Cochlear™

Nucleus® Reliability Report

Nucleus® Reliability Report Volume 8 | June 2011

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Cochlear™

About Cochlear's reliability reporting

Since launching the world's first multi-channel cochlear implant system in 1982, reliability has been a focus for Cochlear. This report presents the reliability of all Nucleus Cochlear implants.

What gets reported?

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 Statement, 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 each device of all implant models and registered recipients worldwide. Results for adults and children are shown separately with 95% confidence intervals as specifically required by the consensus statement.

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). Importantly, these data cover the entire life of each device, and all registered recipients worldwide.

Cumulative Survival Percentage

The Cumulative Survival Percentage (CSP) 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.

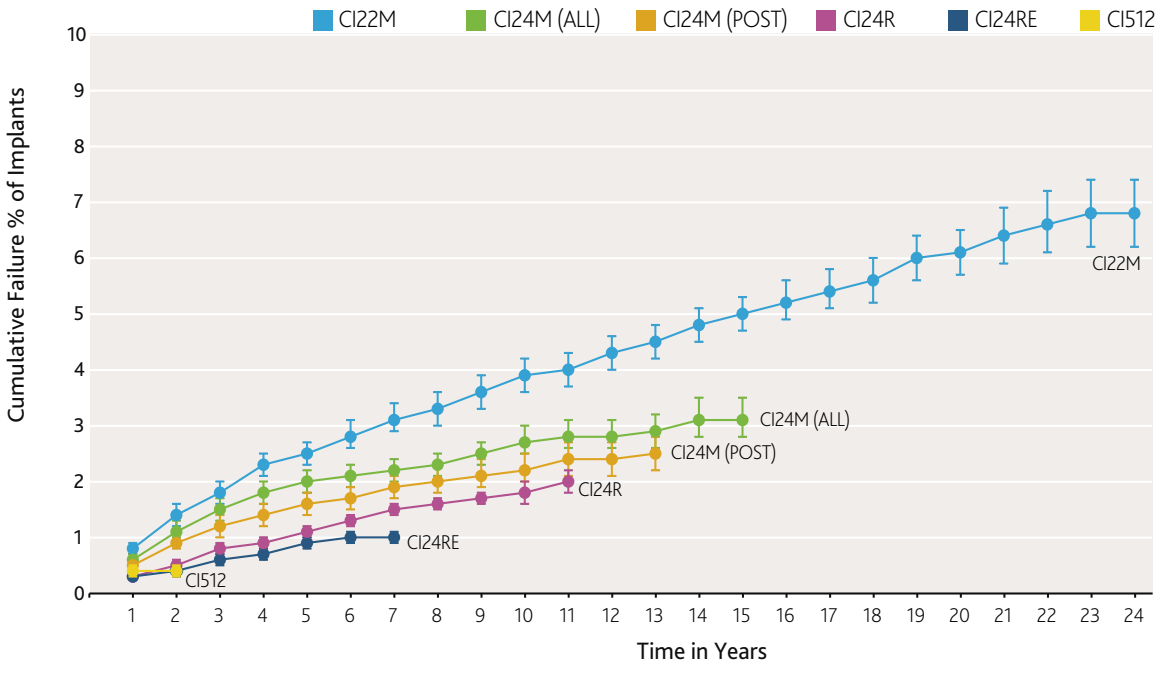
$$CSP = \frac{\text{Devices that have survived for at least "x" years X 100\%}}{\text{All devices implanted for at least "x" years}}$$

Cumulative Failure Percentage

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

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

Nucleus Implant Reliability



ALL PATIENTS COMBINED AS AT JUNE 2011

Implant Reliability June 2011

Number of registered implants* as at June 2011

DEVICE	ADULT	CHILD	COMBINED
CI512	11,913	10,765	22,678
CI24RE	27,870	33,284	61,154
CI24R	17,863	31,014	48,877
CI24M (All)	7,688	11,697	19,385
CI22M	9,959	8,223	18,182

* Note: Implant registrations often lag surgery dates by up to 6 months.

