Cochlear™ Nucleus® Reliability Report

VOLUME 12 | FEBRUARY 2014

Cochlear®

A LIFETIME OF POSSIBILITIES.

2012 Graham Carrick - the first commercial cochlear implant recipient

1982 Graham hears his daughter's voice shortly after receiving his cochlear implant

About Cochlear's reliability reporting

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

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 are provided. Data are now available for a population of over 115,000 CI24RE implants over a period of 10 years, while the CI22M implant has now reached a reporting period of 26 years. An update on the CI500 Series Cochlear Implant is also provided. Upon reintroduction of the CI500 Series, subsequent reliability reports will provide separate data for the original and re-launched CI500 devices.

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

OVER **115,000** CI24RE IMPLANTS OVER A PERIOD OF 10 YEARS WITH **99.0% CSP**

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 the Cumulative Failure Percentage (CFP).

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.

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

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] %

Number of registered implants# - 24 February 2014

DEVICE	ADULT	CHILD	COMBINED
CI22M	9,968	8,214	18,182
CI24M (ALL)	7,860	11,738	19,598
CI24M (POST)*	6,139	9,230	15,369
CI24R	18,587	33,914	52,501
CI24RE	52,432	63,414	115,846
CI500	15,134	14,612	29,746

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

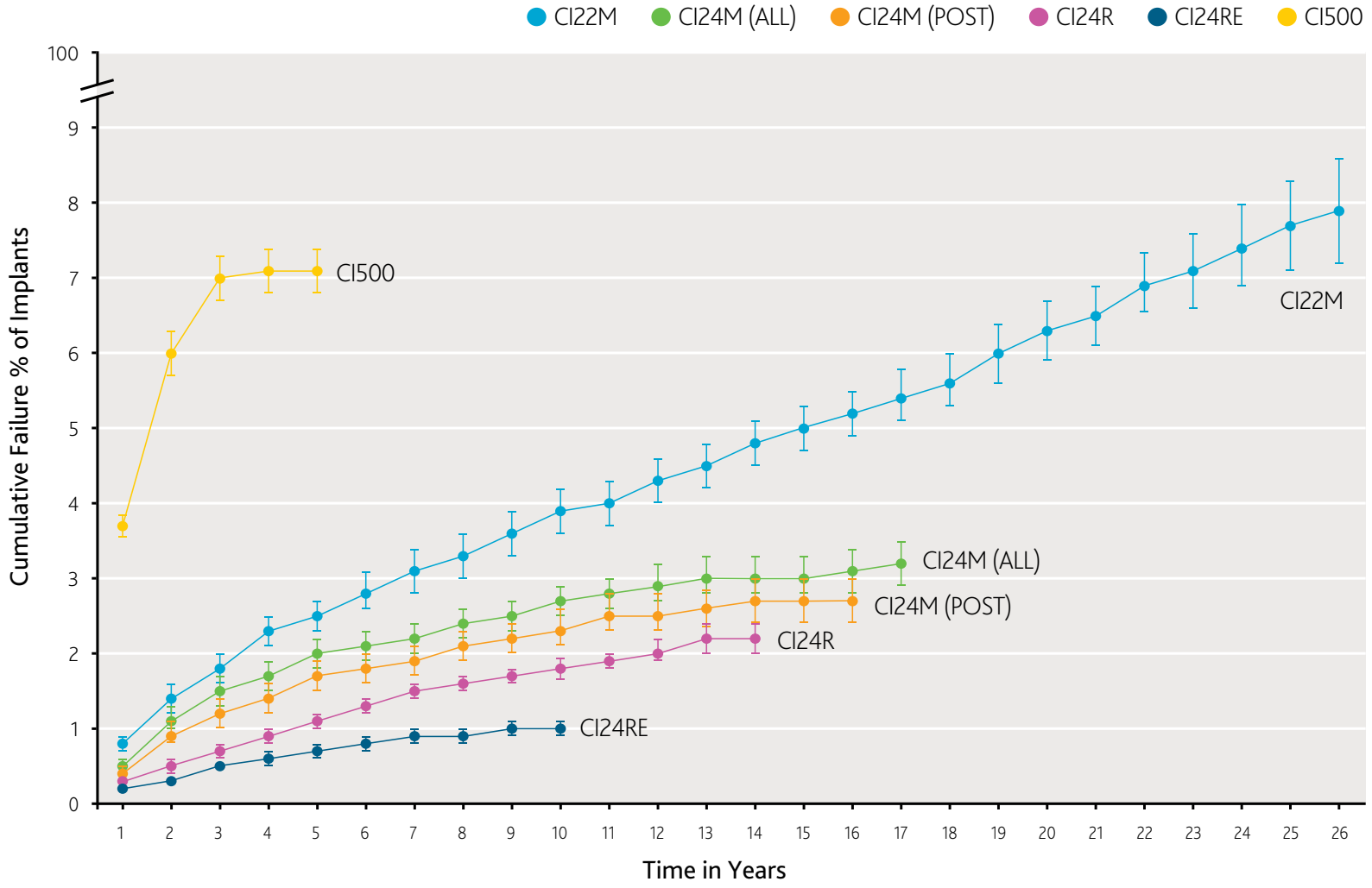
Cumulative Survival Percentage (CSP) for combined adult and child data

