



COCHLEAR™ NUCLEUS® SYSTEM RELIABILITY REPORT

Volume 6 | December 2021

Reporting to ANSI/AAMI C186 Standard

ABOUT THIS DOCUMENT

This document provides reliability data for the internal (cochlear implant) and external (sound processor) components of our Cochlear™ Implant Systems.

This data meets the reporting standards and methodology recommended by ANSI/AAMI C186 – Cochlear implant systems: Requirements for safety, functional verification, labelling and reliability reporting¹.

THE ANSI/AAMI CI86 STANDARD

In 2017, the ANSI/AAMI CI86 Guidelines were approved, outlining procedures that manufacturers should follow when reporting the reliability of cochlear implants and sound processors.

The guidelines require manufacturers to provide information to the public about the percentage of implanted devices that have been removed following implantation. This number is the cumulative removal percentage, or CRP. Age-related differences may affect the CRP, so data is shown for patients who are both older (10 years of age or older) and younger (less than 10 years of age) at the time they received the implant. Typically, children younger than 10 years of age have a higher chance of activity-related damage to the device.

The guidelines also require manufacturers to provide information about returned device failure rates for sound processor models sold in the US. This metric is the Failed Component Return Rate (FCRR).

You will note that no hearing implant device has perfect reliability over time. If a cochlear implant is removed, the surgeon returns the device to the implant manufacturer for testing. If the manufacturer finds that the device is not working properly, additional tests are performed to determine the cause of the failure. Once testing is complete, the results are sent to the hearing professional and the manufacturer's reliability data is updated. As part of the requirements of ANSI/AAMI CI86, device manufacturers send detailed reliability reports to the U.S. Food and Drug Administration (FDA) every six months. Frequently, the device manufacturer uses the results of these tests to improve the design of future products.

The guidelines require manufacturers to publish their updated reliability data every six months. To ensure you have the most recent information, check the date on this document. The most recent report is available at www.cochlear.com/reliability.

COCHLEAR™ IMPLANT DATA

In this document, Cumulative Removal Percentage (CRP) is used to measure implant reliability. CRP is the percentage of implanted devices that have been removed following implantation. The CRP provides information regarding the reliability of a certain make and model of implant over time.

For example, if the CRP after five years of experience with a specific implant model is 2%, this means that after five years, the patient's chance of obtaining continued benefit from the cochlear implant system, as described for its intended use, is 98%.

It is important to track device reliability information over time because cochlear implants typically remain implanted for many years. It is also important to track the reasons for removal when devices are replaced. The CRP classifies removed devices into three categories that define the reason for removal:

- **Medical Related.** Examples of medical reasons for device removal include infection, rejection of the device due to allergy, or incorrect positioning of the internal device.
- **Device Failure.** Examples of device failure reasons for removal include suspected implant failure due to mechanical or electrical issues, moisture damage, or other problems with device function.
- **Inconclusive.** Occasionally, testing of the device indicates no fault, despite a reason for removal. For example, a patient experiences unexplained performance decline, but testing of the removed device reveals normal function.

Note: A small difference may exist between the sum of the category CRP figures and the total CRP for an implant. This is because the total CRP is calculated independently of each category CRP figure. The CRP figures are calculated using the general analysis methods described in ISO 5841-2.^{2,3}

NUCLEUS® PROFILE™ PLUS SERIES IMPLANT

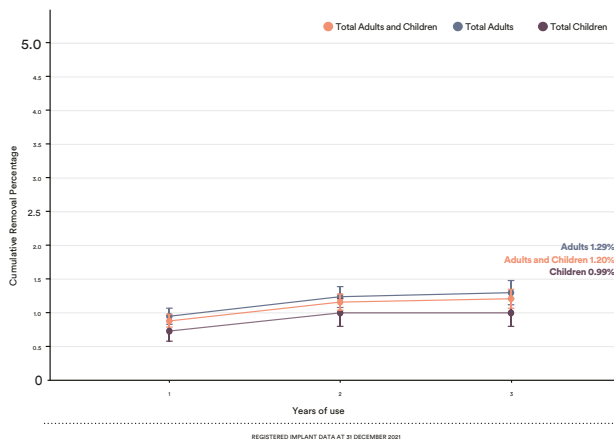
Number of registered Profile™ Plus Series Implants - 31 December 2021

ADULTS	CHILDREN	COMBINED
32,017	15,107	47,124

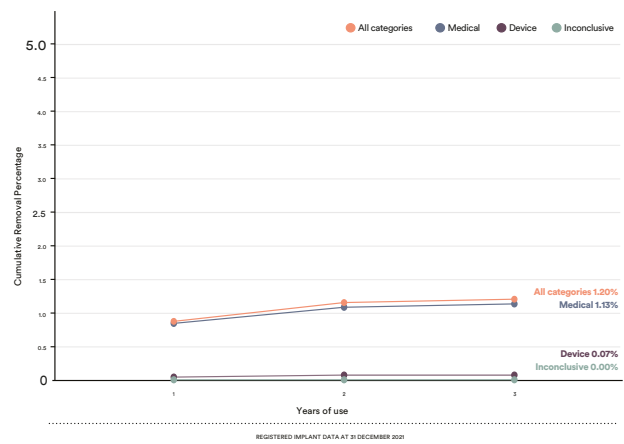
Profile™ Plus Series Implant Cumulative Removal Rates

Group	Adults						Children						Combined Adults and Children						
	Sub-category	Medical Related	Device Failure	Inconclusive	Total	Total	Medical Related	Device Failure	Inconclusive	Total	Total	Medical Related	Device Failure	Inconclusive	Total	Total			
Years	CRP	CRP	CRP	CRP	CL _{up} *	CL _{low} *	CRP	CRP	CRP	CRP	CL _{up} *	CL _{low} *	CRP	CRP	CRP	CRP	CL _{up} *	CL _{low} *	
1		0.91%	0.04%	0.00%	0.94%	0.12%	0.12%	0.68%	0.04%	0.00%	0.72%	0.15%	0.15%	0.84%	0.04%	0.00%	0.87%	0.09%	0.09%
2		1.16%	0.07%	0.00%	1.23%	0.15%	0.15%	0.92%	0.08%	0.00%	0.99%	0.20%	0.20%	1.08%	0.07%	0.00%	1.15%	0.12%	0.12%
3		1.22%	0.07%	0.00%	1.29%	0.18%	0.18%	0.92%	0.08%	0.00%	0.99%	0.20%	0.20%	1.13%	0.07%	0.00%	1.20%	0.14%	0.14%

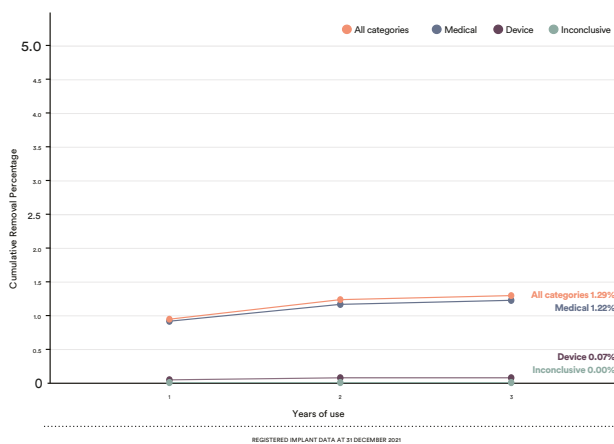
Profile™ Plus Series Implant - removal rates for all analysis categories and different patient populations



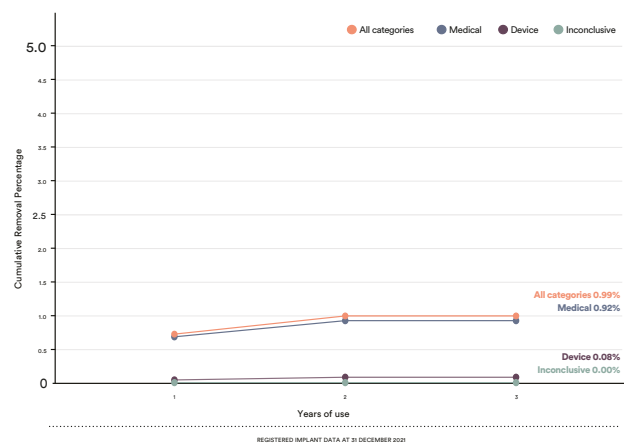
Profile™ Plus Series Implant - removal rates by analysis category for adults and children



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



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



* CL_{up} and CL_{low} are 95% confidence limits.

