

# Cochlear™

## Leading the Industry in Cochlear Implant Reliability



Cochlear™  
**Nucleus<sup>5</sup>**

The Cochlear Nucleus® CI512  
Cochlear Implant



red dot design award  
winner 2010

*Hear now. And always*

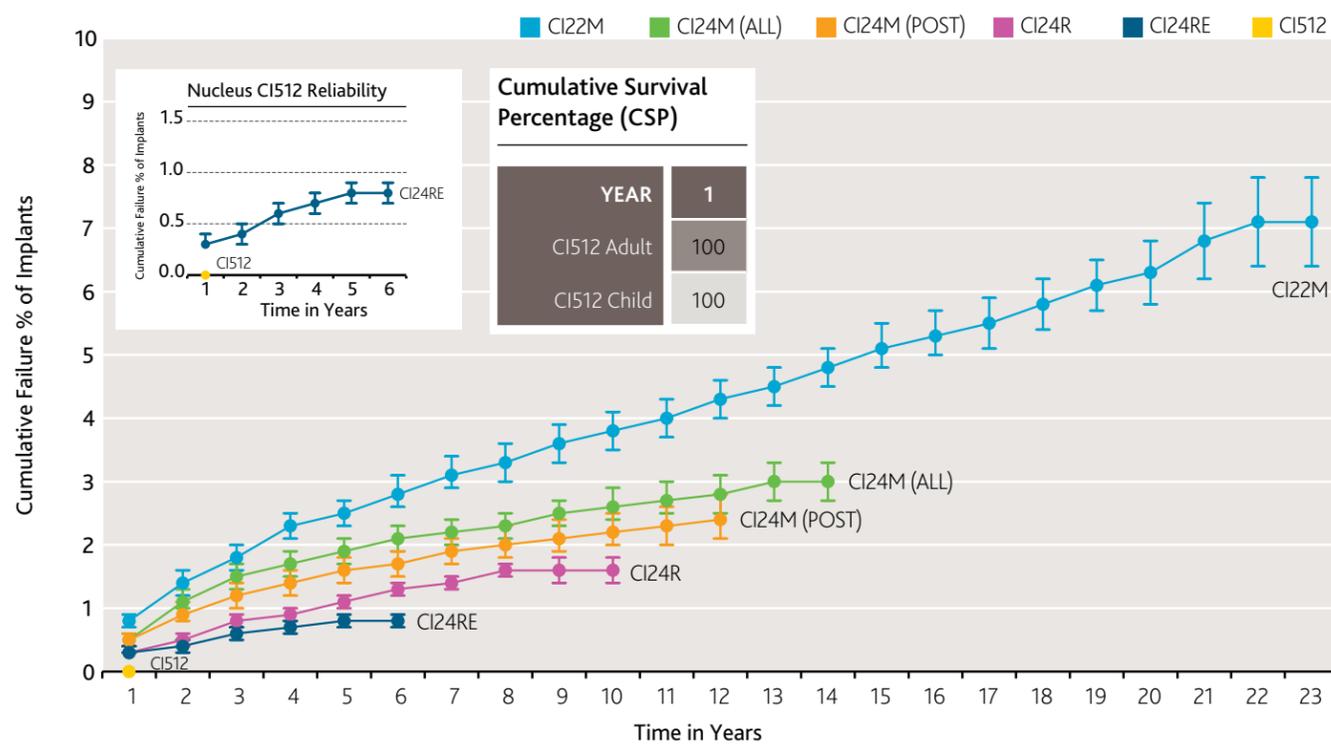


**Cochlear™**

# Nucleus® implant reliability

At Cochlear™, we take implant reliability seriously. Since launching the world's first cochlear implant system in 1982, each successive release of our Nucleus Cochlear Implant has been more reliable than the last. Now our latest generation implant - the Nucleus CI512 - continues this legacy in implant reliability. As of June 1, 2010 the Nucleus CI512 has achieved a 100% cumulative survival rate.

## Nucleus Implants Reliability



ALL PATIENTS COMBINED AS OF 1 JUNE 2010

## Registered Implants as of 1 June 2010

DEVICE	ADULT	CHILD	TOTAL
CI512	3,652	3,334	6,986
CI24RE	26,065	29,670	55,735
CI24R	17,573	28,452	46,025
CI24M (All)	7,632	11,638	19,270
CI22M	9,956	8,220	18,176

## 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
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	94.5	94.2	93.9	93.7	93.2	92.9	92.9
CI24M (All)	99.5	98.9	98.5	98.3	98.1	97.9	97.8	97.7	97.5	97.4	97.3	97.2	97.0	97.0	-	-	-	-	-	-	-	-	-
CI24M (Post)	99.5	99.1	98.8	98.6	98.4	98.3	98.1	98.0	97.9	97.8	97.7	97.6	-	-	-	-	-	-	-	-	-	-	-
CI24R	99.7	99.5	99.2	99.1	98.9	98.7	98.6	98.4	98.4	-	-	-	-	-	-	-	-	-	-	-	-	-	-
CI24RE	99.7	99.6	99.4	99.3	99.2	99.2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
CI512	100*	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

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.