YEARS	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	26
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	93.7	93.5	93.1	92.9	92.6	92.3	92.1
CI24M (All)	99.5	98.9	98.5	98.3	98.0	97.9	97.8	97.6	97.5	97.3	97.2	97.1	97.0	97.0	97.0	96.9	96.8									
CI24M (Post)	99.6	99.1	98.8	98.6	98.3	98.2	98.1	97.9	97.8	97.7	97.5	97.5	97.4	97.3	97.3	97.3										
CI24R	99.7	99.5	99.3	99.1	98.9	98.7	98.5	98.4	98.3	98.2	98.1	98.0	97.8	97.8												
CI24RE	99.8	99.7	99.5	99.4	99.3	99.2	99.1	99.1	99.0	99.0																
CI500	96.3	94.0	93.0	92.9	92.9																					

Cumulative Failure Percentage (CFP) for combined adult and child data

YEARS	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	26
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	6.3	6.5	6.9	7.1	7.4	7.7	7.9
CI24M (All)	0.5	1.1	1.5	1.7	2.0	2.1	2.2	2.4	2.5	2.7	2.8	2.9	3.0	3.0	3.0	3.1	3.2									
CI24M (Post)	0.4	0.9	1.2	1.4	1.7	1.8	1.9	2.1	2.2	2.3	2.5	2.5	2.6	2.7	2.7	2.7										
CI24R	0.3	0.5	0.7	0.9	1.1	1.3	1.5	1.6	1.7	1.8	1.9	2.0	2.2	2.2												
CI24RE	0.2	0.3	0.5	0.6	0.7	0.8	0.9	0.9	1.0	1.0																
CI500	3.7	6.0	7.0	7.1	7.1																					

Nucleus Implant Reliability



REGISTERED IMPLANT DATA COMBINED FOR ADULT AND CHILD AS AT 24 FEBRUARY 2014

Nucleus CI24RE Implant

The combined Cumulative Survival Percentage for registered implants worldwide is 99.0% within 10 years.

Within nine years, CSP is 99.4% for adults and 98.7% for children. The population size for the CI24RE adult and child data is sufficient to report at nine years. There are sufficient data to report at 10 years for the combined data.

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, more recently, the Nucleus CP910 and CP920 Sound Processors.

