Number of registered CI500 Series Implants – 31 December 2022

| 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 |
|-----------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| 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

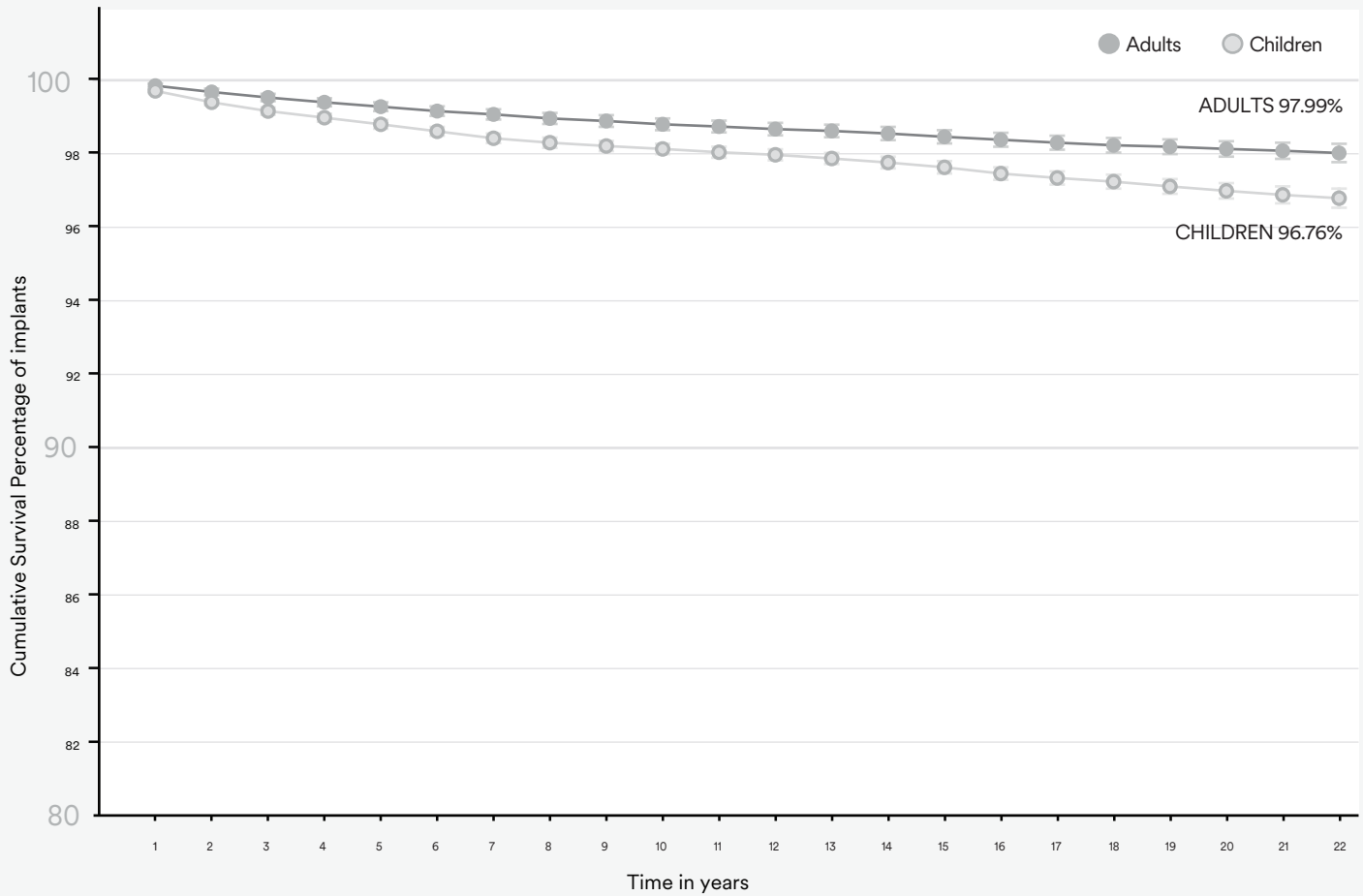
| ADULTS | CHILDREN | COMBINED |
|--------|----------|----------|
| 18,705 | 34,855 | 53,560 |



