Cochlear™

Nucleus® Reliability Report

Nucleus® Reliability Report Volume 10 | February 2012

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About Cochlear's reliability reporting

The Nucleus Reliability Report makes available all data relating to cochlear implant device failures in accordance with the International Standard ISO 5841-2:2000[1] and the reporting principles described in the European and Global Consensus Statement on Cochlear Implant Failures and Explantations[2,3].

In compliance with the European and Global Consensus Statements, Cochlear reports all failures in the reliability calculation, including those caused by external impact and electrode failures that lead to a loss of clinical benefit. The data in each report covers the entire life of all implant models and registered implants worldwide. Results for adults and children are shown separately with 95% confidence intervals as specifically required by the consensus statement.

In this reliability report the latest data on all Nucleus implants is provided. Data is now available for a population of over 70,000 CI24RE model implants over a period of 7 years, while the CI22M implant has now reached a reporting period of 25 years. An update on the CI500 series cochlear implant is also provided with the latest data as of February 2012.

Reading this report

Cochlear's reliability data show both the percentage of devices that are still functioning and those no longer functioning over a given period of time. Respectively, these are known as the Cumulative Survival Percentage (CSP) and Cumulative Failure Percentage (CFP).

Cumulative Survival Percentage

The Cumulative Survival Percentage is the cumulative percentage of functioning implants over time and can be used to predict the reliability of the device within a given time period.

$$CSP = \frac{\text{Devices that have survived for at least "x" years X 100\%}}{\text{All devices implanted for at least "x" years}}$$

Cumulative Failure Percentage

The Cumulative Failure Percentage is the cumulative percentage of devices that are no longer functioning after a given period of time.

$$CFP = [100 - CSP]\ \%$$

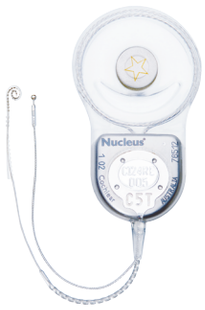
Number of registered implants# - February 2012

DEVICE	ADULT	CHILD	COMBINED
CI22M	9,964	8,218	18,182
CI24M (All)	7,786	11,667	19,453
CI24M (Post)	5,615	8,471	14,086
CI24R	18,247	32,231	50,478
CI24RE	32,626	38,328	70,954
CI500	15,092	14,324	29,369

Note: Implant registrations often lag surgery dates by up to 6 months.
'Post' refers to the addition of a structural support component to improve impact strength.

Nucleus CI24RE Implant

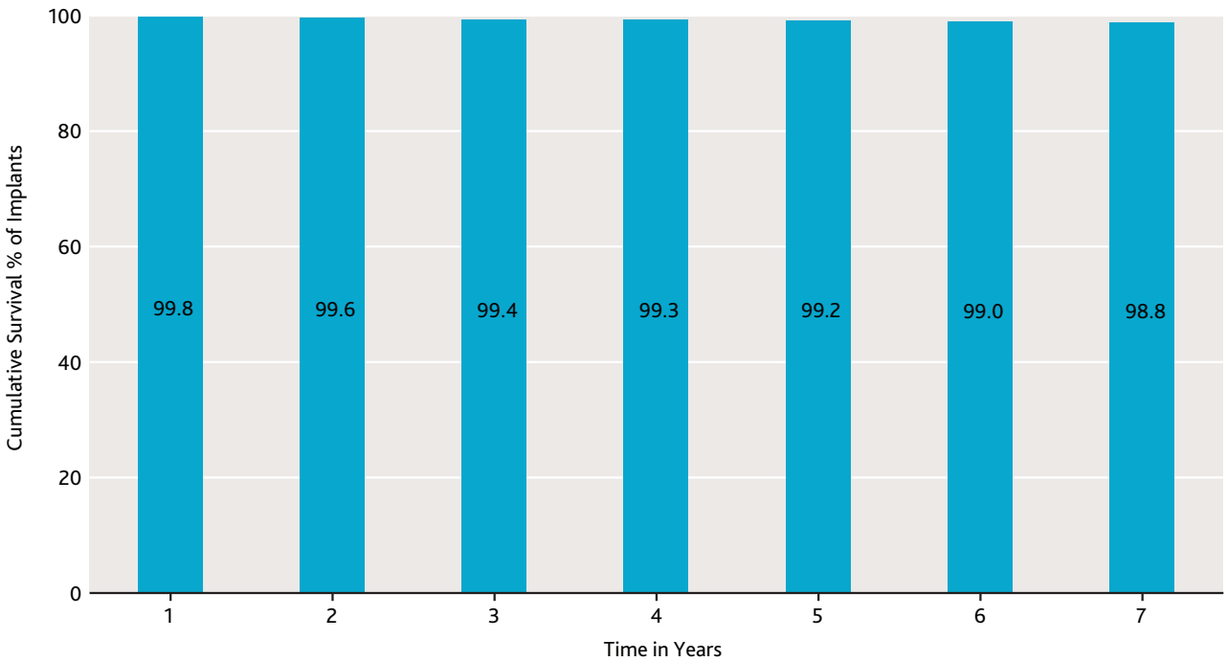
The Cumulative Survival Percentage for registered implants worldwide is 98.8% within 7 years.



