Hear now. And always

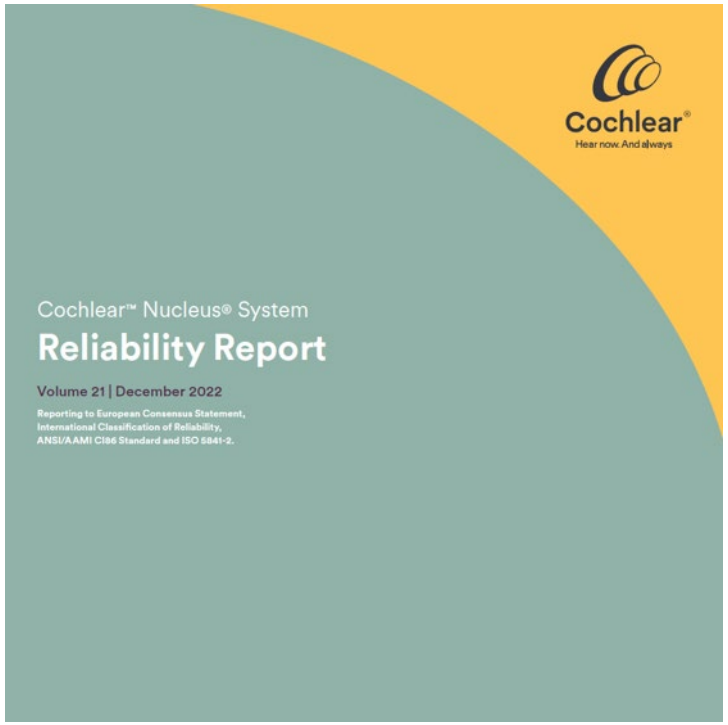
FOR PROFESSIONALS

Cochlear™ Nucleus® Reliability Report (ANSI/AAMI CI86)

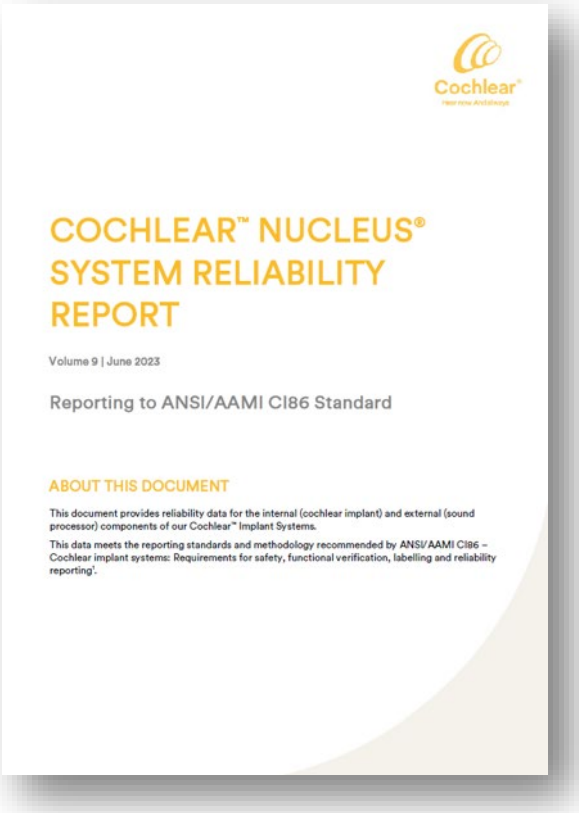
Volume 9

Transparency through reliability reporting

- Access to reliability data is important as comparing reliability between manufacturers can help candidates and professionals make informed decisions about which implant system to choose.
- Cochlear publishes two reliability reports annually to provide easy access to the most comparable data whilst continuing to meet all relevant, industry-recognised cochlear implant reliability reporting requirements.
- Cochlear was the first hearing implant manufacturer to meet the reliability reporting requirements of both the European Consensus Statement[1] and the American ANSI/AAMI CI86 Standard[2].



Cochlear™ Nucleus® System Reliability Report



Cochlear™ Nucleus® System Reliability Report (ANSI/AAMI CI86)

Why do implant reliability figures differ between our reports?

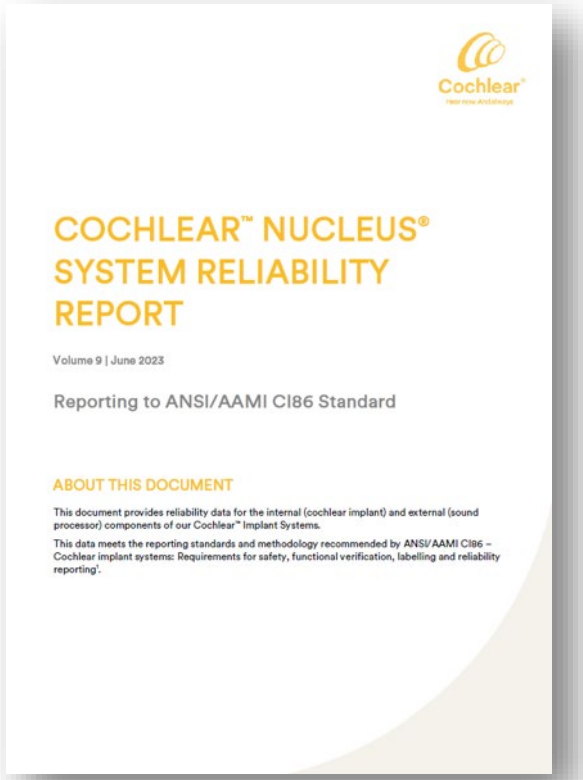
The European Consensus Statement and ANSI/AAMI CI86 use different calculations for implant reliability.

The requirements of ANSI/AAMI CI86, primarily the inclusion of device removal for medical reasons, result in lower implant reliability figures than those reported using the Consensus Statement requirements.

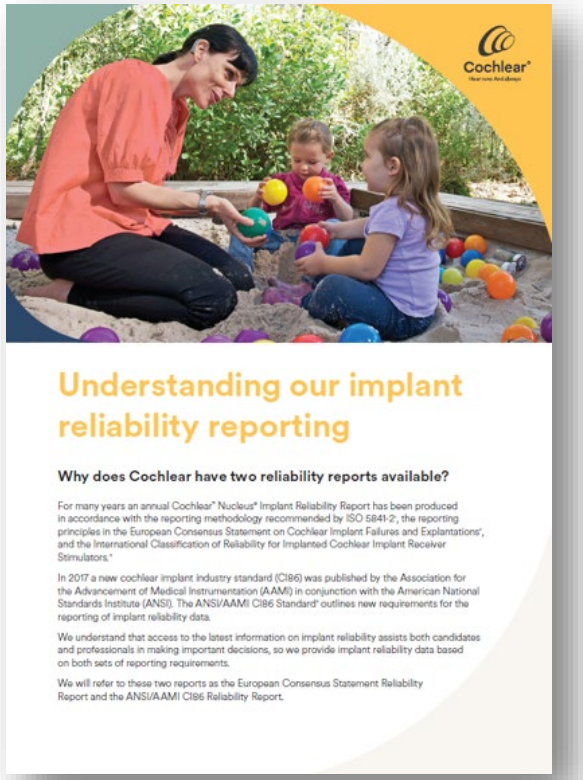
	European Consensus Statement Reliability Report	ANSI/AAMI CI86 Reliability Report
 **IMPLANT RELIABILITY METRIC**	The reliability metric used is Cumulative Survival Percentage (CSP). CSP measures the percentage of functioning implants, at given time intervals, after implantation.	The reliability metric used is Cumulative Removal Percentage (CRP). CRP measures the percentage of implanted devices that have been removed, at given time intervals, after implantation.
 **DEFINITION OF ADULT AND CHILD POPULATION**	A child is defined as a recipient who was aged less than 18 at the time of implantation.	A child is defined as a recipient who was aged less than 10 at the time of implantation.
 **INCLUSION OF SOUND PROCESSOR RELIABILITY**	Sound processor reliability data is not included.	The standard specifies principles for the reporting of sound processor reliability. Data is reported for all sound processors which are currently marketed in the US.

