COCHLEAR™ NUCLEUS® IMPLANT RELIABILITY REPORT

Volume 16 | December 2017

Hear now. And always

Cochlear®

OUR MISSION

We help people hear and be heard.

We **empower** people to connect with others and live a full life.

We **transform** the way people understand and treat hearing loss.

We **innovate** and bring to market a range of implantable hearing solutions that deliver a lifetime of hearing outcomes.

Cochlear's implants are the most reliable[1] in the industry*. That's one reason why more people around the world choose Cochlear than any other cochlear implant brand.

* Latest generation of cochlear implants currently available as at 31 December 2017.

WHY RELIABILITY MATTERS

High implant reliability means greater patient satisfaction and less risk of additional surgery. When considering a cochlear implant, it's important that you have access to the latest data on short- and long-term reliability, including success and failure rates for both adults and children.

ABOUT RELIABILITY REPORTING

The global standards for cochlear implant reliability reporting are based on the reporting methodology recommended by ***International Standard ISO 5841-2***[2,3], the reporting principles outlined in the ***European Consensus Statement on Cochlear Implant Failures and Explantations***[4], and expert recommendations from the ***International Classification of Reliability for Implanted Cochlear Implant Receiver Stimulators***.[5]

This report meets the standards for cochlear implant reliability reporting outlined in the applicable standards referred to above.

COCHLEAR'S IMPLANTS ARE THE
MOST RELIABLE[1]
IN THE INDUSTRY*

* Latest generation of cochlear implants currently available as at 31 December 2017.

HOW TO READ THIS REPORT

What is Cumulative Survival Percentage (CSP)?

CSP is cumulative percentage of functioning implants over time, which indicates the reliability of the device within a given time period. In this report, CSP includes both device and accident-related issues.

The reliability calculations used in this report are in accordance with the International Standard ISO 5841-2.[2,3] They are probability calculations, which use a modified Actuarial Analysis estimator. This data estimates the probability of survival within a period of time and is represented as CSP.

What data is in this report?

The data in this report covers the entire life of implant models and registered implants* worldwide.

What is combined data?

Combined data is the cumulative survival percentage of both adults and children populations combined.

How are results shown?

Results for adults and children are shown separately with 95% confidence intervals (I) as stipulated by the consensus statement.[4]

* An implant is registered with Cochlear when the recipient/clinic/hospital submits the registration of the implanted device. Implant registrations often lag behind surgery dates.

COMPLIANCE WITH INTERNATIONAL REPORTING STANDARDS

In 2005, the major European cochlear implant centres, global regulatory authorities and device manufacturers developed the ***European Consensus Statement on Cochlear Implant Failures and Explantations***.[4] The consensus statement outlines how device failures and reliability should be reported, and the seven principles of best practice reporting.

CONSENSUS STATEMENT PRINCIPLES

All device failures must be reported to the competent authority and must be included in the calculation of the Cumulative Survival Rate (CSR*). Reporting of the CSR should be in accordance with International Standard ISO 5841-2:2000.[2]

Manufacturer's reports of device failure should indicate the sources of data and the sample size. There must be no exclusions. The time period over which the data was collected should be specified.

Reports of CSR should give complete historical data of a given device, describing any technical modifications (which can be integrated into historical data by starting at time 0).

The complete data set of the 'mother' product should always be supplied when presenting data on subsequent device modifications.**

A new device can be attributed when there has been a change in either the case and/or the electrodes and/or the electronics and has been labelled by its own CE mark.

The CSR should be split into data for adults and for children and 95% confidence intervals (80% or 90% if the population is below 1,000 units) should be provided.

Device survival time starts to count with closure of the wound intraoperatively.

* CSR is identical to Cumulative Survival Percentage (CSP).
** 'Mother' data refers to all data collected for a particular model of implant including all modifications to that model.

COCHLEAR REPORTING PRACTICE	COCHLEAR COMPLIANCE	MED-EL COMPLIANCE[6]	ADVANCED BIONICS COMPLIANCE[7]	OTICON COMPLIANCE[8]
All device failures are reported to the competent authority. Cochlear uses the calculation procedures of both ISO 5841-2:2000[2] and ISO 5841-2:2014.[3] All device failure modes are included, including failures due to external impact.	✔	? Compliance with ISO 5841-2[2,3] not explicitly stated.	✔	✔
The source of data is Cochlear's global complaints handling database. Sample size and time period are specified with each report.	✔	✘ Sample size not included.	✔	✘ Sample size not included.
All models and all versions of each model are included in reports. Descriptions of any significant technical modfications are given.	✔	✘ COMBI 40+ no longer reported. PULSAR no longer reported.	✔	✘ Pre-2006 devices are no longer reported.
Reports aggregate the reliability of all devices (pre- and post-modification). If the post-modification is significantly different, post-modification is reported separately from the aggregate of all devices.	✔	✘ COMBI 40+ no longer reported. PULSAR no longer reported.	✔	✔
A new device is attributed when there has been a change in either the case and/or the electrodes and/or the electronics and has been labelled by its own CE mark. Market practice is that all cochlear implants are labeled by one CE mark per authority.	✔	? Not explicitly stated.	? Not explicitly stated.	✔
Reports show separate data for adults and children. This Nucleus® Reliability Report contains reliability data with 95% confidence intervals, in compliance with the consensus statement.[4]	✔	✘ No split data on adults and children. Confidence intervals not included.	✔	✘ No split data on adults and children.
Device survival time begins with closure of the wound.	✔	? Not explicitly stated.	✔	? Not explicitly stated.

