Cochlear™

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Nucleus® Reliability Report

Introduction

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.

In 2005, Cochlear's latest generation cochlear implant system, Nucleus® Freedom™, was released. After three years, the Freedom or CI24RE implant reliability data continues to indicate excellent implant reliability. Hearing performance outcomes are also continuing to improve, with the three month CNC word score mean exceeding 50% for the first time in any industry publication[1].

The past 25 years have shown improved recipient benefits with implantation, which has led to expanding patient candidacy criteria and a growing acceptance of the safety and efficacy of cochlear implants. Implants are now being implanted in children as young as 12 months, for those with severe to profound hearing loss, and increasingly bilateral cochlear implantation is becoming the clinical standard.

Traditionally, cochlear implant candidates received a single cochlear implant. However, the emerging trend is to fit patients with an implant in each ear – bilateral cochlear implantation. Recently published data provides evidence to support bilateral implantation, and indicates that bilateral recipients can more effectively localize sound and achieve improved speech understanding in background noise[2-16]. Cochlear's history of consistent implant reliability and safety has been an important factor in meeting expanding candidature and recipient expectations for both unilateral and bilateral implantation.

As at 30 June 2007, there were 20,215 recipients with the Nucleus Freedom implant, and 94,926 Nucleus recipients in total. After three years on the market, the Cumulative Failure Percentage (CFP) of the Freedom implant is (per June data) 0.30% for adults and children combined.

Results Summary

Nucleus® Freedom™ – CI24RE
At three years, CFP is 0.23% for adults and 0.37% for children.

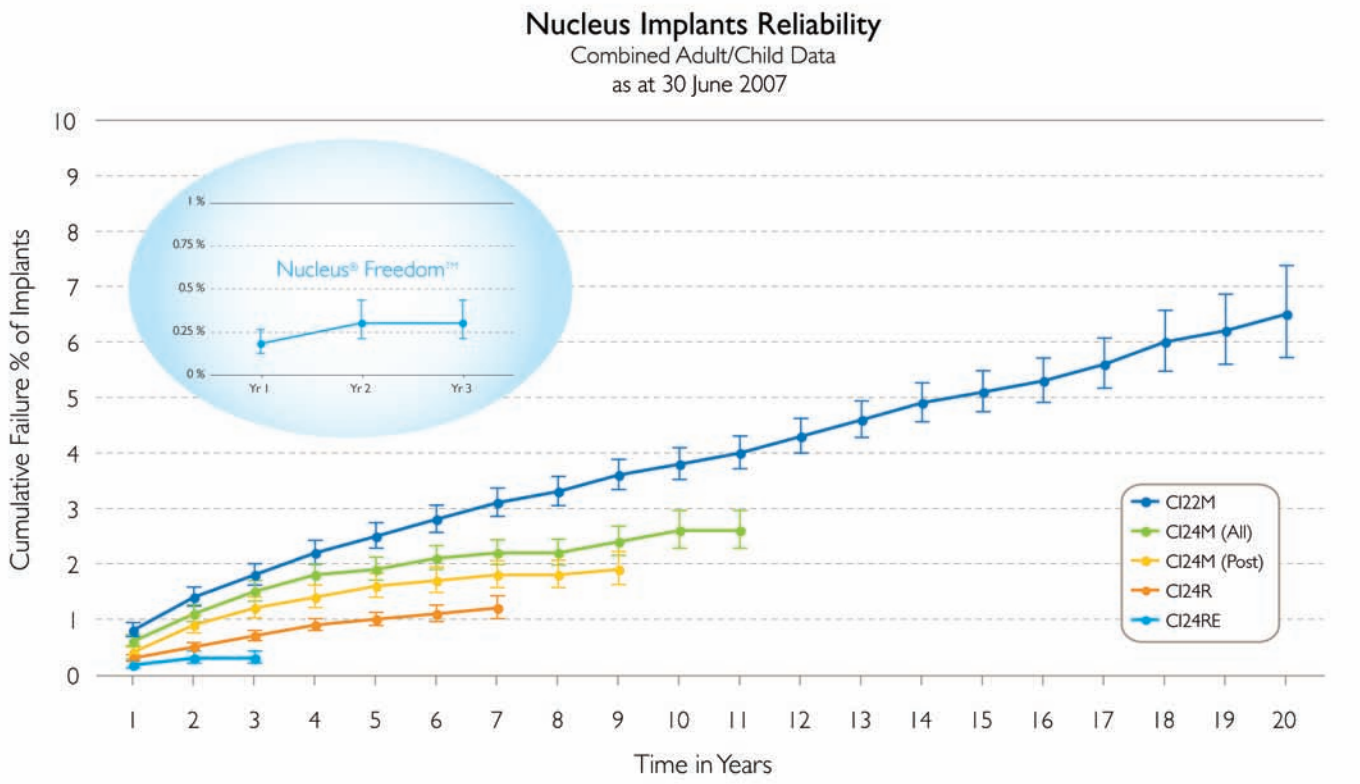
Nucleus® 24 – CI24R
At seven years, CFP is 0.9% for adults and 1.5% for children.