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 |



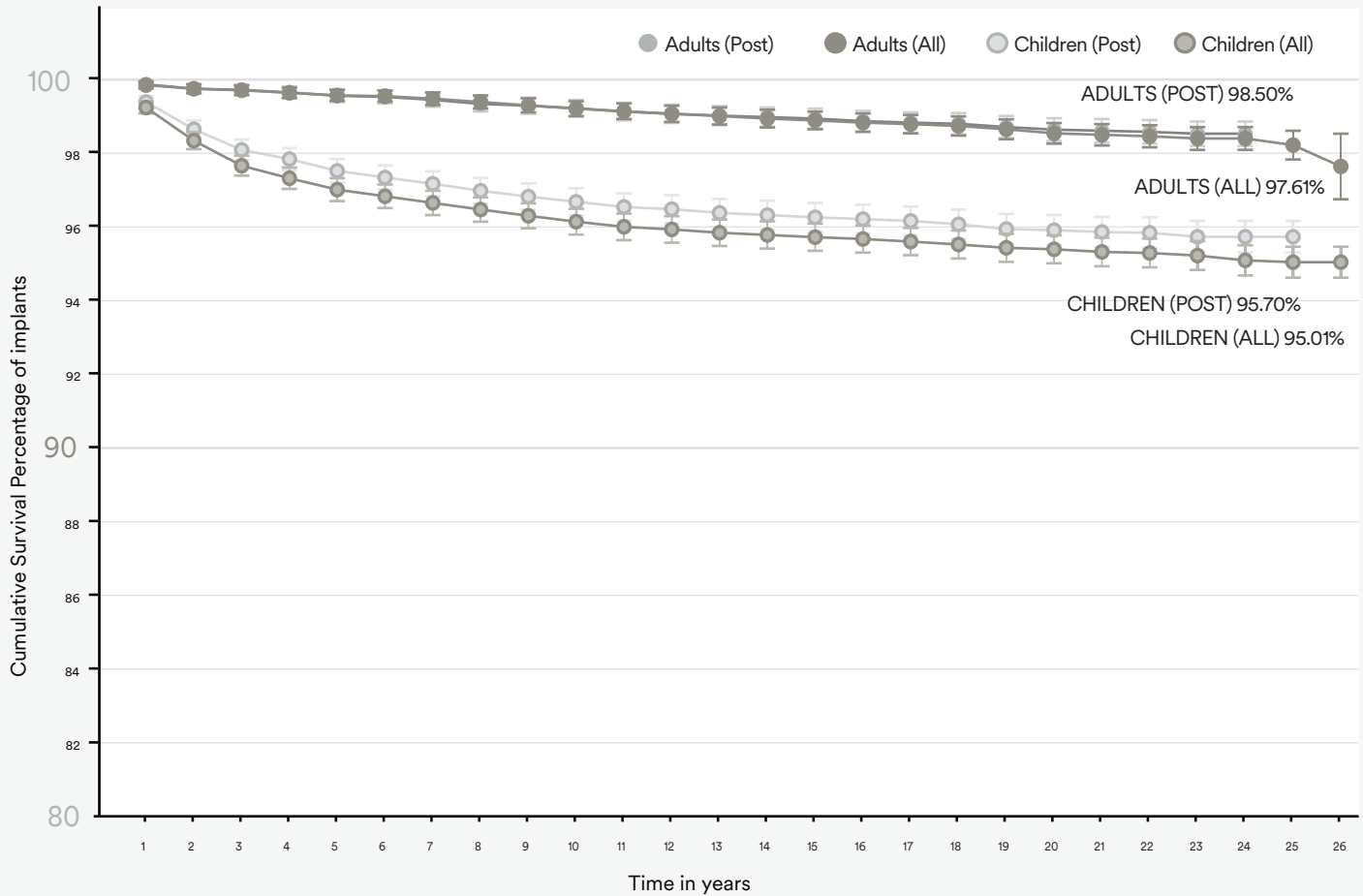
CI24M Implant Cumulative Survival Percentage