Note: A small difference may exist between the sum of the category CRP figures and the total CRP for an implant. This is because the total CRP is calculated independently of each category CRP figure. The CRP figures are calculated using the general analysis methods described in ISO 5841-2.^{2,3}

NUCLEUS PROFILE SERIES IMPLANT

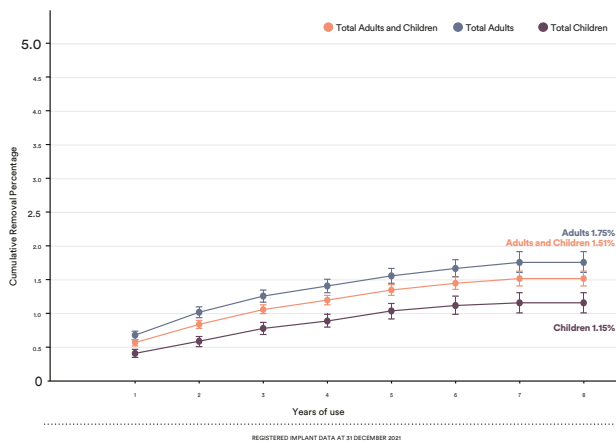
Number of registered Profile™ Series Implants - 31 December 2021

ADULTS	CHILDREN	COMBINED
58,537	42,504	101,041

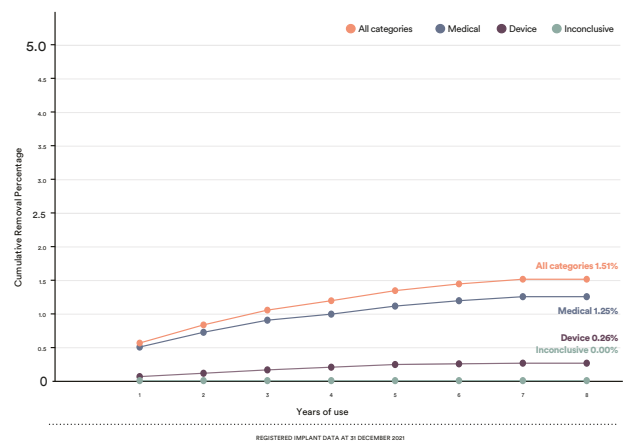
Profile™ Series Implant Cumulative Removal Rates

Group	Adults						Children						Combined Adults and Children						
	Sub-category	Medical Related	Device Failure	Inconclusive	Total	Total	Medical Related	Device Failure	Inconclusive	Total	Total	Medical Related	Device Failure	Inconclusive	Total	Total			
	Years	CRP	CRP	CRP	CRP	CL _{up} *	CL _{low} *	CRP	CRP	CRP	CRP	CL _{up} *	CL _{low} *	CRP	CRP	CRP	CRP	CL _{up} *	CL _{low} *
1		0.62%	0.04%	0.00%	0.67%	0.07%	0.07%	0.33%	0.07%	0.00%	0.40%	0.06%	0.06%	0.50%	0.06%	0.00%	0.56%	0.05%	0.05%
2		0.93%	0.08%	0.00%	1.01%	0.08%	0.08%	0.43%	0.14%	0.00%	0.58%	0.07%	0.07%	0.72%	0.11%	0.00%	0.83%	0.06%	0.06%
3		1.14%	0.11%	0.00%	1.25%	0.09%	0.09%	0.55%	0.22%	0.00%	0.77%	0.09%	0.09%	0.90%	0.16%	0.00%	1.05%	0.07%	0.07%
4		1.26%	0.14%	0.00%	1.40%	0.10%	0.10%	0.60%	0.29%	0.00%	0.88%	0.10%	0.10%	0.99%	0.20%	0.00%	1.19%	0.07%	0.07%
5		1.37%	0.18%	0.00%	1.55%	0.11%	0.11%	0.72%	0.31%	0.00%	1.03%	0.11%	0.11%	1.11%	0.24%	0.00%	1.34%	0.08%	0.08%
6		1.46%	0.20%	0.00%	1.66%	0.12%	0.12%	0.79%	0.33%	0.00%	1.11%	0.13%	0.13%	1.19%	0.25%	0.00%	1.44%	0.09%	0.09%
7		1.53%	0.22%	0.00%	1.75%	0.15%	0.15%	0.83%	0.33%	0.00%	1.15%	0.15%	0.15%	1.25%	0.26%	0.00%	1.51%	0.11%	0.11%
8		1.53%	0.22%	0.00%	1.75%	0.15%	0.15%	0.83%	0.33%	0.00%	1.15%	0.15%	0.15%	1.25%	0.26%	0.00%	1.51%	0.11%	0.11%

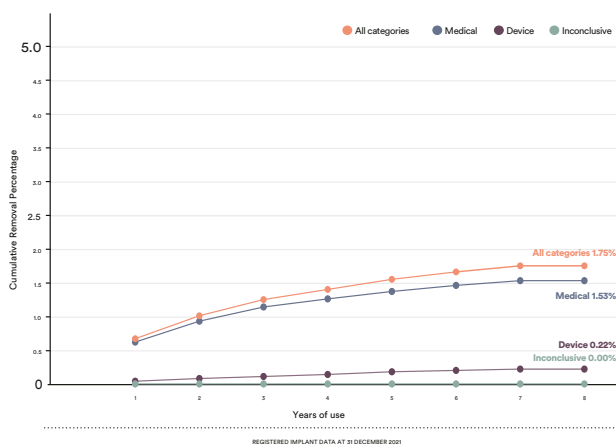
Profile™ Series Implant - removal rates for all analysis categories and different patient populations



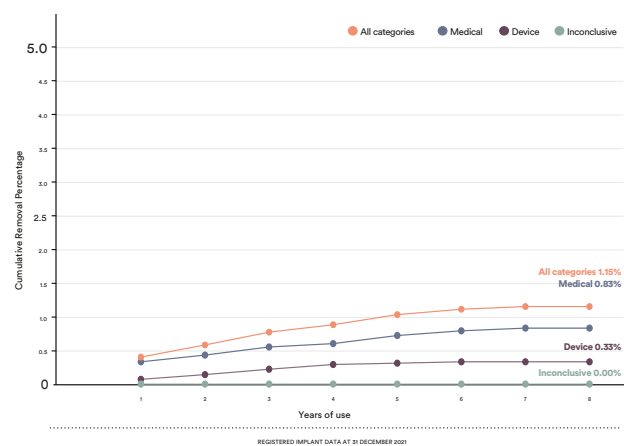
Profile™ Series Implant - removal rates by analysis category for adults and children



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



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



* CL_{up} and CL_{low} are 95% confidence limits.

Note: A small difference may exist between the sum of the category CRP figures and the total CRP for an implant. This is because the total CRP is calculated independently of each category CRP figure. The CRP figures are calculated using the general analysis methods described in ISO 5841-2.^{2,3}

NUCLEUS CI24RE SERIES IMPLANT

Number of registered CI24RE Series Implants - 31 December 2021

ADULTS	CHILDREN	COMBINED
96,149	112,411	208,560

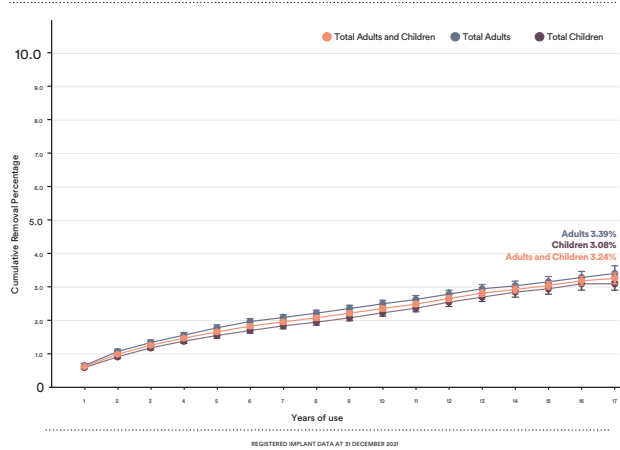
CI24RE Series Implant Cumulative Removal Rates