## Cumulative Failure Percentage (CFP)

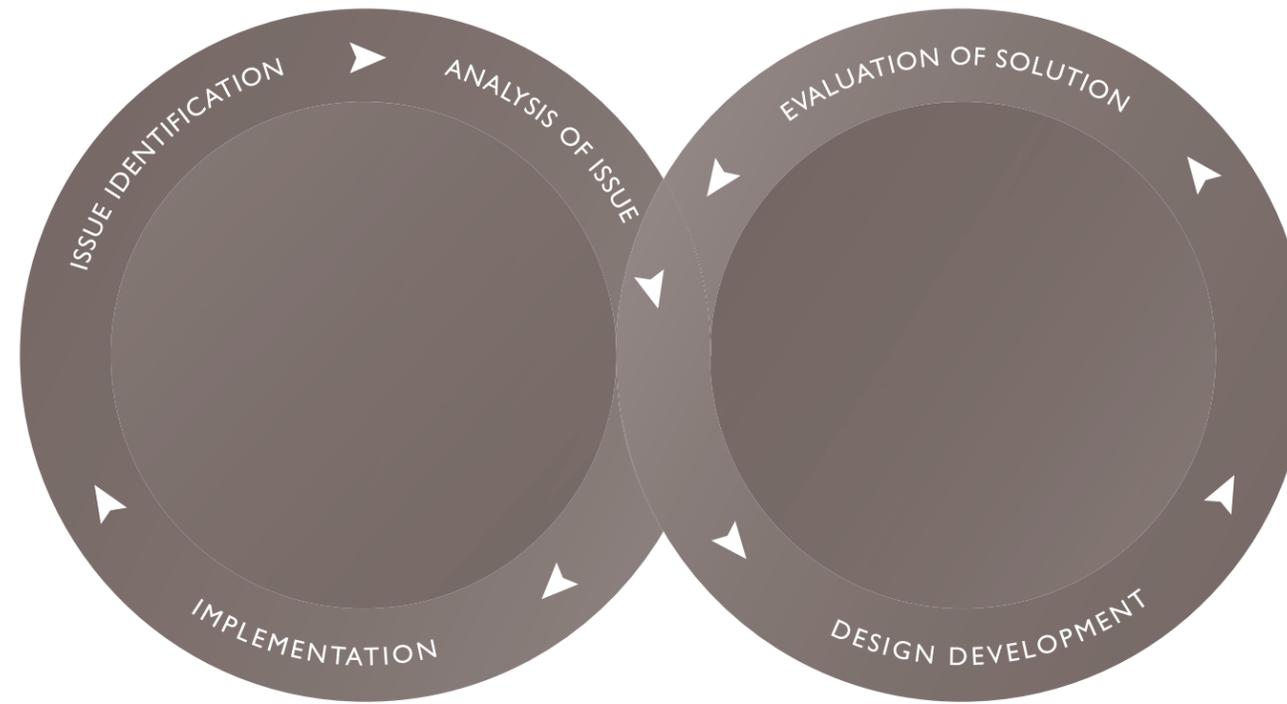
YEAR	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23
CI22M	0.8	1.4	1.8	2.3	2.5	2.8	3.1	3.3	3.6	3.8	4.0	4.3	4.5	4.8	5.1	5.3	5.5	5.8	6.1	6.3	6.8	7.1	7.1
CI24M (All)	0.5	1.1	1.5	1.7	1.9	2.1	2.2	2.3	2.5	2.6	2.7	2.8	3.0	3.0	-	-	-	-	-	-	-	-	-
CI24M (Post)	0.5	0.9	1.2	1.4	1.6	1.7	1.9	2.0	2.1	2.2	2.3	2.4	-	-	-	-	-	-	-	-	-	-	-
CI24R	0.3	0.5	0.8	0.9	1.1	1.3	1.4	1.6	1.6	-	-	-	-	-	-	-	-	-	-	-	-	-	-
CI24RE	0.3	0.4	0.6	0.7	0.8	0.8	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
CI512	0.0*	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

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

\* Within 1 year

# Commitment to continuous improvement

Over 25 years, Cochlear™ has released five generations of implants with the most recent being the Nucleus® CI512 Cochlear Implant. Following best practice in design processes Cochlear has applied the principles of continuous improvement in the design and development of these implant platforms. This philosophy of continuous improvement has resulted in each generation of implant being more reliable than the previous generation. Continuous improvement is also applied within the lifecycle of each generation of device.



