COCHLEAR™ NUCLEUS® SYSTEM RELIABILITY REPORT

Volume 3 | June 2020

Reporting to ANSI/AAMI CI86 Standard

ABOUT THIS DOCUMENT

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

This data meets the reporting standards and methodology recommended by ANSI/AAMI CI86 – Cochlear implant systems: Requirements for safety, functional verification, labeling and reliability reporting[1].

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 also 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 on the manufacturer's website.

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.

NUCLEUS® PROFILE™ PLUS SERIES IMPLANT

Number of registered Profile™ Plus Series Implants - 30 June 2020

ADULTS	CHILDREN	COMBINED
10,190	4,539	14,729

Profile Plus Series Implant Cumulative Removal Rates

Group	Adults						Children						Combined Adults and Children					
Sub-category	Medical Related	Device Failure	Inconclu-sive	Total	Total		Medical Related	Device Failure	Inconclu-sive	Total	Total		Medical Related	Device Failure	Inconclu-sive	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	0.54%	0.04%	0.00%	0.58%	0.78%	0.38%	0.64%	0.00%	0.00%	0.64%	0.96%	0.32%	0.57%	0.03%	0.00%	0.60%	0.77%	0.43%

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

Children 0.64%
Adults and Children 0.60%
Adults 0.58%

REGISTERED IMPLANT DATA AT 30 JUNE 2020

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

All categories 0.60%
Medical 0.57%
Device 0.03%
Inconclusive 0.00%

REGISTERED IMPLANT DATA AT 30 JUNE 2020

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

All categories 0.58%
Medical 0.54%
Device 0.04%
Inconclusive 0.00%

REGISTERED IMPLANT DATA AT 30 JUNE 2020

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

All categories 0.54%
Medical 0.64%
Device 0.00%
Inconclusive 0.00%

REGISTERED IMPLANT DATA AT 30 JUNE 2020

* CI_up and CI_low are 95% confidence limits.

NUCLEUS PROFILE SERIES IMPLANT

Number of registered Profile Series Implants - 30 June 2020

| ADULTS	CHILDREN	COMBINED
56,291	36,898	93,189

Profile Series Implant Cumulative Removal Rates

Group	Adults						Children						Combined Adults and Children					
Sub-category	Medical Related	Device Failure	Inconclu-sive	Total	Total		Medical Related	Device Failure	Inconclu-sive	Total	Total		Medical Related	Device Failure	Inconclu-sive	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%	0.04%	0.00%	0.61%	0.68%	0.55%	0.31%	0.07%	0.00%	0.38%	0.44%	0.31%	0.47%	0.05%	0.00%	0.52%	0.57%	0.48%
2	0.86%	0.08%	0.00%	0.93%	1.02%	0.85%	0.41%	0.14%	0.00%	0.55%	0.64%	0.47%	0.69%	0.10%	0.00%	0.79%	0.85%	0.73%
3	1.05%	0.11%	0.00%	1.16%	1.26%	1.06%	0.49%	0.19%	0.00%	0.68%	0.78%	0.59%	0.84%	0.14%	0.00%	0.98%	1.05%	0.91%
4	1.17%	0.12%	0.00%	1.29%	1.40%	1.18%	0.50%	0.24%	0.00%	0.75%	0.85%	0.64%	0.92%	0.17%	0.00%	1.08%	1.16%	1.00%
5	1.27%	0.15%	0.00%	1.42%	1.55%	1.28%	0.58%	0.28%	0.00%	0.86%	1.00%	0.72%	1.01%	0.20%	0.00%	1.21%	1.30%	1.11%
6	1.27%	0.15%	0.00%	1.42%	1.55%	1.28%	0.58%	0.28%	0.00%	0.86%	1.00%	0.72%	1.01%	0.20%	0.00%	1.21%	1.30%	1.11%

Profile Series Implant - removal rates for all analysis categories and different patient populations
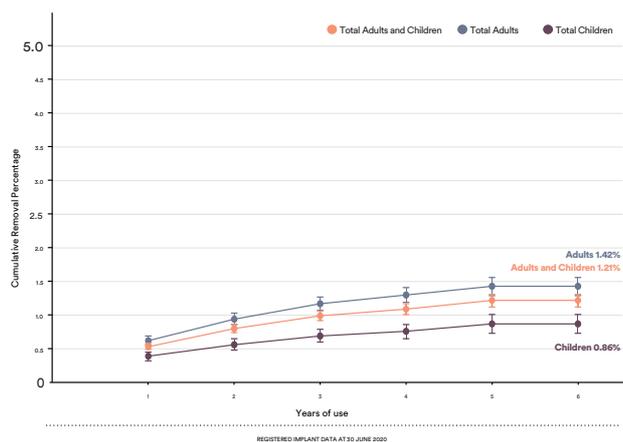
Profile Series Implant - removal rates by analysis category for adults and children
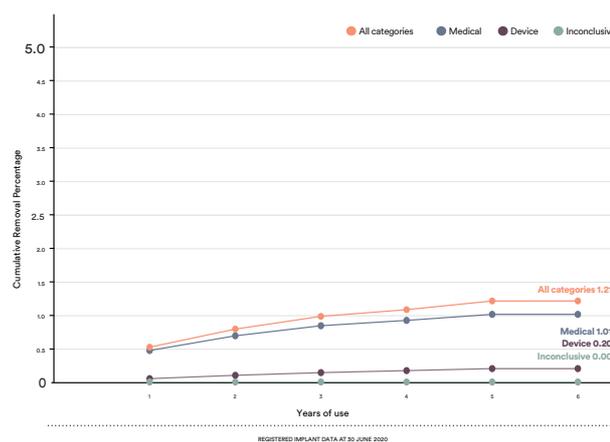
Profile Series Implant - removal rates by analysis category for adults
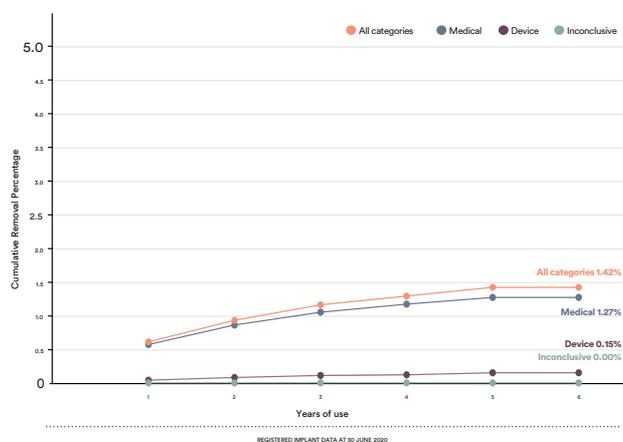
Profile Series Implant - removal rates by analysis category for children
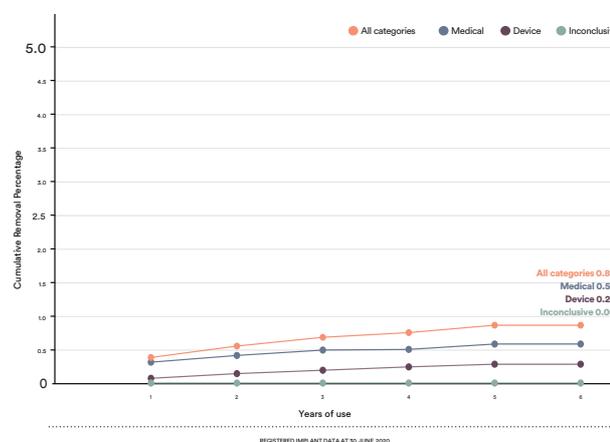
* CI_up and CI_low are 95% confidence limits.