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

Cumulative Survival Percentage (CSP)

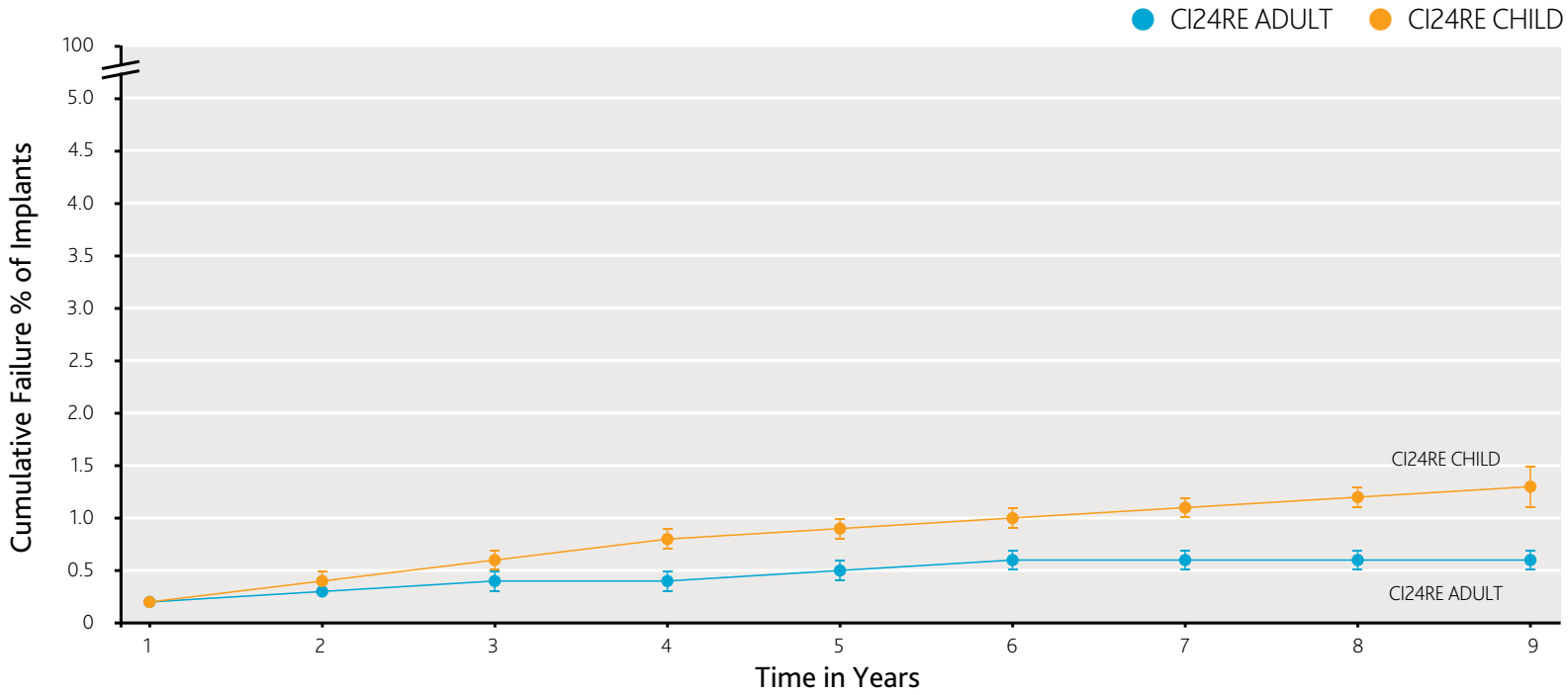
YEARS	1	2	3	4	5	6	7	8	9
CI24RE Adult	99.8	99.7	99.6	99.6	99.5	99.4	99.4	99.4	99.4
CI24RE Child	99.8	99.6	99.4	99.2	99.1	99.0	98.9	98.8	98.7

Cumulative Failure Percentage (CFP)

YEARS	1	2	3	4	5	6	7	8	9
CI24RE Adult	0.2	0.3	0.4	0.4	0.5	0.6	0.6	0.6	0.6
CI24RE Child	0.2	0.4	0.6	0.8	0.9	1.0	1.1	1.2	1.3

* See page 17 for a list of implant types reported with the CI24RE receiver/stimulator.