MORE PEOPLE CHOOSE COCHLEAR THAN ANY OTHER IMPLANT BRAND

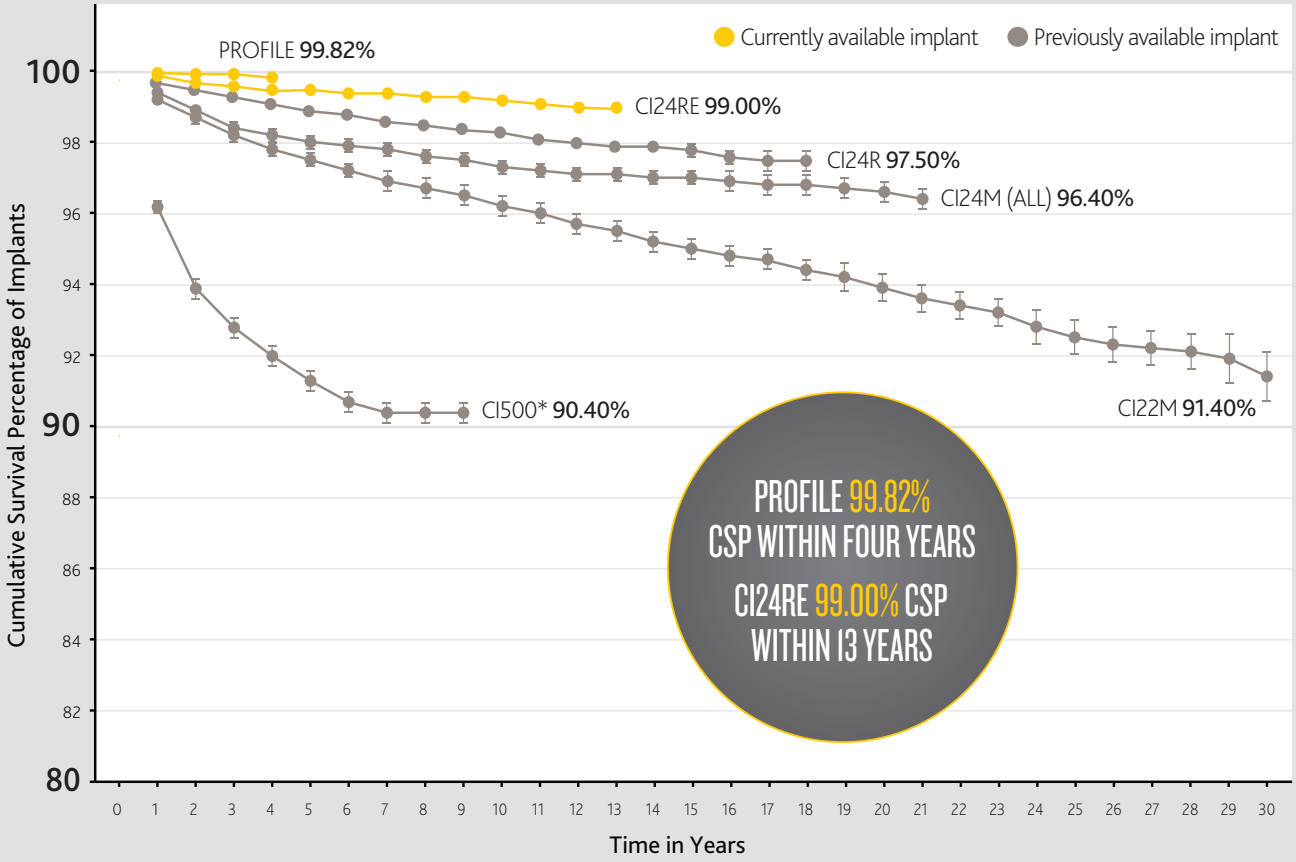
Number of registered implants - 31 December 2017

DEVICE	ADULTS	CHILDREN	COMBINED
Profile	27,807	20,745	48,552
CI24RE	74,818	102,254	177,072
CI500	15,368	14,453	29,821
CI24R	18,671	34,709	53,380
CI24M (All)	7,858	11,873	19,731
CI22M	9,948	8,227	18,175

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

YEARS	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
CI22M	99.2	98.7	98.2	97.8	97.5	97.2	96.9	96.7	96.5	96.2	96.0	95.7	95.5	95.2	95.0	94.8	94.7	94.4	94.2	93.9	93.6	93.4	93.2	92.8	92.5	92.3	92.2	92.1	91.9	91.4
CI24M (All)	99.4	98.9	98.4	98.2	98.0	97.9	97.8	97.6	97.5	97.3	97.2	97.1	97.1	97.0	97.0	96.9	96.8	96.8	96.7	96.6	96.4									
CI24R	99.7	99.5	99.3	99.1	98.9	98.8	98.6	98.5	98.4	98.3	98.2	98.1	98.0	97.9	97.8	97.6	97.5	97.5												
CI24RE	99.9	99.7	99.6	99.5	99.5	99.4	99.4	99.3	99.3	99.2	99.1	99.0	99.0																	
CI500	96.2	93.9	92.8	92.0	91.3	90.7	90.4	90.4	90.4																					
Profile	99.95	99.92	99.92	99.82																										

Nucleus Implant Reliability



REGISTERED IMPLANT DATA COMBINED FOR ADULTS AND CHILDREN AS OF 31 DECEMBER 2017

* Voluntarily recalled in September 2011.
Confidence intervals smaller than 0.1% may not be clearly visible in the graphs.
CSP includes both device and accident-related issues.