Nucleus® 24 – CI24M (All)
At 10 years, CFP is 0.8% for adults and 3.8% for children.

Nucleus® 22 – CI22M
At 20 years, CFP is 4.5% for adults, and at 18 years CFP is 8.9% for children.

Recipients as at 30 June 2007:

Device	Adult	Child	Total
CI24RE	10,225	9,990	20,215
C124R	16,247	21,543	37,790
CI24M(All)	7,409	11,343	18,752
CI22M	9,943	8,226	18,169



Cumulative Failure Percentage (CFP)

	Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Yr 8	Yr 9	Yr 10	Yr 11	Yr 12	Yr 13	Yr 14	Yr 15	Yr 16	Yr 17	Yr 18	Yr 19	Yr 20
CI22M	0.8	1.4	1.8	2.2	2.5	2.8	3.1	3.3	3.6	3.8	4.0	4.3	4.6	4.9	5.1	5.3	5.6	6.0	6.2	6.5
CI24M (All)	0.6	1.1	1.5	1.8	1.9	2.1	2.2	2.2	2.4	2.6	2.6	-	-	-	-	-	-	-	-	-
CI24M (Post)	0.4	0.9	1.2	1.4	1.6	1.7	1.8	1.8	1.9	-	-	-	-	-	-	-	-	-	-	-
CI24R	0.3	0.5	0.7	0.9	1.0	1.1	1.2	-	-	-	-	-	-	-	-	-	-	-	-	-
CI24RE	0.18	0.30	0.30	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Cumulative Survival Percentage (CSP)

	Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Yr 8	Yr 9	Yr 10	Yr 11	Yr 12	Yr 13	Yr 14	Yr 15	Yr 16	Yr 17	Yr 18	Yr 19	Yr 20
CI22M	99.2	98.6	98.2	97.8	97.5	97.2	96.9	96.7	96.4	96.2	96.0	95.7	95.4	95.1	94.9	94.7	94.4	94.0	93.8	93.5
CI24M (All)	99.4	98.9	98.5	98.2	98.1	97.9	97.8	97.8	97.6	97.4	97.4	-	-	-	-	-	-	-	-	-
CI24M (Post)	99.6	99.1	98.8	98.6	98.4	98.3	98.2	98.2	98.1	-	-	-	-	-	-	-	-	-	-	-
CI24R	99.7	99.5	99.3	99.1	99.0	98.9	98.8	-	-	-	-	-	-	-	-	-	-	-	-	-
CI24RE	99.82	99.70	99.70	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

