

Nucleus® Reliability Report

Volume 6 | June 2009

Introduction

Cochlear's industry leading implant reliability reflects our lifetime commitment to recipients. Since the release of Cochlear's first multi-channel system in 1982, there have been many improvements in cochlear implant technology, and in recipient outcomes. Cochlear has produced several generations of Nucleus® cochlear implants, with each successive generation of implant more reliable than the last.

Cochlear applies the lessons it learns from each generation of implant to the next generation to improve reliability and recipient outcomes. In 2005, the Nucleus® Freedom™ cochlear implant system was released. After five years, the Freedom or CI24RE implant reliability data continues to demonstrate excellent reliability. After five years on the market, the Cumulative Failure Percentage (CFP) of the Freedom implant is (per June 2009 data) 0.84% for adults and children combined.

As of June 30 2009, there were 46,047 successful surgeries conducted with the Nucleus Freedom cochlear implant, and 127,455 successful Nucleus cochlear implant surgeries conducted in total.

Results summary

Nucleus® Freedom™ – CI24RE

- At five years, CFP is 0.70% for adults and 0.95% for children.

Nucleus® 24 – CI24R

- At nine years, CFP is 0.9% for adults and 2.0% for children.

Nucleus® 24 – CI24M (All)

- At 12 years, CFP is 0.9% for adults and 3.9% for children.

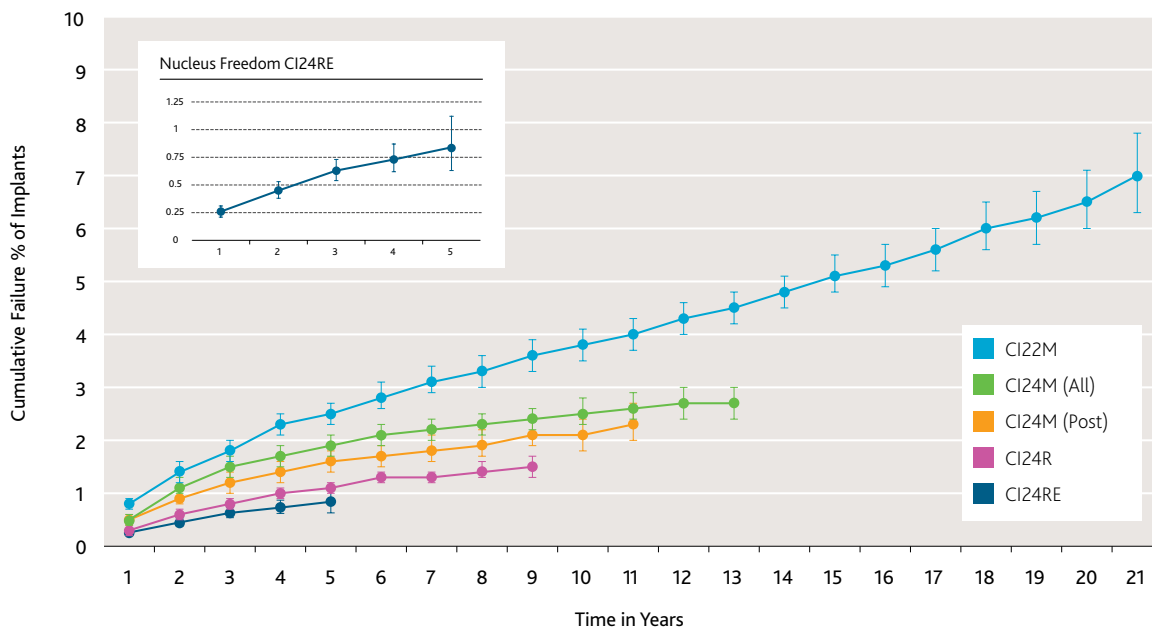
Nucleus® 22 – CI22M

- At 21 years, CFP is 5.4% for adults, and at 20 years CFP is 8.5% for children.