NUCLEUS CI24RE SERIES IMPLANT

Number of registered CI24RE Series Implants - 30 June 2020

| ADULTS	CHILDREN	COMBINED
93,726	105,031	198,757

CI24RE Series Cumulative Removal Rates

Group	Adults						Children						Combined Adults and Children					
Sub-category	Medical Related	Device Failure	Inconclu-sive	Total	Total		Medical Related	Device Failure	Inconclu-sive	Total	Total		Medical Related	Device Failure	Inconclu-sive	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%	0.64%	0.69%	0.59%	0.48%	0.09%	0.01%	0.58%	0.62%	0.53%	0.53%	0.08%	0.01%	0.61%	0.64%	0.57%
2	0.93%	0.12%	0.01%	1.06%	1.13%	1.00%	0.67%	0.22%	0.01%	0.90%	0.96%	0.84%	0.80%	0.17%	0.01%	0.98%	1.02%	0.93%
3	1.14%	0.19%	0.01%	1.34%	1.41%	1.26%	0.82%	0.34%	0.01%	1.17%	1.24%	1.10%	0.98%	0.26%	0.01%	1.25%	1.30%	1.20%
4	1.33%	0.22%	0.01%	1.56%	1.64%	1.48%	0.94%	0.43%	0.02%	1.38%	1.45%	1.31%	1.13%	0.33%	0.02%	1.47%	1.52%	1.41%
5	1.51%	0.26%	0.01%	1.78%	1.87%	1.70%	1.05%	0.50%	0.02%	1.56%	1.64%	1.48%	1.27%	0.38%	0.02%	1.67%	1.73%	1.61%
6	1.64%	0.32%	0.01%	1.97%	2.06%	1.88%	1.14%	0.56%	0.02%	1.71%	1.79%	1.62%	1.39%	0.44%	0.02%	1.84%	1.90%	1.77%
7	1.72%	0.35%	0.01%	2.08%	2.17%	1.98%	1.22%	0.62%	0.02%	1.85%	1.94%	1.76%	1.46%	0.49%	0.02%	1.96%	2.03%	1.90%
8	1.81%	0.37%	0.01%	2.19%	2.29%	2.09%	1.31%	0.65%	0.02%	1.97%	2.07%	1.87%	1.56%	0.51%	0.02%	2.08%	2.15%	2.01%
9	1.92%	0.40%	0.01%	2.33%	2.44%	2.22%	1.41%	0.70%	0.02%	2.12%	2.22%	2.01%	1.66%	0.55%	0.02%	2.22%	2.30%	2.15%
10	2.05%	0.44%	0.01%	2.49%	2.61%	2.38%	1.47%	0.80%	0.03%	2.29%	2.40%	2.17%	1.76%	0.62%	0.02%	2.39%	2.47%	2.30%
11	2.15%	0.48%	0.01%	2.64%	2.77%	2.52%	1.53%	0.89%	0.03%	2.43%	2.55%	2.30%	1.84%	0.68%	0.02%	2.53%	2.62%	2.44%
12	2.25%	0.53%	0.01%	2.79%	2.92%	2.65%	1.62%	0.97%	0.03%	2.61%	2.74%	2.47%	1.94%	0.75%	0.02%	2.69%	2.79%	2.60%
13	2.33%	0.61%	0.01%	2.94%	3.09%	2.79%	1.70%	1.10%	0.03%	2.81%	2.96%	2.65%	2.02%	0.85%	0.02%	2.86%	2.97%	2.76%
14	2.38%	0.69%	0.01%	3.06%	3.22%	2.90%	1.78%	1.25%	0.03%	3.03%	3.22%	2.83%	2.07%	0.96%	0.02%	3.03%	3.15%	2.91%
15	2.43%	0.74%	0.01%	3.17%	3.37%	2.98%	1.78%	1.38%	0.03%	3.15%	3.39%	2.91%	2.11%	1.04%	0.02%	3.15%	3.30%	2.99%

* CI_up and CI_low are 95% confidence limits.

CI24RE Series - removal rates for all analysis categories and different patient populations
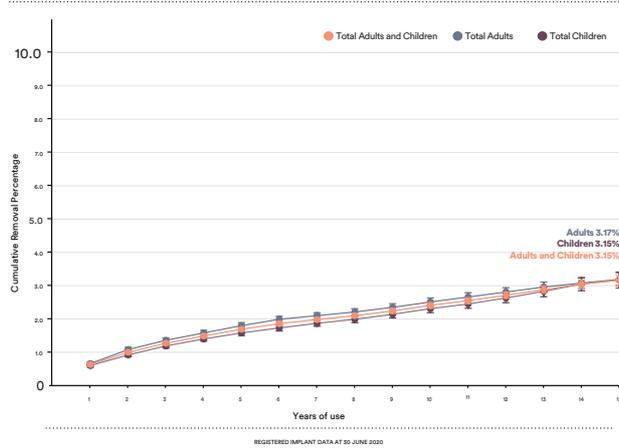
CI24RE Series - removal rates by analysis category for adults and children
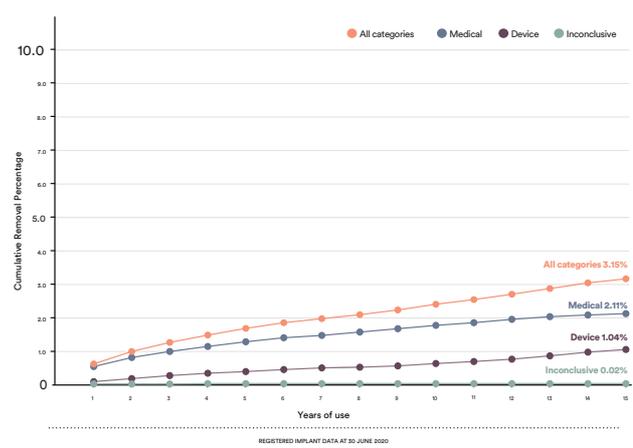
CI24RE Series - removal rates by analysis category for adults
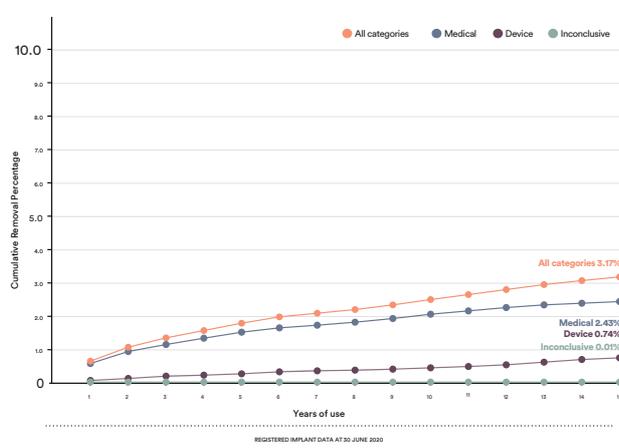
CI24RE Series - removal rates by analysis category for children
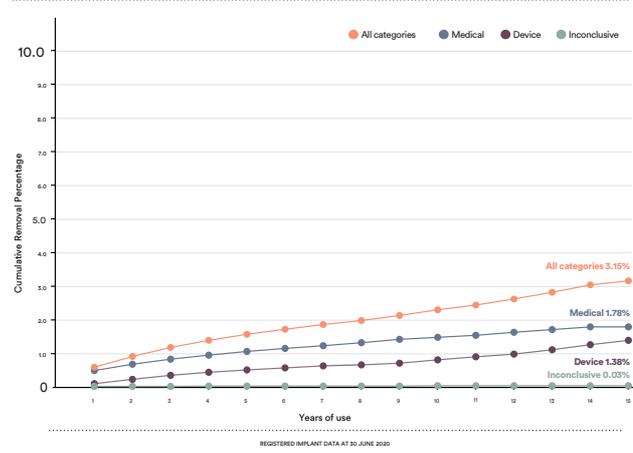
NUCLEUS CI500 SERIES IMPLANT