CURRENTLY AVAILABLE IMPLANTS

NUCLEUS PROFILE SERIES IMPLANT

Number of registered Profile Series implants - 31 December 2017

ADULTS	CHILDREN	COMBINED
27,807	20,745	48,552

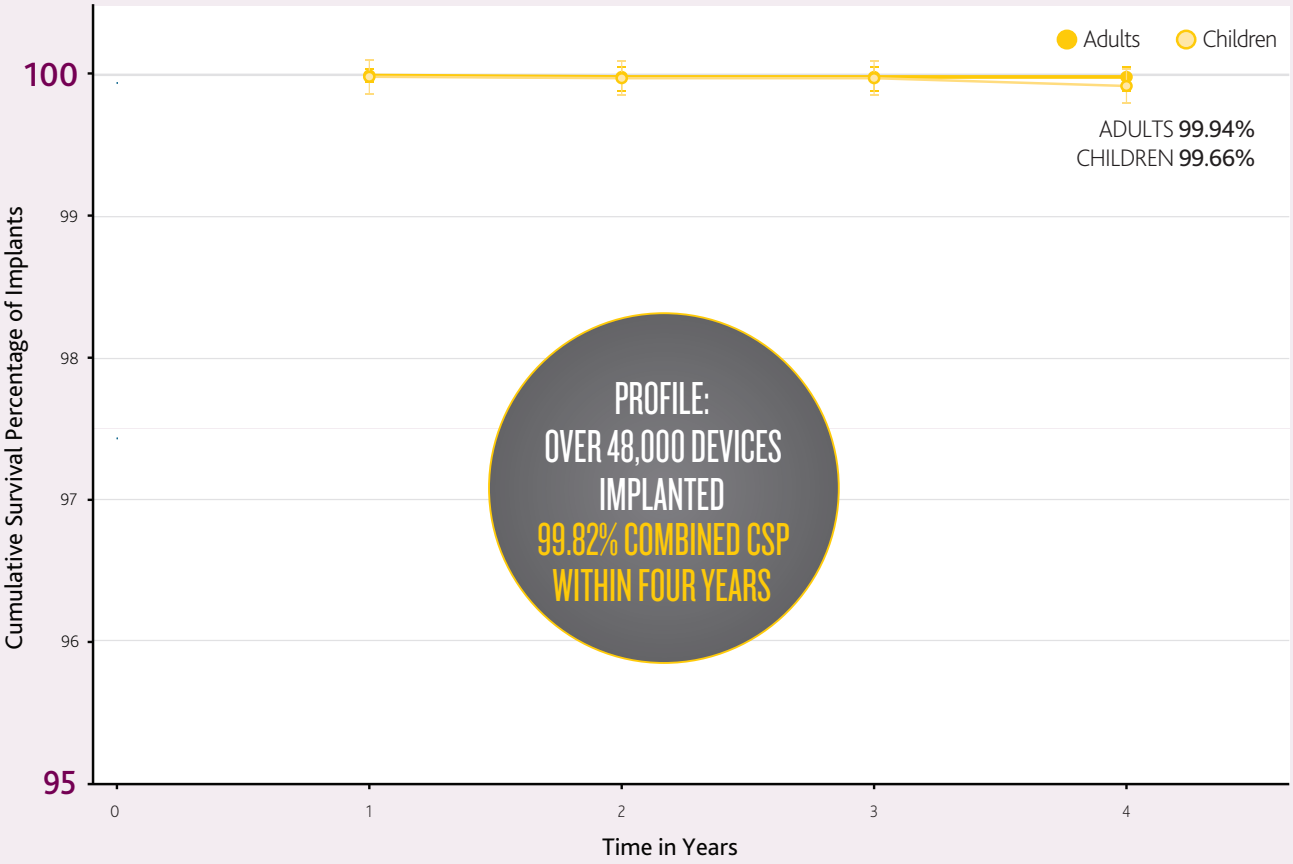
At only 3.9 mm, the thin implant body of the Profile Series is the most discreet choice for all patients.

Commercially released in 2014, the Profile Series sets a new standard in implant reliability with a 99.82% combined Cumulative Survival Percentage within four years.

Profile Series Cumulative Survival Percentage

YEAR	1	2	3	4
Adults	99.98	99.94	99.94	99.94
Children	99.92	99.88	99.88	99.66
Combined	99.95	99.92	99.92	99.82

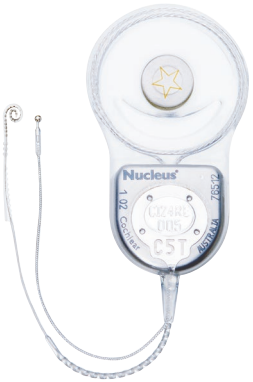
Profile Series Reliability



REGISTERED IMPLANT DATA FOR ADULTS AND CHILDREN AS OF 31 DECEMBER 2017

Confidence intervals smaller than 0.1% may not be clearly visible in the graphs.
CSP includes both device and accident-related issues.