Group	Adults						Children						Combined Adults and Children						
	Sub-category	Medical Related	Device Failure	Inconclusive	Total	Total	Medical Related	Device Failure	Inconclusive	Total	Total	Medical Related	Device Failure	Inconclusive	Total	Total			
	Years	CRP	CRP	CRP	CRP	CI _{up} *	CI _{low} *	CRP	CRP	CRP	CRP	CI _{up} *	CI _{low} *	CRP	CRP	CRP	CRP	CI _{up} *	CI _{low} *
1		0.57%	0.06%	0.01%	0.63%	0.05%	0.05%	0.48%	0.09%	0.01%	0.57%	0.04%	0.04%	0.52%	0.07%	0.01%	0.60%	0.03%	0.03%
2		0.92%	0.12%	0.01%	1.05%	0.07%	0.07%	0.67%	0.21%	0.01%	0.89%	0.06%	0.06%	0.79%	0.17%	0.01%	0.97%	0.04%	0.04%
3		1.13%	0.18%	0.01%	1.32%	0.07%	0.07%	0.83%	0.32%	0.01%	1.16%	0.06%	0.06%	0.97%	0.25%	0.01%	1.24%	0.05%	0.05%
4		1.32%	0.21%	0.01%	1.54%	0.08%	0.08%	0.94%	0.41%	0.02%	1.36%	0.07%	0.07%	1.12%	0.31%	0.01%	1.45%	0.05%	0.05%
5		1.50%	0.25%	0.01%	1.76%	0.08%	0.08%	1.05%	0.47%	0.02%	1.53%	0.08%	0.08%	1.26%	0.36%	0.02%	1.64%	0.06%	0.06%
6		1.64%	0.30%	0.01%	1.95%	0.09%	0.09%	1.14%	0.52%	0.02%	1.68%	0.08%	0.08%	1.38%	0.42%	0.02%	1.81%	0.06%	0.06%
7		1.73%	0.33%	0.01%	2.07%	0.09%	0.09%	1.23%	0.58%	0.02%	1.82%	0.08%	0.08%	1.47%	0.46%	0.02%	1.94%	0.06%	0.06%
8		1.84%	0.35%	0.01%	2.20%	0.10%	0.10%	1.32%	0.60%	0.02%	1.93%	0.09%	0.09%	1.57%	0.48%	0.02%	2.06%	0.07%	0.07%
9		1.96%	0.37%	0.01%	2.34%	0.10%	0.10%	1.40%	0.65%	0.02%	2.06%	0.09%	0.09%	1.67%	0.51%	0.02%	2.20%	0.07%	0.07%
10		2.07%	0.40%	0.01%	2.48%	0.11%	0.11%	1.48%	0.72%	0.02%	2.21%	0.10%	0.10%	1.77%	0.57%	0.02%	2.34%	0.07%	0.07%
11		2.17%	0.44%	0.01%	2.61%	0.11%	0.11%	1.54%	0.79%	0.02%	2.35%	0.11%	0.11%	1.85%	0.62%	0.02%	2.47%	0.08%	0.08%
12		2.29%	0.48%	0.01%	2.77%	0.12%	0.12%	1.65%	0.87%	0.02%	2.53%	0.12%	0.12%	1.96%	0.67%	0.02%	2.64%	0.09%	0.09%
13		2.39%	0.53%	0.01%	2.93%	0.13%	0.13%	1.74%	0.94%	0.02%	2.68%	0.13%	0.13%	2.06%	0.74%	0.02%	2.80%	0.09%	0.09%
14		2.44%	0.58%	0.01%	3.02%	0.14%	0.14%	1.80%	1.02%	0.02%	2.83%	0.14%	0.14%	2.11%	0.80%	0.02%	2.91%	0.10%	0.10%
15		2.50%	0.65%	0.01%	3.14%	0.15%	0.15%	1.84%	1.09%	0.02%	2.93%	0.16%	0.16%	2.16%	0.87%	0.02%	3.03%	0.11%	0.11%
16		2.62%	0.66%	0.01%	3.27%	0.18%	0.18%	1.88%	1.20%	0.02%	3.08%	0.20%	0.20%	2.25%	0.93%	0.02%	3.17%	0.13%	0.13%
17		2.67%	0.72%	0.01%	3.39%	0.24%	0.24%	1.88%	1.20%	0.02%	3.08%	0.20%	0.20%	2.28%	0.96%	0.02%	3.24%	0.16%	0.16%

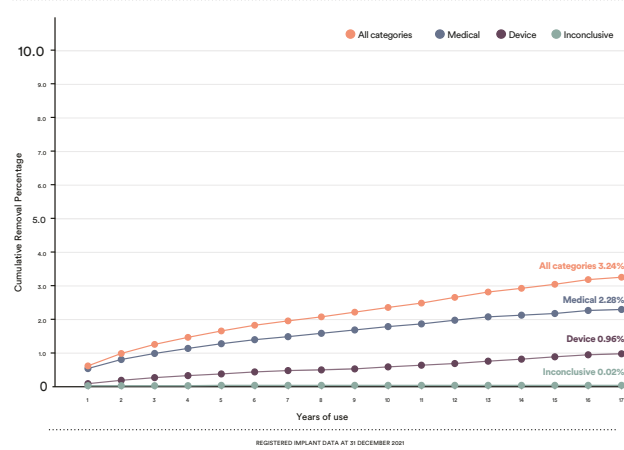
* CI_{up} and CI_{low} are 95% confidence limits.

Note: A small difference may exist between the sum of the category CRP figures and the total CRP for an implant. This is because the total CRP is calculated independently of each category CRP figure. The CRP figures are calculated using the general analysis methods described in ISO 5841-2.^{2,3}

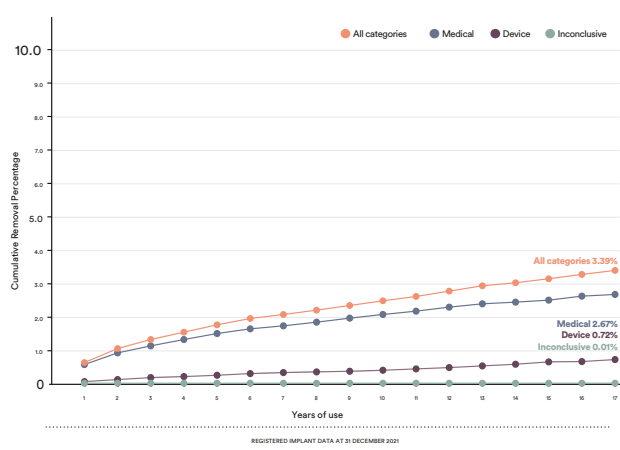
CI24RE Series Implant - removal rates for all analysis categories and different patient populations



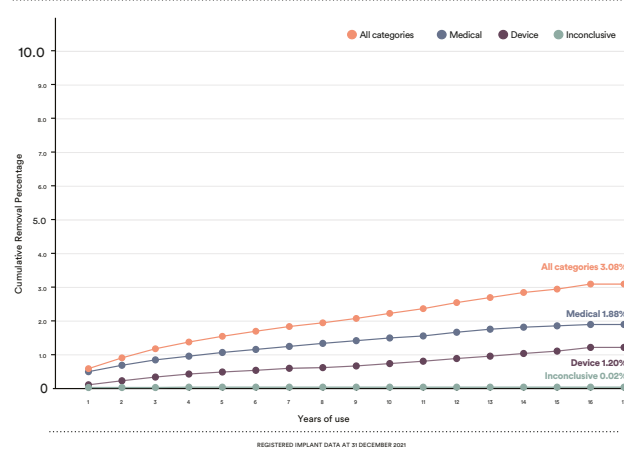
CI24RE Series Implant - removal rates by analysis category for adults and children



CI24RE Series Implant - removal rates by analysis category for adults



CI24RE Series Implant - removal rates by analysis category for children



NUCLEUS CI500 SERIES IMPLANT

Note: the CI500 Series Implant was voluntarily recalled in September 2011.

Number of registered CI500 Series Implants - 31 December 2021

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

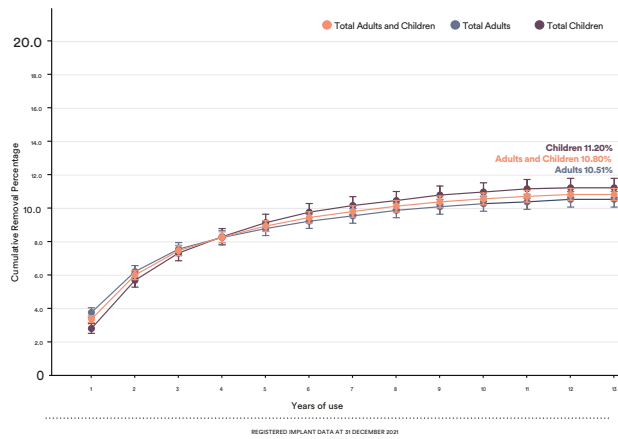
CI500 Series Implant Cumulative Removal Rates

Group Sub- category	Adults						Children						Combined Adults and Children					
	Medical Related	Device Failure	Inconclu- sive	Total	Total		Medical Related	Device Failure	Inconclu- sive	Total	Total		Medical Related	Device Failure	Inconclu- sive	Total	Total	
	CRP	CRP	CRP	CRP	CI _{up} *	CI _{low} *	CRP	CRP	CRP	CRP	CI _{up} *	CI _{low} *	CRP	CRP	CRP	CRP	CI _{up} *	CI _{low} *
1	0.69%	3.04%	0.02%	3.73%	0.28%	0.28%	0.42%	2.36%	0.00%	2.77%	0.29%	0.29%	0.58%	2.76%	0.01%	3.33%	0.20%	0.20%
2	1.05%	5.16%	0.02%	6.18%	0.36%	0.36%	0.54%	5.14%	0.01%	5.66%	0.41%	0.41%	0.84%	5.16%	0.02%	5.97%	0.27%	0.27%
3	1.24%	6.35%	0.02%	7.53%	0.39%	0.39%	0.68%	6.64%	0.02%	7.29%	0.46%	0.46%	1.01%	6.47%	0.02%	7.43%	0.30%	0.30%
4	1.43%	6.86%	0.03%	8.22%	0.41%	0.41%	0.81%	7.51%	0.02%	8.27%	0.49%	0.49%	1.17%	7.13%	0.02%	8.24%	0.31%	0.31%
5	1.63%	7.22%	0.03%	8.76%	0.42%	0.42%	0.98%	8.18%	0.04%	9.11%	0.51%	0.51%	1.36%	7.62%	0.03%	8.91%	0.32%	0.32%
6	1.79%	7.51%	0.03%	9.20%	0.43%	0.43%	1.07%	8.73%	0.04%	9.74%	0.52%	0.52%	1.49%	8.02%	0.03%	9.42%	0.33%	0.33%
7	1.87%	7.76%	0.03%	9.52%	0.44%	0.44%	1.18%	9.03%	0.04%	10.14%	0.53%	0.53%	1.59%	8.29%	0.03%	9.78%	0.34%	0.34%
8	1.99%	7.99%	0.03%	9.85%	0.44%	0.44%	1.28%	9.24%	0.04%	10.44%	0.54%	0.54%	1.70%	8.51%	0.03%	10.10%	0.34%	0.34%
9	2.05%	8.15%	0.03%	10.07%	0.45%	0.45%	1.37%	9.49%	0.04%	10.77%	0.55%	0.55%	1.77%	8.72%	0.03%	10.36%	0.35%	0.35%
10	2.14%	8.26%	0.03%	10.25%	0.45%	0.45%	1.41%	9.64%	0.04%	10.95%	0.55%	0.55%	1.83%	8.84%	0.03%	10.54%	0.35%	0.35%
11	2.18%	8.34%	0.03%	10.36%	0.46%	0.46%	1.53%	9.73%	0.04%	11.14%	0.56%	0.56%	1.91%	8.92%	0.03%	10.69%	0.35%	0.35%
12	2.29%	8.39%	0.03%	10.51%	0.47%	0.47%	1.53%	9.79%	0.04%	11.20%	0.56%	0.56%	1.97%	8.98%	0.03%	10.80%	0.36%	0.36%
13	2.29%	8.39%	0.03%	10.51%	0.47%	0.47%	1.53%	9.79%	0.04%	11.20%	0.56%	0.56%	1.97%	8.98%	0.03%	10.80%	0.36%	0.36%