CI24RE Reliability



REGISTERED IMPLANT DATA FOR ADULT AND CHILD AS AT 24 FEBRUARY 2014

Nucleus CI24R Implant

The combined Cumulative Survival Percentage for registered implants worldwide is 97.8% within 14 years.

Within 14 years, CSP is 98.4% for adults and 97.5% for children.

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

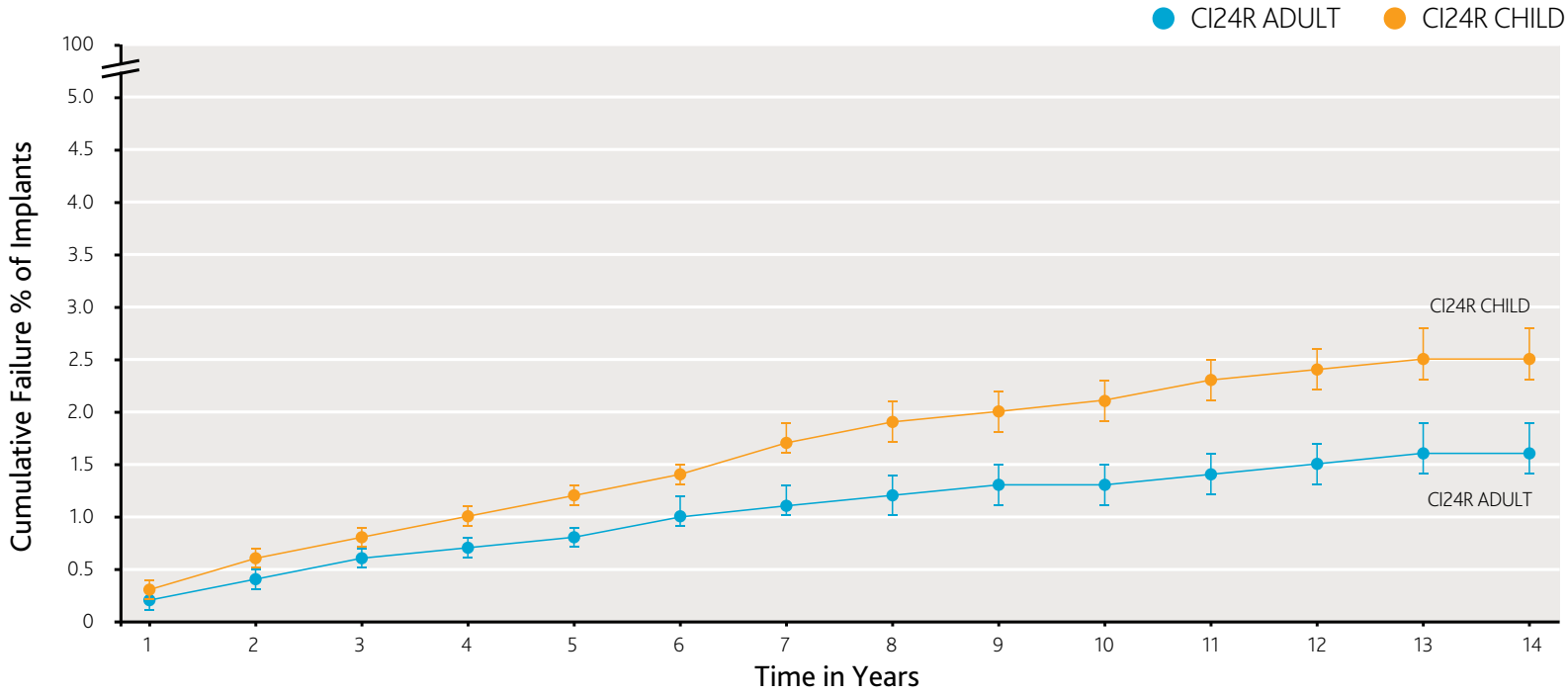
Cumulative Survival Percentage (CSP)