| 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 |



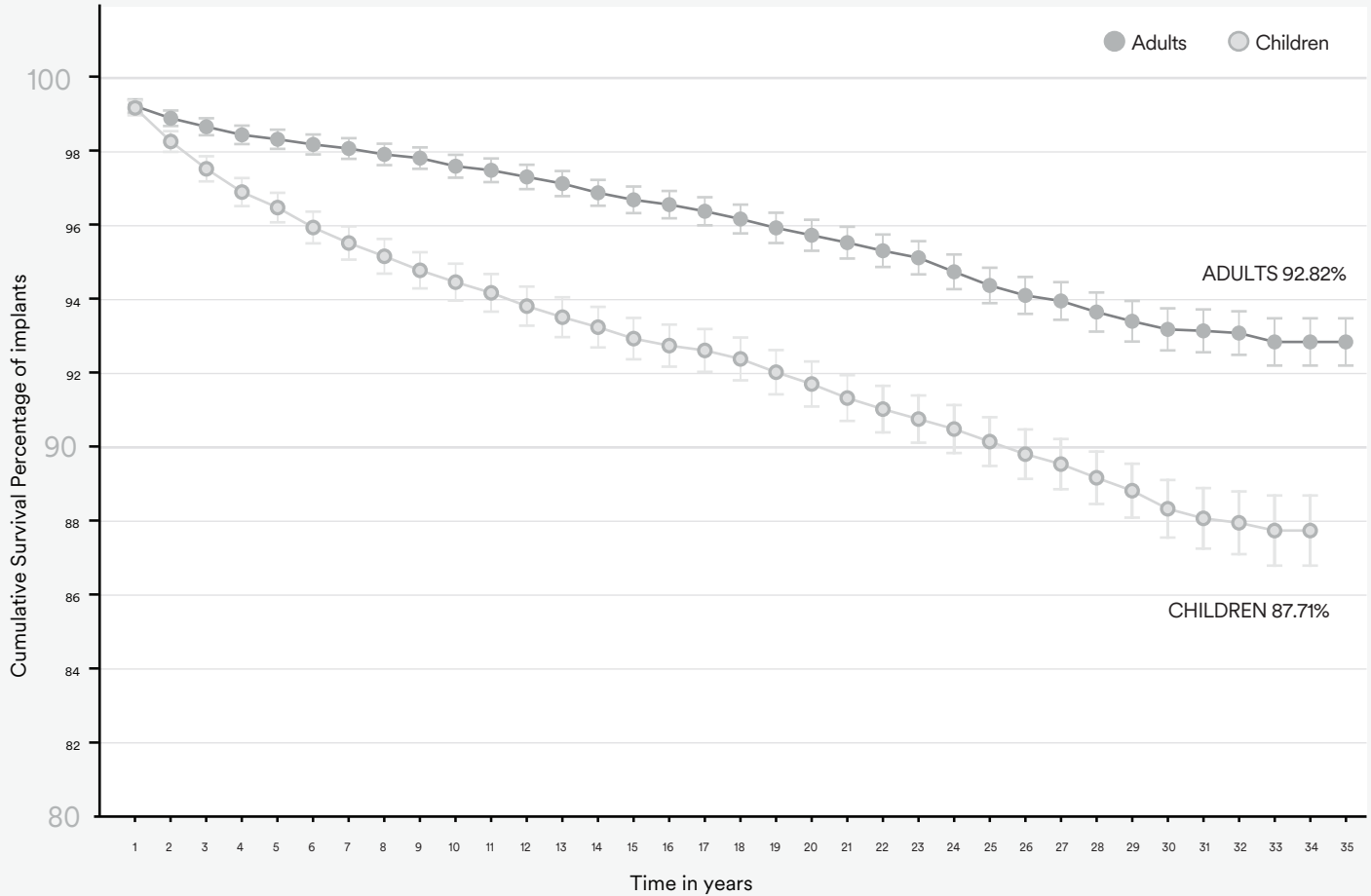
CI22M Implant Cumulative Survival Percentage

| 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.