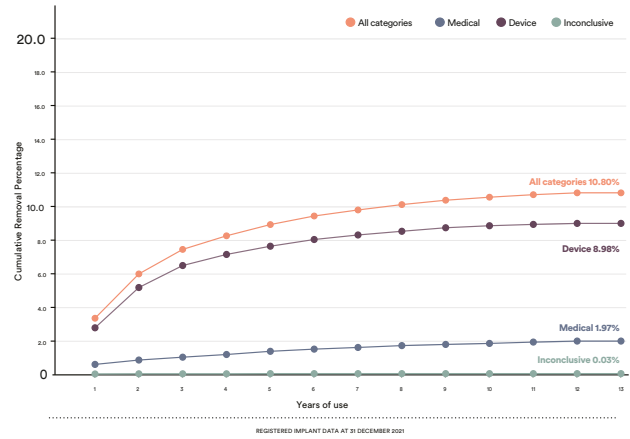
* CI_{up} and CI_{low} are 95% confidence limits.

Note: A small difference may exist between the sum of the category CRP figures and the total CRP for an implant. This is because the total CRP is calculated independently of each category CRP figure. The CRP figures are calculated using the general analysis methods described in ISO 5841-2.^{2,3}

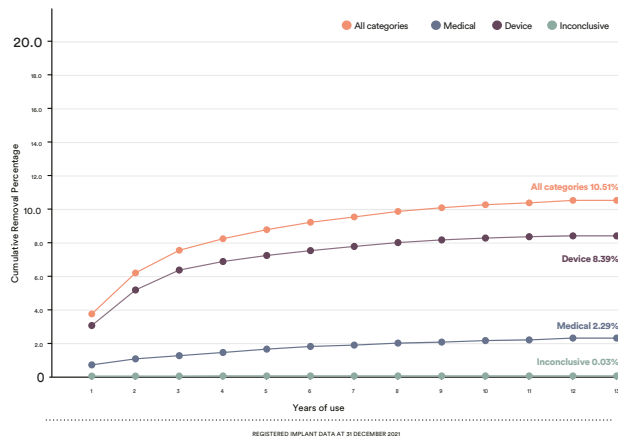
CI500 Series Implant - removal rates for all analysis categories and different patient populations



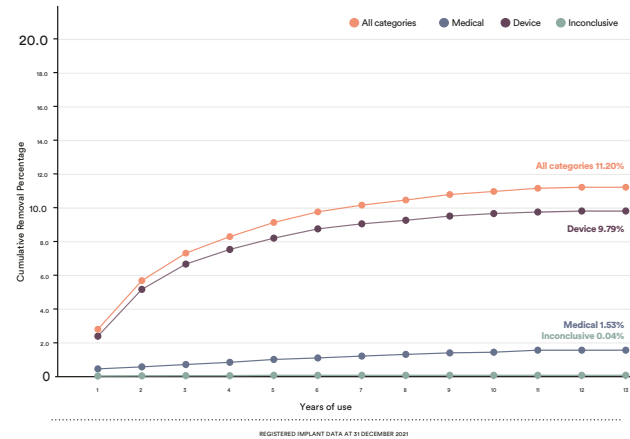
CI500 Series Implant - removal rates by analysis category for adults and children



CI500 Series Implant - removal rates by analysis category for adults



CI500 Series Implant - removal rates by analysis category for children



NUCLEUS CI24R IMPLANT

Number of registered CI24R Implants - 31 December 2021

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

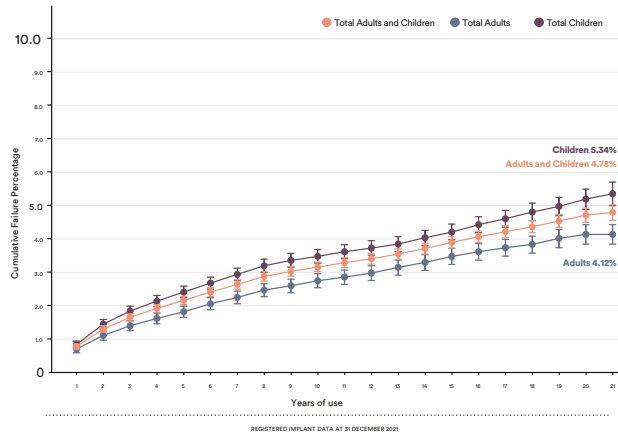
CI24R Series Implant Cumulative Removal Rates

Group	Adults						Children						Combined Adults and Children					
	Medical Related	Device Failure	Inconclusive	Total	Total		Medical Related	Device Failure	Inconclusive	Total	Total		Medical Related	Device Failure	Inconclusive	Total	Total	
	CRP	CRP	CRP	CRP	CI _{up} *	CI _{low} *	CRP	CRP	CRP	CRP	CI _{up} *	CI _{low} *	CRP	CRP	CRP	CRP	CI _{up} *	CI _{low} *
1	0.59%	0.07%	0.02%	0.68%	0.11%	0.11%	0.57%	0.23%	0.02%	0.82%	0.10%	0.10%	0.58%	0.16%	0.02%	0.76%	0.07%	0.07%
2	0.85%	0.21%	0.02%	1.09%	0.13%	0.13%	0.86%	0.55%	0.03%	1.43%	0.13%	0.13%	0.86%	0.40%	0.02%	1.28%	0.10%	0.10%
3	1.03%	0.33%	0.03%	1.38%	0.15%	0.15%	1.03%	0.77%	0.03%	1.82%	0.15%	0.15%	1.03%	0.58%	0.03%	1.63%	0.11%	0.11%
4	1.16%	0.41%	0.03%	1.60%	0.16%	0.16%	1.16%	0.94%	0.04%	2.12%	0.16%	0.16%	1.16%	0.71%	0.03%	1.90%	0.12%	0.12%
5	1.25%	0.51%	0.05%	1.80%	0.17%	0.17%	1.28%	1.09%	0.04%	2.39%	0.17%	0.17%	1.27%	0.83%	0.05%	2.14%	0.12%	0.12%
6	1.35%	0.65%	0.06%	2.04%	0.18%	0.18%	1.39%	1.24%	0.05%	2.66%	0.18%	0.18%	1.37%	0.98%	0.05%	2.39%	0.13%	0.13%
7	1.44%	0.74%	0.06%	2.23%	0.19%	0.19%	1.50%	1.40%	0.05%	2.92%	0.19%	0.19%	1.47%	1.11%	0.05%	2.62%	0.14%	0.14%
8	1.55%	0.86%	0.06%	2.45%	0.20%	0.20%	1.58%	1.58%	0.05%	3.18%	0.20%	0.20%	1.56%	1.27%	0.05%	2.86%	0.14%	0.14%
9	1.59%	0.94%	0.06%	2.58%	0.20%	0.20%	1.63%	1.69%	0.05%	3.34%	0.20%	0.20%	1.62%	1.37%	0.05%	3.01%	0.15%	0.15%
10	1.63%	1.05%	0.06%	2.73%	0.21%	0.21%	1.66%	1.79%	0.05%	3.46%	0.21%	0.21%	1.65%	1.47%	0.05%	3.14%	0.15%	0.15%
11	1.67%	1.12%	0.06%	2.84%	0.21%	0.21%	1.67%	1.91%	0.05%	3.60%	0.21%	0.21%	1.67%	1.57%	0.06%	3.27%	0.15%	0.15%
12	1.72%	1.20%	0.06%	2.96%	0.22%	0.22%	1.70%	1.99%	0.05%	3.71%	0.21%	0.21%	1.71%	1.65%	0.06%	3.39%	0.15%	0.15%
13	1.82%	1.27%	0.07%	3.13%	0.23%	0.23%	1.73%	2.08%	0.05%	3.83%	0.22%	0.22%	1.77%	1.73%	0.06%	3.53%	0.16%	0.16%
14	1.91%	1.32%	0.07%	3.28%	0.23%	0.23%	1.80%	2.20%	0.06%	4.02%	0.23%	0.23%	1.85%	1.82%	0.06%	3.70%	0.16%	0.16%
15	1.98%	1.44%	0.07%	3.46%	0.24%	0.24%	1.85%	2.32%	0.06%	4.19%	0.23%	0.23%	1.92%	1.94%	0.06%	3.88%	0.17%	0.17%
16	2.02%	1.54%	0.07%	3.60%	0.25%	0.25%	1.91%	2.49%	0.06%	4.41%	0.24%	0.24%	1.96%	2.07%	0.06%	4.05%	0.17%	0.17%
17	2.06%	1.63%	0.07%	3.72%	0.25%	0.25%	1.98%	2.60%	0.06%	4.59%	0.25%	0.25%	2.02%	2.17%	0.06%	4.20%	0.18%	0.18%
18	2.09%	1.70%	0.07%	3.82%	0.26%	0.26%	2.01%	2.78%	0.06%	4.79%	0.26%	0.26%	2.05%	2.29%	0.06%	4.35%	0.18%	0.18%
19	2.18%	1.79%	0.07%	4.00%	0.27%	0.27%	2.02%	2.94%	0.06%	4.96%	0.28%	0.28%	2.10%	2.42%	0.06%	4.52%	0.19%	0.19%
20	2.26%	1.84%	0.07%	4.12%	0.29%	0.29%	2.05%	3.14%	0.06%	5.18%	0.31%	0.31%	2.15%	2.54%	0.06%	4.70%	0.21%	0.21%
21	2.26%	1.84%	0.07%	4.12%	0.29%	0.29%	2.05%	3.30%	0.06%	5.34%	0.36%	0.36%	2.15%	2.62%	0.06%	4.78%	0.23%	0.23%