Commercially released in 2005, the CI24RE introduced a new integrated circuit with a mechanical design and production processes based on the proven architecture of the CI24R implant. The new integrated circuit substantially increased the capability and future-readiness of the system. Features include AutoNRT™, numerous stimulation modes and native compatibility with the Nucleus CP810 Sound Processor and CR110 Remote Assistant.

The CI24RE is available with a number of electrode arrays. The reliability data reported here also includes the Cochlear Hybrid™ L24 and the Cochlear Nucleus CI422 with Slim Straight Electrode since these implants are based on the same mechanical architecture.

CI24RE* Reliability



REGISTERED IMPLANTS DATA FOR COMBINED ADULT AND CHILD
AS AT 29 FEBRUARY 2012

Cumulative Survival Percentage

YEAR	1	2	3	4	5	6	7
CI24RE Adult*	99.8	99.6	99.6	99.5	99.4	99.3	99.2
CI24RE Child*	99.7	99.5	99.3	99.1	98.9	98.7	98.4
CI24RE Combined*	99.8	99.6	99.4	99.3	99.2	99.0	98.8
95% Confidence Interval*	+/- 0.0	+0.0/-0.1	+/- 0.1	+/- 0.1	+/- 0.1	+/- 0.1	+/- 0.2

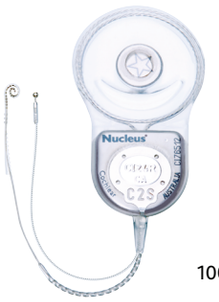
Cumulative Failure Percentage

YEAR	1	2	3	4	5	6	7
CI24RE Adult*	0.2	0.4	0.4	0.5	0.6	0.7	0.8
CI24RE Child*	0.3	0.5	0.7	0.9	1.1	1.3	1.6
CI24RE Combined*	0.2	0.4	0.6	0.7	0.8	1.0	1.2

* See page 9 for a list of implant types reported with the CI24RE receiver stimulator