CI24RE Implant

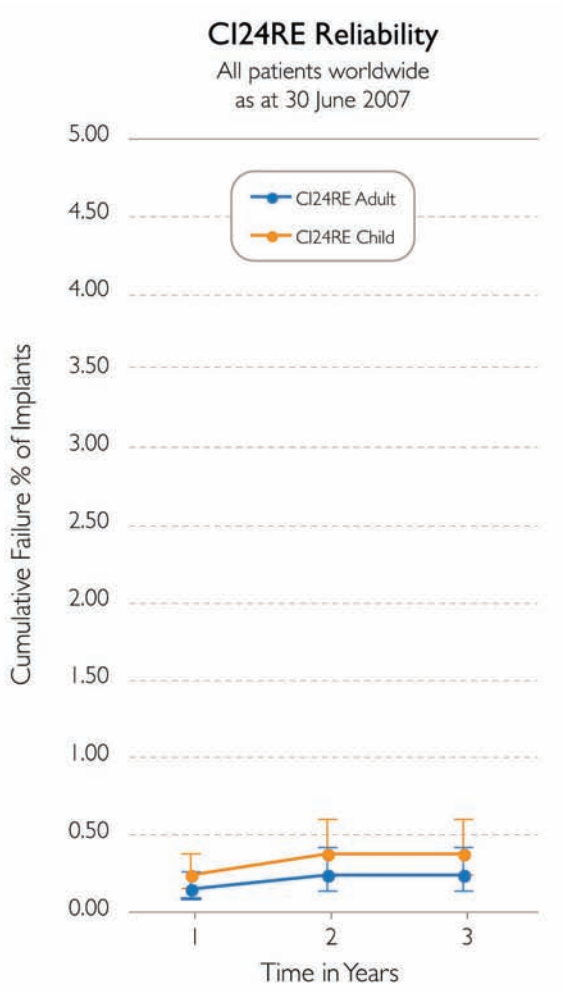
At three years, the CFP is 0.23% for adults and 0.37% for children.

The CI24RE, while continuing to meet minimal access surgery requirements, was improved in internal mechanical design, package strength, and electronic capabilities.

Changes in the implant package from the CI24M to the CI24R and CI24RE included modifications to the shape of the package and reductions in length and width. The CI24RE implant pedestal has a round base and vertical sides; thus drilling is simpler and the implant can be rotated in the bed at the time of implantation to optimize placement on the skull. The depth of the pedestal was also increased for more secure positioning in the mastoid bone.

The total length of the CI24RE is less than that of the CI24M, making it easier to match skull curvature, especially for small children. Extra internal space has been used to strengthen the implant against external impact.

The continued use of a titanium case to house the electronics also helps to reduce the effects of impact, as the titanium case is less likely to crack or shatter on direct impact than other housing materials, such as ceramics.



Cumulative Failure Percentage (CFP)