NUCLEUS CI24RE SERIES IMPLANT



Number of registered CI24RE Series implants - 31 December 2017

ADULTS	CHILDREN	COMBINED
74,818	102,254	177,072

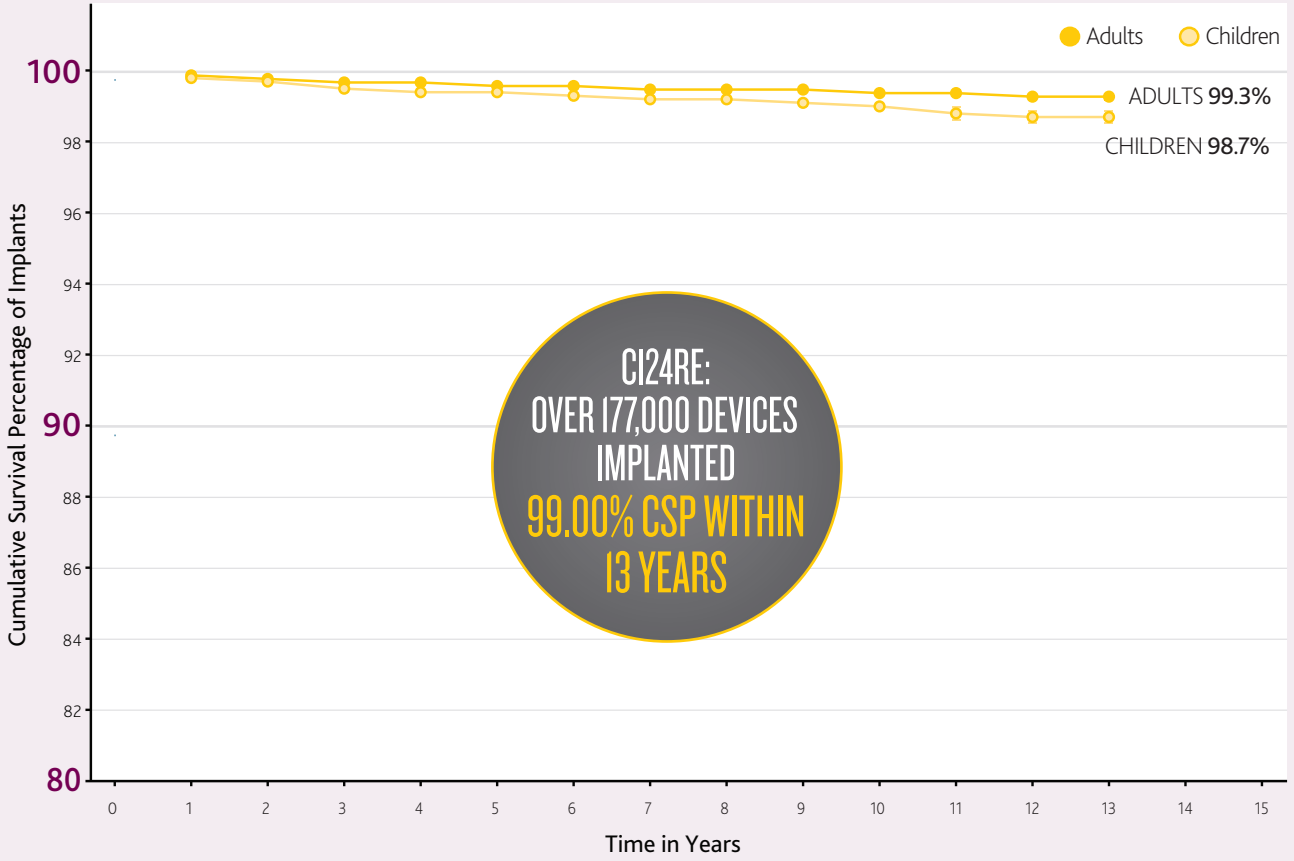
The CI24RE Series is the world's most widely used cochlear implant.

Released in 2005, it has a 99.00% combined Cumulative Survival Percentage within 13 years.

CI24RE Series Cumulative Survival Percentage

YEARS	1	2	3	4	5	6	7	8	9	10	11	12	13
Adults	99.9	99.8	99.7	99.7	99.6	99.6	99.5	99.5	99.5	99.4	99.4	99.3	99.3
Children	99.8	99.7	99.5	99.4	99.4	99.3	99.2	99.2	99.1	99.0	98.8	98.7	98.7
Combined	99.9	99.7	99.6	99.5	99.5	99.4	99.4	99.3	99.3	99.2	99.1	99.0	99.0

CI24RE Series Reliability

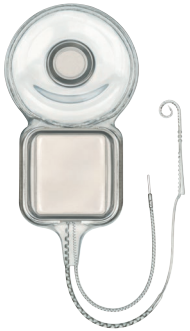


REGISTERED IMPLANT DATA FOR ADULTS AND CHILDREN AS OF 31 DECEMBER 2017

Confidence intervals smaller than 0.1% may not be clearly visible in the graphs.
CSP includes both device and accident-related issues.