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

Number of registered CI500 Series Implants - 30 June 2020

ADULTS	CHILDREN	COMBINED
17,556	12,339	29,895

CI500 Series Cumulative Removal Rates

Group	Adults						Children						Combined Adults and Children					
Sub-category	Medical Related	Device Failure	Inconclu-sive	Total	Total		Medical Related	Device Failure	Inconclu-sive	Total	Total		Medical Related	Device Failure	Inconclu-sive	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	0.69%	3.04%	0.02%	3.73%	4.01%	3.45%	0.41%	2.36%	0.00%	2.76%	3.05%	2.47%	0.57%	2.76%	0.01%	3.33%	3.53%	3.13%
2	1.05%	5.16%	0.02%	6.18%	6.54%	5.82%	0.53%	5.14%	0.01%	5.65%	6.06%	5.24%	0.83%	5.16%	0.02%	5.96%	6.23%	5.69%
3	1.24%	6.36%	0.02%	7.54%	7.93%	7.15%	0.68%	6.62%	0.02%	7.27%	7.73%	6.81%	1.01%	6.47%	0.02%	7.43%	7.73%	7.13%
4	1.43%	6.87%	0.03%	8.23%	8.64%	7.82%	0.80%	7.49%	0.02%	8.25%	8.74%	7.76%	1.17%	7.13%	0.02%	8.24%	8.55%	7.93%
5	1.63%	7.20%	0.03%	8.74%	9.16%	8.32%	0.97%	8.16%	0.04%	9.08%	9.59%	8.57%	1.36%	7.60%	0.03%	8.88%	9.21%	8.56%
6	1.79%	7.50%	0.03%	9.18%	9.61%	8.75%	1.06%	8.71%	0.04%	9.70%	10.23%	9.18%	1.49%	8.00%	0.03%	9.40%	9.73%	9.07%
7	1.88%	7.73%	0.03%	9.49%	9.93%	9.06%	1.17%	9.01%	0.04%	10.11%	10.64%	9.58%	1.58%	8.27%	0.03%	9.75%	10.09%	9.41%
8	1.99%	7.96%	0.03%	9.82%	10.27%	9.38%	1.27%	9.22%	0.04%	10.41%	10.95%	9.87%	1.69%	8.49%	0.03%	10.07%	10.41%	9.72%
9	2.06%	8.10%	0.03%	10.02%	10.47%	9.57%	1.37%	9.39%	0.04%	10.67%	11.21%	10.12%	1.77%	8.64%	0.03%	10.29%	10.64%	9.94%
10	2.14%	8.13%	0.03%	10.13%	10.58%	9.67%	1.40%	9.39%	0.04%	10.69%	11.24%	10.14%	1.84%	8.66%	0.03%	10.36%	10.71%	10.01%
11	2.14%	8.13%	0.03%	10.13%	10.58%	9.67%	1.40%	9.39%	0.04%	10.69%	11.24%	10.14%	1.84%	8.66%	0.03%	10.36%	10.71%	10.01%

* CI_up and CI_low are 95% confidence limits.

CI500 Series - removal rates for all analysis categories and different patient populations
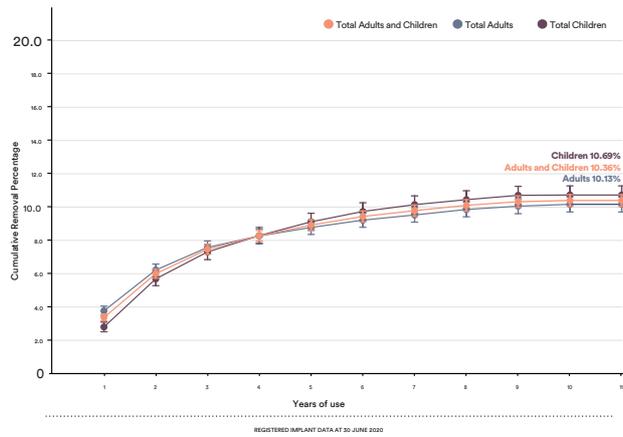
CI500 Series - removal rates by analysis category for adults and children
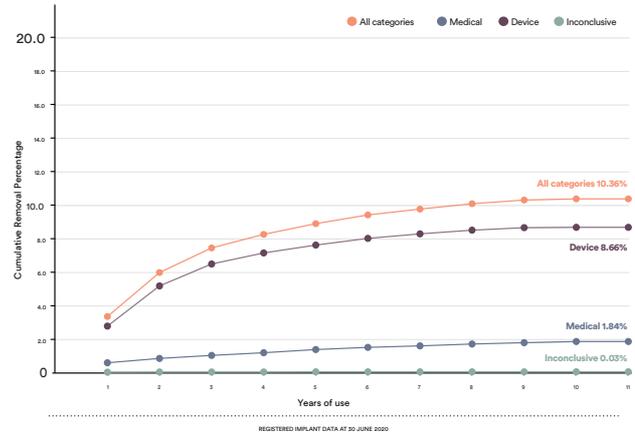

CI500 Series - removal rates by analysis category for adults
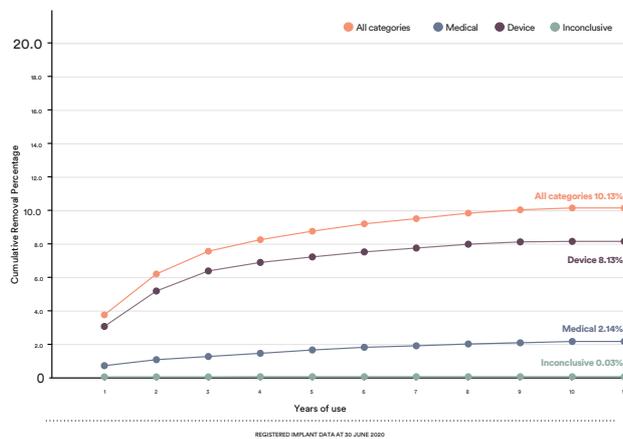
CI500 Series - removal rates by analysis category for children
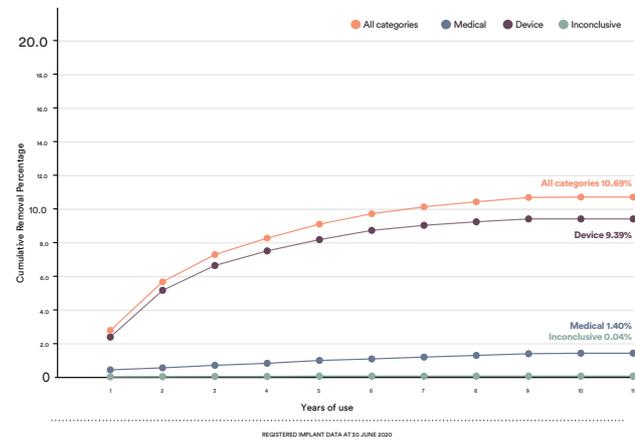
NUCLEUS CI24R IMPLANT

Number of registered CI24R Implants - 30 June 2020

| ADULTS	CHILDREN	COMBINED
23,249	30,279	53,528

CI24R Series Cumulative Removal Rates

Group	Adults						Children						Combined Adults and Children					
Sub-category	Medical Related	Device Failure	Inconclu-sive	Total	Total		Medical Related	Device Failure	Inconclu-sive	Total	Total		Medical Related	Device Failure	Inconclu-sive	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	0.54%	0.06%	0.02%	0.62%	0.73%	0.52%	0.53%	0.21%	0.02%	0.76%	0.86%	0.66%	0.54%	0.15%	0.02%	0.70%	0.77%	0.63%
2	0.81%	0.21%	0.02%	1.04%	1.17%	0.90%	0.82%	0.53%	0.03%	1.37%	1.50%	1.24%	0.82%	0.39%	0.02%	1.23%	1.32%	1.13%
3	0.98%	0.33%	0.03%	1.33%	1.48%	1.18%	0.99%	0.75%	0.03%	1.76%	1.91%	1.62%	0.99%	0.57%	0.03%	1.58%	1.68%	1.47%
4	1.11%	0.41%	0.03%	1.55%	1.70%	1.39%	1.12%	0.92%	0.04%	2.07%	2.23%	1.91%	1.12%	0.70%	0.03%	1.84%	1.95%	1.73%
5	1.21%	0.51%	0.05%	1.75%	1.92%	1.59%	1.24%	1.06%	0.04%	2.33%	2.50%	2.16%	1.23%	0.82%	0.05%	2.08%	2.20%	1.96%
6	1.30%	0.65%	0.06%	1.99%	2.17%	1.81%	1.35%	1.22%	0.05%	2.60%	2.78%	2.42%	1.33%	0.97%	0.05%	2.34%	2.47%	2.21%
7	1.40%	0.74%	0.06%	2.19%	2.38%	2.00%	1.46%	1.38%	0.05%	2.86%	3.05%	2.67%	1.43%	1.10%	0.05%	2.57%	2.70%	2.43%
8	1.51%	0.86%	0.06%	2.41%	2.61%	2.21%	1.54%	1.57%	0.05%	3.13%	3.33%	2.93%	1.52%	1.26%	0.05%	2.82%	2.96%	2.68%
9	1.55%	0.95%	0.06%	2.54%	2.75%	2.34%	1.60%	1.68%	0.05%	3.30%	3.50%	3.10%	1.58%	1.36%	0.05%	2.97%	3.12%	2.83%
10	1.59%	1.06%	0.06%	2.70%	2.91%	2.49%	1.62%	1.79%	0.05%	3.43%	3.63%	3.22%	1.61%	1.47%	0.05%	3.11%	3.26%	2.96%
11	1.63%	1.13%	0.06%	2.80%	3.01%	2.58%	1.64%	1.93%	0.05%	3.58%	3.79%	3.37%	1.63%	1.58%	0.06%	3.24%	3.39%	3.09%
12	1.67%	1.21%	0.06%	2.92%	3.14%	2.70%	1.67%	2.02%	0.06%	3.71%	3.93%	3.49%	1.67%	1.67%	0.06%	3.37%	3.52%	3.21%
13	1.77%	1.28%	0.07%	3.09%	3.32%	2.87%	1.70%	2.12%	0.06%	3.84%	4.06%	3.62%	1.74%	1.75%	0.06%	3.52%	3.68%	3.36%
14	1.86%	1.34%	0.07%	3.24%	3.47%	3.01%	1.77%	2.26%	0.06%	4.06%	4.29%	3.82%	1.82%	1.85%	0.06%	3.70%	3.86%	3.53%
15	1.94%	1.47%	0.07%	3.44%	3.68%	3.20%	1.83%	2.41%	0.06%	4.25%	4.49%	4.01%	1.89%	1.99%	0.06%	3.90%	4.07%	3.73%
16	1.97%	1.58%	0.07%	3.58%	3.83%	3.33%	1.88%	2.60%	0.06%	4.50%	4.75%	4.24%	1.93%	2.14%	0.06%	4.09%	4.27%	3.91%
17	1.99%	1.66%	0.07%	3.69%	3.94%	3.43%	1.98%	2.74%	0.06%	4.72%	4.99%	4.45%	1.98%	2.25%	0.06%	4.25%	4.43%	4.06%
18	2.01%	1.76%	0.07%	3.79%	4.06%	3.52%	2.01%	2.92%	0.06%	4.93%	5.23%	4.64%	2.01%	2.38%	0.06%	4.41%	4.60%	4.21%
19	2.10%	1.89%	0.07%	4.01%	4.32%	3.70%	2.01%	3.05%	0.06%	5.06%	5.38%	4.74%	2.06%	2.51%	0.06%	4.58%	4.80%	4.36%