1985

U.S. commercial release



CI22M

- Titanium encasing, based on pacemaker technology
- Sets benchmark in strength and reliability

1998



CI24M

- New levels of verification testing prove design characteristics for reliability
- Hybrid technology for the electronic module improves reliability of the electronics

2000



CI24R

- New double-strength titanium shell and dome top provides additional top strength and better protection against impact

2005



CI24RE

- New chip-scale packaging lowers chip height, introduces greater margin between chip and titanium casing providing even better protection against impact

2009



CI512

- Stronger receiver/stimulator package, based on a titanium chassis construction, which increases the impact resistance of the implant by a factor of 2.5

# Designed for reliability

## Nucleus® CI512 Implant platform

The Nucleus CI512 Implant utilizes the CI500 series receiver/stimulator. The mechanical architecture was completely redesigned to reduce the thickness of the implant while further increasing strength, for improved reliability.

### Design objectives

A key objective of the CI512 package was to further increase the impact resilience of the implant including the silicone coating to the leads and around the titanium casing.

Core features introduced in the CI512 receiver/stimulator include:

- A very thin package, which means it has a lower profile from the skull, decreasing the probability of damage due to impact to the device and meeting surgeons' requests for a thinner implant.
- A stronger receiver-stimulator package, based on a titanium chassis construction, which increases the impact resistance of the implant by a factor of 2.5.
- Horizontally oriented lead exits to lower the profile and allow the lead exit to be routed in a bony channel for greater protection against impact.
- Stronger silicone coating the device, improving the resilience of the coating to impact and handling. Tensile strength, elongation and tear resistance are improved with this newer silicone formulation.
- Greater volume of silicone around the leads, particularly designed to protect the lead exit of the device from impact.

### Designed to withstand its environment

Continuous improvement principles are also applied to the verification testing regime that is used in implant development. Reliability testing for the Nucleus CI512 has been the most comprehensive and extensive program of verification ever conducted by Cochlear™ and included:

- impact testing according to the European standard<sup>1</sup>
- long-term saline soak at temperatures simulating the human body
- strength and abrasion of silicone coating, and
- qualification of the electronic module to military specifications<sup>2</sup>.

Cochlear™ designs its products for the best implant reliability and the Nucleus 5 is **NO** exception