ANSI/AAMI CI86 Reliability Report

- Our ninth *ANSI/AAMI CI86 Reliability Report* is based on data to June 2023.
- The report is available at www.cochlear.com/reliability
- A supporting *Fact Sheet* is also available to explain the variations in implant reliability data between our two reliability reports.



Cochlear Nucleus System Reliability Report (ANSI/AAMI CI86) Volume 9



Fact Sheet

Cochlear®

Implant reliability

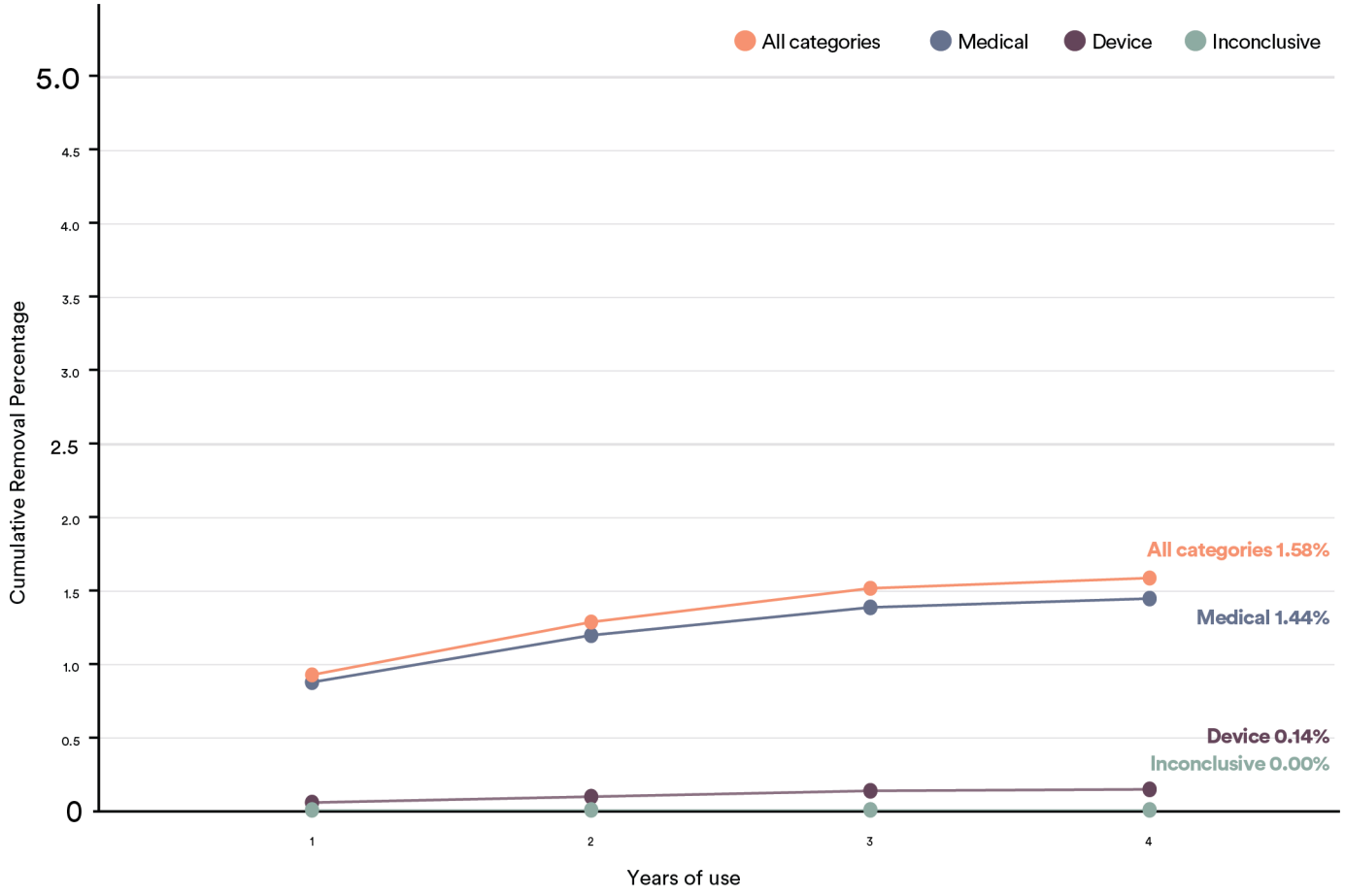
Nucleus® Profile™ Plus Series Implant reliability

Number of registered Profile™ Plus Series Implants - 30 June 2023

ADULTS	CHILDREN	COMBINED
60,009	26,593	86,602

Commercially released in 2019, the Profile™ Plus Series Implant has a 1.58% Cumulative Removal Percentage within four years.

Profile™ Plus Series Implant - removal rates by analysis category for adults and children