* CI_up and CI_low are 95% confidence limits.

CI24R Series - failure rates for all analysis categories and different patient populations
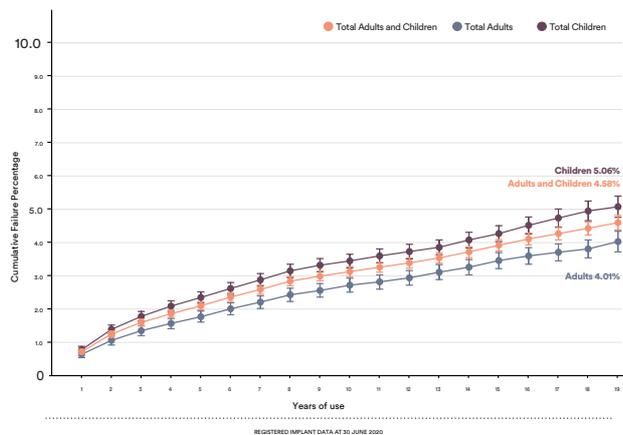
CI24R Series - failure rates by analysis category for adults and children
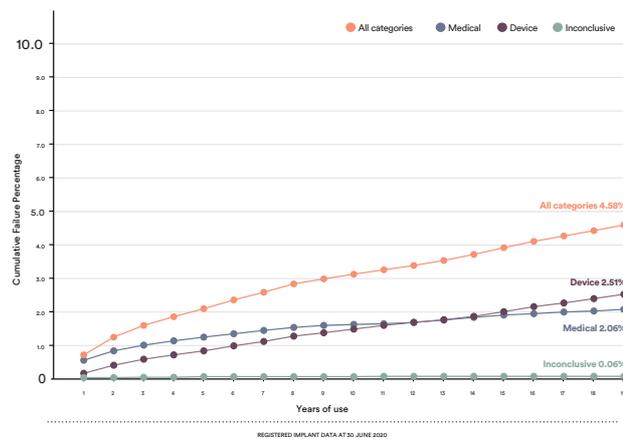
CI24R Series - failure rates by analysis category for adults
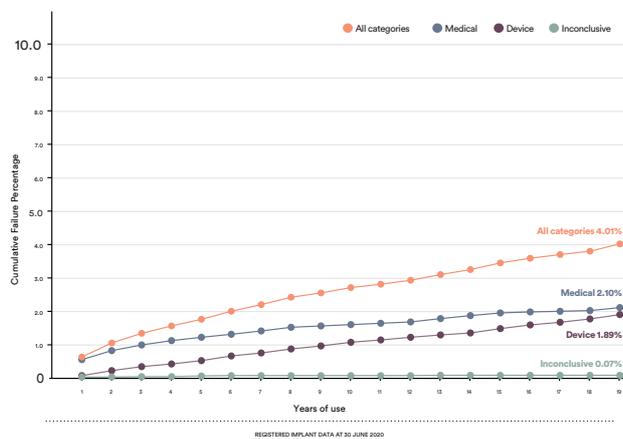
CI24R Series - failure rates by analysis category for children
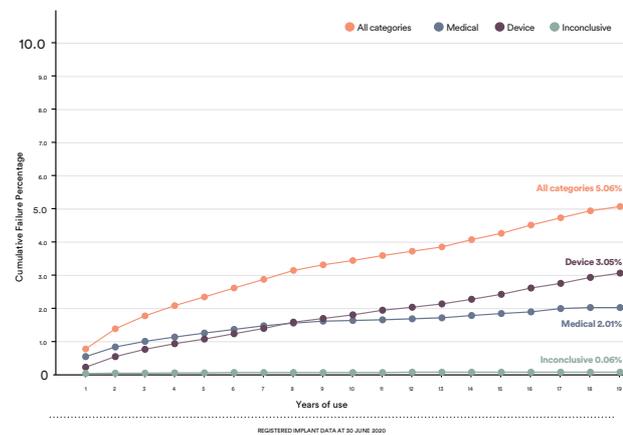
NUCLEUS CI24M IMPLANT