## Nucleus CI512 Technology

### EXTRACOCHELEAR ELECTRODE BUILT INTO RECEIVER/STIMULATOR

- thinner and more robust

### POLISHED SMOOTH TITANIUM FINISH

- designed to reduce the risk of biofilm

### ROBUST TITANIUM CHASSIS

- 2.5 times more impact resistant than our previous generation Freedom™ Implant

### WORLD'S THINNEST COCHLEAR IMPLANT

- 3.9 mm thin

### SIDE BY SIDE ELECTRODE EXIT

- lower profile and designed for increased robustness

### SHORTER GROUND LEAD

- easier to place

### THINNER REMOVABLE MAGNET

- for MRI safety

### STRONGER SILICONE

- improved durability

### LARGER, GRADUAL INDENTATION

- for greater flexibility
- designed to reduce the risk of biofilm

### THINNER AND MORE FLEXIBLE ANTENNA COIL

- fits to natural shape of skull

### 165° FORM FACTOR AND FLEXIBILITY

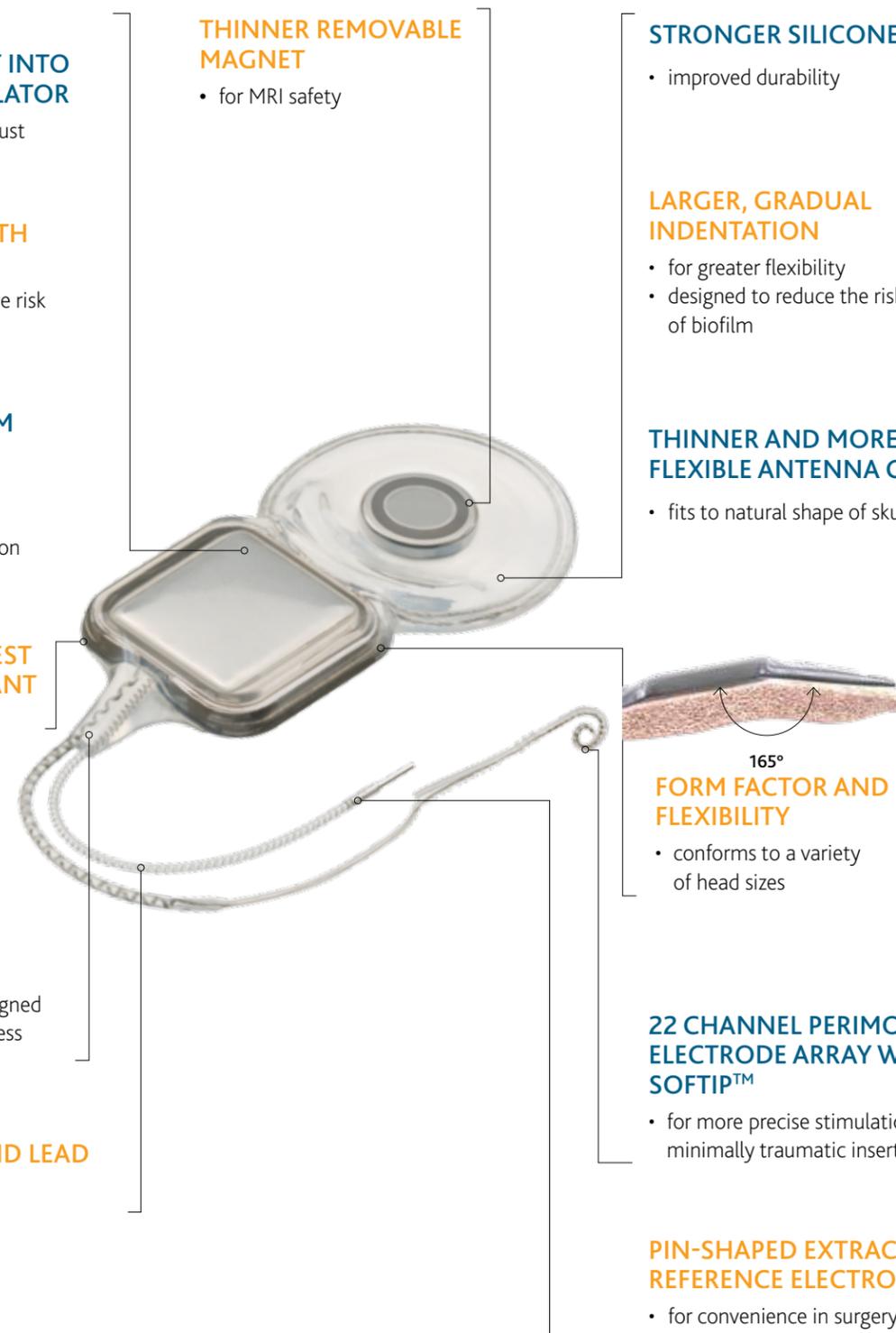
- conforms to a variety of head sizes

### 22 CHANNEL PERIMODIOLAR ELECTRODE ARRAY WITH SOFTIP™

- for more precise stimulation and minimally traumatic insertion

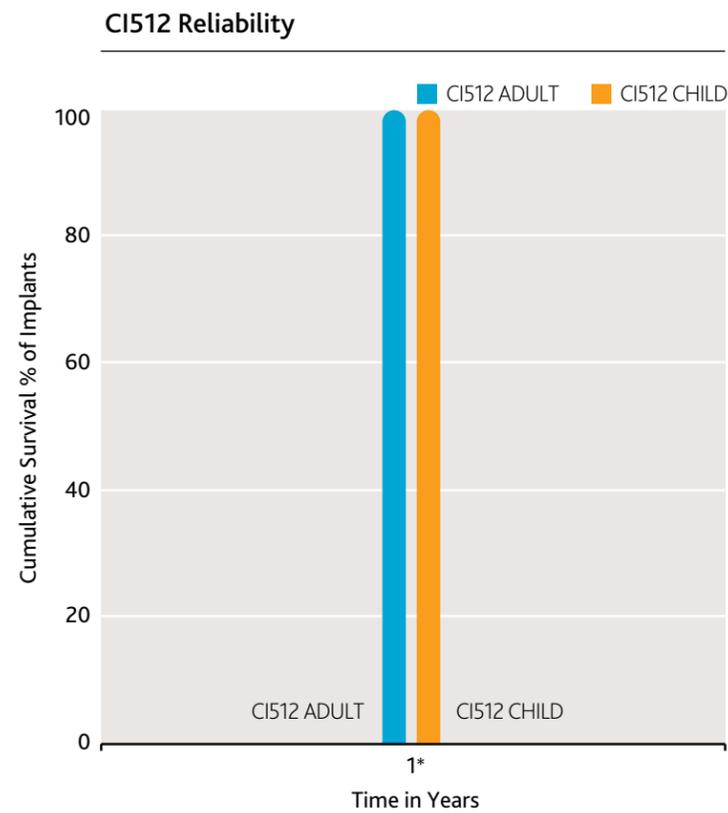
### PIN-SHAPED EXTRACOCHELEAR REFERENCE ELECTRODE

- for convenience in surgery



# Nucleus® 5 CI512 Implant (CI500 Series)

Within one year, CSP is 100% for adults and 100% for children.