	Yr 1	Yr 2	Yr 3
CI24RE Adult	0.14	0.23	0.23
CI24RE Child	0.23	0.37	0.37

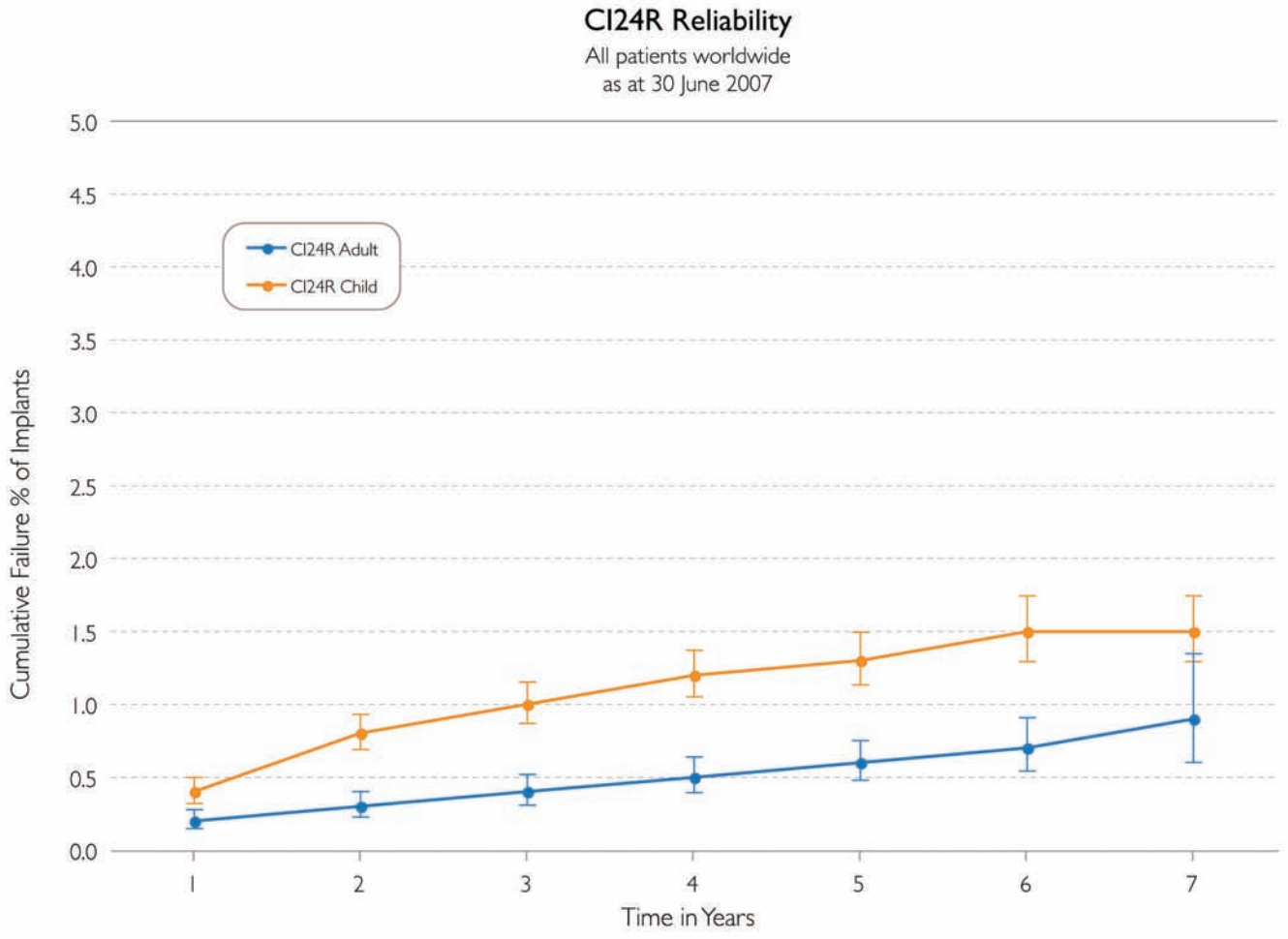
Cumulative Survival Percentage (CSP)

	Yr 1	Yr 2	Yr 3
CI24RE Adult	99.86	99.77	99.77
CI24RE Child	99.77	99.63	99.63

CI24R Implant

At eight years, the CFP is 0.9% for adults and 1.5% for children.

The CI24R implant was introduced in 2000. The implant has a perimodiolar array with 22 half-banded electrodes. The dimensions of the CI24R receiver-stimulator were considerably smaller than those of the CI24M and the package was designed with a low profile to allow very young children (older than 12 months) to be considered for implantation. The implant is well suited to minimal access surgery. The enhanced design of the Contour Advance™, introduced in 2003, was designed to minimize force on cochlea structures, and provide ease of insertion of the electrode array with minimal insertion force.