Cumulative Survival Percentage (CSP)

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
CI22M	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	94.6	94.4	94.0	93.9	93.6	93.4	93.2	93.2
CI24M (All)	99.4	98.9	98.5	98.2	98.0	97.9	97.8	97.7	97.5	97.3	97.2	97.2	97.1	96.9	96.9	-	-	-	-	-	-	-	-	-
CI24M (Post)	99.5	99.1	98.8	98.6	98.4	98.3	98.1	98.0	97.9	97.8	97.6	97.6	97.5	-	-	-	-	-	-	-	-	-	-	-
CI24R	99.7	99.5	99.2	99.1	98.9	98.7	98.5	98.4	98.3	98.2	98.0	-	-	-	-	-	-	-	-	-	-	-	-	-
CI24RE	99.7	99.6	99.4	99.3	99.1	99.0	99.0	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
CI512	99.6	99.6	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

The Cumulative Survival Percentage (CSP) 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.

Cumulative Failure Percentage (CFP)

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
CI22M	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	5.4	5.6	6.0	6.1	6.4	6.6	6.8	6.8
CI24M (All)	0.6	1.1	1.5	1.8	2.0	2.1	2.2	2.3	2.5	2.7	2.8	2.8	2.9	3.1	3.1	–	–	–	–	–	–	–	–	–
CI24M (Post)	0.5	0.9	1.2	1.4	1.6	1.7	1.9	2.0	2.1	2.2	2.4	2.4	2.5	–	–	–	–	–	–	–	–	–	–	–
CI24R	0.3	0.5	0.8	0.9	1.1	1.3	1.5	1.6	1.7	1.8	2.0	–	–	–	–	–	–	–	–	–	–	–	–	–
CI24RE	0.3	0.4	0.6	0.7	0.9	1.0	1.0	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
CI512	0.4	0.4	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–

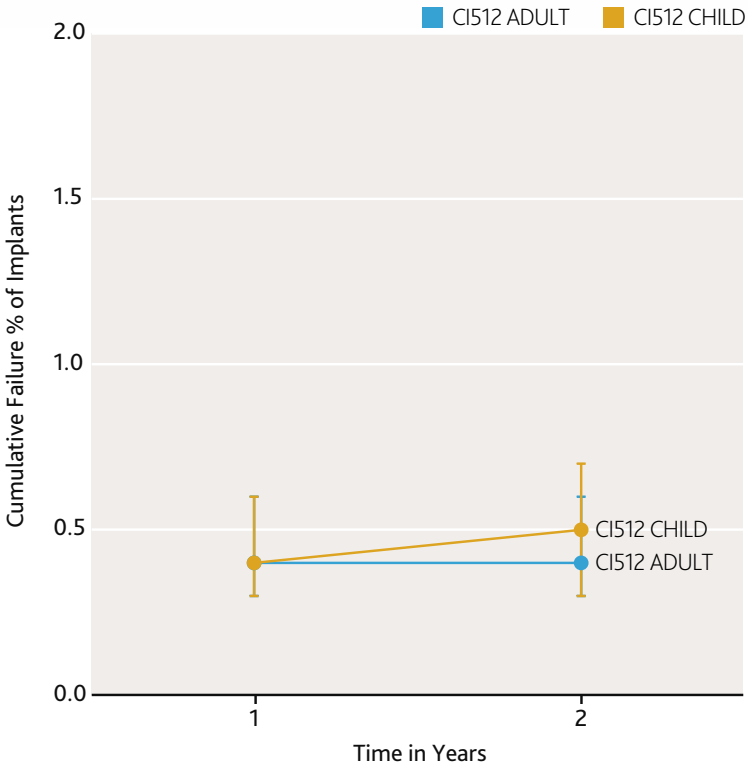
The Cumulative Failure Percentage (CFP) is the cumulative percentage of implants that are no longer functioning after a given period of time.

CI512 Implant

Within two years, CSP is 99.6% for adults and 99.5% for children.