Number of registered CI24M Implants - 30 June 2020

| ADULTS	CHILDREN	COMBINED
9,687	9,835	19,522

CI24M Series 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	0.27%	0.10%	0.01%	0.38%	0.51%	0.26%	0.39%	0.72%	0.01%	1.11%	1.32%	0.90%	0.33%	0.41%	0.01%	0.75%	0.87%	0.63%
2	0.41%	0.21%	0.02%	0.64%	0.80%	0.48%	0.60%	1.70%	0.02%	2.31%	2.61%	2.01%	0.51%	0.96%	0.02%	1.48%	1.65%	1.31%
3	0.51%	0.28%	0.02%	0.81%	0.99%	0.63%	0.84%	2.39%	0.02%	3.23%	3.58%	2.88%	0.67%	1.34%	0.02%	2.03%	2.23%	1.83%
4	0.69%	0.35%	0.03%	1.07%	1.28%	0.86%	0.95%	2.73%	0.02%	3.68%	4.05%	3.31%	0.82%	1.55%	0.03%	2.39%	2.60%	2.17%
5	0.83%	0.39%	0.03%	1.25%	1.47%	1.03%	1.12%	3.11%	0.03%	4.22%	4.62%	3.83%	0.98%	1.76%	0.03%	2.75%	2.98%	2.52%
6	0.97%	0.42%	0.04%	1.43%	1.66%	1.19%	1.30%	3.33%	0.04%	4.62%	5.04%	4.21%	1.14%	1.88%	0.04%	3.04%	3.28%	2.80%
7	1.08%	0.50%	0.04%	1.62%	1.87%	1.36%	1.43%	3.50%	0.05%	4.93%	5.36%	4.50%	1.25%	2.01%	0.05%	3.29%	3.54%	3.04%
8	1.22%	0.56%	0.04%	1.81%	2.08%	1.54%	1.52%	3.69%	0.05%	5.20%	5.64%	4.76%	1.37%	2.14%	0.05%	3.52%	3.78%	3.26%
9	1.35%	0.63%	0.04%	2.01%	2.29%	1.73%	1.66%	3.82%	0.07%	5.48%	5.93%	5.03%	1.50%	2.24%	0.06%	3.76%	4.03%	3.49%
10	1.43%	0.71%	0.04%	2.18%	2.47%	1.88%	1.80%	3.97%	0.07%	5.76%	6.22%	5.30%	1.62%	2.35%	0.06%	3.99%	4.26%	3.71%
11	1.53%	0.82%	0.04%	2.38%	2.69%	2.08%	1.96%	4.10%	0.07%	6.05%	6.53%	5.58%	1.75%	2.48%	0.06%	4.24%	4.52%	3.95%
12	1.61%	0.89%	0.04%	2.53%	2.85%	2.21%	2.04%	4.20%	0.07%	6.22%	6.70%	5.74%	1.82%	2.56%	0.06%	4.39%	4.68%	4.10%
13	1.67%	0.92%	0.04%	2.62%	2.94%	2.30%	2.08%	4.30%	0.07%	6.36%	6.84%	5.87%	1.87%	2.63%	0.06%	4.51%	4.80%	4.21%
14	1.72%	0.98%	0.04%	2.72%	3.05%	2.39%	2.12%	4.32%	0.07%	6.42%	6.91%	5.94%	1.92%	2.67%	0.06%	4.59%	4.89%	4.29%
15	1.74%	1.02%	0.04%	2.78%	3.12%	2.45%	2.16%	4.38%	0.07%	6.51%	7.00%	6.02%	1.95%	2.71%	0.06%	4.67%	4.97%	4.37%
16	1.79%	1.06%	0.04%	2.87%	3.21%	2.53%	2.30%	4.43%	0.07%	6.69%	7.19%	6.20%	2.05%	2.76%	0.06%	4.80%	5.11%	4.50%
17	1.90%	1.10%	0.04%	3.02%	3.37%	2.67%	2.41%	4.45%	0.07%	6.83%	7.33%	6.32%	2.16%	2.79%	0.06%	4.94%	5.25%	4.63%
18	2.14%	1.17%	0.04%	3.33%	3.70%	2.96%	2.50%	4.57%	0.07%	7.02%	7.53%	6.51%	2.32%	2.89%	0.06%	5.19%	5.51%	4.87%
19	2.23%	1.21%	0.04%	3.46%	3.84%	3.07%	2.61%	4.63%	0.07%	7.19%	7.71%	6.67%	2.42%	2.93%	0.06%	5.34%	5.67%	5.02%
20	2.23%	1.36%	0.04%	3.60%	4.00%	3.21%	2.70%	4.65%	0.07%	7.29%	7.82%	6.77%	2.47%	3.02%	0.06%	5.47%	5.80%	5.14%
21	2.29%	1.39%	0.04%	3.68%	4.09%	3.28%	2.73%	4.72%	0.07%	7.39%	7.92%	6.85%	2.51%	3.07%	0.06%	5.55%	5.89%	5.22%
22	2.29%	1.39%	0.04%	3.68%	4.09%	3.28%	2.86%	4.77%	0.07%	7.56%	8.12%	7.00%	2.58%	3.09%	0.06%	5.65%	6.00%	5.30%
23	2.29%	1.39%	0.04%	3.68%	4.09%	3.28%	2.99%	4.77%	0.07%	7.68%	8.29%	7.07%	2.64%	3.09%	0.06%	5.71%	6.08%	5.34%

* CI_up and CI_low are 95% confidence limits.

CI24M Series - removal rates for all analysis categories and different patient populations
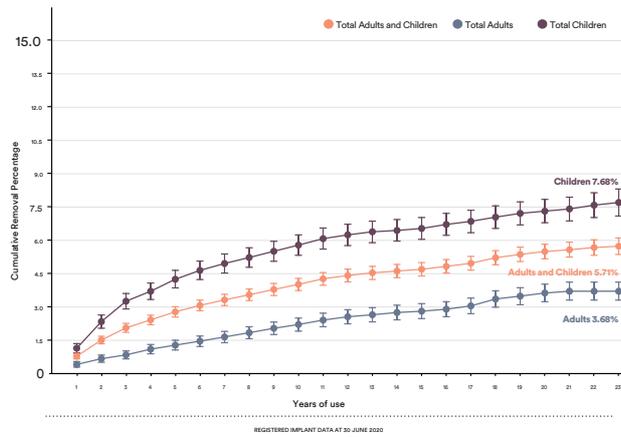
CI24M Series - removal rates by analysis category for adults and children
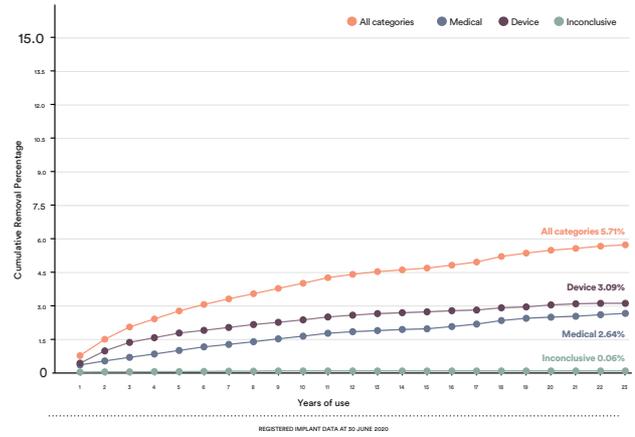
CI24M Series - removal rates by analysis category for adults
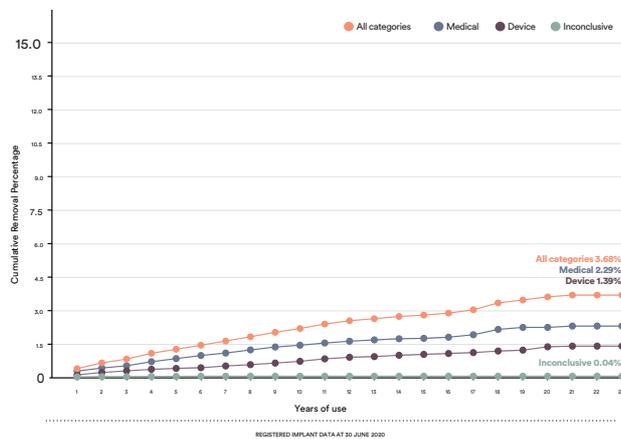
CI24M Series - removal rates by analysis category for children
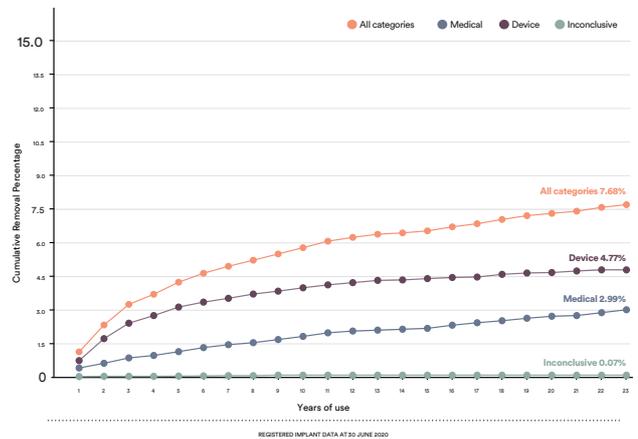
NUCLEUS CI22M IMPLANT