PREVIOUSLY AVAILABLE IMPLANTS

NUCLEUS CI500 SERIES IMPLANT



Number of registered CI500 Series implants - 31 December 2017

ADULTS	CHILDREN	COMBINED
15,368	14,453	29,821

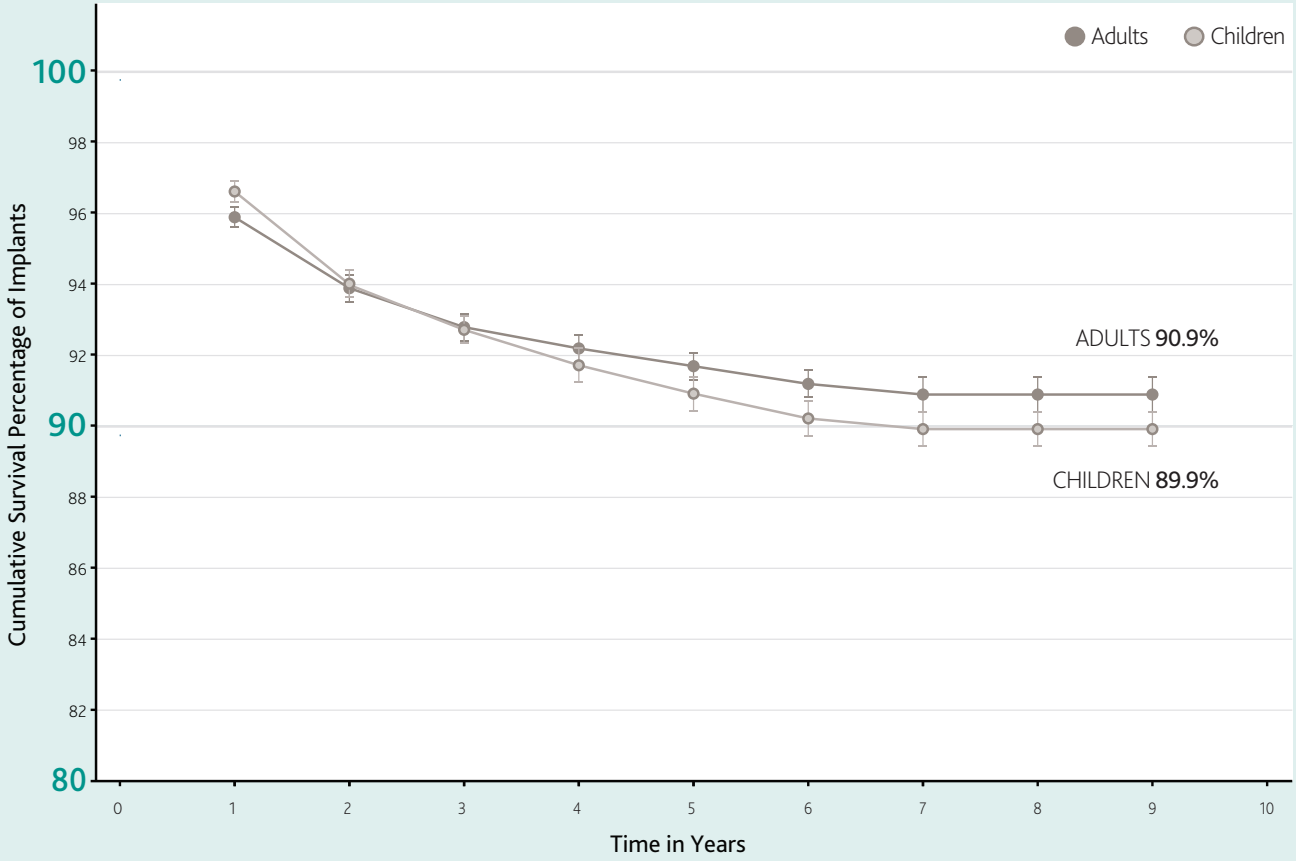
Released in 2009, the CI500 Series has a combined Cumulative Survival Percentage of 90.4% within nine years.

The CI500 Series was voluntarily recalled in September 2011.

CI500 Series Cumulative Survival Percentage

YEARS	1	2	3	4	5	6	7	8	9
Adults	95.9	93.9	92.8	92.2	91.7	91.2	90.9	90.9	90.9
Children	96.6	94.0	92.7	91.7	90.9	90.2	89.9	89.9	89.9
Combined	96.2	93.9	92.8	92.0	91.3	90.7	90.4	90.4	90.4

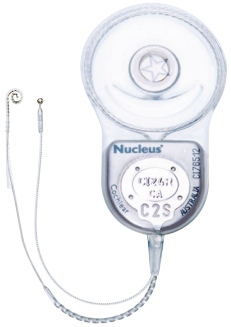
CI500 Series Reliability



REGISTERED IMPLANT DATA FOR ADULTS AND CHILDREN AS OF 31 DECEMBER 2017

Confidence intervals smaller than 0.1% may not be clearly visible in the graphs.
CSP includes both device and accident-related issues.