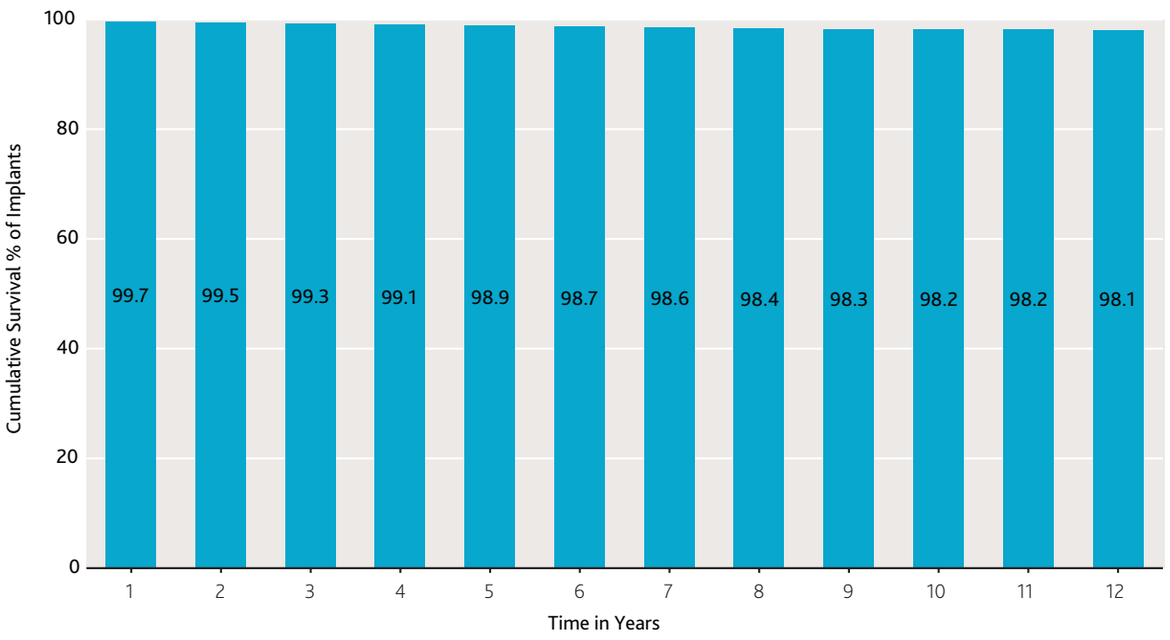
Nucleus CI24R Implant

The Cumulative Survival Percentage for registered implants worldwide is 98.1% within 12 years.



The CI24R, was released in 2000 with perimodiolar (Nucleus® Contour Advance™) and straight arrays (Nucleus® 24k).

CI24R Reliability



REGISTERED IMPLANTS DATA FOR COMBINED ADULT AND CHILD
AS AT 29 FEBRUARY 2012

Cumulative Survival Percentage

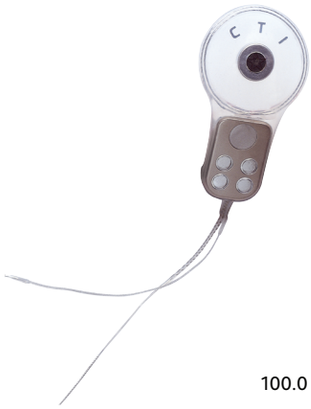
YEAR	1	2	3	4	5	6	7	8	9	10	11	12
CI24R Adult	99.8	99.6	99.4	99.3	99.2	99.0	99.0	98.9	98.8	98.8	98.7	98.5
CI24R Child	99.7	99.4	99.2	99.0	98.8	98.5	98.3	98.1	97.9	97.8	97.7	97.7
CI24R Combined	99.7	99.5	99.3	99.1	98.9	98.7	98.6	98.4	98.3	98.2	98.2	98.1
95% Confidence Interval	+0.0/-0.1	+/- 0.1	+/- 0.1	+/- 0.1	+/- 0.1	+/- 0.1	+/- 0.1	+/- 0.1	+/- 0.1	+/- 0.1	+/- 0.2	+0.2/-0.3

Cumulative Failure Percentage

YEAR	1	2	3	4	5	6	7	8	9	10	11	12
CI24R Adult	0.2	0.4	0.6	0.7	0.8	1.0	1.0	1.1	1.2	1.2	1.3	1.5
CI24R Child	0.3	0.6	0.8	1.0	1.2	1.5	1.7	1.9	2.1	2.2	2.3	2.3
CI24R Combined	0.3	0.5	0.7	0.9	1.1	1.3	1.4	1.6	1.7	1.8	1.8	1.9