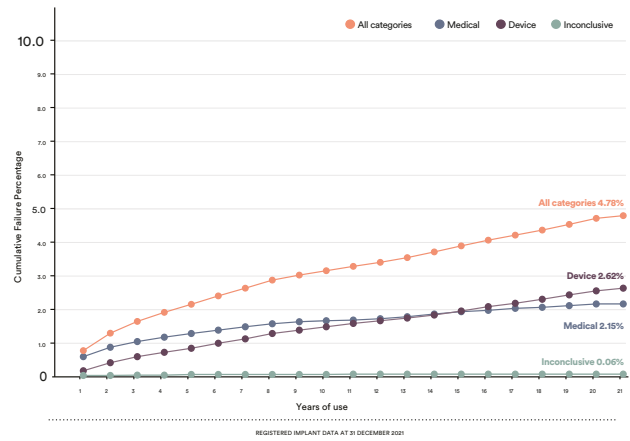
* CI_{up} and CI_{low} are 95% confidence limits.

Note: A small difference may exist between the sum of the category CRP figures and the total CRP for an implant. This is because the total CRP is calculated independently of each category CRP figure. The CRP figures are calculated using the general analysis methods described in ISO 5841-2.^{2,3}

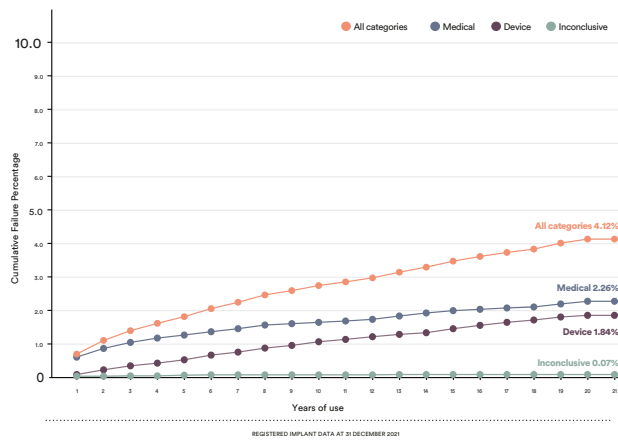
CI24R Implant - failure rates for all analysis categories and different patient populations



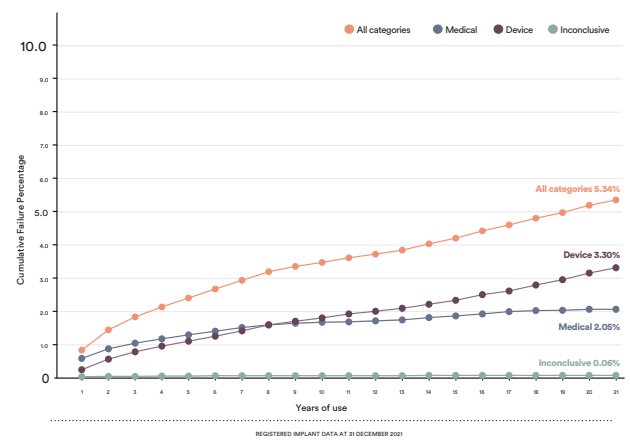
CI24R Implant - failure rates by analysis category for adults and children



CI24R Implant - failure rates by analysis category for adults



CI24R Implant - failure rates by analysis category for children



NUCLEUS CI24M IMPLANT

Number of registered CI24M Implants - 31 December 2021

ADULTS	CHILDREN	COMBINED
9,677	9,846	19,523

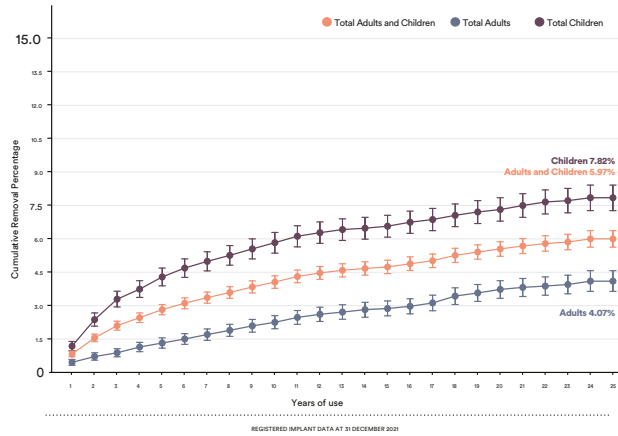
CI24M Series Implant Cumulative Removal Rates

Group	Adults						Children						Combined Adults and Children					
	Medical Related	Device Failure	Inconclu- sive	Total			Medical Related	Device Failure	Inconclu- sive	Total			Medical Related	Device Failure	Inconclu- sive	Total		
	CRP	CRP	CRP	CRP	CI _{up} *	CI _{low} *	CRP	CRP	CRP	CRP	CI _{up} *	CI _{low} *	CRP	CRP	CRP	CRP	CI _{up} *	CI _{low} *
1	0.31%	0.10%	0.01%	0.42%	0.13%	0.13%	0.42%	0.72%	0.01%	1.15%	0.21%	0.21%	0.37%	0.42%	0.01%	0.79%	0.12%	0.12%
2	0.46%	0.21%	0.02%	0.68%	0.16%	0.16%	0.63%	1.71%	0.02%	2.34%	0.30%	0.30%	0.54%	0.97%	0.02%	1.52%	0.17%	0.17%
3	0.55%	0.28%	0.02%	0.85%	0.18%	0.18%	0.87%	2.40%	0.02%	3.26%	0.35%	0.35%	0.71%	1.35%	0.02%	2.07%	0.20%	0.20%
4	0.73%	0.35%	0.03%	1.11%	0.21%	0.21%	0.98%	2.74%	0.02%	3.71%	0.37%	0.37%	0.86%	1.56%	0.03%	2.43%	0.22%	0.22%
5	0.88%	0.39%	0.03%	1.29%	0.23%	0.23%	1.15%	3.11%	0.03%	4.26%	0.40%	0.40%	1.01%	1.76%	0.03%	2.79%	0.23%	0.23%
6	1.01%	0.42%	0.04%	1.47%	0.24%	0.24%	1.33%	3.33%	0.04%	4.66%	0.42%	0.42%	1.17%	1.89%	0.04%	3.08%	0.24%	0.24%
7	1.13%	0.50%	0.04%	1.67%	0.26%	0.26%	1.46%	3.51%	0.05%	4.96%	0.43%	0.43%	1.29%	2.02%	0.05%	3.33%	0.25%	0.25%
8	1.27%	0.56%	0.04%	1.86%	0.27%	0.27%	1.54%	3.70%	0.05%	5.23%	0.44%	0.44%	1.41%	2.14%	0.05%	3.56%	0.26%	0.26%
9	1.40%	0.63%	0.04%	2.06%	0.28%	0.28%	1.68%	3.83%	0.07%	5.52%	0.45%	0.45%	1.54%	2.25%	0.06%	3.81%	0.27%	0.27%
10	1.48%	0.71%	0.04%	2.22%	0.30%	0.30%	1.82%	3.98%	0.07%	5.80%	0.46%	0.46%	1.65%	2.36%	0.06%	4.03%	0.28%	0.28%
11	1.59%	0.82%	0.04%	2.44%	0.31%	0.31%	1.98%	4.12%	0.07%	6.09%	0.47%	0.47%	1.79%	2.48%	0.06%	4.28%	0.29%	0.29%
12	1.67%	0.89%	0.04%	2.58%	0.32%	0.32%	2.06%	4.21%	0.07%	6.25%	0.48%	0.48%	1.87%	2.57%	0.06%	4.44%	0.29%	0.29%
13	1.73%	0.93%	0.04%	2.68%	0.33%	0.33%	2.10%	4.31%	0.07%	6.39%	0.49%	0.49%	1.92%	2.64%	0.06%	4.56%	0.29%	0.29%
14	1.77%	0.99%	0.04%	2.79%	0.33%	0.33%	2.15%	4.33%	0.07%	6.45%	0.49%	0.49%	1.96%	2.68%	0.06%	4.64%	0.30%	0.30%
15	1.80%	1.03%	0.04%	2.84%	0.34%	0.34%	2.18%	4.38%	0.07%	6.54%	0.49%	0.49%	1.99%	2.72%	0.06%	4.71%	0.30%	0.30%
16	1.86%	1.06%	0.04%	2.94%	0.34%	0.34%	2.32%	4.44%	0.07%	6.72%	0.50%	0.50%	2.09%	2.77%	0.06%	4.85%	0.30%	0.30%
17	1.96%	1.11%	0.04%	3.09%	0.35%	0.35%	2.41%	4.46%	0.07%	6.84%	0.50%	0.50%	2.19%	2.80%	0.06%	4.99%	0.31%	0.31%
18	2.19%	1.19%	0.04%	3.40%	0.37%	0.37%	2.49%	4.58%	0.07%	7.03%	0.51%	0.51%	2.34%	2.90%	0.06%	5.23%	0.32%	0.32%
19	2.30%	1.22%	0.04%	3.54%	0.38%	0.38%	2.58%	4.65%	0.07%	7.18%	0.52%	0.52%	2.44%	2.95%	0.06%	5.38%	0.32%	0.32%
20	2.34%	1.35%	0.04%	3.70%	0.39%	0.39%	2.67%	4.68%	0.07%	7.29%	0.52%	0.52%	2.50%	3.03%	0.06%	5.52%	0.33%	0.33%
21	2.39%	1.39%	0.04%	3.79%	0.40%	0.40%	2.74%	4.79%	0.07%	7.47%	0.53%	0.53%	2.57%	3.11%	0.06%	5.65%	0.34%	0.34%
22	2.43%	1.41%	0.04%	3.85%	0.41%	0.41%	2.86%	4.83%	0.07%	7.63%	0.54%	0.54%	2.65%	3.14%	0.06%	5.76%	0.34%	0.34%
23	2.51%	1.41%	0.04%	3.92%	0.42%	0.42%	2.93%	4.83%	0.07%	7.69%	0.55%	0.55%	2.72%	3.14%	0.06%	5.83%	0.35%	0.35%
24	2.51%	1.57%	0.04%	4.07%	0.47%	0.47%	2.93%	4.97%	0.07%	7.82%	0.58%	0.58%	2.72%	3.28%	0.06%	5.97%	0.37%	0.37%
25	2.51%	1.57%	0.04%	4.07%	0.47%	0.47%	2.93%	4.97%	0.07%	7.82%	0.58%	0.58%	2.72%	3.28%	0.06%	5.97%	0.37%	0.37%