Cumulative Failure Percentage (CFP)

	Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7
CI24R Adult	0.2	0.3	0.4	0.5	0.6	0.7	0.9
CI24R Child	0.4	0.8	1.0	1.2	1.3	1.5	1.5

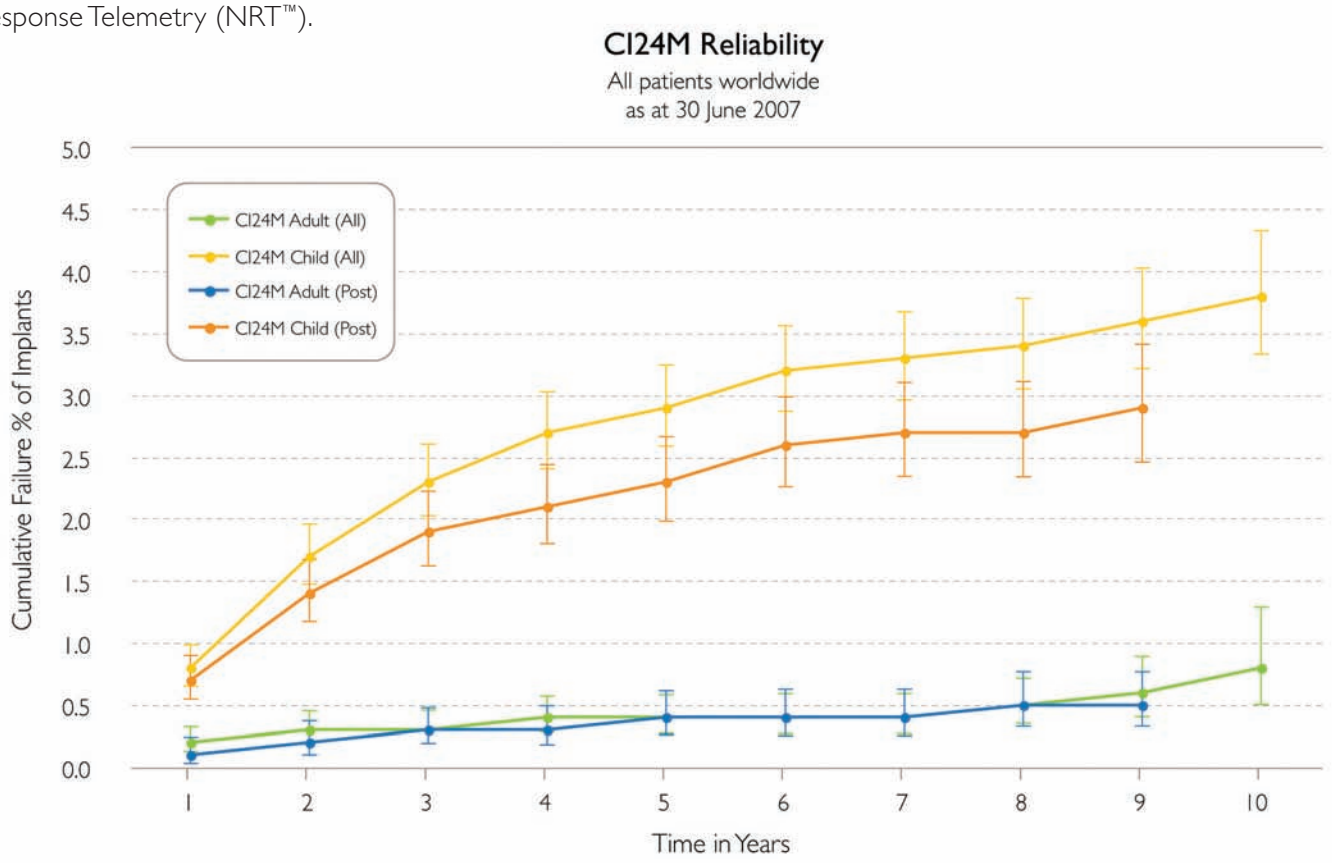
Cumulative Survival Percentage (CSP)

	Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7
CI24R Adult	99.8	99.7	99.6	99.5	99.4	99.3	99.1
CI24R Child	99.6	99.2	99.0	98.8	98.7	98.5	98.5

CI24M Implant

At 10 years, the CFP is 0.8% for adults and 3.8% for children.

The CI24M was released in 1997 and 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. The CI24M allowed for an increase in available pulse rates up to 14.4 kHz. 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™).