ALL PATIENTS COMBINED AS OF 1 JUNE 2010

### Cumulative Survival Percentage (CSP)

YEAR	1
CI512 Adult	100
CI512 Child	100

### Cumulative Failure Percentage (CFP)

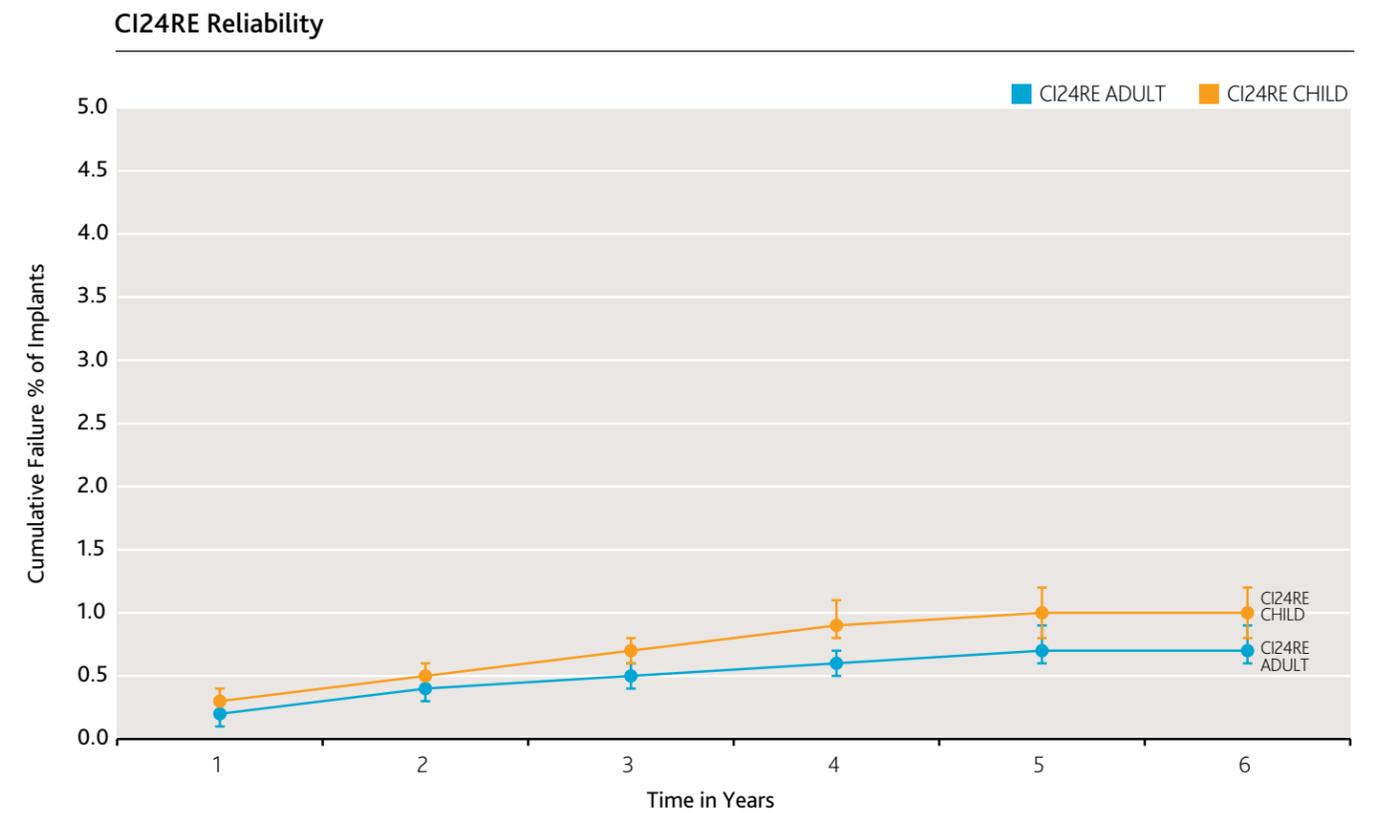
YEAR	1
CI512 Adult	0.0
CI512 Child	0.0

\*Within 1 year

# Freedom™ Implant (CI24RE)

At six years, CSP is 99.3% for adults and 99.0% 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.



ALL PATIENTS COMBINED AS OF 1 JUNE 2010

### Cumulative Survival Percentage (CSP)

YEAR	1	2	3	4	5	6
CI24RE Adult	99.8	99.6	99.5	99.4	99.3	99.3
CI24RE Child	99.7	99.5	99.3	99.1	99.0	99.0