REGISTERED IMPLANT DATA AT 30 JUNE 2023

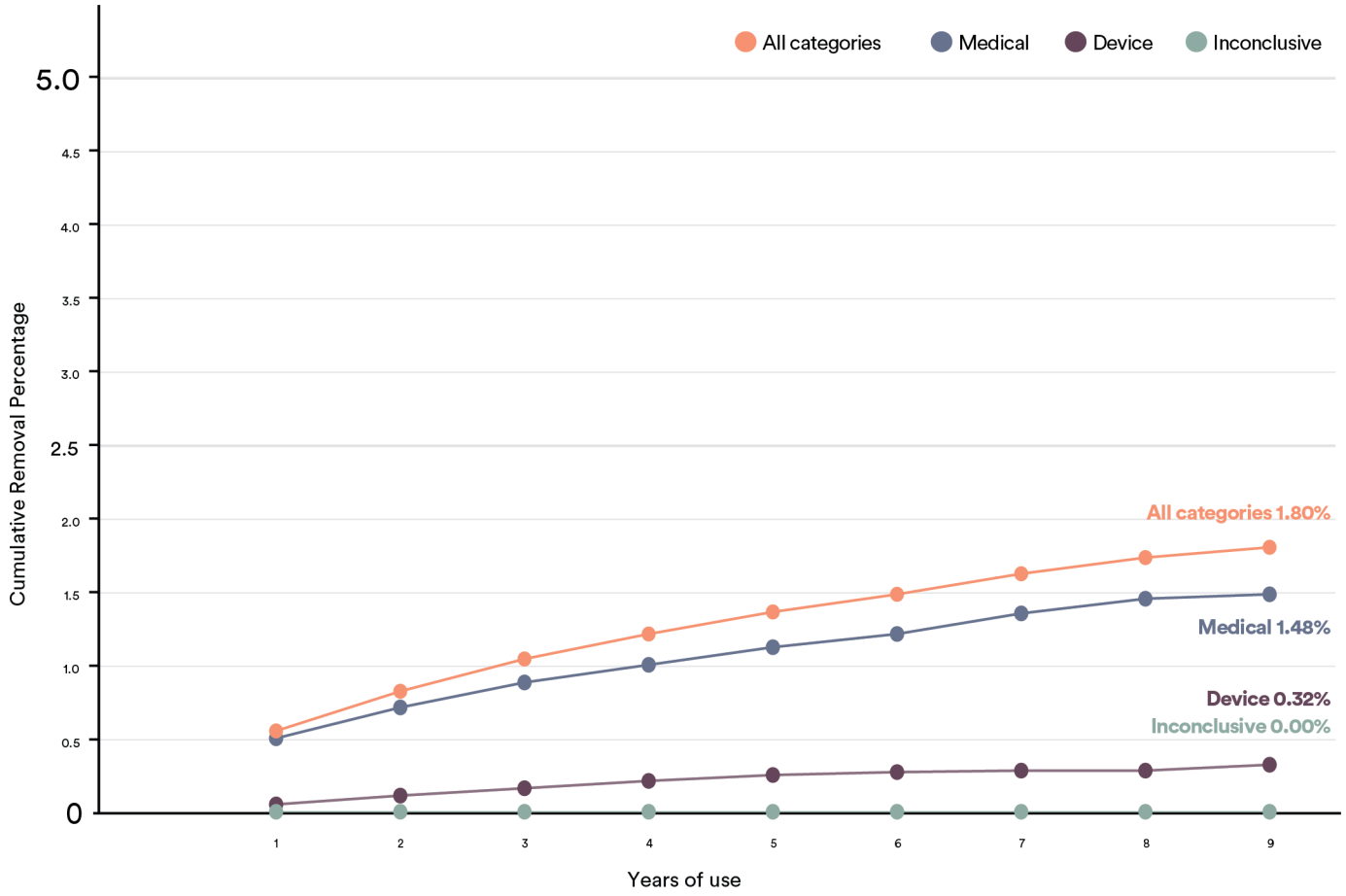
Nucleus Profile Series Implant reliability

Number of registered Profile™ Series Implants - 30 June 2023

ADULTS	CHILDREN	COMBINED
61,534	49,812	111,346

The Profile Series Implant has a 1.80% Cumulative Removal Percentage within nine years.

Profile™ Series Implant - removal rates by analysis category for adults and children



REGISTERED IMPLANT DATA AT 30 JUNE 2023

Nucleus CI24RE Series Implant reliability

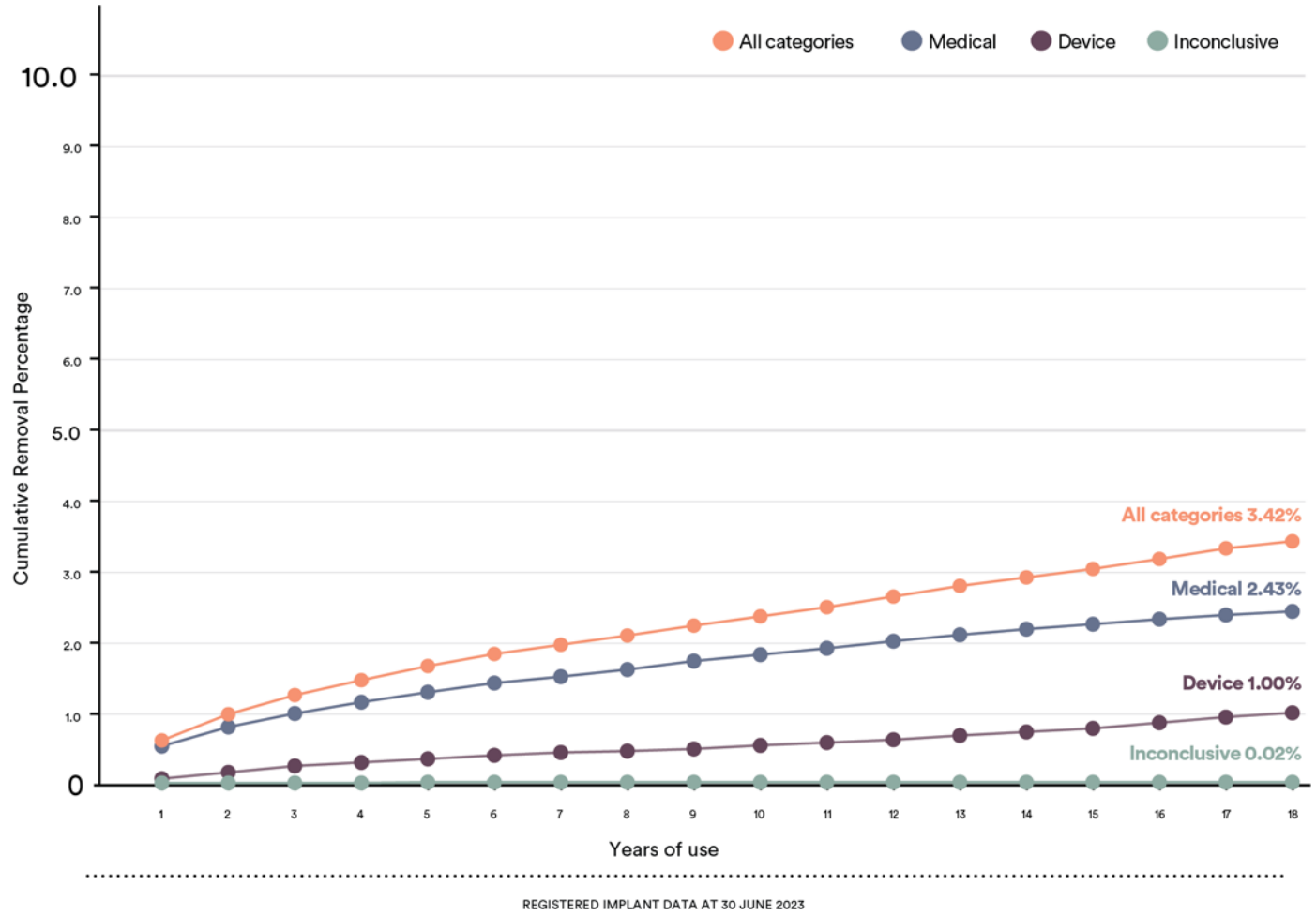
Number of registered CI24RE Series Implants - 30 June 2023

ADULTS	CHILDREN	COMBINED
98,533	118,739	217,272

The CI24RE Series Implant is the world's most widely used cochlear implant.*,3-5

Released in 2005, it has a 3.42% Cumulative Removal Percentage within 18 years.

CI24RE Series Implant - removal rates by analysis category for adults and children



* Based on available data.