Cumulative Failure Percentage (CFP)

	Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Yr 8	Yr 9	Yr 10
CI24M Adult (All)	0.2	0.3	0.3	0.4	0.4	0.4	0.4	0.5	0.6	0.8
CI24M Child (All)	0.8	1.7	2.3	2.7	2.9	3.2	3.3	3.4	3.6	3.8
CI24M Adult (Post)	0.1	0.2	0.3	0.3	0.4	0.4	0.4	0.5	0.5	-
CI24M Child (Post)	0.7	1.4	1.9	2.1	2.3	2.6	2.7	2.7	2.9	-

Cumulative Survival Percentage (CSP)

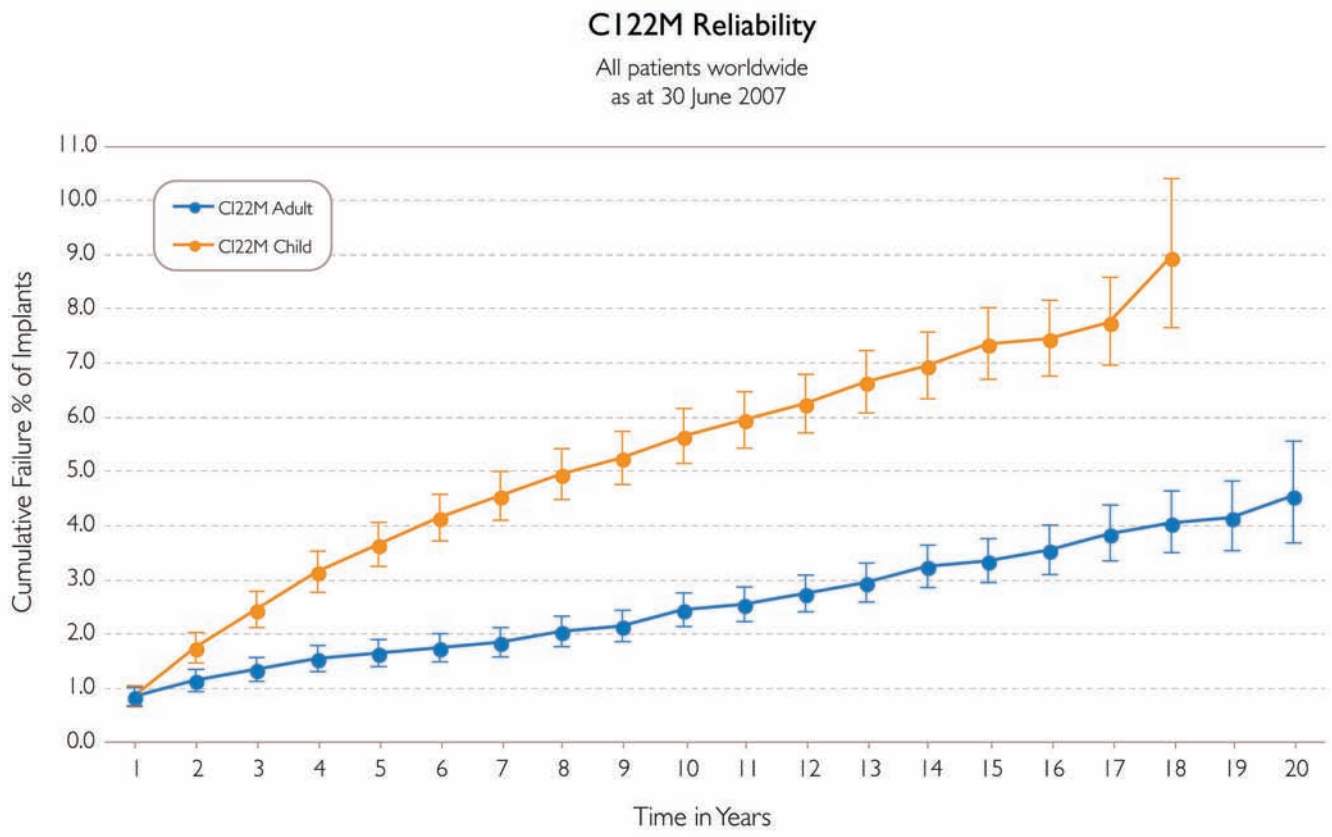
	Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Yr 8	Yr 9	Yr 10
CI24M Adult (All)	99.8	99.7	99.7	99.6	99.6	99.6	99.6	99.5	99.4	99.2
CI24M Child (All)	99.2	98.3	97.7	97.3	97.1	96.8	96.7	96.6	96.4	96.2
CI24M Adult (Post)	99.9	99.8	99.7	99.7	99.6	99.6	99.6	99.5	99.5	-
CI24M Child (Post)	99.3	98.6	98.1	97.9	97.7	97.4	97.3	97.3	97.1	-