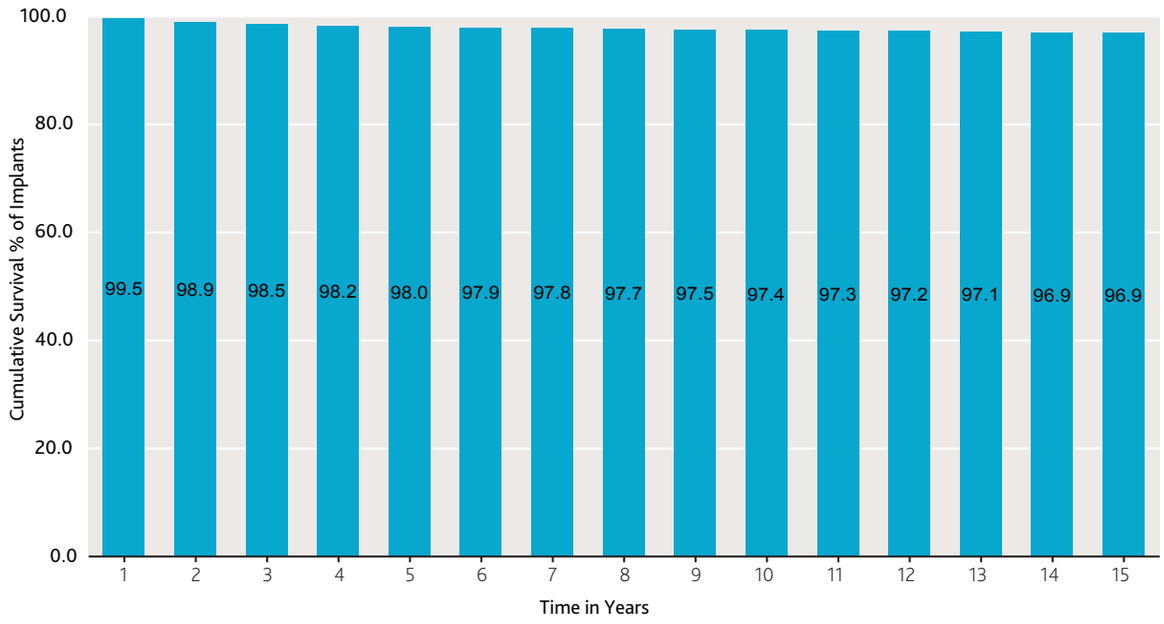
Nucleus CI24M Implant

The Cumulative Survival Percentage for registered implants worldwide is 96.9% within 15 years.



The CI24M, released in 1997, consisted of the CI24M receiver/stimulator and a 22-electrode straight array. The CI24M introduced new stimulation capability by the addition of a plate electrode on the package and a lead wire connected to a ball electrode, enabling monopolar stimulation mode. Telemetry was included to measure electrode voltage compliance and impedance and to diagnose implant and electrode function. Telemetry also supported the world's first recording of the electrically evoked compound action potential (ECAP) using the intracochlear electrodes via Neural Response Telemetry (NRT).

CI24M Reliability



REGISTERED IMPLANTS DATA FOR COMBINED ADULT AND CHILD
AS AT 29 FEBRUARY 2012

Cumulative Survival Percentage

YEAR	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
CI24M Adult (All)	99.7	99.5	99.4	99.3	99.2	99.2	99.1	99.1	99.0	98.9	98.9	98.8	98.7	98.6	98.6
CI24M Child (All)	99.3	98.5	97.8	97.5	97.2	97.0	96.9	96.7	96.5	96.3	96.2	96.2	96.0	95.9	95.9
CI24M Adult (Post†)	99.8	99.5	99.5	99.4	99.3	99.2	99.2	99.1	99.0	99.0	98.9	98.9	98.8	98.8	-
CI24M Child (Post†)	99.4	98.8	98.3	98.1	97.8	97.6	97.5	97.3	97.1	97.0	96.8	96.8	96.6	96.6	-
CI24M (All) Combined	99.5	98.9	98.5	98.2	98.0	97.9	97.8	97.7	97.5	97.4	97.3	97.2	97.1	96.9	96.9
95% Confidence Interval	+/- 0.1	+0.1/-0.2	+/- 0.2	+/- 0.2	+/- 0.2	+/- 0.2	+/- 0.2	+/- 0.2	+/- 0.2	+/- 0.2	+0.2/-0.3	+0.2/-0.3	+/- 0.3	+/- 0.3	+/- 0.3

Cumulative Failure Percentage

YEAR	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
CI24M Adult (All)	0.3	0.5	0.6	0.7	0.8	0.8	0.9	0.9	1.0	1.1	1.1	1.2	1.3	1.4	1.4
CI24M Child (All)	0.7	1.5	2.2	2.5	2.8	3.0	3.1	3.3	3.5	3.7	3.8	3.8	4.0	4.1	4.1
CI24M Adult (Post†)	0.2	0.5	0.5	0.6	0.7	0.8	0.8	0.9	1.0	1.0	1.1	1.1	1.2	1.2	-
CI24M Child (Post†)	0.6	1.2	1.7	1.9	2.2	2.4	2.5	2.7	2.9	3.0	3.2	3.2	3.4	3.4	-
CI24M (All) Combined	0.5	1.1	1.5	1.8	2.0	2.1	2.2	2.3	2.5	2.6	2.7	2.8	2.9	3.1	3.1