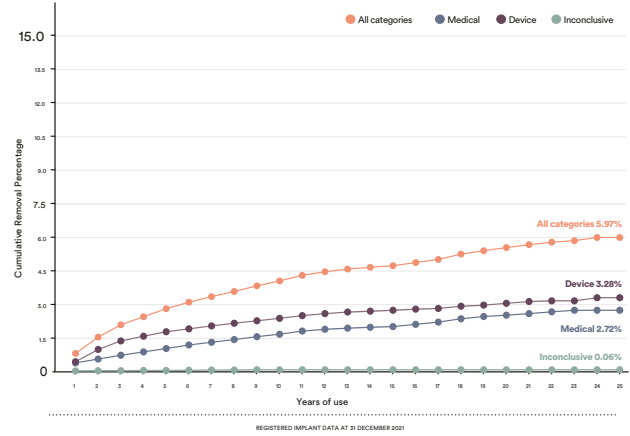
* CI_{up} and CI_{low} are 95% confidence limits.

Note: A small difference may exist between the sum of the category CRP figures and the total CRP for an implant. This is because the total CRP is calculated independently of each category CRP figure. The CRP figures are calculated using the general analysis methods described in ISO 5841-2.^{2,3}

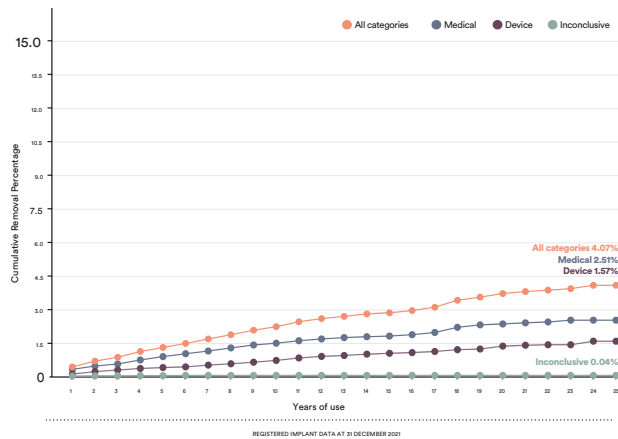
CI24M Implant - removal rates for all analysis categories and different patient populations



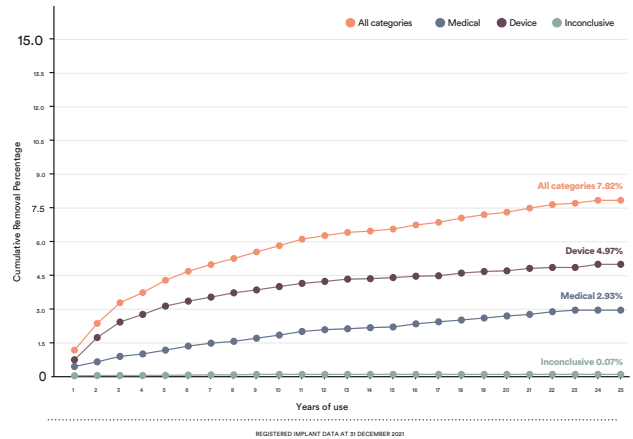
CI24M Implant - removal rates by analysis category for adults and children



CI24M Implant - removal rates by analysis category for adults



CI24M Implant - removal rates by analysis category for children



NUCLEUS CI22M IMPLANT

Number of registered CI22M Implants - 31 December 2021

ADULTS	CHILDREN	COMBINED
11,116	6,545	17,661

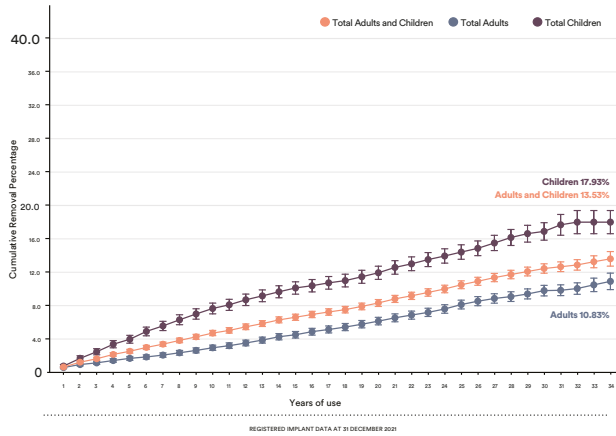
CI22M Series Implant Cumulative Failure Rates