NUCLEUS CI24R IMPLANT



Number of registered CI24R implants - 31 December 2017

ADULTS	CHILDREN	COMBINED
18,671	34,709	53,380

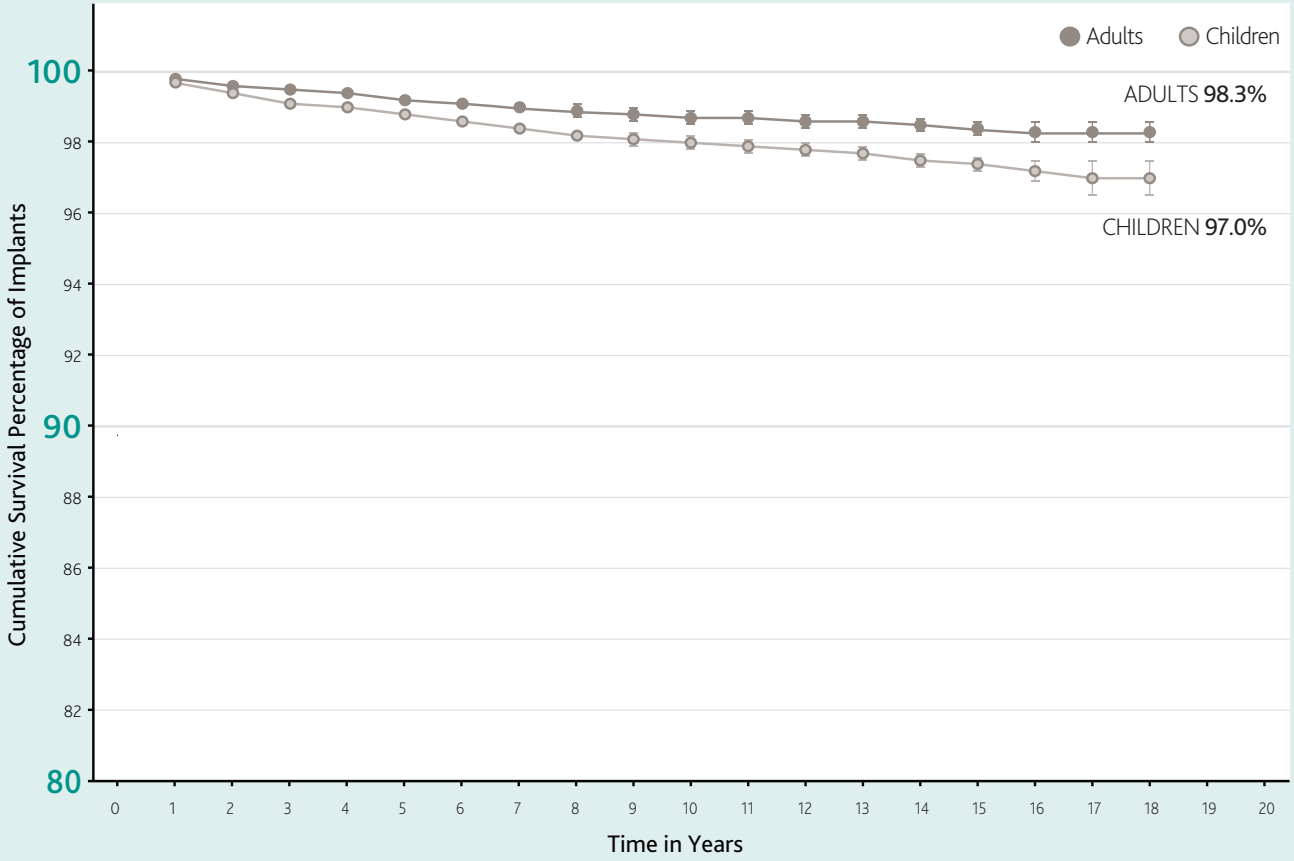
The CI24R was released in 2000 with perimodiolar (Contour Advance®) and straight electrodes.

Within 18 years, the CI24R implant has a combined Cumulative Survival Percentage of 97.5%.

CI24R Cumulative Survival Percentage

YEARS	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Adults	99.8	99.6	99.5	99.4	99.2	99.1	99.0	98.9	98.8	98.7	98.7	98.6	98.6	98.5	98.4	98.3	98.3	98.3
Children	99.7	99.4	99.1	99.0	98.8	98.6	98.4	98.2	98.1	98.0	97.9	97.8	97.7	97.5	97.4	97.2	97.0	97.0
Combined	99.7	99.5	99.3	99.1	98.9	98.8	98.6	98.5	98.4	98.3	98.2	98.1	98.0	97.9	97.8	97.6	97.5	97.5

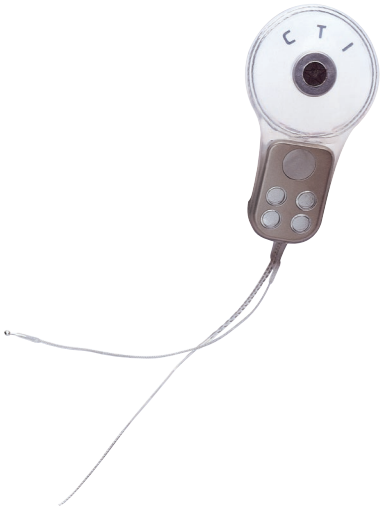
CI24R Reliability



REGISTERED IMPLANT DATA FOR ADULTS AND CHILDREN AS OF 31 DECEMBER 2017

Confidence intervals smaller than 0.1% may not be clearly visible in the graphs.
CSP includes both device and accident-related issues.