Number of registered CI22M implants - 30 June 2020

ADULTS	CHILDREN	COMBINED
11,123	6,539	17,662

CI22M Series Cumulative Failure Rates

Group	Adults						Children						Combined Adults and Children					
Sub-category	Medical Related	Device Failure	Inconclu-sive	Total	Total		Medical Related	Device Failure	Inconclu-sive	Total	Total		Medical Related	Device Failure	Inconclu-sive	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	0.05%	0.43%	0.02%	0.49%	0.62%	0.36%	0.09%	0.52%	0.06%	0.68%	0.87%	0.48%	0.06%	0.46%	0.03%	0.56%	0.67%	0.45%
2	0.09%	0.68%	0.08%	0.85%	1.03%	0.68%	0.15%	1.33%	0.12%	1.60%	1.91%	1.30%	0.11%	0.92%	0.10%	1.13%	1.29%	0.98%
3	0.10%	0.85%	0.10%	1.05%	1.24%	0.86%	0.19%	2.01%	0.20%	2.39%	2.77%	2.02%	0.13%	1.28%	0.14%	1.55%	1.73%	1.37%
4	0.13%	1.08%	0.12%	1.33%	1.54%	1.11%	0.23%	2.84%	0.24%	3.30%	3.73%	2.86%	0.17%	1.74%	0.16%	2.06%	2.27%	1.85%
5	0.18%	1.26%	0.16%	1.59%	1.82%	1.35%	0.38%	3.28%	0.25%	3.89%	4.36%	3.42%	0.25%	2.01%	0.19%	2.45%	2.68%	2.22%
6	0.26%	1.30%	0.20%	1.76%	2.00%	1.51%	0.71%	3.87%	0.30%	4.83%	5.36%	4.31%	0.43%	2.26%	0.23%	2.90%	3.15%	2.65%
7	0.38%	1.42%	0.20%	1.98%	2.24%	1.72%	0.92%	4.31%	0.32%	5.49%	6.05%	4.94%	0.58%	2.50%	0.24%	3.29%	3.56%	3.02%
8	0.49%	1.58%	0.21%	2.26%	2.54%	1.98%	1.17%	4.76%	0.38%	6.23%	6.82%	5.64%	0.74%	2.76%	0.27%	3.74%	4.03%	3.46%
9	0.64%	1.69%	0.21%	2.54%	2.83%	2.24%	1.47%	5.14%	0.42%	6.92%	7.55%	6.30%	0.95%	2.98%	0.29%	4.18%	4.47%	3.88%
10	0.74%	1.90%	0.23%	2.86%	3.17%	2.55%	1.65%	5.59%	0.47%	7.59%	8.24%	6.94%	1.08%	3.28%	0.32%	4.63%	4.94%	4.31%
11	0.91%	1.99%	0.23%	3.11%	3.44%	2.78%	1.82%	5.87%	0.48%	8.03%	8.69%	7.36%	1.24%	3.43%	0.33%	4.95%	5.27%	4.62%
12	1.09%	2.14%	0.23%	3.43%	3.78%	3.09%	2.14%	6.16%	0.50%	8.63%	9.32%	7.94%	1.48%	3.63%	0.33%	5.37%	5.71%	5.04%
13	1.29%	2.29%	0.23%	3.78%	4.14%	3.42%	2.24%	6.55%	0.50%	9.10%	9.81%	8.40%	1.64%	3.88%	0.33%	5.77%	6.12%	5.42%
14	1.47%	2.53%	0.23%	4.18%	4.56%	3.80%	2.41%	6.86%	0.54%	9.59%	10.31%	8.87%	1.81%	4.14%	0.35%	6.20%	6.57%	5.84%
15	1.57%	2.66%	0.23%	4.41%	4.80%	4.02%	2.58%	7.15%	0.55%	10.05%	10.79%	9.31%	1.94%	4.34%	0.35%	6.52%	6.89%	6.15%
16	1.78%	2.83%	0.23%	4.78%	5.19%	4.38%	2.70%	7.31%	0.55%	10.32%	11.07%	9.57%	2.12%	4.50%	0.35%	6.85%	7.23%	6.47%
17	1.91%	2.97%	0.23%	5.05%	5.46%	4.63%	2.87%	7.51%	0.55%	10.67%	11.42%	9.91%	2.26%	4.66%	0.35%	7.15%	7.54%	6.76%
18	2.02%	3.15%	0.23%	5.33%	5.76%	4.90%	2.93%	7.74%	0.55%	10.94%	11.70%	10.17%	2.35%	4.86%	0.35%	7.43%	7.82%	7.03%
19	2.14%	3.39%	0.23%	5.68%	6.12%	5.24%	3.03%	8.12%	0.55%	11.40%	12.18%	10.62%	2.47%	5.15%	0.35%	7.82%	8.22%	7.42%
20	2.33%	3.58%	0.23%	6.05%	6.50%	5.59%	3.21%	8.45%	0.55%	11.88%	12.67%	11.08%	2.65%	5.40%	0.35%	8.23%	8.65%	7.82%
21	2.44%	3.88%	0.23%	6.45%	6.92%	5.98%	3.51%	8.84%	0.55%	12.53%	13.34%	11.71%	2.83%	5.74%	0.35%	8.73%	9.15%	8.30%
22	2.57%	4.09%	0.25%	6.78%	7.26%	6.30%	3.66%	9.17%	0.55%	12.97%	13.80%	12.15%	2.97%	5.99%	0.36%	9.11%	9.54%	8.67%
23	2.73%	4.28%	0.25%	7.12%	7.62%	6.63%	3.92%	9.47%	0.55%	13.50%	14.35%	12.66%	3.17%	6.23%	0.36%	9.52%	9.97%	9.08%
24	2.86%	4.59%	0.25%	7.54%	8.06%	7.03%	4.12%	9.72%	0.55%	13.91%	14.77%	13.05%	3.32%	6.51%	0.36%	9.94%	10.40%	9.48%
25	2.97%	5.06%	0.25%	8.10%	8.64%	7.56%	4.20%	10.17%	0.55%	14.42%	15.30%	13.54%	3.42%	6.98%	0.36%	10.48%	10.96%	10.01%
26	3.09%	5.42%	0.25%	8.57%	9.14%	8.01%	4.27%	10.45%	0.55%	14.75%	15.65%	13.85%	3.53%	7.31%	0.36%	10.90%	11.39%	10.41%
27	3.14%	5.67%	0.25%	8.85%	9.43%	8.27%	4.43%	10.89%	0.55%	15.31%	16.26%	14.36%	3.61%	7.61%	0.36%	11.26%	11.77%	10.76%
28	3.23%	5.81%	0.25%	9.07%	9.67%	8.47%	4.67%	11.27%	0.55%	15.88%	16.90%	14.86%	3.74%	7.81%	0.36%	11.58%	12.11%	11.05%
29	3.27%	6.11%	0.25%	9.40%	10.04%	8.76%	4.67%	11.64%	0.55%	16.23%	17.33%	15.14%	3.77%	8.13%	0.36%	11.91%	12.47%	11.35%
30	3.32%	6.54%	0.25%	9.87%	10.57%	9.17%	4.67%	11.88%	0.55%	16.46%	17.64%	15.29%	3.81%	8.53%	0.36%	12.33%	12.95%	11.72%
31	3.32%	6.63%	0.25%	9.95%	10.67%	9.23%	5.75%	12.38%	0.55%	17.87%	19.84%	15.91%	3.96%	8.67%	0.36%	12.60%	13.27%	11.93%
32	3.47%	6.63%	0.25%	10.09%	10.86%	9.32%	5.75%	13.36%	0.55%	18.79%	21.43%	16.15%	4.09%	8.79%	0.36%	12.84%	13.59%	12.10%

* CI_up and CI_low are 95% confidence limits.

CI22M Series - removal rates for all analysis categories and different patient populations
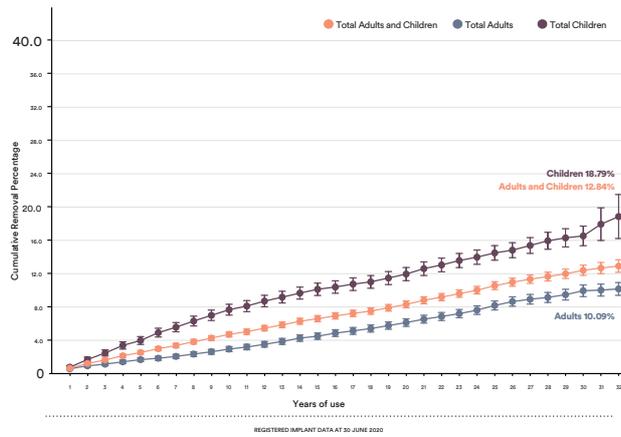
CI22M Series - removal rates by analysis category for adults and children
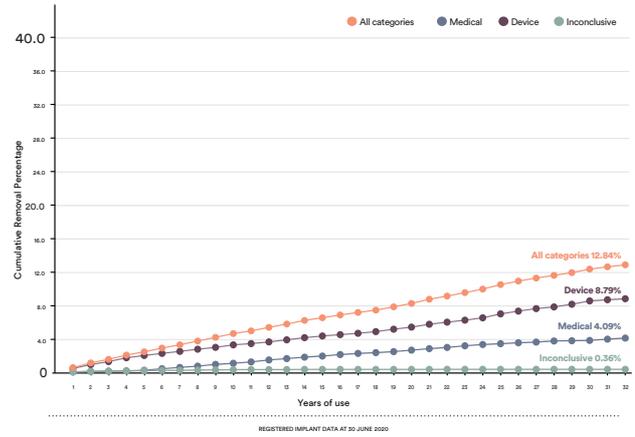
CI22M Series - removal rates by analysis category for adults
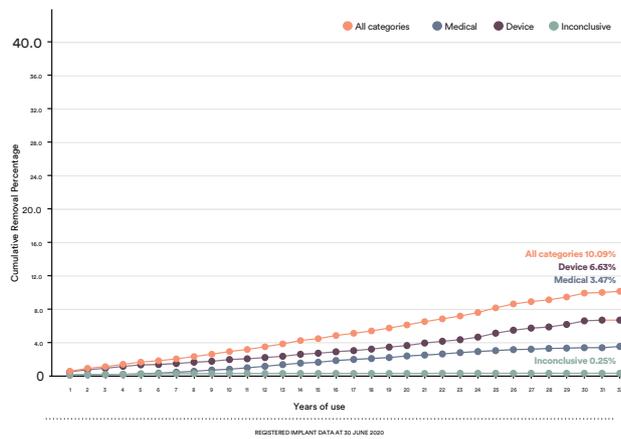
CI22M Series - removal rates by analysis category for children
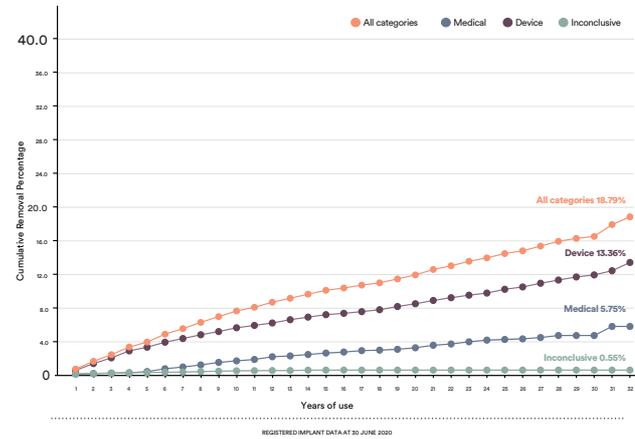
SOUND PROCESSOR DATA