The CI512 implant was commercially released in June 2009 and is the thinnest titanium implant in the industry, 40% thinner than our previous generation, making it the ideal choice for all ages - even the smallest children. The mechanical architecture of CI512 was redesigned to reduce the thickness of the implant while increasing its strength.

CI512 Reliability



ADULT/CHILD DATA AS AT JUNE 2011

Cumulative Survival Percentage (CSP)

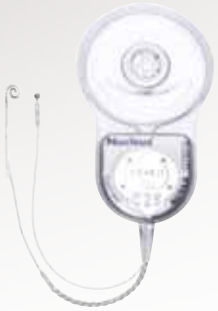
YEAR	1	2
CI512 Adult	99.6	99.6
CI512 Child	99.6	99.5

Cumulative Failure Percentage (CFP)

YEAR	1	2
CI512 Adult	0.4	0.4
CI512 Child	0.4	0.5

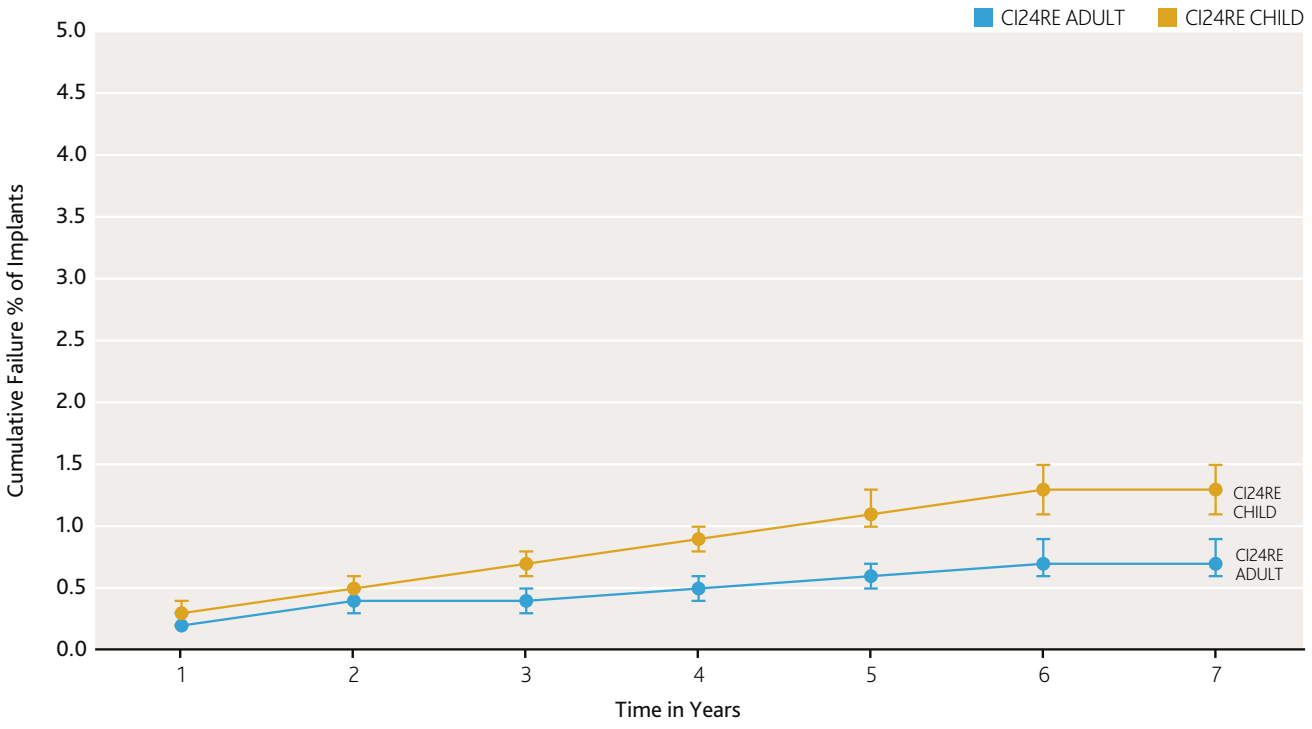
CI24RE Implant

At seven years, CSP is 99.3% for adults 98.7%for children.