Notes:
- 'All' refers to all devices manufactured.
- 'Post' (i.e. Post Modification) refers to devices with a strengthened case.

C122M Implant

At 20 years, CFP is 4.5% for adults, and at 18 years CFP is 8.9% for children.

The CI22M implant was initially released in 1985 and was based on Cochlear's earliest model implant, the CS22. Today, there are over 18,000 recipients with a CI22M device. In 1986, the CI22M was released with an internal magnet to hold the external transmitting coil in place.



Cumulative Failure Percentage (CFP)

	Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Yr 8	Yr 9	Yr 10	Yr 11	Yr 12	Yr 13	Yr 14	Yr 15	Yr 16	Yr 17	Yr 18	Yr 19	Yr 20
CI22M Adult	0.8	1.1	1.3	1.5	1.6	1.7	1.8	2.0	2.1	2.4	2.5	2.7	2.9	3.2	3.3	3.5	3.8	4.0	4.1	4.5
CI22M Child	0.8	1.7	2.4	3.1	3.6	4.1	4.5	4.9	5.2	5.6	5.9	6.2	6.6	6.9	7.3	7.4	7.7	8.9	-	-

Cumulative Survival Percentage (CSP)

	Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Yr 8	Yr 9	Yr 10	Yr 11	Yr 12	Yr 13	Yr 14	Yr 15	Yr 16	Yr 17	Yr 18	Yr 19	Yr 20
CI22M Adult	99.2	98.9	98.7	98.5	98.4	98.3	98.2	98.0	97.9	97.6	97.5	97.3	97.1	96.8	96.7	96.5	96.2	96.0	95.9	95.5
CI22M Child	99.2	98.3	97.6	96.9	96.4	95.9	95.5	95.1	94.8	94.4	94.1	93.8	93.4	93.1	92.7	92.6	92.3	91.1	-	-

About the Nucleus Reliability Report

This report has been produced for over 15 years, twice a year, to update cochlear implant professionals on the reliability of the Cochlear Nucleus implants in the field.

This report is prepared in accordance with International Standard ISO 5841-2[17] and the reporting principles described in the European Consensus Statement on Cochlear Implant Failures and Explantations[18].

The Cumulative Failure Percentage (CFP) demonstrates the percentage of devices that are no longer functioning over a given period of time. As the index is cumulative, a CFP that does not increase over time indicates no new failures. Cochlear includes all failures in the calculation, including those caused by external impact or electrode failures that lead to loss of clinical benefit. The data covers all implant models and results for adults and children are shown separately. The Cumulative Survival Percentage (CSP) is simply 100% minus the CFP. The CSP shows the cumulative number of functioning implants over time. The data in this report covers the entire life of each device and all registered recipients worldwide.

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

Receiver / Stimulator	Implants
CI24RE	Nucleus® Freedom™ with Contour Advance™ Electrode, and Nucleus® Freedom™ with Straight Electrode
C124R	Nucleus® 24 Contour Advance™, Nucleus® 24 Contour™
CI24M	Nucleus® 24, Nucleus® 24 Double Array and Nucleus® 24 ABI
CI22M	Nucleus® 22

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