YEARS	1	2	3	4	5	6	7	8	9	10	11	12	13	14
CI24R Adult	99.8	99.6	99.4	99.3	99.2	99.0	98.9	98.8	98.7	98.7	98.6	98.5	98.4	98.4
CI24R Child	99.7	99.4	99.2	99.0	98.8	98.6	98.3	98.1	98.0	97.9	97.7	97.6	97.5	97.5

Cumulative Failure Percentage (CFP)

YEARS	1	2	3	4	5	6	7	8	9	10	11	12	13	14
CI24R Adult	0.2	0.4	0.6	0.7	0.8	1.0	1.1	1.2	1.3	1.3	1.4	1.5	1.6	1.6
CI24R Child	0.3	0.6	0.8	1.0	1.2	1.4	1.7	1.9	2.0	2.1	2.3	2.4	2.5	2.5

CI24R Reliability



REGISTERED IMPLANT DATA FOR ADULT AND CHILD AS AT 24 FEBRUARY 2014

Nucleus CI24M Implant

The combined Cumulative Survival Percentage for registered implants worldwide is 96.8% within 17 years.

Within 17 years, CSP is 98.3% for adults and 95.8% 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 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®).

Cumulative Survival Percentage (CSP)

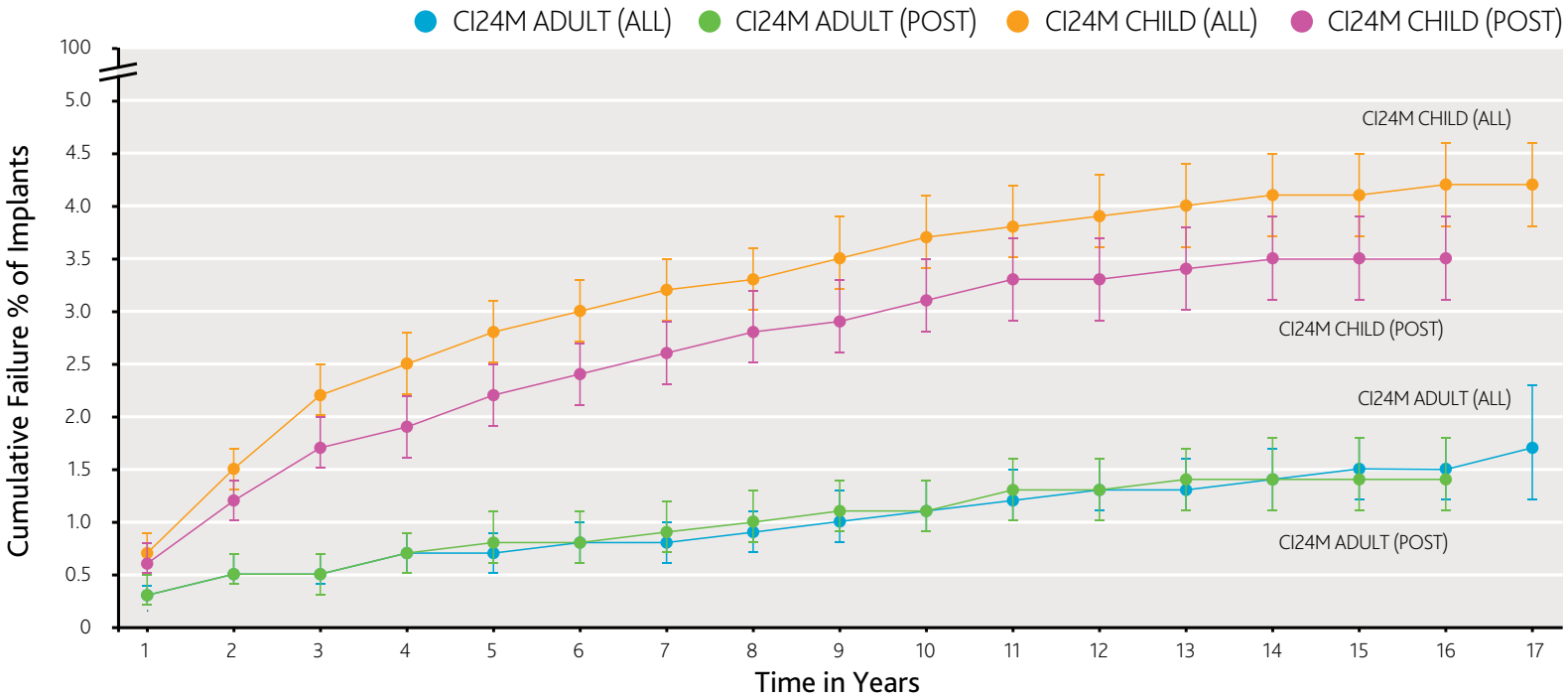
YEARS	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
CI24M Adult (All)	99.7	99.5	99.5	99.3	99.3	99.2	99.2	99.1	99.0	98.9	98.8	98.7	98.7	98.6	98.5	98.5	98.3
CI24M Child (All)	99.3	98.5	97.8	97.5	97.2	97.0	96.8	96.7	96.5	96.3	96.2	96.1	96.0	95.9	95.9	95.8	95.8
CI24M Adult (Post*)	99.7	99.5	99.5	99.3	99.2	99.2	99.1	99.0	98.9	98.9	98.7	98.7	98.6	98.6	98.6	98.6	#
CI24M Child (Post*)	99.4	98.8	98.3	98.1	97.8	97.6	97.4	97.2	97.1	96.9	96.7	96.7	96.6	96.5	96.5	96.5	#