The Freedom implant, commercially launched in 2005, has improved electronic capabilities compared with previous implants. Significant advantages include the availability of telemetry enabling new AutoNRT™ functionality. The Freedom implant has the same small physical packaging and accrues the same surgical benefits as the CI24R implant. In addition, the Freedom implant was strengthened to protect the sensitive electronics against external impact.

CI24RE Reliability



ADULT/CHILD DATA AS AT JUNE 2011

Cumulative Survival Percentage (CSP)

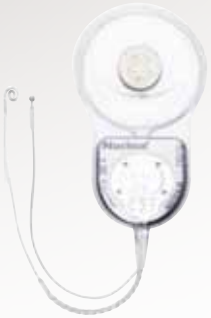
YEAR	1	2	3	4	5	6	7
CI24RE Adult	99.8	99.6	99.6	99.5	99.4	99.3	99.3
CI24RE Child	99.7	99.5	99.3	99.1	98.9	98.7	98.7

Cumulative Failure Percentage (CFP)

YEAR	1	2	3	4	5	6	7
CI24RE Adult	0.2	0.4	0.4	0.5	0.6	0.7	0.7
CI24RE Child	0.3	0.5	0.7	0.9	1.1	1.3	1.3

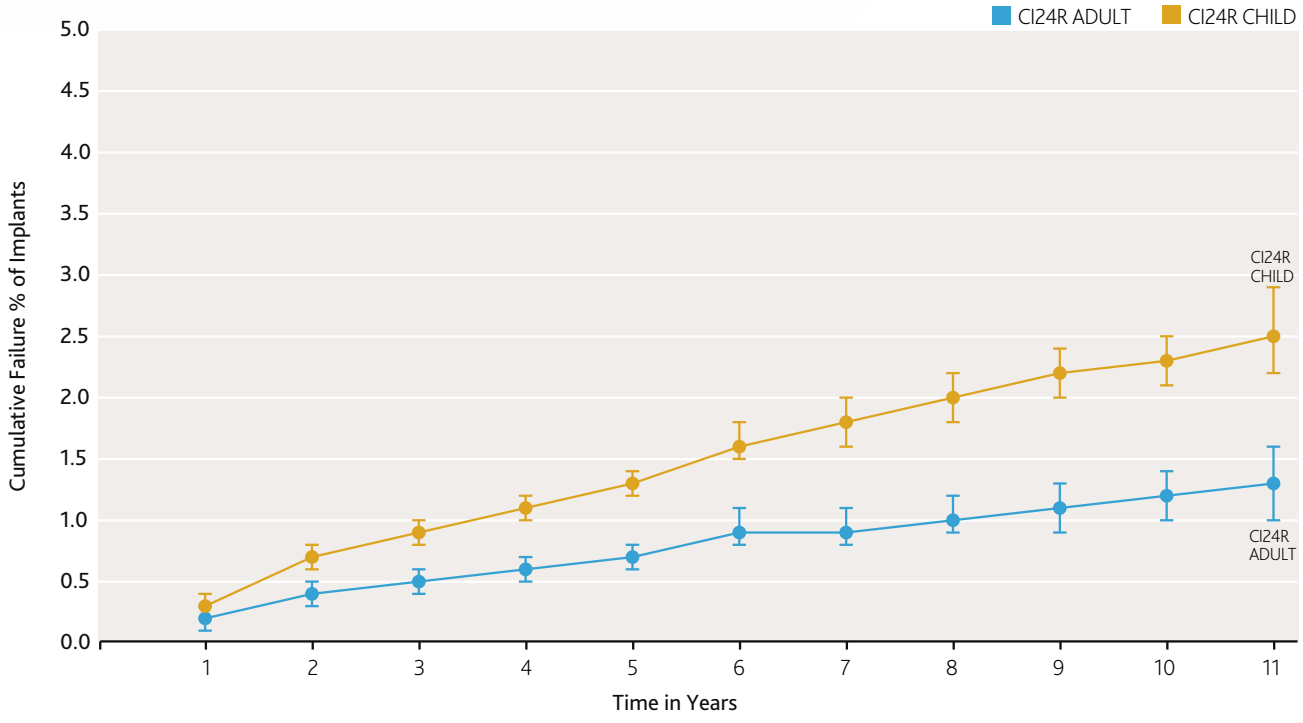
CI24R Implant

At eleven years, CSP is 98.7% for adults and 97.5% for children.