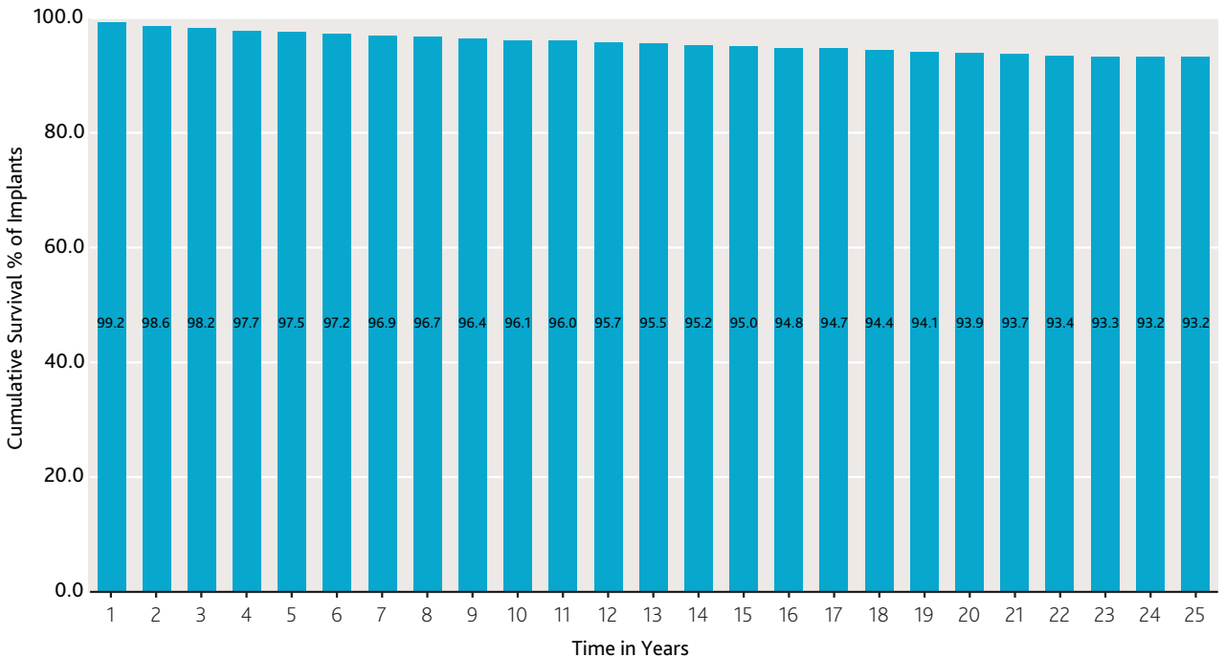
† 'Post' refers to the addition of a structural support component to improve impact strength.

Nucleus CI22M Implant

The Cumulative Survival Percentage for registered implants worldwide is 93.2% within 25 years.

The CI22M implant, released in 1985, was Cochlear's first commercial implant. In 1986, the CI22M was released with an internal magnet to hold the external transmitting coil in place.

CI22M Reliability



REGISTERED IMPLANTS DATA FOR COMBINED ADULT AND CHILD
AS AT 29 FEBRUARY 2012

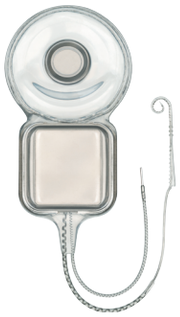
Cumulative Survival Percentage

YEAR	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
CI22M Adult	99.2	98.9	98.7	98.5	98.3	98.2	98.1	98.0	97.8	97.6	97.5	97.3	97.1	96.9	96.7	96.5	96.3	96.1	95.8	95.6	95.4	95.1	95.1	94.9	-
CI22M Child	99.1	98.3	97.5	96.9	96.4	95.9	95.5	95.1	94.8	94.4	94.2	93.8	93.5	93.3	93.0	92.9	92.7	92.4	92.0	91.9	91.7	91.5	91.1	-	-
CI22M Combined	99.2	98.6	98.2	97.7	97.5	97.2	96.9	96.7	96.4	96.1	96.0	95.7	95.5	95.2	95.0	94.8	94.7	94.4	94.1	93.9	93.7	93.4	93.3	93.2	93.2
95% Confidence Interval	+/- 0.1	+/- 0.2	+/- 0.2	+/- 0.2	+/- 0.2	+0.2/ -0.3	+0.2/ -0.3	+/- 0.3	+/- 0.3	+/- 0.3	+/- 0.3	+/- 0.3	+/- 0.3	+/- 0.3	+/- 0.3	+/- 0.3	+0.3/ -0.4	+/- 0.4	+/- 0.4	+/- 0.4	+0.4/ -0.5	+/- 0.5	+/- 0.5	+/- 0.6	+/- 0.6