Cumulative Failure Percentage (CFP)

YEARS	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
CI24M Adult (All)	0.3	0.5	0.5	0.7	0.7	0.8	0.8	0.9	1.0	1.1	1.2	1.3	1.3	1.4	1.5	1.5	1.7
CI24M Child (All)	0.7	1.5	2.2	2.5	2.8	3.0	3.2	3.3	3.5	3.7	3.8	3.9	4.0	4.1	4.1	4.2	4.2
CI24M Adult (Post*)	0.3	0.5	0.5	0.7	0.8	0.8	0.9	1.0	1.1	1.1	1.3	1.3	1.4	1.4	1.4	1.4	#
CI24M Child (Post*)	0.6	1.2	1.7	1.9	2.2	2.4	2.6	2.8	2.9	3.1	3.3	3.3	3.4	3.5	3.5	3.5	#

* 'Post' refers to the addition of a structural support component to improve impact strength.
# refers to individual populations less than the minimum required for a valid calculation.

CI24M Reliability



REGISTERED IMPLANT DATA FOR ADULT AND CHILD AS AT 24 FEBRUARY 2014

Nucleus CI22M Implant

The combined Cumulative Survival Percentage for registered implants worldwide is 92.1% within 26 years.

Within 26 years, CSP is 93.8% for adults, and at 25 years CSP is 90.2% 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.

Cumulative Survival Percentage (CSP)