The CI24R, released in 2000, was made available with perimodiolar (Nucleus® 24 Contour™) and straight (Nucleus® 24k) electrode arrays with 22 intracochlear electrodes. The dimensions of the CI24R implant housing were considerably smaller than those of the CI24M, and the housing was designed with a low profile to allow very young children (older than 12 months) to be considered for implantation. The CI24R implant is well suited to minimal-access surgery. The enhanced design of the Contour Advance™ electrode, introduced in 2003, was designed to minimise force on sensitive structures of the cochlea, and to provide ease of insertion of the electrode array with minimal insertion force.

CI24R Reliability



ADULT/CHILD DATA AS AT JUNE 2011

Cumulative Survival Percentage (CSP)

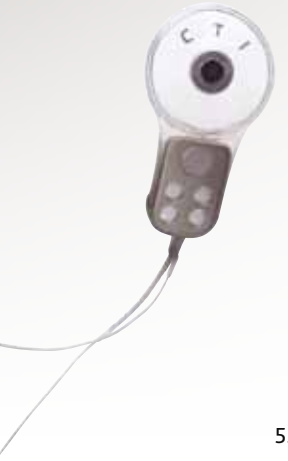
YEAR	1	2	3	4	5	6	7	8	9	10	11
CI24R Adult	99.8	99.6	99.5	99.4	99.3	99.1	99.1	99.0	98.9	98.8	98.7
CI24R Child	99.7	99.3	99.1	98.9	98.7	98.4	98.2	98.0	97.8	97.7	97.5

Cumulative Failure Percentage (CFP)

YEAR	1	2	3	4	5	6	7	8	9	10	11
CI24R Adult	0.2	0.4	0.5	0.6	0.7	0.9	0.9	1.0	1.1	1.2	1.3
CI24R Child	0.3	0.7	0.9	1.1	1.3	1.6	1.8	2.0	2.2	2.3	2.5