Nucleus CI500 Series Implant reliability

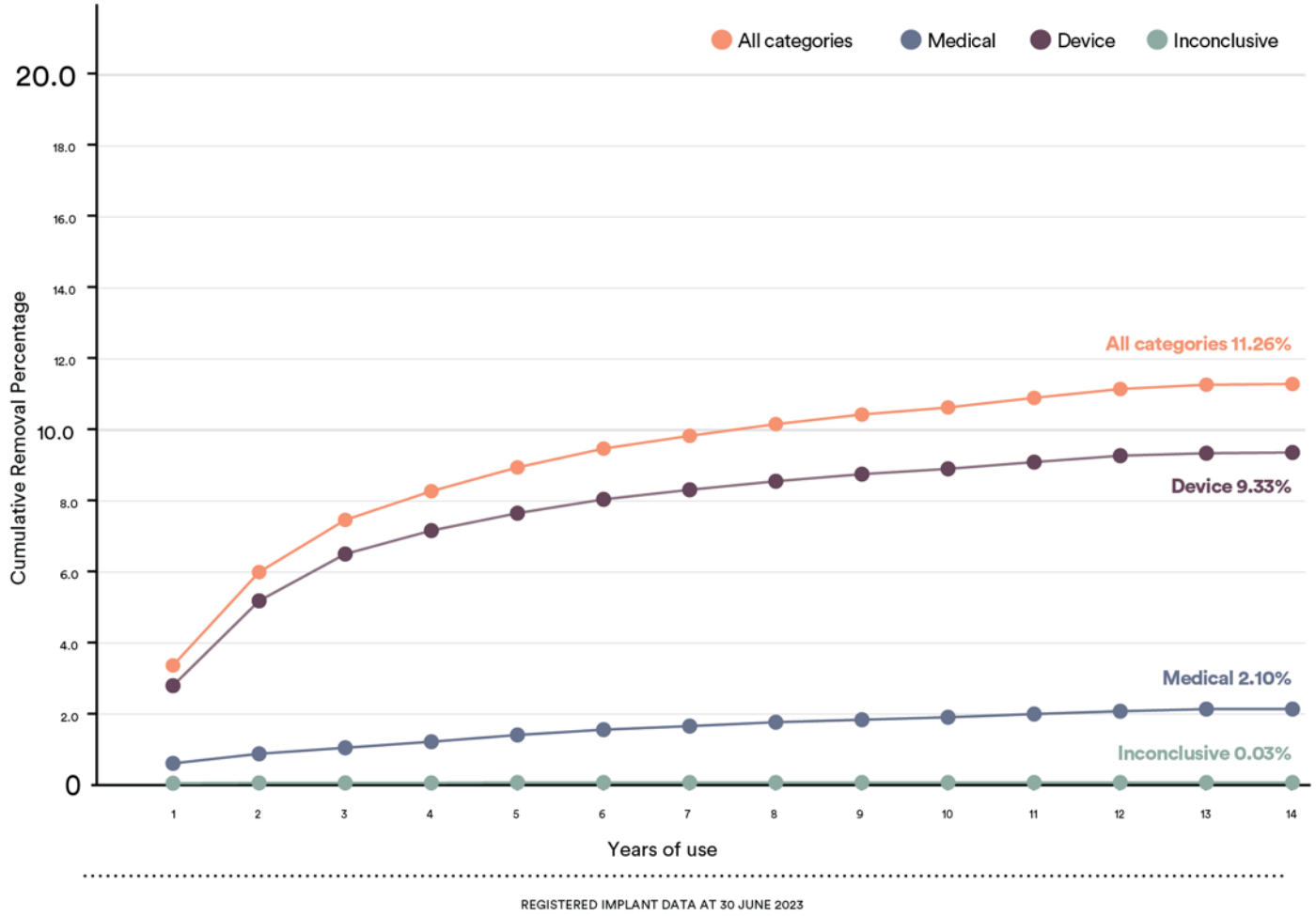
Number of registered CI500 Series Implants - 30 June 2023

ADULTS	CHILDREN	COMBINED
17,539	12,356	29,895

Released in 2009, the CI500 Series Implant has a Cumulative Removal Percentage of 11.26% within 14 years.

The CI500 Series Implant was voluntarily recalled in September 2011.

CI500 Series Implant - removal rates by analysis category for adults and children



REGISTERED IMPLANT DATA AT 30 JUNE 2023

Nucleus CI24R Implant reliability

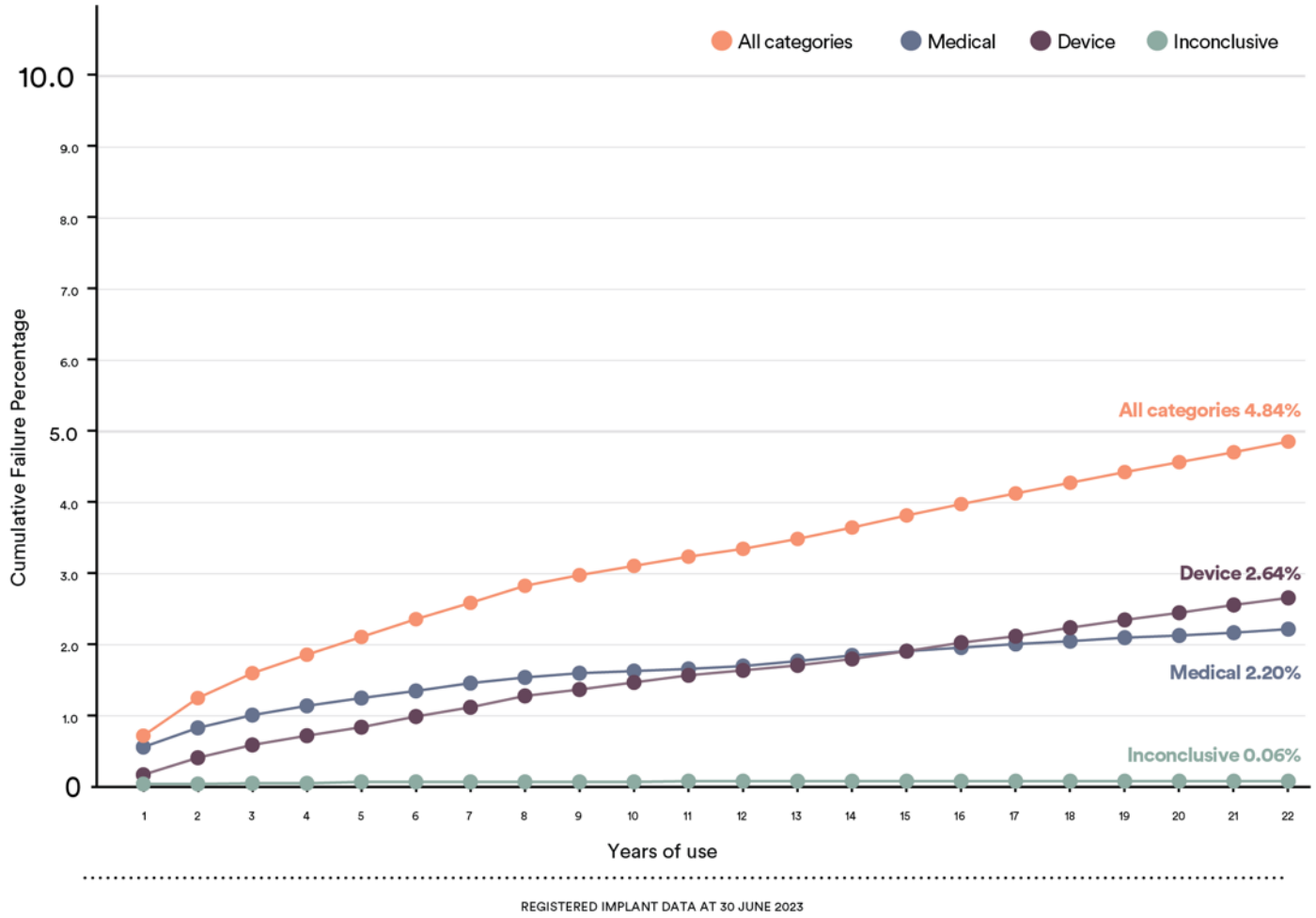
Number of registered CI24R Implants - 30 June 2023

ADULTS	CHILDREN	COMBINED
23,241	30,319	53,560

The CI24R Implant was released in 2000 with straight and perimodiolar electrodes (Contour® in 2000, Contour Advance® in 2002).