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.

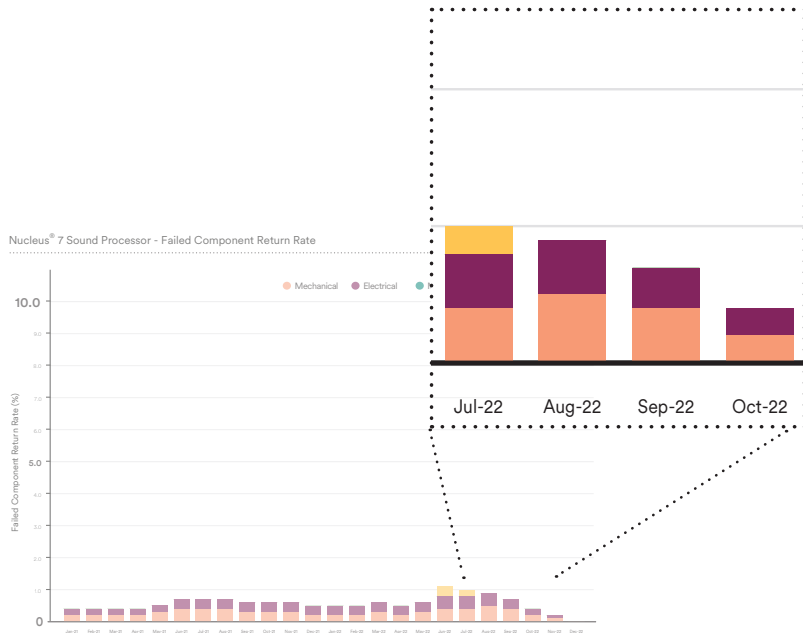
What is Failed Component Return Rate (FCRR)?

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 |
|-------------------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|
| 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*