NUCLEUS CI24M IMPLANT



Number of registered CI24M implants - 31 December 2017

	ADULTS	CHILDREN	COMBINED
ALL	7,858	11,873	19,731
POST**	6,154	9,350	15,504

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

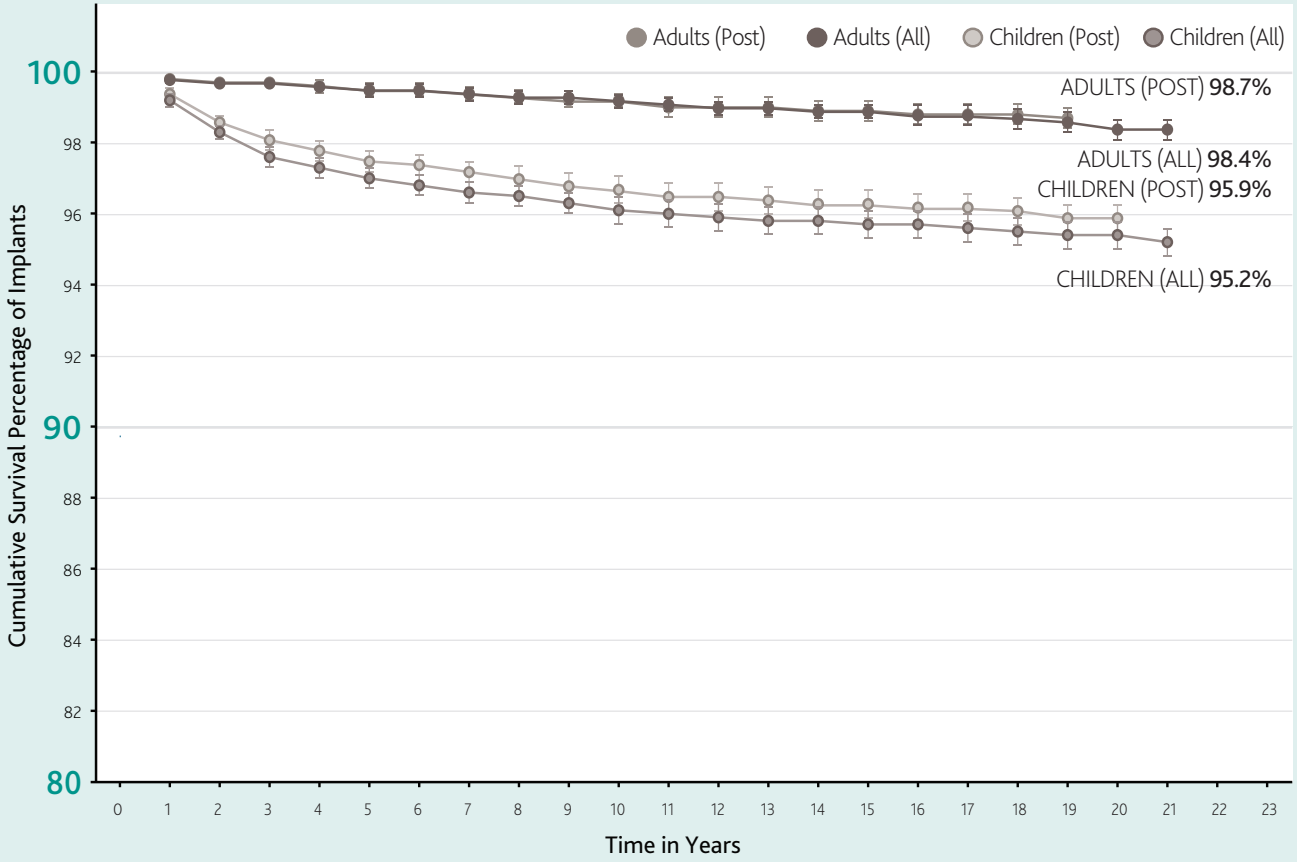
Within 21 years, the CI24M implant has a combined Cumulative Survival Percentage of 96.4%.

CI24M Cumulative Survival Percentage

YEARS	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Adults (All)	99.8	99.7	99.7	99.6	99.5	99.5	99.4	99.3	99.3	99.2	99.1	99.0	99.0	98.9	98.9	98.8	98.8	98.7	98.6	98.4	98.4
Children (All)	99.2	98.3	97.6	97.3	97.0	96.8	96.6	96.5	96.3	96.1	96.0	95.9	95.8	95.8	95.7	95.7	95.6	95.5	95.4	95.4	95.2
Combined (All)	99.4	98.9	98.4	98.2	98.0	97.9	97.8	97.6	97.5	97.3	97.2	97.1	97.1	97.0	97.0	96.9	96.8	96.8	96.7	96.6	96.4
Adults (Post)	99.8	99.7	99.7	99.6	99.5	99.5	99.4	99.3	99.2	99.2	99.0	99.0	99.0	98.9	98.9	98.8	98.8	98.8	98.7	#	#
Children (Post)	99.4	98.6	98.1	97.8	97.5	97.4	97.2	97.0	96.8	96.7	96.5	96.5	96.4	96.3	96.3	96.2	96.2	96.1	95.9	95.9	#
Combined (Post)	99.5	99.1	98.7	98.5	98.3	98.2	98.1	97.9	97.8	97.7	97.5	97.5	97.4	97.4	97.3	97.3	97.2	97.1	97.0	97.0	#

** 'Post' refers to the addition of a structural support component to improve impact strength.
# Individual populations are less than the minimum required for a valid calculation.[3]

CI24M Reliability



REGISTERED IMPLANT DATA FOR ADULTS AND CHILDREN AS OF 31 DECEMBER 2017

Confidence intervals smaller than 0.1% may not be clearly visible in the graphs.
CSP includes both device and accident-related issues.

NUCLEUS CI22M IMPLANT

Number of registered CI22M implants - 31 December 2017

ADULTS	CHILDREN	COMBINED
9,948	8,227	18,175

Released in 1985, the CI22M implant was the first commercially available multi-channel cochlear implant in the world.

Within 30 years, the CI22M implant has a combined Cumulative Survival Percentage of 91.4%.