### Cumulative Failure Percentage (CFP)

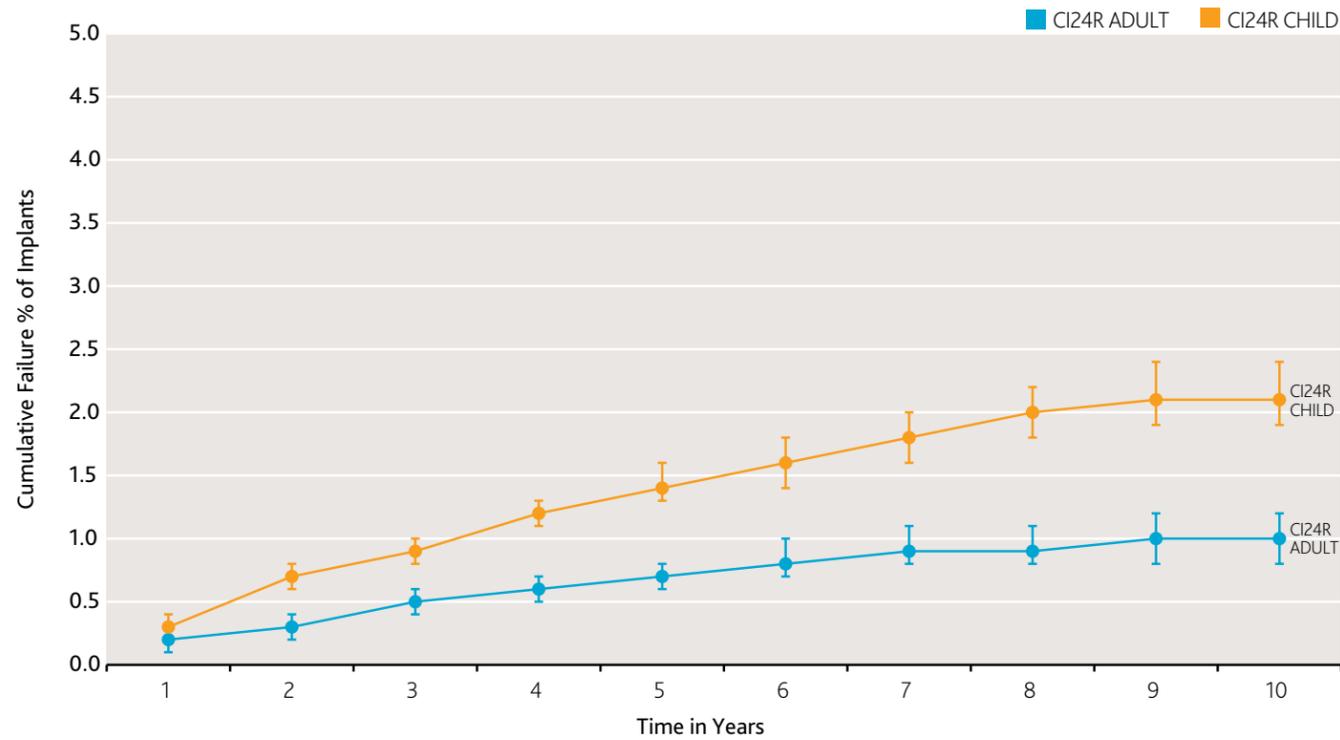
YEAR	1	2	3	4	5	6
CI24RE Adult	0.2	0.4	0.5	0.6	0.7	0.7
CI24RE Child	0.3	0.5	0.7	0.9	1.0	1.0

## Nucleus® 24 Implant (CI24R)

At 10 years, CSP is 99.0 % for adults and 97.9% 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 1 JUNE 2010

### Cumulative Survival Percentage (CSP)

YEAR	1	2	3	4	5	6	7	8	9	10
CI24R Adult	99.8	99.7	99.5	99.4	99.3	99.2	99.1	99.1	99.0	99.0
CI24R Child	99.7	99.3	99.1	98.8	98.6	98.4	98.2	98.0	97.9	97.9

### Cumulative Failure Percentage (CFP)

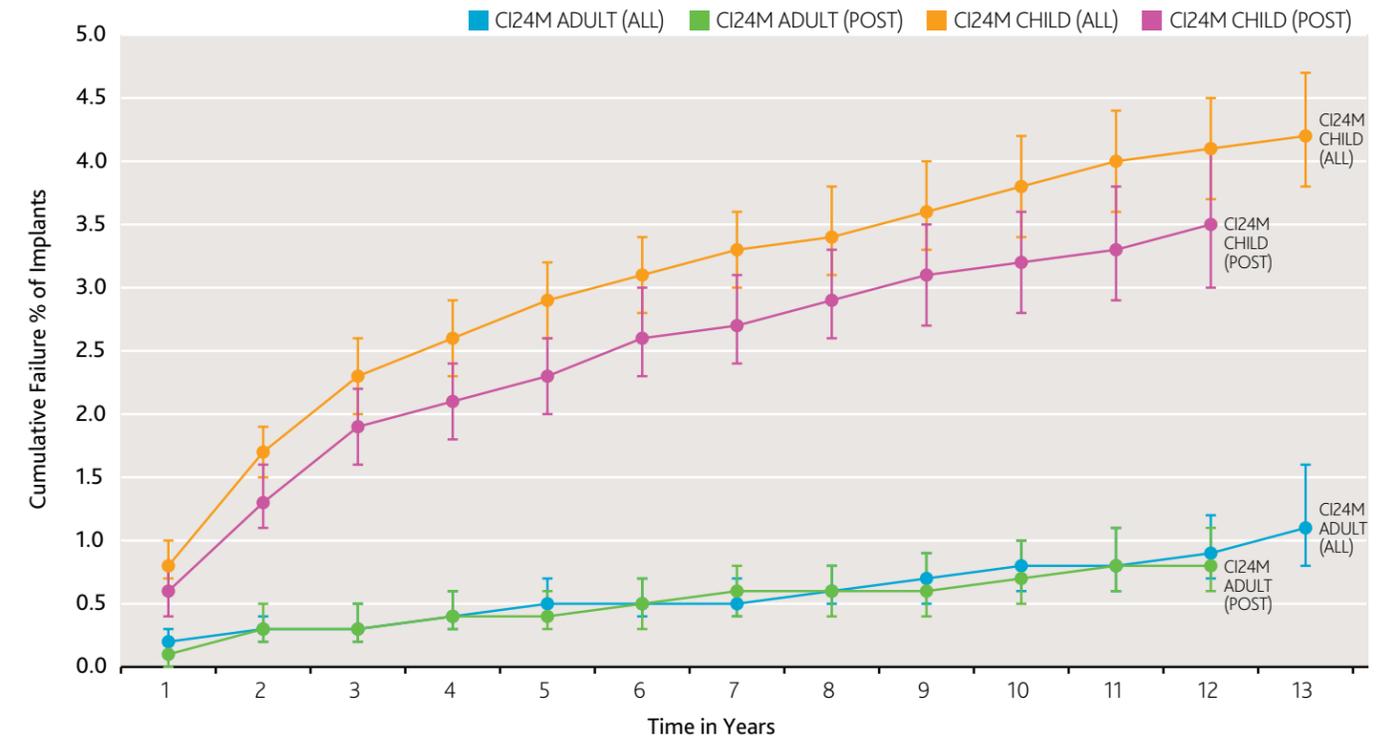
YEAR	1	2	3	4	5	6	7	8	9	10
CI24R Adult	0.2	0.3	0.5	0.6	0.7	0.8	0.9	0.9	1.0	1.0
CI24R Child	0.3	0.7	0.9	1.2	1.4	1.6	1.8	2.0	2.1	2.1