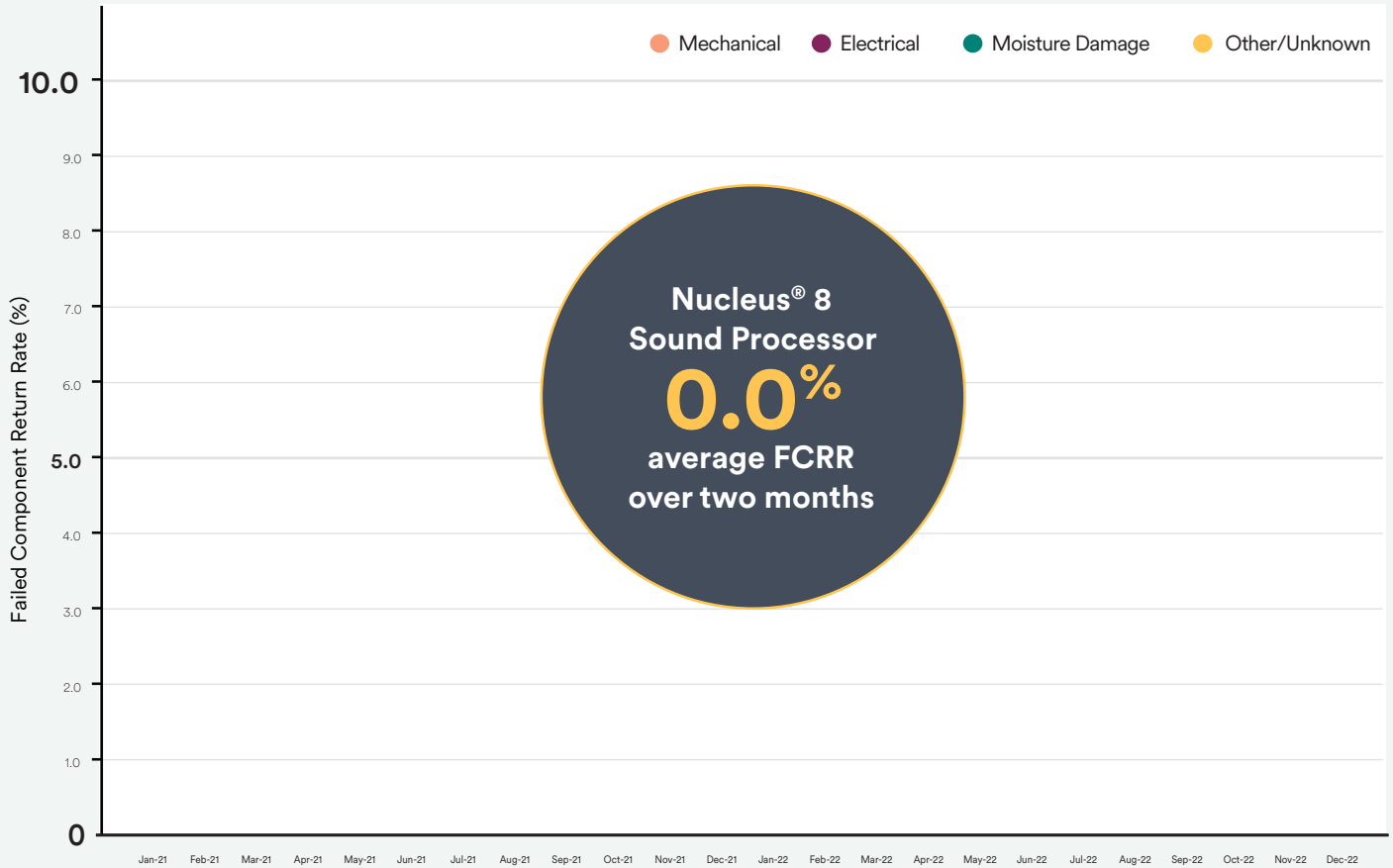
Nucleus 8 Sound Processor – Failed Component Return Rate

| Fail mode | Jan-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% |

* Non-regulatory approved product in Japan. The all product data should be reported to meet the requirements for the International Classification of Reliability for Implanted Cochlear Implant Receiver Stimulators.