In this document, 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 is the percentage of 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%.

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.

- **Electronic 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 discoloration), corrosion, and/or moisture damage that did not result in a functional failure.

NUCLEUS® 7 SOUND PROCESSOR

Nucleus® 7 Sound Processor Component Return Rate

Fail mode	Jul-18	Aug-18	Sep-18	Oct-18	Nov-18	Dec-18	Jan-19	Feb-19	Mar-19	Apr-19	May-19	Jun-19
Mechanical	0.2%	0.2%	0.2%	0.2%	0.1%	0.1%	0.2%	0.1%	0.1%	0.2%	0.2%	0.2%
Electronic	0.2%	0.2%	0.1%	0.2%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.2%
Moisture Damage	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/Unknown	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%	0.3%	0.3%	0.3%	0.2%	0.3%	0.4%	0.3%	0.3%	0.3%	0.3%

Fail mode	Jul-19	Aug-19	Sep-19	Oct-19	Nov-19	Dec-19	Jan-20	Feb-20	Mar-20	Apr-20	May-20	Jun-20
Mechanical	0.3%	0.3%	0.2%	0.2%	0.1%	0.1%	0.2%	0.1%	0.1%	0.1%	0.1%	0.1%
Electronic	0.2%	0.3%	0.2%	0.3%	0.2%	0.2%	0.3%	0.2%	0.2%	0.2%	0.2%	0.2%
Moisture Damage	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/Unknown	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%	0.3%	0.3%	0.2%	0.2%	0.2%	0.2%	0.2%	0.1%	0.1%	0.1%

**Nucleus 7 Sound Processor - Failed Component Return Rate**
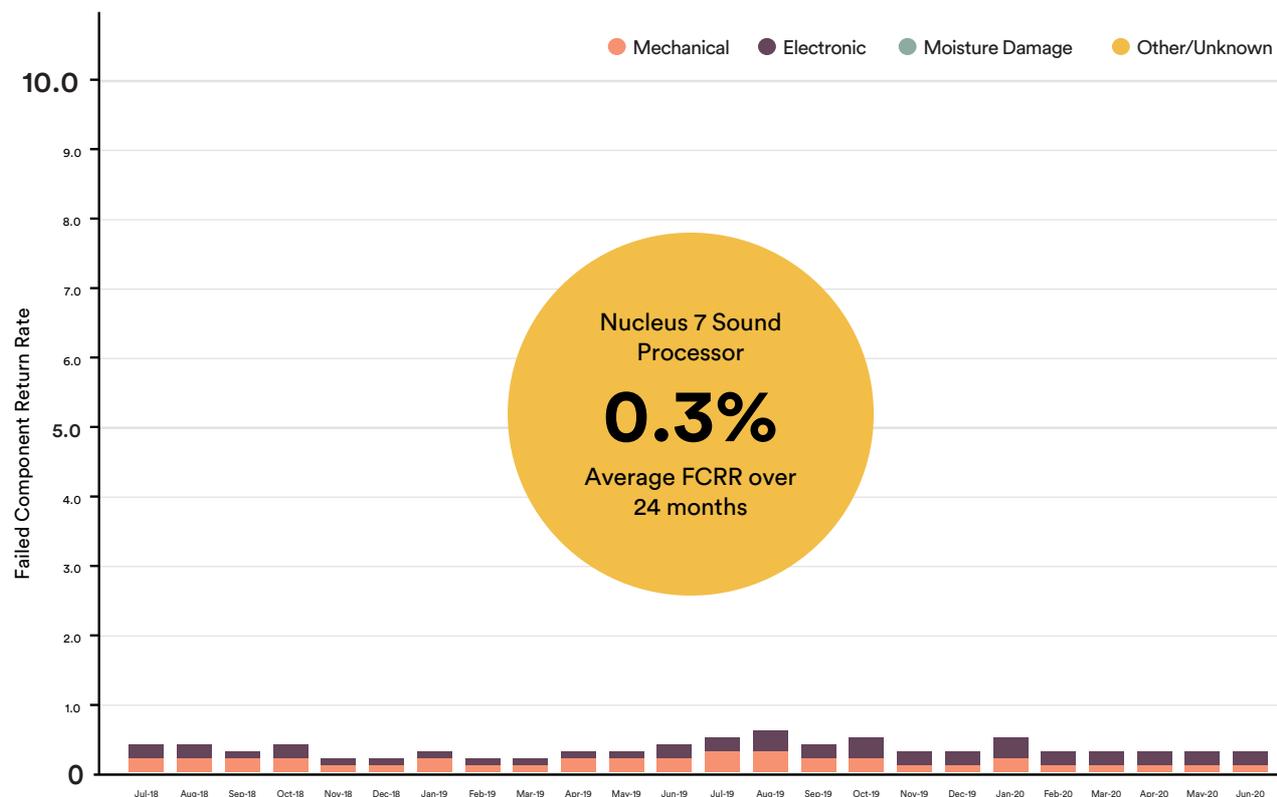
NUCLEUS KANSO® SOUND PROCESSOR

Nucleus Kanso Sound Processor Component Return Rate

Fail mode	Jul-18	Aug-18	Sep-18	Oct-18	Nov-18	Dec-18	Jan-19	Feb-19	Mar-19	Apr-19	May-19	Jun-19
Mechanical	0.0%	0.1%	0.0%	0.1%	0.1%	0.1%	0.1%	0.1%	0.0%	0.1%	0.1%	0.1%
Electronic	0.3%	0.3%	0.3%	0.3%	0.3%	0.2%	0.3%	0.3%	0.3%	0.4%	0.4%	0.4%
Moisture Damage	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/Unknown	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	0.4%	0.5%	0.5%	0.4%	0.5%	0.4%	0.5%	0.5%	0.5%	0.5%	0.3%	0.4%

Fail mode	Jul-19	Aug-19	Sep-19	Oct-19	Nov-19	Dec-19	Jan-20	Feb-20	Mar-20	Apr-20	May-20	Jun-20
Mechanical	0.1%	0.1%	0.1%	0.0%	0.1%	0.0%	0.1%	0.1%	0.1%	0.1%	0.1%	0.0%
Electronic	0.4%	0.5%	0.4%	0.4%	0.4%	0.3%	0.4%	0.3%	0.3%	0.2%	0.2%	0.2%
Moisture Damage	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/Unknown	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	0.4%	0.3%	0.3%	0.4%	0.3%	0.3%	0.4%	0.3%	0.3%	0.2%	0.2%	0.2%