Group	Adults						Children						Combined Adults and Children					
	Medical Related	Device Failure	Inconclusive	Total	Total		Medical Related	Device Failure	Inconclusive	Total	Total		Medical Related	Device Failure	Inconclusive	Total	Total	
	CRP	CRP	CRP	CRP	CL _{up} *	CL _{low} *	CRP	CRP	CRP	CRP	CL _{up} *	CL _{low} *	CRP	CRP	CRP	CRP	CL _{up} *	CL _{low} *
1	0.05%	0.43%	0.02%	0.50%	0.13%	0.13%	0.09%	0.52%	0.06%	0.67%	0.20%	0.20%	0.07%	0.46%	0.03%	0.56%	0.11%	0.11%
2	0.10%	0.68%	0.08%	0.86%	0.17%	0.17%	0.15%	1.33%	0.12%	1.60%	0.31%	0.31%	0.12%	0.92%	0.10%	1.14%	0.16%	0.16%
3	0.11%	0.85%	0.10%	1.06%	0.19%	0.19%	0.19%	2.01%	0.20%	2.39%	0.37%	0.37%	0.14%	1.28%	0.14%	1.55%	0.18%	0.18%
4	0.14%	1.08%	0.12%	1.34%	0.22%	0.22%	0.23%	2.84%	0.23%	3.29%	0.43%	0.43%	0.17%	1.74%	0.16%	2.07%	0.21%	0.21%
5	0.19%	1.26%	0.16%	1.60%	0.24%	0.24%	0.38%	3.28%	0.25%	3.89%	0.47%	0.47%	0.26%	2.01%	0.19%	2.45%	0.23%	0.23%
6	0.27%	1.31%	0.20%	1.77%	0.25%	0.25%	0.71%	3.86%	0.30%	4.83%	0.52%	0.52%	0.43%	2.26%	0.23%	2.91%	0.25%	0.25%
7	0.39%	1.42%	0.20%	1.99%	0.26%	0.26%	0.92%	4.31%	0.32%	5.49%	0.56%	0.56%	0.58%	2.50%	0.24%	3.30%	0.27%	0.27%
8	0.50%	1.58%	0.21%	2.27%	0.28%	0.28%	1.17%	4.75%	0.38%	6.22%	0.59%	0.59%	0.75%	2.76%	0.27%	3.75%	0.28%	0.28%
9	0.65%	1.69%	0.22%	2.55%	0.30%	0.30%	1.47%	5.14%	0.42%	6.92%	0.62%	0.62%	0.95%	2.98%	0.29%	4.18%	0.30%	0.30%
10	0.75%	1.91%	0.23%	2.87%	0.32%	0.32%	1.65%	5.59%	0.47%	7.58%	0.65%	0.65%	1.08%	3.28%	0.32%	4.63%	0.31%	0.31%
11	0.92%	1.99%	0.23%	3.12%	0.33%	0.33%	1.82%	5.86%	0.48%	8.02%	0.67%	0.67%	1.25%	3.44%	0.33%	4.95%	0.32%	0.32%
12	1.10%	2.14%	0.23%	3.44%	0.35%	0.35%	2.14%	6.15%	0.50%	8.62%	0.69%	0.69%	1.48%	3.63%	0.33%	5.38%	0.34%	0.34%
13	1.30%	2.29%	0.23%	3.79%	0.36%	0.36%	2.24%	6.54%	0.50%	9.09%	0.70%	0.70%	1.65%	3.88%	0.33%	5.77%	0.35%	0.35%
14	1.48%	2.53%	0.23%	4.19%	0.38%	0.38%	2.41%	6.85%	0.54%	9.58%	0.72%	0.72%	1.82%	4.14%	0.35%	6.21%	0.36%	0.36%
15	1.58%	2.67%	0.23%	4.43%	0.39%	0.39%	2.58%	7.14%	0.55%	10.04%	0.74%	0.74%	1.95%	4.34%	0.35%	6.53%	0.37%	0.37%
16	1.79%	2.84%	0.23%	4.80%	0.41%	0.41%	2.70%	7.31%	0.55%	10.31%	0.75%	0.75%	2.12%	4.50%	0.35%	6.86%	0.38%	0.38%
17	1.92%	2.98%	0.23%	5.06%	0.42%	0.42%	2.87%	7.50%	0.55%	10.65%	0.76%	0.76%	2.27%	4.67%	0.35%	7.16%	0.39%	0.39%
18	2.03%	3.16%	0.23%	5.35%	0.43%	0.43%	2.92%	7.73%	0.55%	10.92%	0.77%	0.77%	2.36%	4.87%	0.35%	7.44%	0.39%	0.39%
19	2.15%	3.39%	0.23%	5.69%	0.44%	0.44%	3.03%	8.11%	0.55%	11.38%	0.78%	0.78%	2.48%	5.15%	0.35%	7.83%	0.40%	0.40%
20	2.34%	3.58%	0.23%	6.06%	0.46%	0.46%	3.20%	8.44%	0.55%	11.86%	0.79%	0.79%	2.66%	5.40%	0.35%	8.24%	0.41%	0.41%
21	2.45%	3.88%	0.23%	6.46%	0.47%	0.47%	3.50%	8.82%	0.55%	12.50%	0.81%	0.81%	2.83%	5.73%	0.35%	8.73%	0.43%	0.43%
22	2.58%	4.09%	0.25%	6.79%	0.48%	0.48%	3.64%	9.14%	0.55%	12.93%	0.82%	0.82%	2.97%	5.98%	0.36%	9.10%	0.43%	0.43%
23	2.73%	4.27%	0.25%	7.11%	0.50%	0.50%	3.90%	9.43%	0.55%	13.44%	0.84%	0.84%	3.16%	6.21%	0.36%	9.50%	0.44%	0.44%
24	2.86%	4.57%	0.25%	7.52%	0.51%	0.51%	4.12%	9.68%	0.55%	13.87%	0.85%	0.85%	3.33%	6.48%	0.36%	9.92%	0.45%	0.45%
25	2.96%	5.00%	0.26%	8.05%	0.53%	0.53%	4.22%	10.07%	0.55%	14.34%	0.87%	0.87%	3.43%	6.90%	0.37%	10.42%	0.47%	0.47%
26	3.07%	5.31%	0.26%	8.45%	0.55%	0.55%	4.46%	10.32%	0.55%	14.79%	0.88%	0.88%	3.59%	7.19%	0.37%	10.84%	0.48%	0.48%
27	3.14%	5.58%	0.26%	8.78%	0.56%	0.56%	4.68%	10.79%	0.55%	15.43%	0.91%	0.91%	3.71%	7.53%	0.37%	11.28%	0.49%	0.49%
28	3.25%	5.70%	0.26%	9.00%	0.58%	0.58%	4.98%	11.16%	0.60%	16.09%	0.96%	0.96%	3.88%	7.73%	0.38%	11.65%	0.51%	0.51%
29	3.27%	6.01%	0.26%	9.32%	0.60%	0.60%	5.11%	11.52%	0.60%	16.55%	1.00%	1.00%	3.94%	8.06%	0.38%	12.01%	0.53%	0.53%
30	3.31%	6.38%	0.26%	9.72%	0.64%	0.64%	5.11%	11.80%	0.60%	16.82%	1.05%	1.05%	3.96%	8.40%	0.38%	12.37%	0.56%	0.56%
31	3.31%	6.43%	0.26%	9.76%	0.64%	0.64%	5.48%	12.31%	0.60%	17.61%	1.24%	1.24%	4.04%	8.55%	0.38%	12.58%	0.58%	0.58%
32	3.46%	6.50%	0.26%	9.97%	0.68%	0.68%	5.48%	12.65%	0.60%	17.93%	1.39%	1.39%	4.16%	8.67%	0.38%	12.80%	0.62%	0.62%
33	3.81%	6.62%	0.26%	10.41%	0.81%	0.81%	5.48%	12.65%	0.60%	17.93%	1.39%	1.39%	4.47%	8.77%	0.38%	13.18%	0.72%	0.72%
34	4.04%	6.84%	0.26%	10.83%	0.99%	0.99%	5.48%	12.65%	0.60%	17.93%	1.39%	1.39%	4.67%	8.95%	0.38%	13.53%	0.87%	0.87%

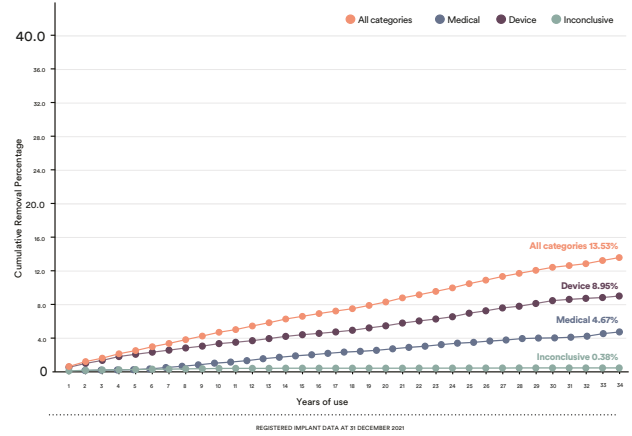
* CL_{up} and CL_{low} are 95% confidence limits.

Note: A small difference may exist between the sum of the category CRP figures and the total CRP for an implant. This is because the total CRP is calculated independently of each category CRP figure. The CRP figures are calculated using the general analysis methods described in ISO 5841-2.^{2,3}

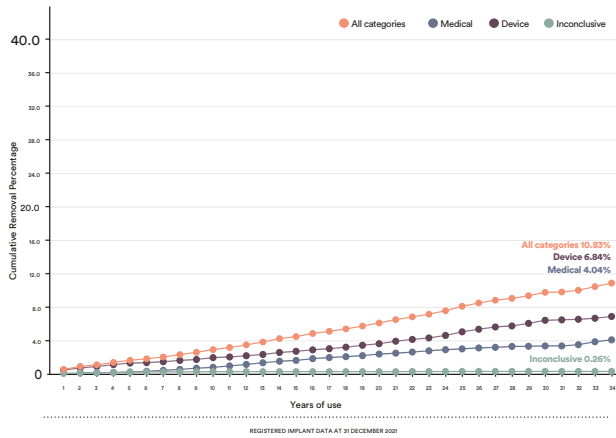
CI22M Implant - removal rates for all analysis categories and different patient populations



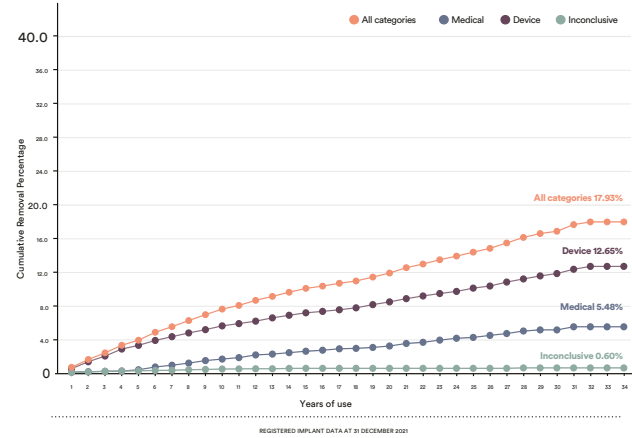
CI22M Implant - removal rates by analysis category for adults and children



CI22M Implant - removal rates by analysis category for adults



CI22M Implant - removal rates by analysis category for children



SOUND PROCESSOR DATA

The Failed Component Return Rate (FCRR) is the metric used 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 percentage is calculated as the total number of failed sound processors received within a month divided by the total number of the same sound processor sold between launch and 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%.