Within 22 years, the CI24R Implant has a Cumulative Removal Percentage of 4.84%.

CI24R Implant - failure rates by analysis category for adults and children



REGISTERED IMPLANT DATA AT 30 JUNE 2023

Nucleus CI24M Implant reliability

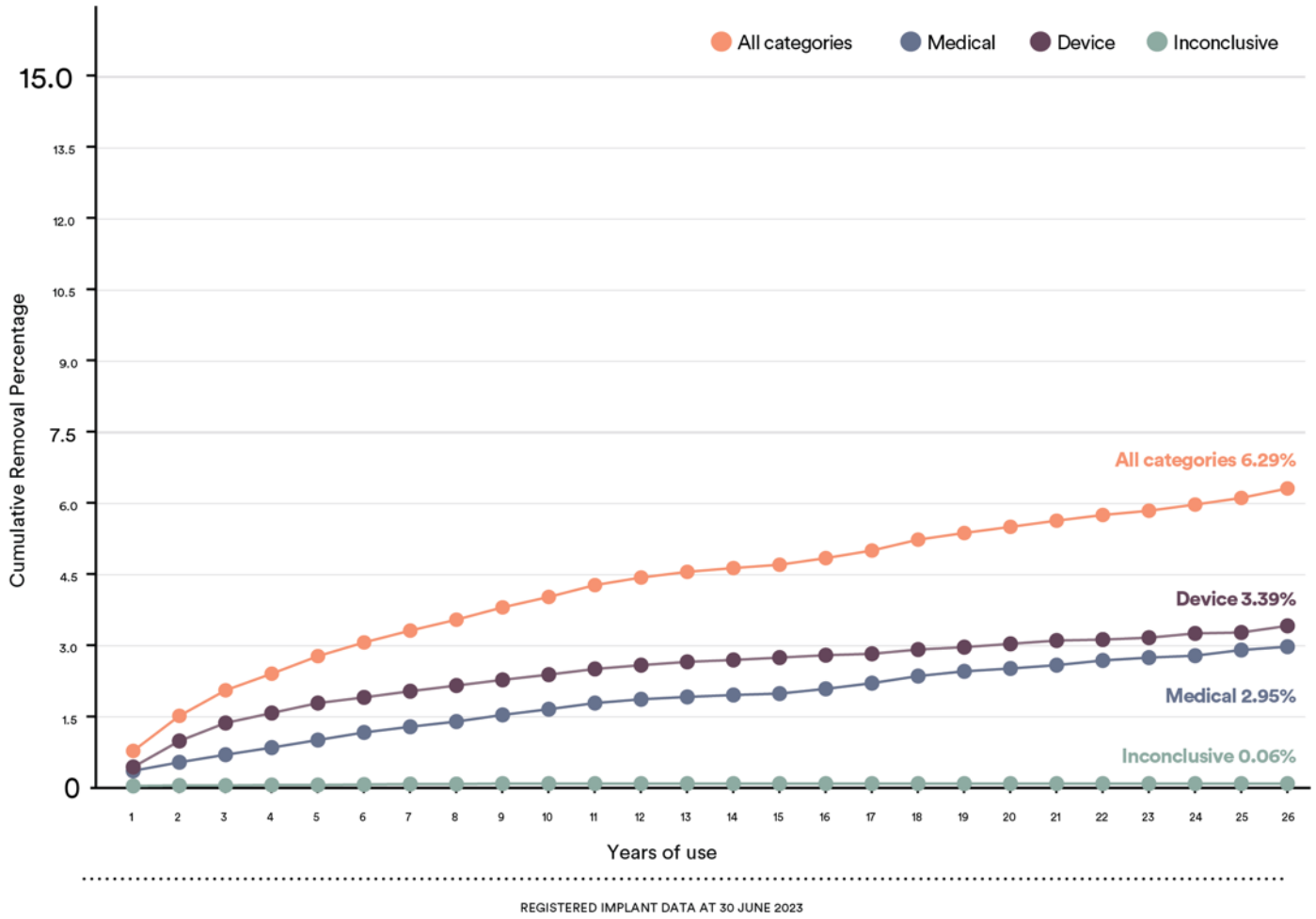
Number of registered CI24M Implants - 30 June 2023

ADULTS	CHILDREN	COMBINED
9677	9846	19,523

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

Within 26 years, the CI24M Implant has a Cumulative Removal Percentage of 6.29%.

CI24M Implant - removal rates by analysis category for adults and children



REGISTERED IMPLANT DATA AT 30 JUNE 2023

* The CI24M Implant is MRI conditional within defined conditions. Please refer to the instructions for use for detailed conditions for MRI scans.

Nucleus CI22M Implant reliability

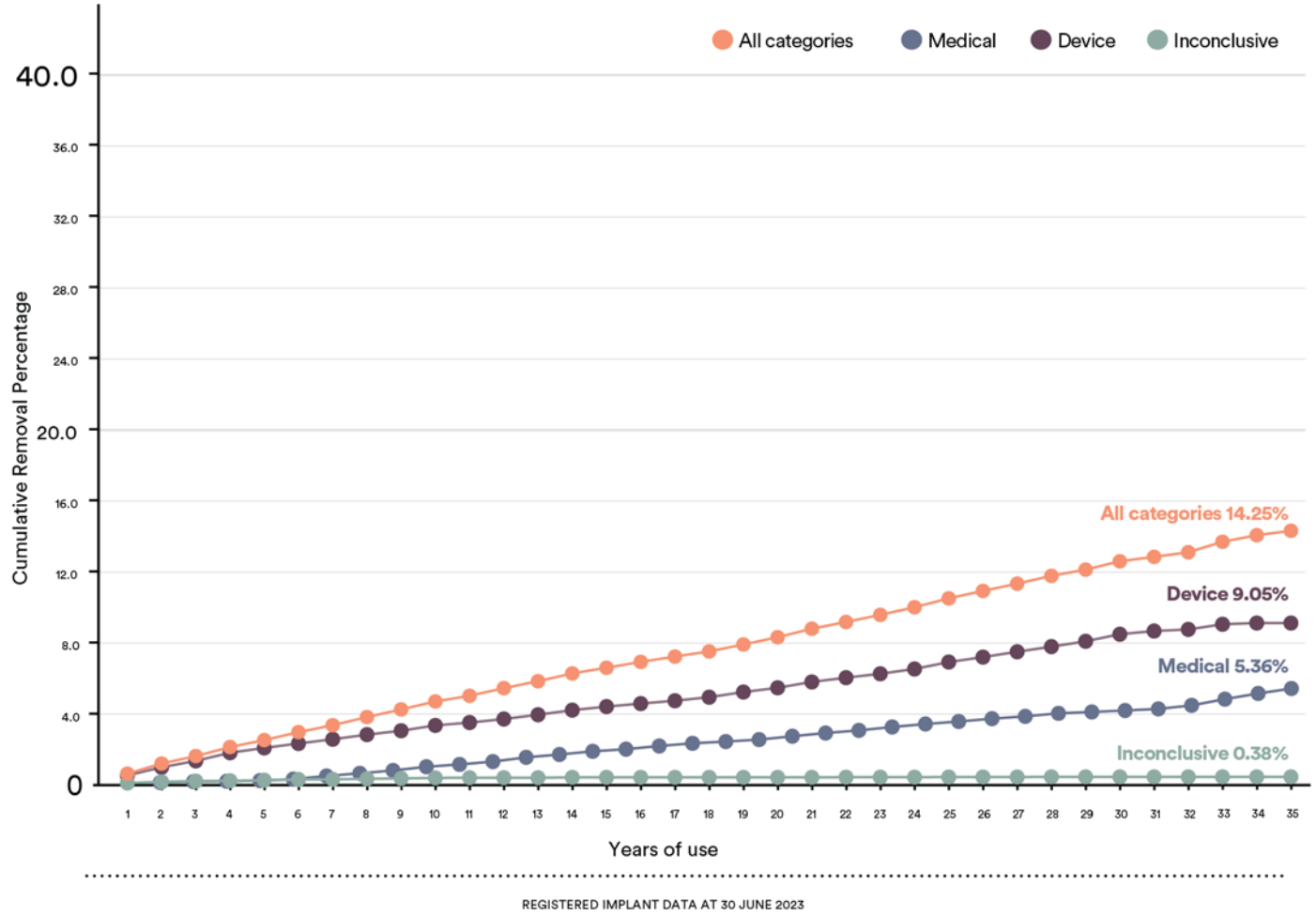
Number of registered CI22M Implants - 30 June 2023