Nucleus Kanso Sound Processor - Failed Component Return Rate

Nucleus Kanso
Sound Processor

0.4%

Average FCRR over
24 months
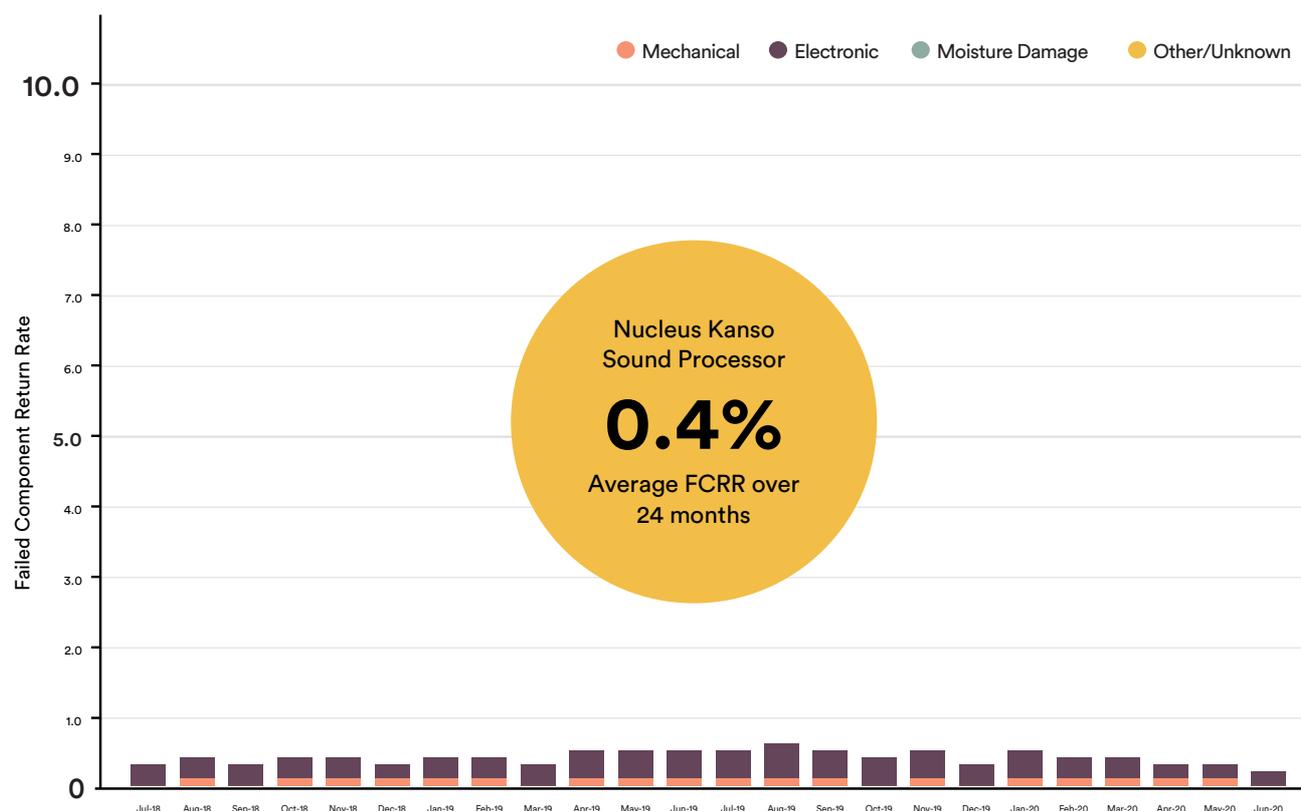
NUCLEUS 6 SOUND PROCESSOR

Nucleus 6 Sound Processor Component Return Rate

Fail mode	Jul-18	Aug-18	Sep-18	Oct-18	Nov-18	Dec-18	Jan-19	Feb-19	Mar-19	Apr-19	May-19	Jun-19
Mechanical	0.3%	0.3%	0.3%	0.3%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%
Electronic	1.0%	0.9%	0.8%	0.8%	0.6%	0.5%	0.6%	0.5%	0.5%	0.5%	0.6%	0.7%
Moisture Damage	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/Unknown	0.1%	0.1%	0.1%	0.1%	0.1%	0.0%	0.0%	0.0%	0.0%	0.0%	0.1%	0.1%
Fault-Free	0.3%	0.3%	0.3%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.2%	0.3%	0.2%

Fail mode	Jul-19	Aug-19	Sep-19	Oct-19	Nov-19	Dec-19	Jan-20	Feb-20	Mar-20	Apr-20	May-20	Jun-20
Mechanical	0.2%	0.2%	0.2%	0.2%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%
Electronic	0.9%	0.8%	0.7%	0.8%	0.6%	0.5%	0.5%	0.5%	0.4%	0.3%	0.3%	0.3%
Moisture Damage	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/Unknown	0.1%	0.1%	0.1%	0.1%	0.0%	0.0%	0.1%	0.1%	0.1%	0.0%	0.0%	0.0%
Fault-Free	0.2%	0.2%	0.2%	0.2%	0.1%	0.1%	0.2%	0.2%	0.1%	0.1%	0.1%	0.1%

Nucleus 6 Sound Processor - Failed Component Return Rate
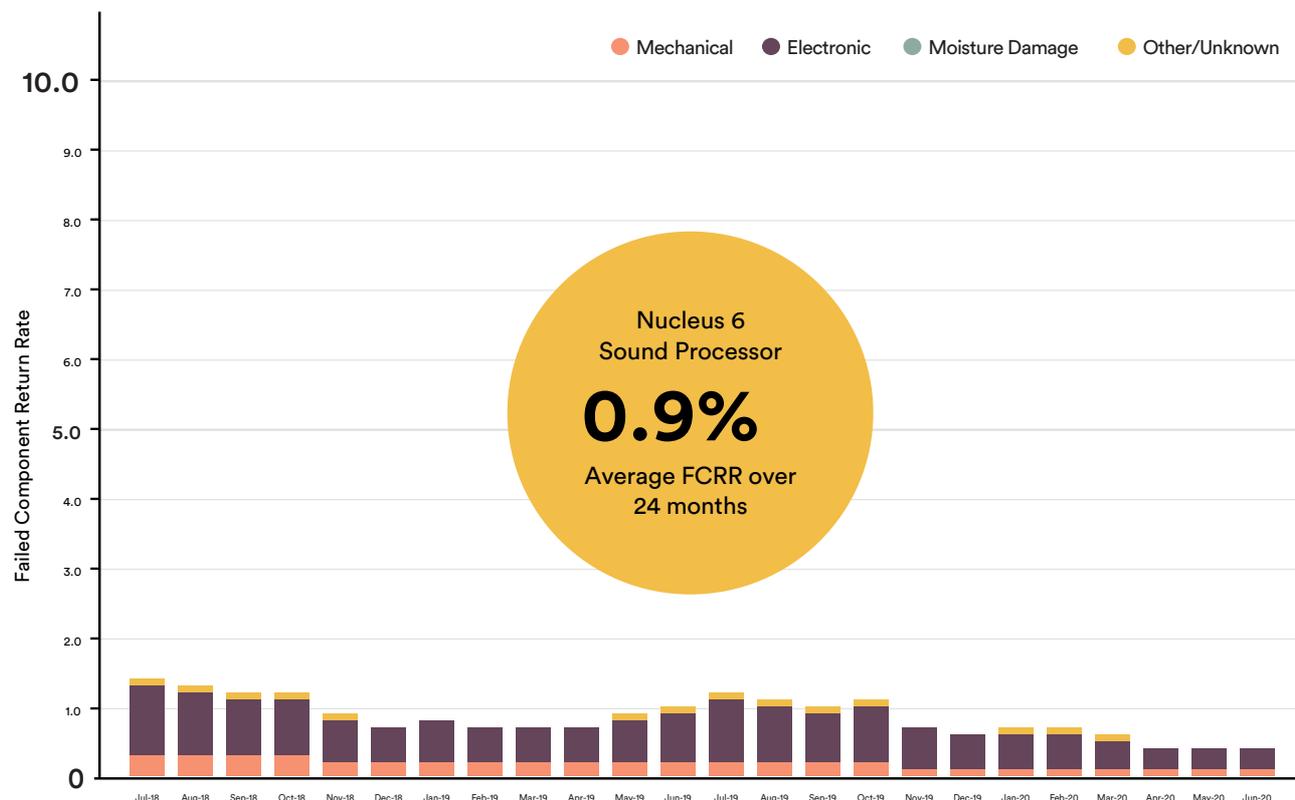
APPENDIX

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)
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: Cochlear implant systems: Requirements for safety, functional verification, labeling and reliability reporting (2017). Arlington, VA: American National Standards Institute.

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.

Cochlear, 科利耳, コクレア, 코클리어, Hear now. And always, Nucleus, Kanso, Advance Off-Stylet, AutoNRT, Contour Advance, Custom Sound, Freedom, NRT, SmartSound, the elliptical logo, and marks bearing an ® or ™ symbol, are either trademarks or registered trademarks of Cochlear Limited (unless otherwise noted).