The FCRR classifies reasons for failure into the following categories:

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

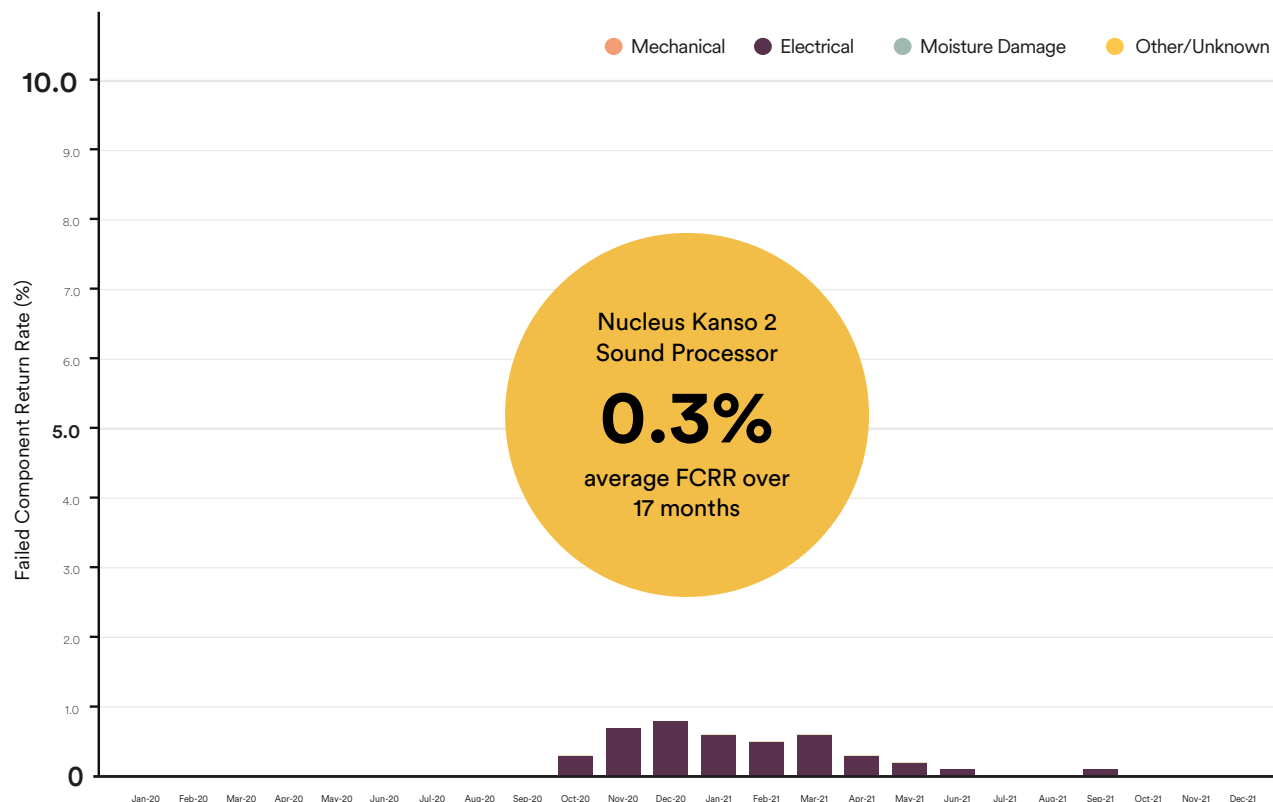
NUCLEUS® KANSO® 2 SOUND PROCESSOR

Nucleus Kanso 2 Sound Processor - Component Return Rate

Fail mode	Jan-20	Feb-20	Mar-20	Apr-20	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20
Mechanical	-	-	-	-	-	-	-	0.0%	0.0%	0.0%	0.0%	0.0%
Electrical	-	-	-	-	-	-	-	0.0%	0.0%	0.3%	0.7%	0.8%
Moisture	-	-	-	-	-	-	-	0.0%	0.0%	0.0%	0.0%	0.0%
Other	-	-	-	-	-	-	-	0.0%	0.0%	0.0%	0.0%	0.0%
Fault-Free	-	-	-	-	-	-	-	0.1%	0.0%	0.1%	0.3%	0.3%

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%	0.0%	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	0.3%	0.3%	0.2%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.0%	0.0%	0.0%

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



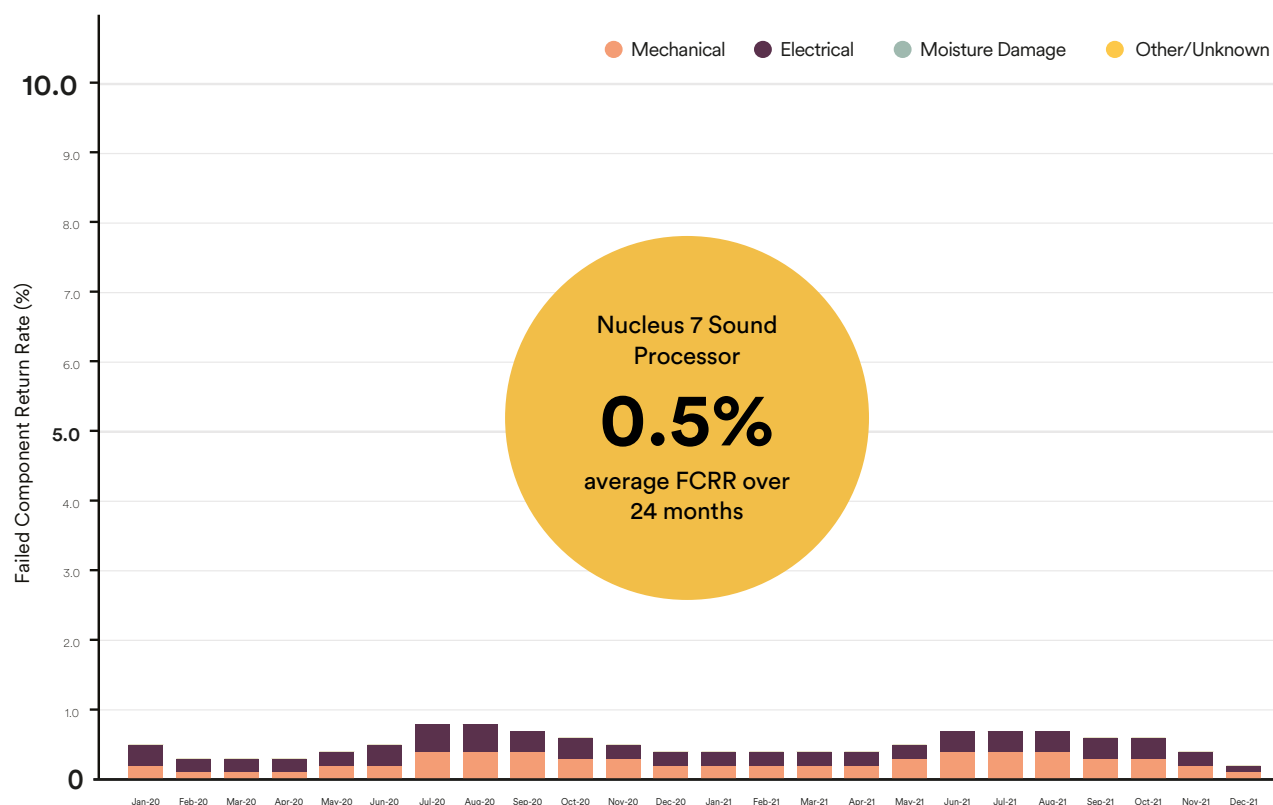
NUCLEUS 7 SOUND PROCESSOR

Nucleus 7 Sound Processor - Component Return Rate

Fail mode	Jan-20	Feb-20	Mar-20	Apr-20	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20
Mechanical	0.2%	0.1%	0.1%	0.1%	0.2%	0.2%	0.4%	0.4%	0.4%	0.3%	0.3%	0.2%
Electrical	0.3%	0.2%	0.2%	0.2%	0.2%	0.3%	0.4%	0.4%	0.3%	0.3%	0.2%	0.2%
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%	0.1%	0.2%	0.2%	0.1%	0.1%	0.2%	0.1%	0.2%

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%	0.2%	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® 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. ANSI/AAMI CI86. Cochlear implant systems: Requirements for safety, functional verification,. (2017). Arlington, VA: American National Standards Institute.
2. 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. 2000.
3. 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. 2014.

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 instructions for use. Not all products are available in all countries. Please contact your local Cochlear representative for product information.

ACE, Advance Off-Stylet, AOS, AutoNRT, Autosensitivity, Beam, Bring Back the Beat, Button, Carina, Cochlear, 科利耳, コクレア, 코클리어, Cochlear SoftWear, Codacs, Contour, 콘트וא, Contour Advance, Custom Sound, ESPrIt, Freedom, Hear now. And always, Hugfit, Hybrid, Invisible Hearing, Kansa, MET, MicroDrive, MP3000, myCochlear, mySmartSound, NRT, Nucleus, Osia, Outcome Focused Fitting, Off-Stylet, Profile, Slimline, SmartSound, Softip, SPrint, True Wireless, the elliptical logo, and Whisper are either trademarks or registered trademarks of Cochlear Limited. Ardium, Baha, Baha SoftWear, BCDrive, DermaLock, EveryWear, Human Design, Piezo Power, SoundArc, Vistafix, and WindShield are either trademarks or registered trademarks of Cochlear Bone Anchored Solutions AB.