ADULTS	CHILDREN	COMBINED
11,116	6545	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 Cumulative Removal Percentage of 14.25%.

CI22M Implant - removal rates by analysis category for adults and children



REGISTERED IMPLANT DATA AT 30 JUNE 2023

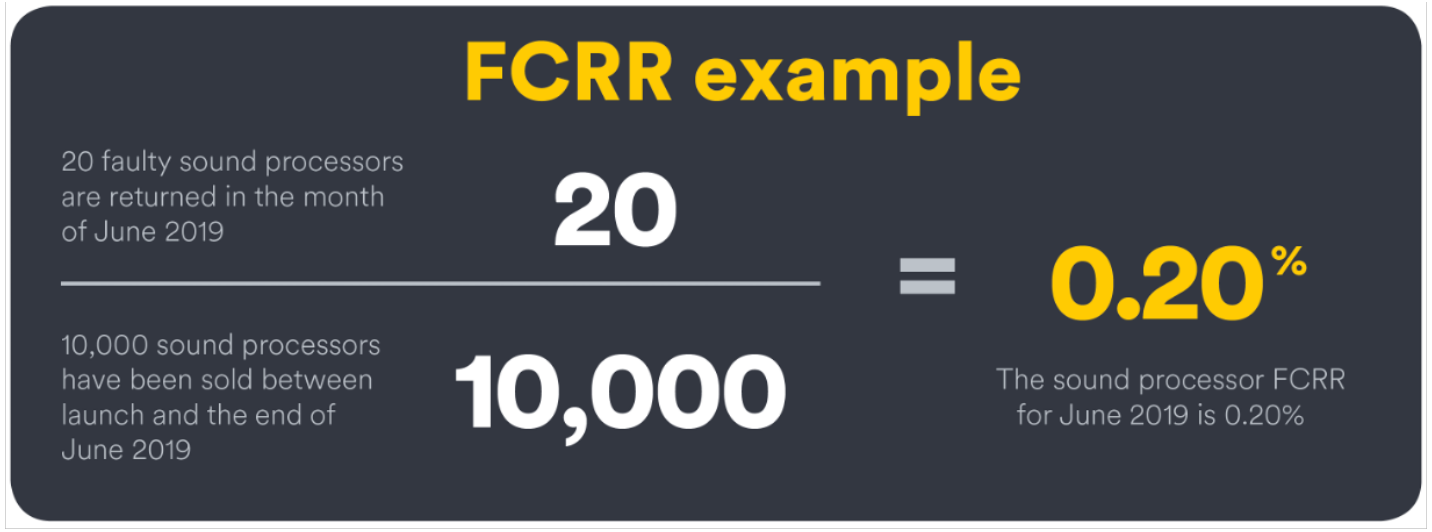
Cochlear®

Sound processor reliability

How is sound processor reliability measured?

In the ANSI/AAMI CI86 Standard, the measure for sound processor reliability is the Failed Component Return Rate (FCRR).

The FCRR is a percentage calculated by comparing the number of failed sound processors returned within a month to the cumulative sales of the same sound processor between launch and the end of that month. The FCRR is reported as a monthly figure over a period of 24 months.



The categories of sound processor failure

Returned sound processors are classified by the reason for failure:

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.

Electrical Failure. A functional failure of the electronics or the electronic assembly.

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.

Fail mode	Jul-21	Aug-21	Sep-21	Oct-21
Mechanical	0.4%	0.4%	0.3%	0.3%
Electrical	0.3%	0.3%	0.3%	0.3%
Moisture	0.0%	0.0%	0.0%	0.0%
Other	0.0%	0.0%	0.0%	0.0%
Fault-Free	0.3%	0.2%	0.2%	0.2%

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

Fault-Free. 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. Fault-free devices are not included in the FCRR calculation.

Note: data on this page are for example only.

Data used to calculate sound processor reliability

Failed processors

Cochlear tests all returned sound processors to determine if they are working and, if not, why they failed. The FCRR calculation includes four types of processor failure: mechanical failure, electronic failure, moisture damage failure and unknown failure. If a returned processor is found to be fully functional it is reported as fault free and not included in the FCRR calculation.

Processor sales

The sales figure used to calculate the monthly FCRR is total sales from the launch of the processor to the end of that month. Whilst 24 months of data are reported, the cumulative sales figure may span a longer period, for example if the processor was launched 36 months prior.

Global vs US data

Cochlear has used global sales and returns data to calculate the FCRR in the ANSI/AAMI CI86 Reliability Report, not US specific data. This is primarily because we operate a global returns centre.

Comparing the reliability of sound processors

Compare the FCRR over time

Monthly processor return volumes are variable and can be impacted by factors such as seasonality. By considering the full 24 months of FCRR, rather than individual months, you will gain a better view of overall processor reliability.

Evaluate product generations

Predictors of manufacturer reliability would include both a consistent record of sound processor reliability and improving FCRR data for each new generation of processor.