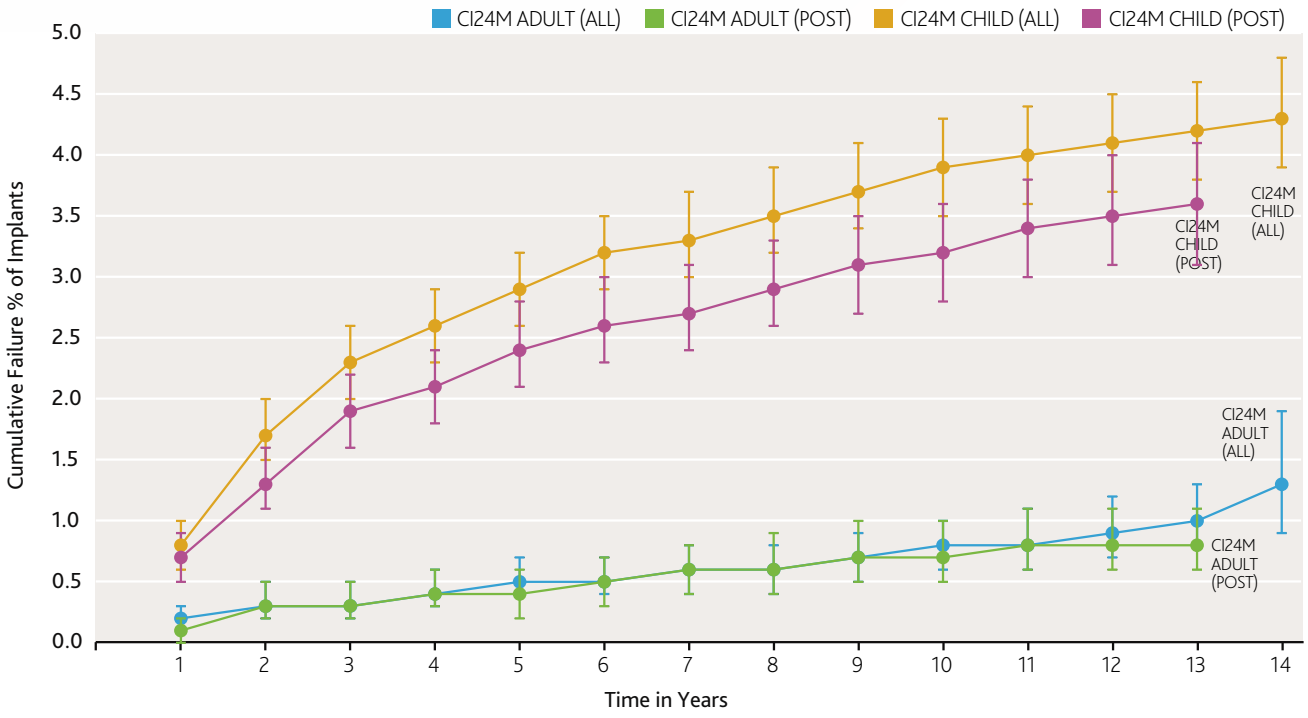
CI24M Implant

At fourteen years, CSP is 98.7% for adults and 95.7% for children.



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 an additional lead wire connected to a ball electrode, enabling monopolar stimulation mode. In addition, 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



ADULT/CHILD DATA AS AT JUNE 2011

Cumulative Survival Percentage (CSP)

YEAR	1	2	3	4	5	6	7	8	9	10	11	12	13	14
CI24M Adult (All)	99.8	99.7	99.7	99.6	99.5	99.5	99.4	99.4	99.3	99.2	99.2	99.1	99.0	98.7
CI24M Child (All)	99.2	98.3	97.7	97.4	97.1	96.8	96.7	96.5	96.3	96.1	96.0	95.9	95.8	95.7
CI24M Adult (Post)	99.9	99.7	99.7	99.6	99.6	99.5	99.4	99.4	99.3	99.3	99.2	99.2	99.2	-
CI24M Child (Post)	99.3	98.7	98.1	97.9	97.6	97.4	97.3	97.1	96.9	96.8	96.6	96.5	96.4	-

Cumulative Failure Percentage (CFP)