Successful Surgeries as of 30 June 2009

DEVICE	ADULT	CHILD	TOTAL
CI24RE	22,034	24,013	46,047
CI24R	17,266	26,841	44,107
CI24M (All)	7,569	11,562	19,131
CI22M	9,946	8,224	18,170

Nucleus Implants Reliability



ALL PATIENTS COMBINED AS OF 30 JUNE 2009

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
CI22M	0.8	1.4	1.8	2.3	2.5	2.8	3.1	3.3	3.6	3.8	4.0	4.3	4.5	4.8	5.1	5.3	5.6	6.0	6.2	6.5	7.0
CI24M (All)	0.5	1.1	1.5	1.7	1.9	2.1	2.2	2.3	2.4	2.5	2.6	2.7	2.7	-	-	-	-	-	-	-	-
CI24M (Post)	0.5	0.9	1.2	1.4	1.6	1.7	1.8	1.9	2.1	2.1	2.3	-	-	-	-	-	-	-	-	-	-
CI24R	0.3	0.6	0.8	1.0	1.1	1.3	1.3	1.4	1.5	-	-	-	-	-	-	-	-	-	-	-	-
CI24RE	0.26	0.45	0.63	0.73	0.84	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Cumulative Survival Percentage (CSP)

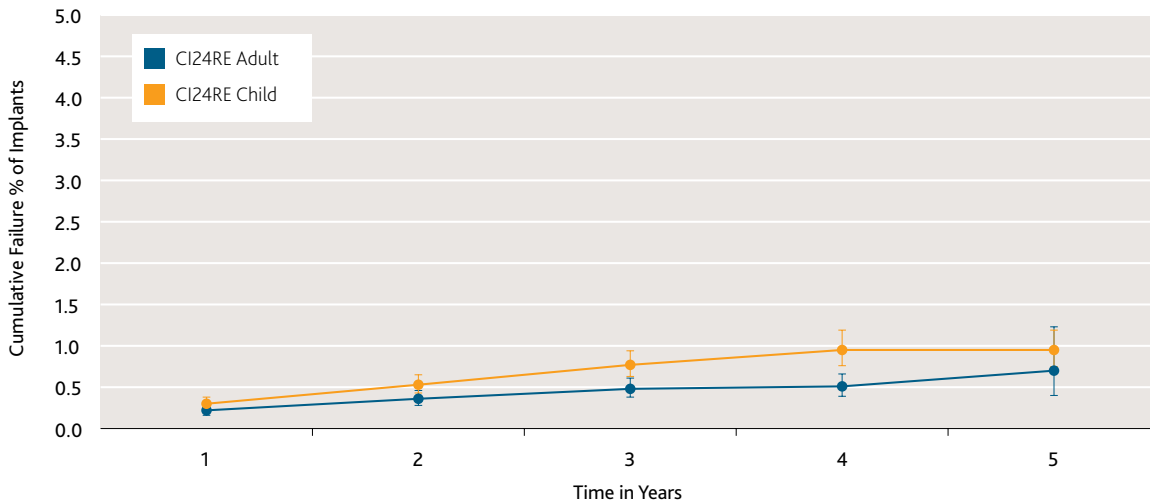
YEAR	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
CI22M	99.2	98.6	98.2	97.7	97.5	97.2	96.9	96.7	96.4	96.2	96.0	95.7	95.5	95.2	94.9	94.7	94.4	94.0	93.8	93.5	93.0
CI24M (All)	99.5	98.9	98.5	98.3	98.1	97.9	97.8	97.7	97.6	97.5	97.4	97.3	97.3	-	-	-	-	-	-	-	-
CI24M (Post)	99.5	99.1	98.8	98.6	98.4	98.3	98.2	98.1	97.9	97.9	97.7	-	-	-	-	-	-	-	-	-	-
CI24R	99.7	99.4	99.2	99.0	98.9	98.7	98.7	98.6	98.5	-	-	-	-	-	-	-	-	-	-	-	-
CI24RE	99.74	99.55	99.37	99.27	99.16	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

CI24RE Implant

At five years, CFP is 0.70% for adults and 0.95% for children.