## Nucleus 24 Implant (CI24M)

At 13 years, CSP is 98.9% for adults and 95.8% for children.

The CI24M, released in the U.S. in 1998, 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



ALL PATIENTS COMBINED AS OF 1 JUNE 2010

### Cumulative Survival Percentage (CSP)

YEAR	1	2	3	4	5	6	7	8	9	10	11	12	13
CI24M Adult (All)	99.8	99.7	99.7	99.6	99.5	99.5	99.5	99.4	99.3	99.2	99.2	99.1	98.9
CI24M Child (All)	99.2	98.3	97.7	97.4	97.1	96.9	96.7	96.6	96.4	96.2	96.0	95.9	95.8
CI24M Adult (Post)	99.9	99.7	99.7	99.6	99.6	99.5	99.4	99.4	99.3	99.2	99.2	-	-
CI24M Child (Post)	99.4	98.7	98.1	97.9	97.7	97.4	97.3	97.1	96.9	96.8	96.7	96.5	-

### Cumulative Failure Percentage (CFP)

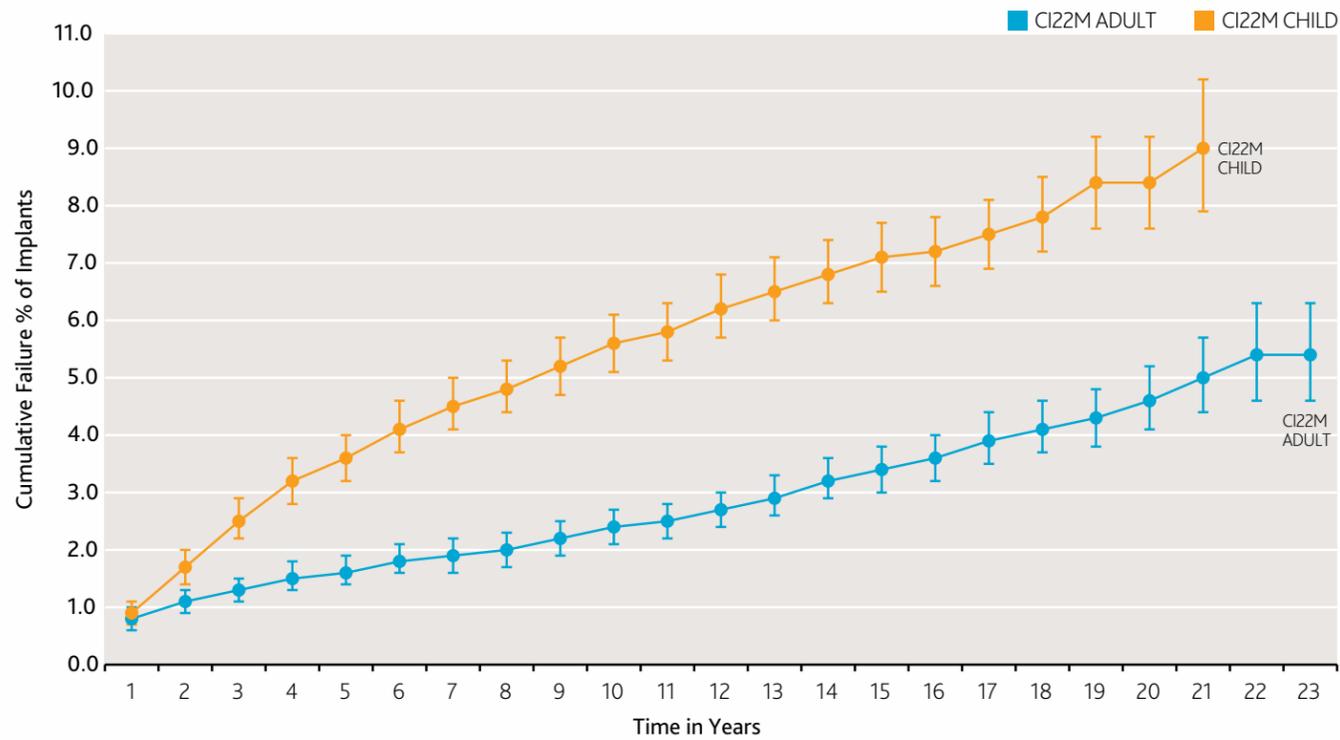
YEAR	1	2	3	4	5	6	7	8	9	10	11	12	13
CI24M Adult (All)	0.2	0.3	0.3	0.4	0.5	0.5	0.5	0.6	0.7	0.8	0.8	0.9	1.1
CI24M Child (All)	0.8	1.7	2.3	2.6	2.9	3.1	3.3	3.4	3.6	3.8	4.0	4.1	4.2
CI24M Adult (Post)	0.1	0.3	0.3	0.4	0.4	0.5	0.6	0.6	0.6	0.7	0.8	0.8	-
CI24M Child (Post)	0.6	1.3	1.9	2.1	2.3	2.6	2.7	2.9	3.1	3.2	3.3	3.5	-