Nucleus® 8 Sound Processor - Failed Component Return Rate



Nucleus Kanso[®] 2 Sound Processor

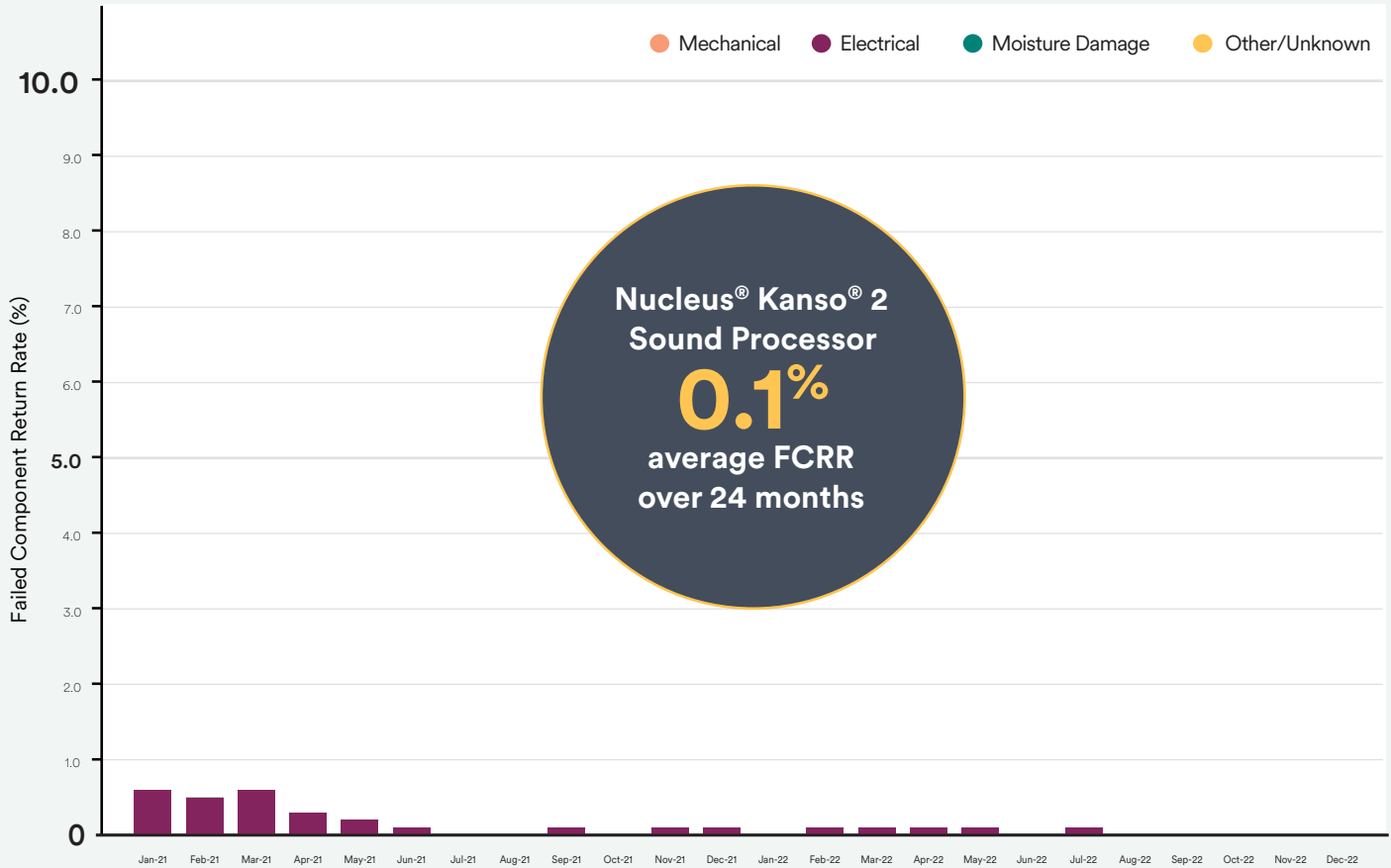


Nucleus Kanso 2 Sound Processor – Failed Component Return Rate

| Fail mode | Jan-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% |

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



Nucleus[®] 7 Sound Processor

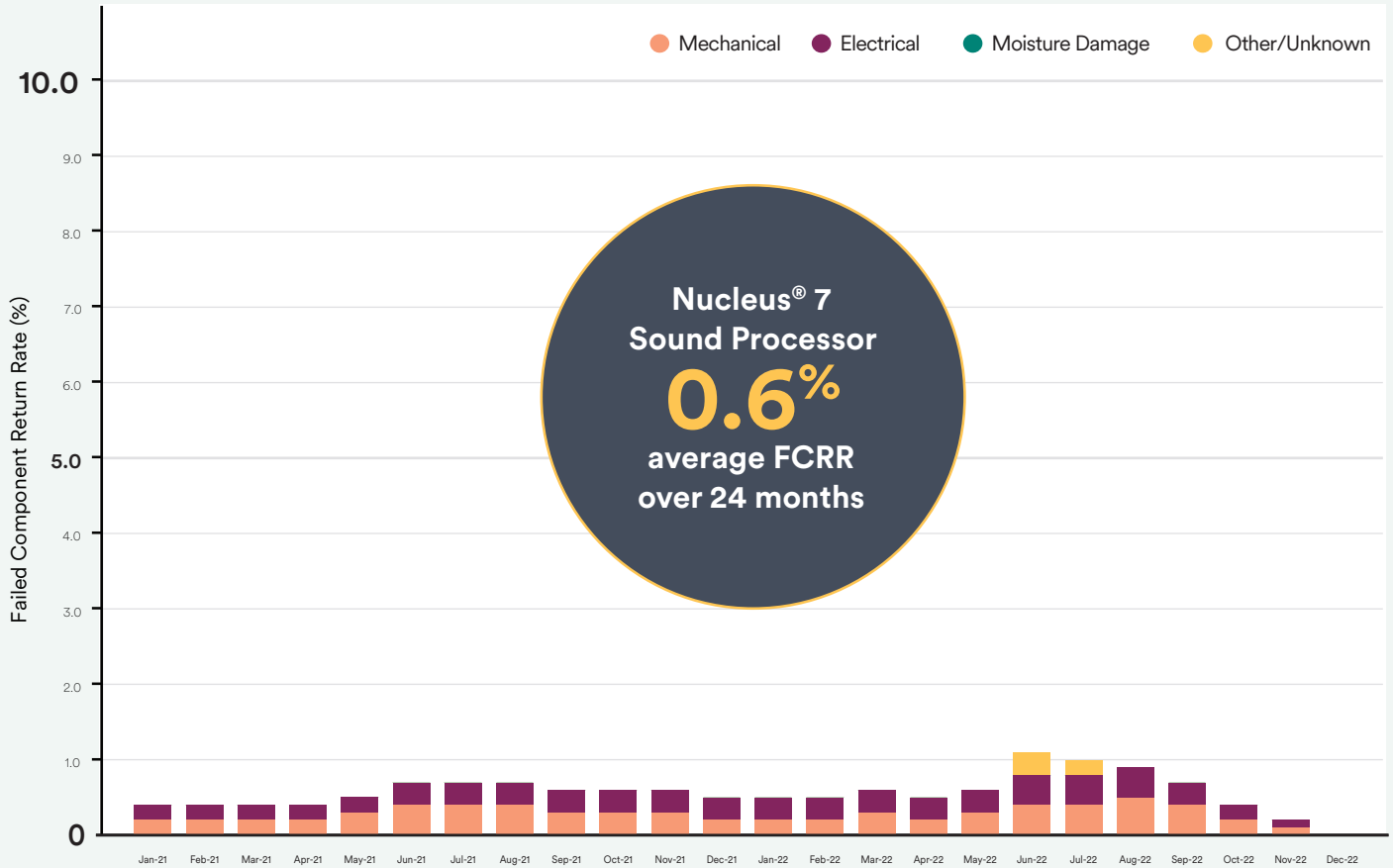


Nucleus 7 Sound Processor – Failed Component Return Rate

| 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 |
|-------------------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|
| 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% |

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 |

* Non-regulatory approved product in Japan. The all product data should be reported to meet the requirements for International Standard ISO 5841-21, the reporting principles outlined in the European Consensus Statement on Cochlear Implant Failures and Explantations, and the International Classification of Reliability for Implanted Cochlear Implant Receiver Stimulators.

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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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| Trade Name: | Regulatory Number: |
|---------------------|--------------------|
| コクレアインプラント6 | 30200BZX00205000 |
| コクレアインプラント5 | 22700BZX00337000 |
| N24 システム | 21100BZY00464000 |
| コントゥアインプラント | 21800BZY10061000 |
| コクレアインプラント ミニシステム22 | 20300BZY00060000 |
| Kanso 2 サウンドプロセッサ | 30300BZX00273000 |
| Nucleus 7 サウンドプロセッサ | 23000BZX00310000 |

This material is intended for health professionals. If you are a consumer, 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 read the instructions 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.

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