The Freedom implant, commercially launched in 2005, has improved electronic capabilities compared with previous implants. Significant advantages include more efficient asynchronous stimulation and 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



ALL PATIENTS COMBINED AS OF 30 JUNE 2009

Cumulative Failure Percentage (CFP)

YEAR	1	2	3	4	5
CI24RE Adult	0.22	0.36	0.48	0.51	0.70
CI24RE Child	0.30	0.53	0.77	0.95	0.95

Cumulative Survival Percentage (CSP)

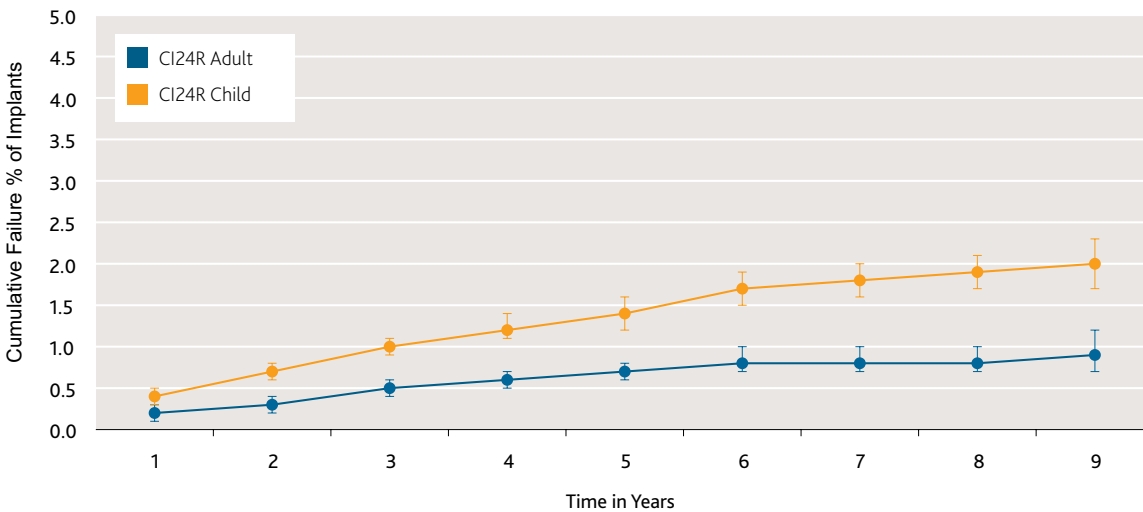
YEAR	1	2	3	4	5
CI24RE Adult	99.78	99.64	99.52	99.49	99.30
CI24RE Child	99.70	99.47	99.23	99.05	99.05

CI24R Implant

At nine years, CFP is 0.9% for adults and 2.0% 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 minimize force on sensitive structures of the cochlea, and to provide ease of insertion of the electrode array with minimal insertion force.

CI24R Reliability



ALL PATIENTS COMBINED AS OF 30 JUNE 2009

Cumulative Failure Percentage (CFP)

YEAR	1	2	3	4	5	6	7	8	9
CI24R Adult	0.2	0.3	0.5	0.6	0.7	0.8	0.8	0.8	0.9
CI24R Child	0.4	0.7	1.0	1.2	1.4	1.7	1.8	1.9	2.0

Cumulative Survival Percentage (CSP)