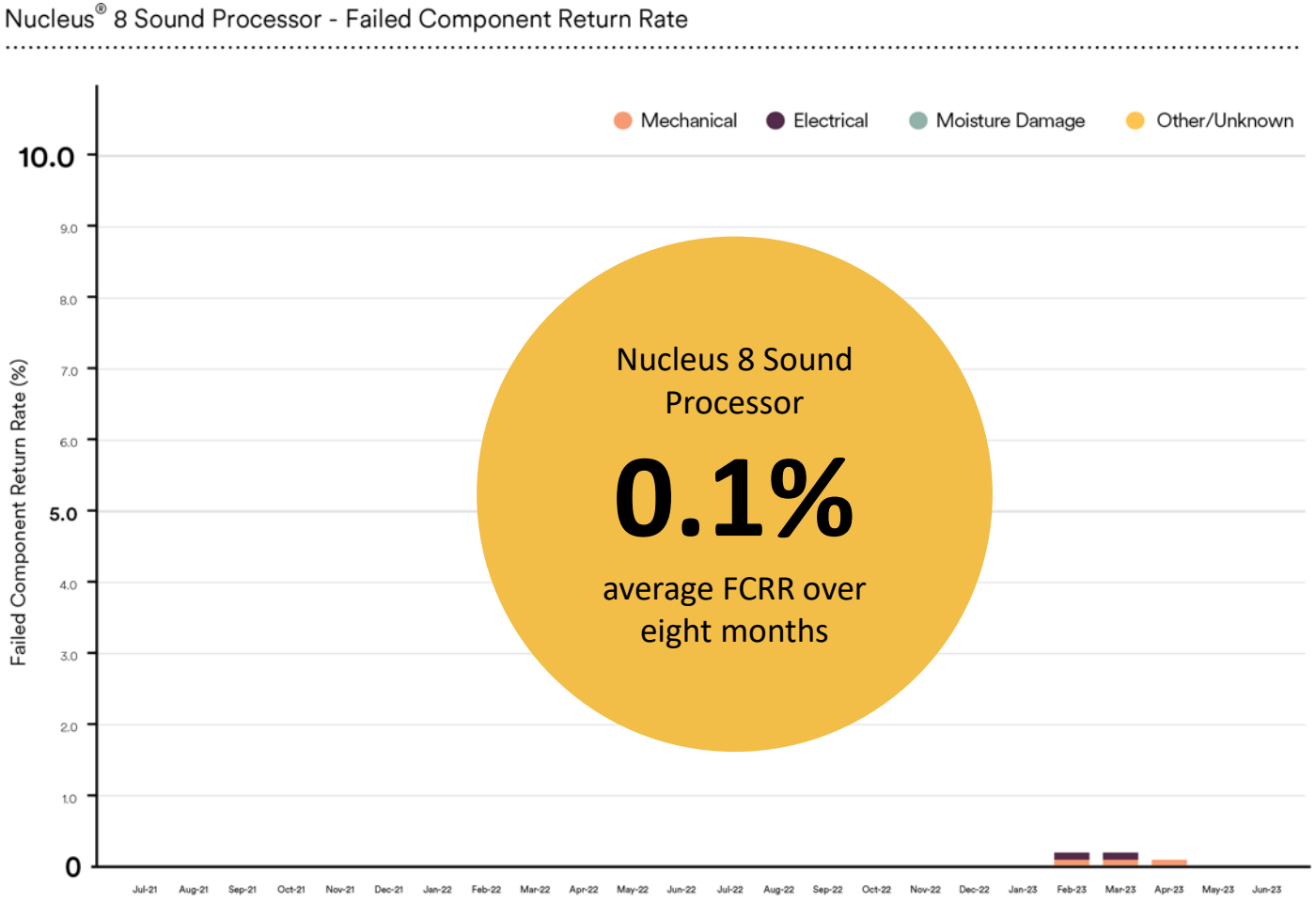
Consider product life-cycle

FCRR can be impacted by how long a sound processor has been available in the market as it is based on sales and returns volumes. The FCRR of a newly launched device, for example, may not be comparable with the FCRR of a device which has been available for a number of years.

Nucleus® 8 Sound Processor

Released in 2022, the Nucleus 8 Sound Processor is the world's smallest and lightest behind-the-ear sound processor[6], and the first cochlear implant sound processor that's ready for Bluetooth LE Audio technology.*

* 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

Nucleus 8 Sound Processor - Failed Component Return Rate

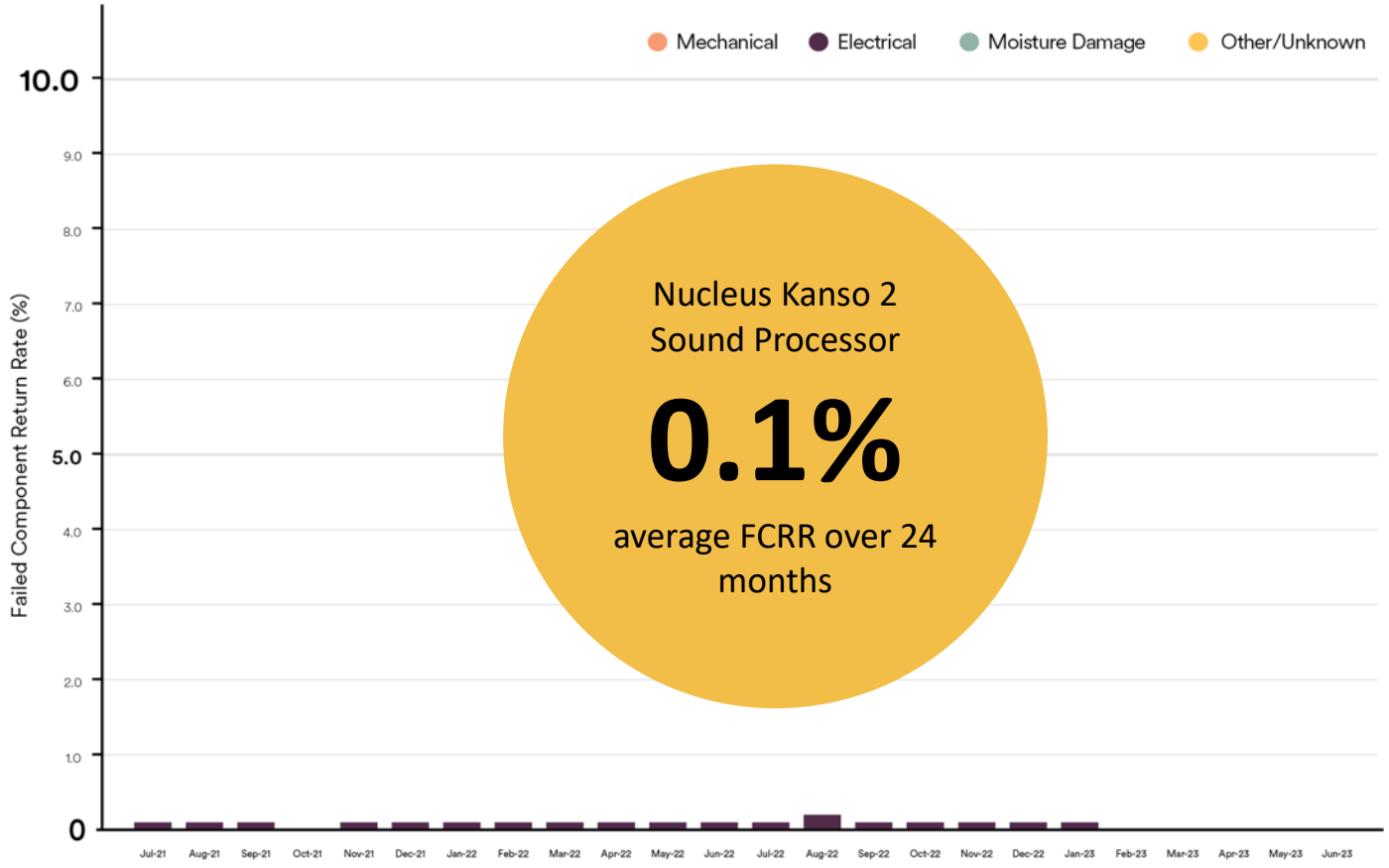
Fail mode	Jul-21	Aug-21	Sep-21	Oct-21	Nov-21	Dec-21	Jan-22	Feb-22	Mar-22	Apr-22	May-22	Jun-22
Mechanical	-	-	-	-	-	-	-	-	-	-	-	-
Electrical	-	-	-	-	-	-	-	-	-	-	-	-
Moisture	-	-	-	-	-	-	-	-	-	-	-	-
Other	-	-	-	-	-	-	-	-	-	-	-	-
Fault-Free	-	-	-	-	-	-	-	-	-	-	-	-