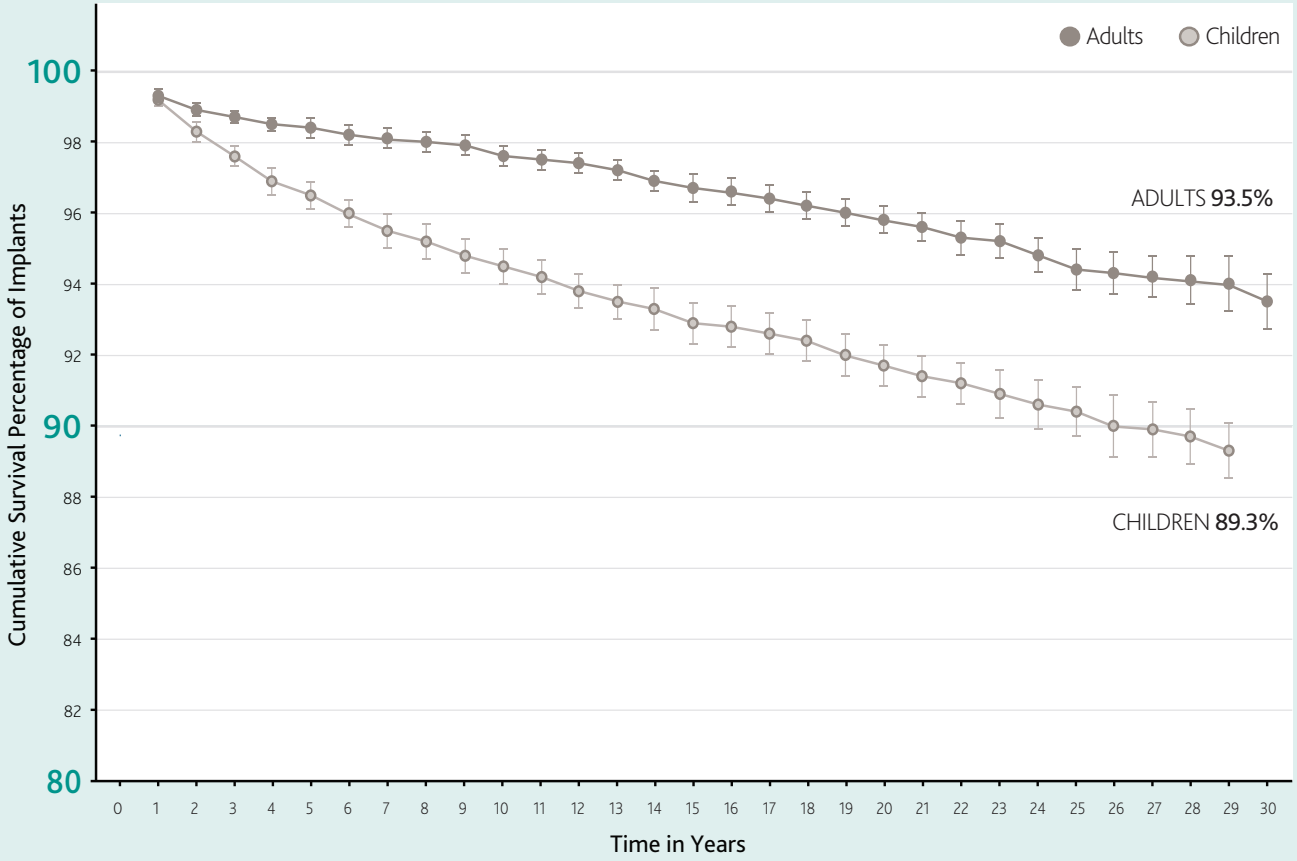
CI22M Cumulative Survival Percentage

YEARS	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Adults	99.3	98.9	98.7	98.5	98.4	98.2	98.1	98.0	97.9	97.6	97.5	97.4	97.2	96.9	96.7
Children	99.2	98.3	97.6	96.9	96.5	96.0	95.5	95.2	94.8	94.5	94.2	93.8	93.5	93.3	92.9
Combined	99.2	98.7	98.2	97.8	97.5	97.2	96.9	96.7	96.5	96.2	96.0	95.7	95.5	95.2	95.0

16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
96.6	96.4	96.2	96.0	95.8	95.6	95.3	95.2	94.8	94.4	94.3	94.2	94.1	94.0	93.5
92.8	92.6	92.4	92.0	91.7	91.4	91.2	90.9	90.6	90.4	90.0	89.9	89.7	89.3	#
94.8	94.7	94.4	94.2	93.9	93.6	93.4	93.2	92.8	92.5	92.3	92.2	92.1	91.9	91.4

Individual populations are less than the minimum required for a valid calculation.[3]

CI22M Reliability



REGISTERED IMPLANT DATA FOR ADULTS AND CHILDREN AS OF 31 DECEMBER 2017

Confidence intervals smaller than 0.1% may not be clearly visible in the graphs.
CSP includes both device and accident-related issues.

APPENDIX

GRAPHICAL REPRESENTATION

Each graph represents a type of device based on the receiver/stimulator portion.

RECEIVER/ STIMULATOR	IMPLANTS*
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.

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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.

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7. 2017 Global Implant Reliability Report. 027-N025-02. Advanced Bionics AG and affiliates.; 2017.

8. Oticon Medical Reliability Report H1 2017. Oticon Medical; 2017.

Hear now. And always

As the global leader in implantable hearing solutions, Cochlear is dedicated to bringing the gift of sound to people with moderate to profound hearing loss. We have helped over 450,000 people of all ages live full and active lives by reconnecting them with family, friends and community.

We aim to give our recipients the best lifelong hearing experience and access to innovative future technologies. For our professional partners, we offer the industry's largest clinical, research and support networks.

That's why more people choose Cochlear than any other hearing implant company.

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