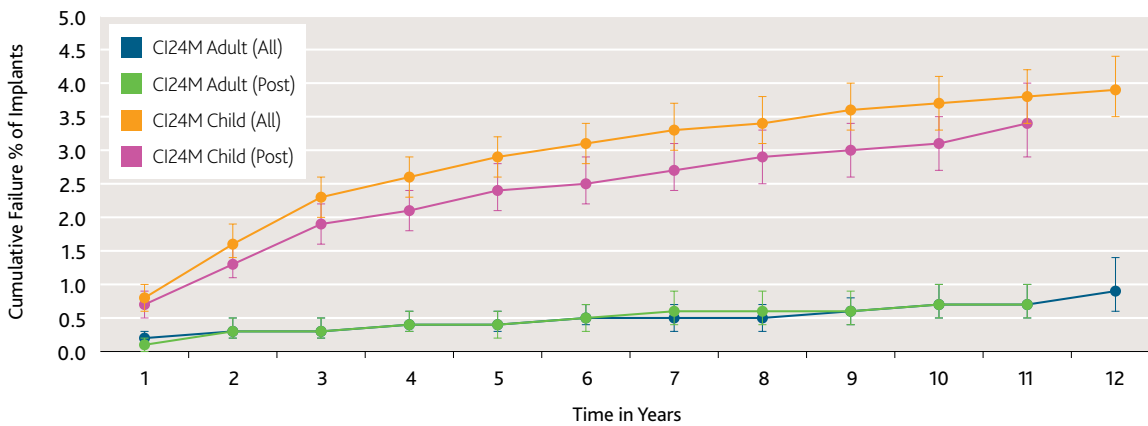
YEAR	1	2	3	4	5	6	7	8	9
CI24R Adult	99.8	99.7	99.5	99.4	99.3	99.2	99.2	99.2	99.1
CI24R Child	99.6	99.3	99.0	98.8	98.6	98.3	98.2	98.1	98.0

CI24M Implant

At 12 years, CFP is 0.9% for adults and 3.9% 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, intended to be placed under the temporalis muscle. 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



ALL PATIENTS COMBINED AS OF 30 JUNE 2009

Cumulative Failure Percentage (CFP)

YEAR	1	2	3	4	5	6	7	8	9	10	11	12
CI24M Adult (All)	0.2	0.3	0.3	0.4	0.4	0.5	0.5	0.5	0.6	0.7	0.7	0.9
CI24M Child (All)	0.8	1.6	2.3	2.6	2.9	3.1	3.3	3.4	3.6	3.7	3.8	3.9
CI24M Adult (Post)	0.1	0.3	0.3	0.4	0.4	0.5	0.6	0.6	0.6	0.7	0.7	-
CI24M Child (Post)	0.7	1.3	1.9	2.1	2.4	2.5	2.7	2.9	3.0	3.1	3.4	-

Cumulative Survival Percentage (CSP)

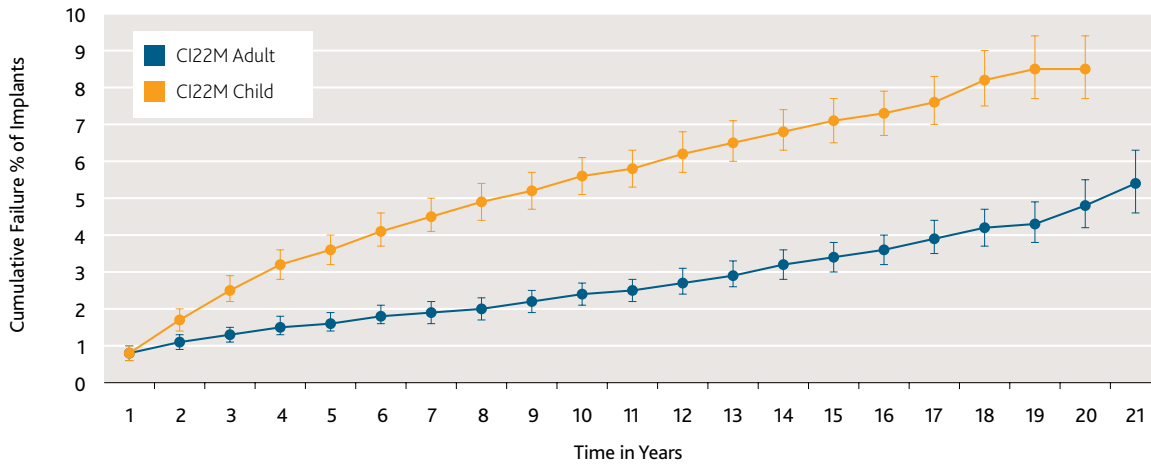
YEAR	1	2	3	4	5	6	7	8	9	10	11	12
CI24M Adult (All)	99.8	99.7	99.7	99.6	99.6	99.5	99.5	99.5	99.4	99.3	99.3	99.1
CI24M Child (All)	99.2	98.4	99.7	97.4	97.1	96.9	96.7	96.6	96.4	96.3	96.2	96.1
CI24M Adult (Post)	99.9	99.7	99.7	99.6	99.6	99.5	99.4	99.4	99.4	99.3	99.3	-
CI24M Child (Post)	99.3	98.7	98.1	97.9	97.6	97.5	97.3	97.1	97.0	96.9	96.6	-