Fail mode	Jul-22	Aug-22	Sep-22	Oct-22	Nov-22	Dec-22	Jan-23	Feb-23	Mar-23	Apr-23	May-23	Jun-23
Mechanical	-	-	-	-	0.0%	0.0%	0.0%	0.1%	0.1%	0.1%	0.0%	0.0%
Electrical	-	-	-	-	0.0%	0.0%	0.0%	0.1%	0.1%	0.0%	0.0%	0.0%
Moisture	-	-	-	-	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%
Fault-Free	-	-	-	-	0.0%	0.0%	0.0%	0.0%	0.1%	0.0%	0.0%	0.0%

Nucleus Kanso® 2 Sound Processor

Released in 2020, the Nucleus® Kanso® 2 Sound Processor combines our latest connectivity features* with a simple and durable all-in-one design in the smallest and lightest rechargeable off-the-ear sound processor.[6]

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



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

Nucleus Kanso 2 Sound Processor

Nucleus Kanso 2 Sound Processor - Failed Component Return Rate

Fail mode	Jul-21	Aug-21	Sep-21	Oct-21	Nov-21	Dec-21	Jan-22	Feb-22	Mar-22	Apr-22	May-22	Jun-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%	0.0%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	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%	0.1%

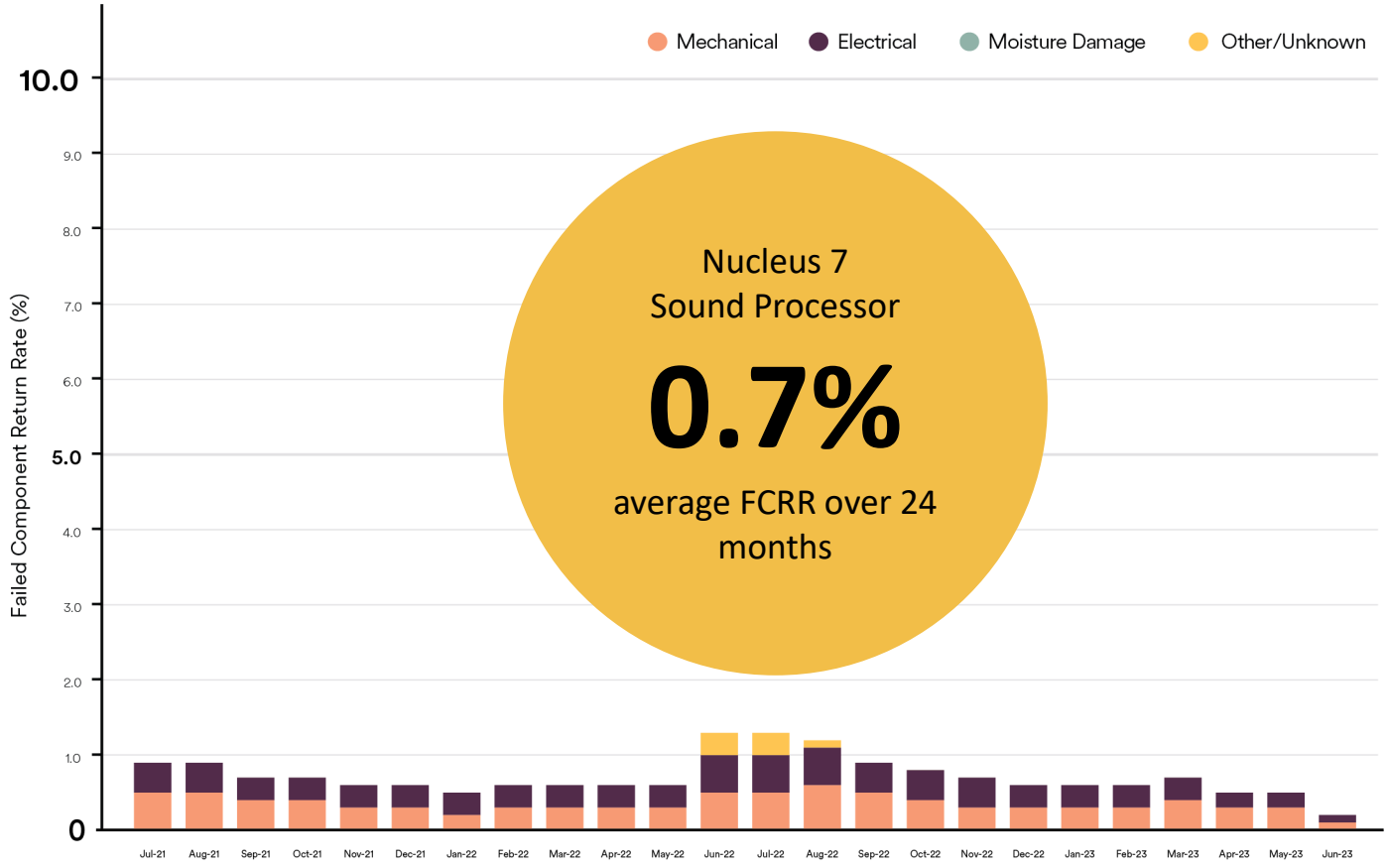
Fail mode	Jul-22	Aug-22	Sep-22	Oct-22	Nov-22	Dec-22	Jan-23	Feb-23	Mar-23	Apr-23	May-23	Jun-23
Mechanical	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Electrical	0.1%	0.2%	0.1%	0.1%	0.1%	0.1%	0.1%	0.0%	0.0%	0.0%	0.0%	0.0%
Moisture	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
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	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.0%	0.0%	0.0%	0.0%	0.0%

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.*

* 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



Nucleus 7 Sound Processor

Nucleus 7 Sound Processor - Failed Component Return Rate

Fail mode	Jul-21	Aug-21	Sep-21	Oct-21	Nov-21	Dec-21	Jan-22	Feb-22	Mar-22	Apr-22	May-22	Jun-22
Mechanical	0.5%	0.5%	0.4%	0.4%	0.3%	0.3%	0.2%	0.3%	0.3%	0.3%	0.3%	0.5%
Electrical	0.4%	0.4%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%	0.5%
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%	0.3%
Fault-Free	0.2%	0.2%	0.2%	0.2%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.2%

Fail mode	Jul-22	Aug-22	Sep-22	Oct-22	Nov-22	Dec-22	Jan-23	Feb-23	Mar-23	Apr-23	May-23	Jun-23
Mechanical	0.5%	0.6%	0.5%	0.4%	0.3%	0.3%	0.3%	0.3%	0.4%	0.3%	0.3%	0.1%
Electrical	0.5%	0.5%	0.4%	0.4%	0.4%	0.3%	0.3%	0.3%	0.3%	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	0.3%	0.1%	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%	0.1%	0.1%	0.0%

References

1. European Consensus Statement on Cochlear Implant Failures and Explantations. Otol Neurotol. 2005 Nov;26(6):1097-9
2. ANSI/AAMI CI86. Cochlear implant systems: Requirements for safety, functional verification,. (2017). Arlington, VA: American National Standards Institute.
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www.cochlear.com