Cumulative Failure Percentage

YEAR	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
CI22M Adult	0.8	1.1	1.3	1.5	1.7	1.8	1.9	2.0	2.2	2.4	2.5	2.7	2.9	3.1	3.3	3.5	3.7	3.9	4.2	4.4	4.6	4.9	4.9	5.1	-
CI22M Child	0.9	1.7	2.5	3.1	3.6	4.1	4.5	4.9	5.2	5.6	5.8	6.2	6.5	6.7	7.0	7.1	7.3	7.6	8.0	8.1	8.3	8.5	8.9	-	-
CI22M Combined	0.8	1.4	1.8	2.3	2.5	2.8	3.1	3.3	3.6	3.9	4.0	4.3	4.5	4.8	5.0	5.2	5.3	5.6	5.9	6.1	6.3	6.6	6.7	6.8	6.8

Nucleus CI500 Series Implant - Reliability and Voluntary Recall Update

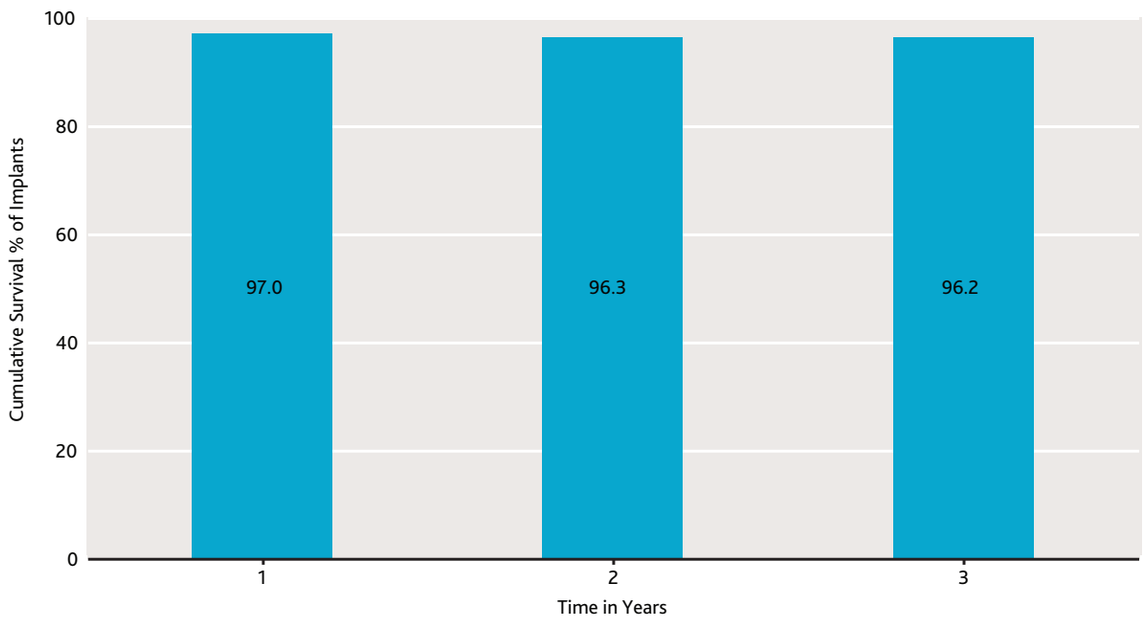


Cochlear has provided regular updates on the overall proportion of CI500 Series implants that have failed since the voluntary recall in September 2011. Cochlear will continue to monitor and report on this population of devices in future reliability reports.

IMPORTANT: The reliability calculations used in this report are in accordance with the ISO 5841-2:2000 standard. They are probability calculations which use a modified Kaplan-Meier estimator. This estimates the probability of survival over a period of time and is represented as Cumulative Survival Percentage (CSP) and Cumulative Failure Percentage (CFP).

In the clinical updates on the status of the Nucleus CI500 Series, what is reported is the proportion of Nucleus CI500 Series devices that have failed at a particular time. This uses the absolute number of failures divided by the total Nucleus CI500 Series registered population to give an overall percentage of devices failed. It is for this reason that you may notice differences between the numbers reported in this reliability report and the the numbers reported in the clinic updates. The probability calculations (CSP, CSP) cannot be compared to the overall proportion of devices failed at a point in time.