CI22M Implant

At 21 years, CFP is 5.4% for adults, and at 20 years CFP is 8.5% for children.

The CI22M implant, released in 1985, was based on Cochlear's earliest model implant – the CS22. In 1986, the CI22M was released with an internal magnet to hold the external transmitting coil in place.

CI22M Reliability



ALL PATIENTS COMBINED AS OF 30 JUNE 2009

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
CI22M Adult	0.8	1.1	1.3	1.5	1.6	1.8	1.9	2.0	2.2	2.4	2.5	2.7	2.9	3.2	3.4	3.6	3.9	4.2	4.3	4.8	5.4
CI22M Child	0.8	1.7	2.5	3.2	3.6	4.1	4.5	4.9	5.2	5.6	5.8	6.2	6.5	6.8	7.1	7.3	7.6	8.2	8.5	8.5	-

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
CI22M Adult	99.2	98.9	98.7	98.5	98.4	98.2	98.1	98.0	97.8	97.6	97.5	97.3	97.1	96.8	96.6	96.4	96.1	95.8	95.7	95.2	94.6
CI22M Child	99.2	98.3	97.5	96.8	96.4	95.9	95.5	95.1	94.8	94.4	94.2	93.8	93.5	93.2	92.9	92.7	92.4	91.8	91.5	91.5	-

About the Nucleus Reliability Report

This report is prepared in accordance with International Standard ISO 5841-2:2000¹ and the reporting principles described in the European Consensus Statement on Cochlear Implant Failures and Explantations².

Cochlear has a long history of openly and regularly reporting device failures in accordance with these international standards and principles. This report has been produced for over 15 years to update cochlear implant professionals on the reliability of Nucleus implants in the field.

In compliance with the European Consensus Statement, Cochlear reports all failures in the reliability calculation, including those caused by external impact and electrode failures that lead to loss of clinical benefit. The data cover all implant models, and results for adults and children are shown separately with 95% confidence intervals.

Cumulative Survival Percentage

The Cumulative Survival Percentage (CSP) is the cumulative number of functioning implants over time and can be used to predict the reliability of the device within a given time period. The data in this report cover the entire life of each device and all registered recipients worldwide.

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

Cumulative Failure Percentage

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

$$\text{CFP} = [100 - \text{CSP}] \%$$

Graphical Representation

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

RECEIVER / STIMULATOR	IMPLANTS
CI24RE	<ul style="list-style-type: none">• Nucleus® Freedom™ with Contour Advance® electrode• Nucleus® Freedom™ with straight electrode
CI24R	<ul style="list-style-type: none">• Nucleus® 24 with Contour Advance® electrode• Nucleus® 24 with Contour™ electrode• Nucleus® 24k with straight electrode
CI24M	<ul style="list-style-type: none">• Nucleus® 24 with straight electrode• Nucleus® 24 with Double Array• Nucleus® 24 auditory brainstem implant [ABI]
CI22M	<ul style="list-style-type: none">• Nucleus® 22

References

- 1 International Organization for Standardization, International Standard ISO 5841-2 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. 2005 Nov; 26(6): 1097-1099.

Hear now. And always

This is Cochlear's promise to you. 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 180,000 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 your life you will Hear now. And always

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