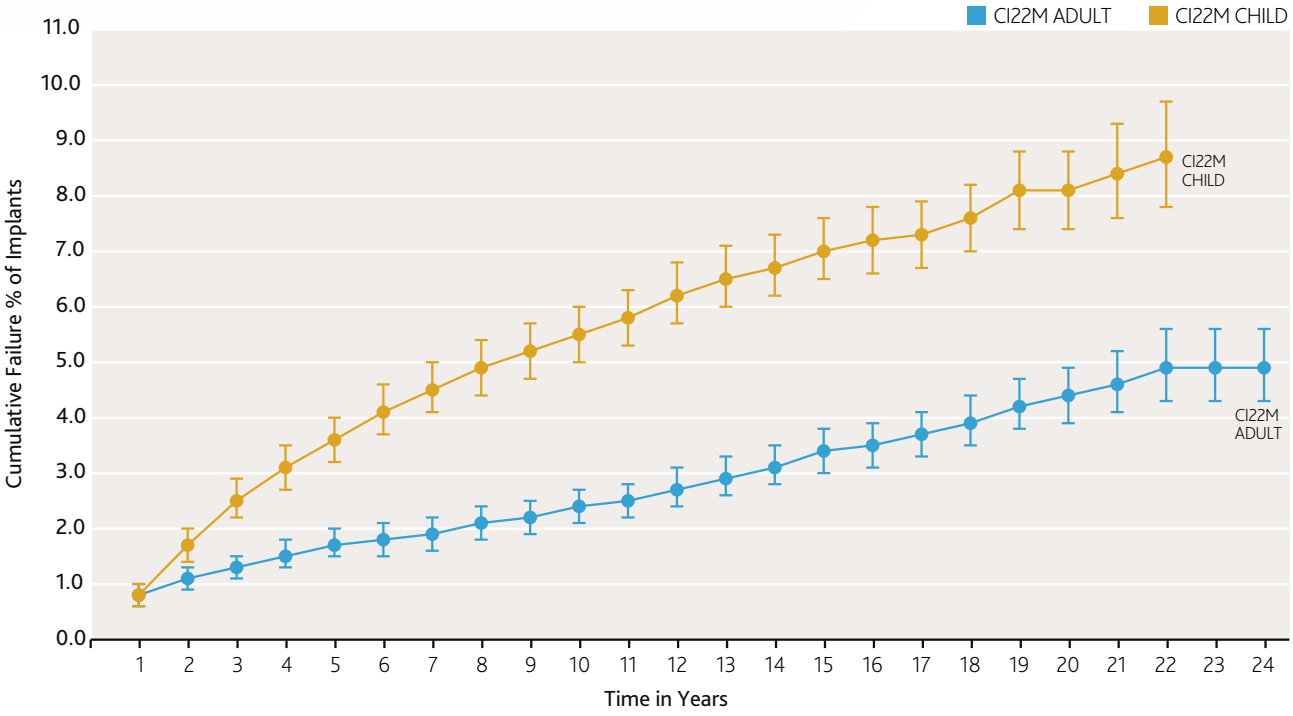
YEAR	1	2	3	4	5	6	7	8	9	10	11	12	13	14
CI24M Adult (All)	0.2	0.3	0.3	0.4	0.5	0.5	0.6	0.6	0.7	0.8	0.8	0.9	1.0	1.3
CI24M Child (All)	0.8	1.7	2.3	2.6	2.9	3.2	3.3	3.5	3.7	3.9	4.0	4.1	4.2	4.3
CI24M Adult (Post)	0.1	0.3	0.3	0.4	0.4	0.5	0.6	0.6	0.7	0.7	0.8	0.8	0.8	-
CI24M Child (Post)	0.7	1.3	1.9	2.1	2.4	2.6	2.7	2.9	3.1	3.2	3.4	3.5	3.6	-

CI22M Implant

At twenty-four years, CSP is 95.1% for adults and at 22 years CSP is 91.3% for children.

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



ADULT/CHILD DATA AS AT JUNE 2011

Cumulative Survival Percentage (CSP)

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
CI22M Adult	99.2	98.9	98.7	98.5	98.3	98.2	98.1	97.9	97.8	97.6	97.5	97.3	97.1	96.9	96.6	96.5	96.3	96.1	95.8	95.6	95.4	95.1	95.1	95.1
CI22M Child	99.2	98.3	97.5	96.9	96.4	95.9	95.5	95.1	94.8	94.5	94.2	93.8	93.5	93.3	93.0	92.8	92.7	92.4	91.9	91.9	91.6	91.3	-	-

Cumulative Failure Percentage (CFP)

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
CI22M Adult	0.8	1.1	1.3	1.5	1.7	1.8	1.9	2.1	2.2	2.4	2.5	2.7	2.9	3.1	3.4	3.5	3.7	3.9	4.2	4.4	4.6	4.9	4.9	4.9
CI22M Child	0.8	1.7	2.5	3.1	3.6	4.1	4.5	4.9	5.2	5.5	5.8	6.2	6.5	6.7	7.0	7.2	7.3	7.6	8.1	8.1	8.4	8.7	-	-

100% 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, categorization 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. All patients and all devices implanted (since 1985) are included.
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. As usual, this Nucleus 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 anytime after wound closure.

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 with Contour Advance electrode
CI24RE	• Nucleus Freedom with Contour Advance electrode • Nucleus Freedom with straight electrode
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

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 (in print), 2010

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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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