# Nucleus® 22 Implant (CI22M)

At 23 years, CSP is 94.6% for adults, and at 21 years CSP is 91.0% 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



ALL PATIENTS COMBINED AS OF 1 JUNE 2010

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
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	95.9	95.7	95.4	95.0	94.6	94.6
CI22M Child	99.1	98.3	97.5	96.8	96.4	95.9	95.5	95.2	94.8	94.4	94.2	93.8	93.5	93.2	92.9	92.8	92.5	92.2	91.6	91.6	91.0	-	-

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
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	4.1	4.3	4.6	5.0	5.4	5.4
CI22M Child	0.9	1.7	2.5	3.2	3.6	4.1	4.5	4.8	5.2	5.6	5.8	6.2	6.5	6.8	7.1	7.2	7.5	7.8	8.4	8.4	9.0	-	-

# About Cochlear's reliability reporting

## What gets reported?

Our Reliability Report makes available all data relating to cochlear implant device failures in accordance with the International Standard ISO 5841-2:2000<sup>3</sup> and the reporting principles described in the European and Global Consensus Statement on Cochlear Implant Failures and Explantations.<sup>4,5</sup>

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 recipients worldwide.

### 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.

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

### Cumulative Failure Percentage

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

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

# 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<sup>4,5</sup> 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.		All device failures are reported to the competent authority. Cochlear uses the applicable definitions, categorization scheme and calculation procedures of ISO 5841-2:2000. 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 the regulatory body.		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 the regulatory body.
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 that occur anytime after wound closure are counted.

## 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. EN45502-2-3: 2010 Active implantable medical devices. Particular requirements for cochlear and auditory brainstem implant systems.
2. MIL-STD-883 Test method standard for microcircuits.
3. 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.
4. European Consensus Statement on Cochlear Implant Failures and Explantations. Otol Neurotol. 26: 1097-1099, 2005.
5. 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.

# Hear now. And always

**This is the Cochlear™ 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 200,000 cochlear implant and Baha® recipients 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 person with hearing loss receiving any one of the Cochlear hearing solutions, our commitment is that for the rest of your life we will be here to support you **Hear now. And always**

As your patient's partner in hearing for life, Cochlear believes it is important to convey not only the benefits, but also the potential risks associated with any cochlear implant.

Not everyone with hearing loss is a candidate for cochlear implantation. Before any cochlear implant surgery, please review the CDC recommendations regarding vaccination with your patient. Cochlear implants are contraindicated for patients with lesions of the auditory nerve, absent cochlear development, active ear infections or active disease of the middle ear.

Cochlear implantation is a surgical procedure, and carries with it the risks typical for surgery. Patients may lose residual hearing in the implanted ear. Electrical stimulation may result in some side effects, including ringing in the ear, stimulation of the facial nerve; in rare cases this may cause pain. Though rare, it is possible that additional surgery may be required at some point to resolve complications with a cochlear implant. For complete information regarding indications, warnings and adverse effects, please refer to the Nucleus CI512 Package Insert (available at [www.cochlearamericas.com/NucleusIndications](http://www.cochlearamericas.com/NucleusIndications)).



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