CI500 Reliability



REGISTERED IMPLANTS DATA FOR COMBINED ADULT AND CHILD
AS AT 29 FEBRUARY 2012

Cumulative Survival Percentage

YEAR	1	2	3
CI500 Adult	96.7	96.0	96.0
CI500 Child	97.4	96.6	96.5
CI500 Combined	97.0	96.3	96.2
95% Confidence Interval	+/- 0.2	+/- 0.3	+/- 0.3

Cumulative Failure Percentage

YEAR	1	2	3
CI500 Adult	3.3	4.0	4.0
CI500 Child	2.6	3.4	3.5
CI500 Combined	3.0	3.7	3.8

Full Compliance with International Reporting Standards

In 2005 a consensus regarding the reporting of common device failures was reached between the major European cochlear implant centres, global regulatory authorities and device manufacturers. This consensus statement was further refined by the International Consensus Group for Cochlear Implant Reliability Reporting.

The resulting European and Global Consensus Statement on Cochlear Implant Failures and Explantations[2,3] provides a definition of - and seven principles of best practice reporting on - device failure.

Cochlear's definition of device failure and principles of best-practice reporting is in agreement with the consensus statement. Cochlear defines device failure as:

- any device that is explanted and out-of-specification resulting in the loss of clinical benefit; and
- any device that remains in-situ and is out-of-specification resulting in the loss of clinical benefit.

CONSENSUS STATEMENT PRINCIPLE	COCHLEAR COMPLIANCE	COCHLEAR REPORTING PRACTICE
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 ISO standard 5841-2:2000[1].	✓	All device failures are reported to the competent authority. Cochlear uses the applicable definitions, categorisation scheme and calculation procedures of ISO 5841-2:2000[1]. All device failure modes are included, including failures due to external impact.
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.	✓	The source of data is Cochlear's global complaints handling database. Sample size and time period are specified with each report.
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).	✓	All models and all versions of each model are included in reports. Descriptions of any significant technical modifications are given.
The complete data set of the 'mother' product should always be supplied when presenting data on subsequent device modifications.	✓	Reports aggregate the reliability of all devices (pre and post modification). If the post-modification is significantly different, "post mod" is reported separately from the aggregate of all devices.
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.	✓	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.
Cumulative survival rates 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.	✓	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.
Device survival time starts to count with closure of the wound intraoperatively.	✓	All failures are counted that occur any time after wound closure.

†† CSR is identical to Cumulative Survival Percentage (CSP).

Graphical representation

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

RECEIVER / STIMULATOR	IMPLANTS
CI500 Series	• Cochlear Nucleus CI512 cochlear implant • Cochlear Nucleus CI513 cochlear implant** • Cochlear Nucleus CI551 cochlear implant** • Cochlear Nucleus ABI541 Auditory Brainstem Implant**
CI24RE	• Nucleus Freedom with Contour Advance Electrode • Nucleus Freedom with Straight Electrode • Cochlear Nucleus CI422 cochlear implant with Slim Straight Electrode** • Cochlear Hybrid L24 cochlear 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

** Approved in some countries.

1. International Organization for Standardization, International Standard ISO 5481-2 Implants for Surgery - Cardiac Pacemakers – Part 2: Reporting of Clinical Performance of Populations of Pulse Generators or Leads, Oct 15, 2000.
2. European Consensus Statement on Cochlear Implant Failures and Explantations. Otol Neurotol. 26: 1097-1099, 2005.
3. Battmer RD, Backous DD, Balkany TJ, Briggs RJS , Gantz BJ, van Hasselt A, Kim CS, Kubo T, Lenarz T, Pillsbury HC, O'Donoghue GM. International Classification of Reliability for Implanted Cochlear Implant Receiver Stimulators, Otol Neurotol, 2010.

NOTES

NOTES

Hear now. And always

As the global leader in hearing solutions, Cochlear is dedicated to bringing the gift of sound to people all over the world. With our hearing solutions, Cochlear has reconnected over 250,000 people to their families, friends and communities in more than 100 countries.

Along with the industry's largest investment in research and development, we continue to partner with leading international researchers and hearing professionals, ensuring that we are at the forefront in the science of hearing.

For the hearing impaired receiving any one of Cochlear's hearing solutions, our commitment is that for the rest of their life they will Hear now. And always

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