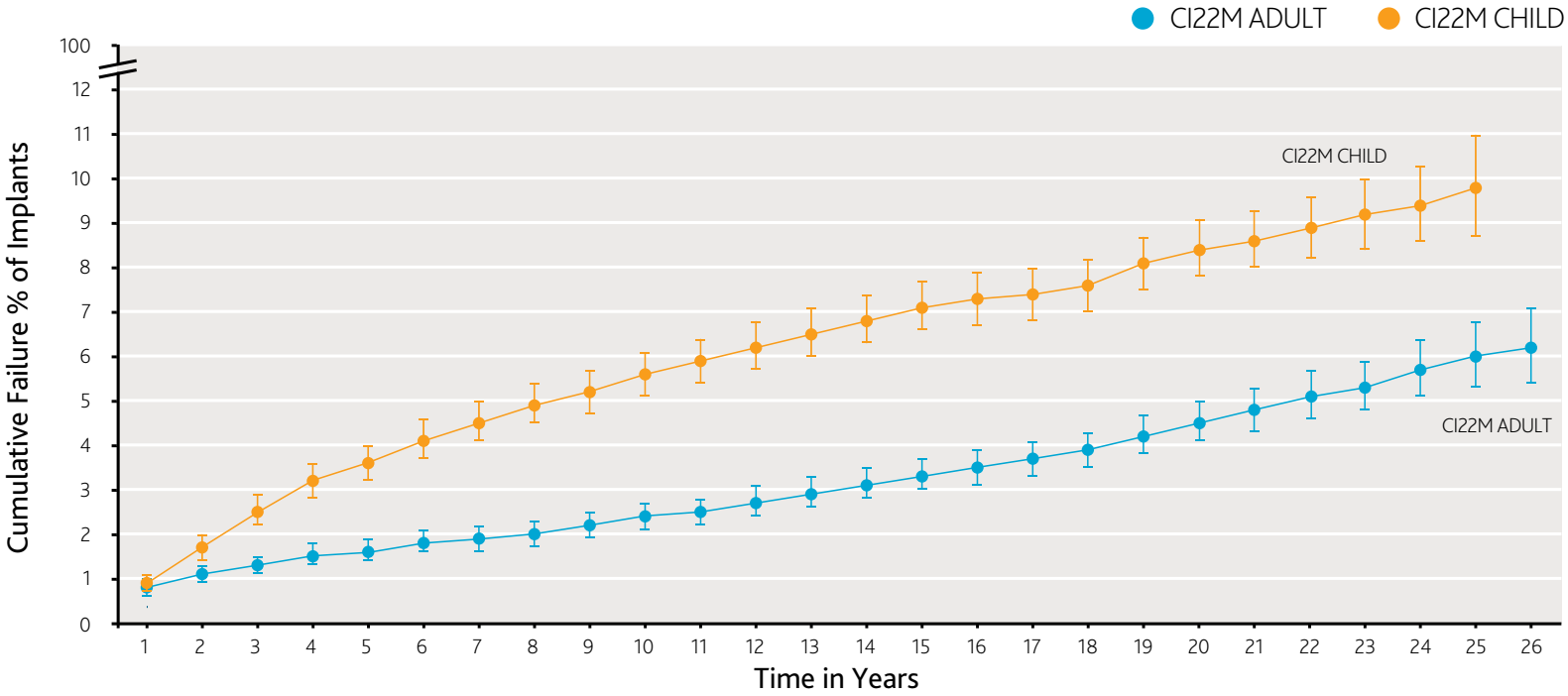
YEARS	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26
CI22M Adult	99.2	98.9	98.7	98.5	98.4	98.2	98.1	98.0	97.8	97.6	97.5	97.3	97.1	96.9	96.7	96.5	96.3	96.1	95.8	95.5	95.2	94.9	94.7	94.3	94.0	93.8
CI22M Child	99.1	98.3	97.5	96.8	96.4	95.9	95.5	95.1	94.8	94.4	94.1	93.8	93.5	93.2	92.9	92.7	92.6	92.4	91.9	91.6	91.4	91.1	90.8	90.6	90.2	#

Cumulative Failure Percentage (CFP)

YEARS	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	26
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	3.1	3.3	3.5	3.7	3.9	4.2	4.5	4.8	5.1	5.3	5.7	6.0	6.2
CI22M Child	0.9	1.7	2.5	3.2	3.6	4.1	4.5	4.9	5.2	5.6	5.9	6.2	6.5	6.8	7.1	7.3	7.4	7.6	8.1	8.4	8.6	8.9	9.2	9.4	9.8	#

refers to individual populations less than the minimum required for a valid calculation.

CI22M Reliability



REGISTERED IMPLANT DATA FOR ADULT AND CHILD AS AT 24 FEBRUARY 2014

Nucleus CI500 Series Implant

The combined Cumulative Survival Percentage for registered implants worldwide is 92.9% within five years.

Within five years, CSP is 93.0% for adults and 92.8% for children.

The CI500 Series Implant was voluntarily recalled in September 2011.

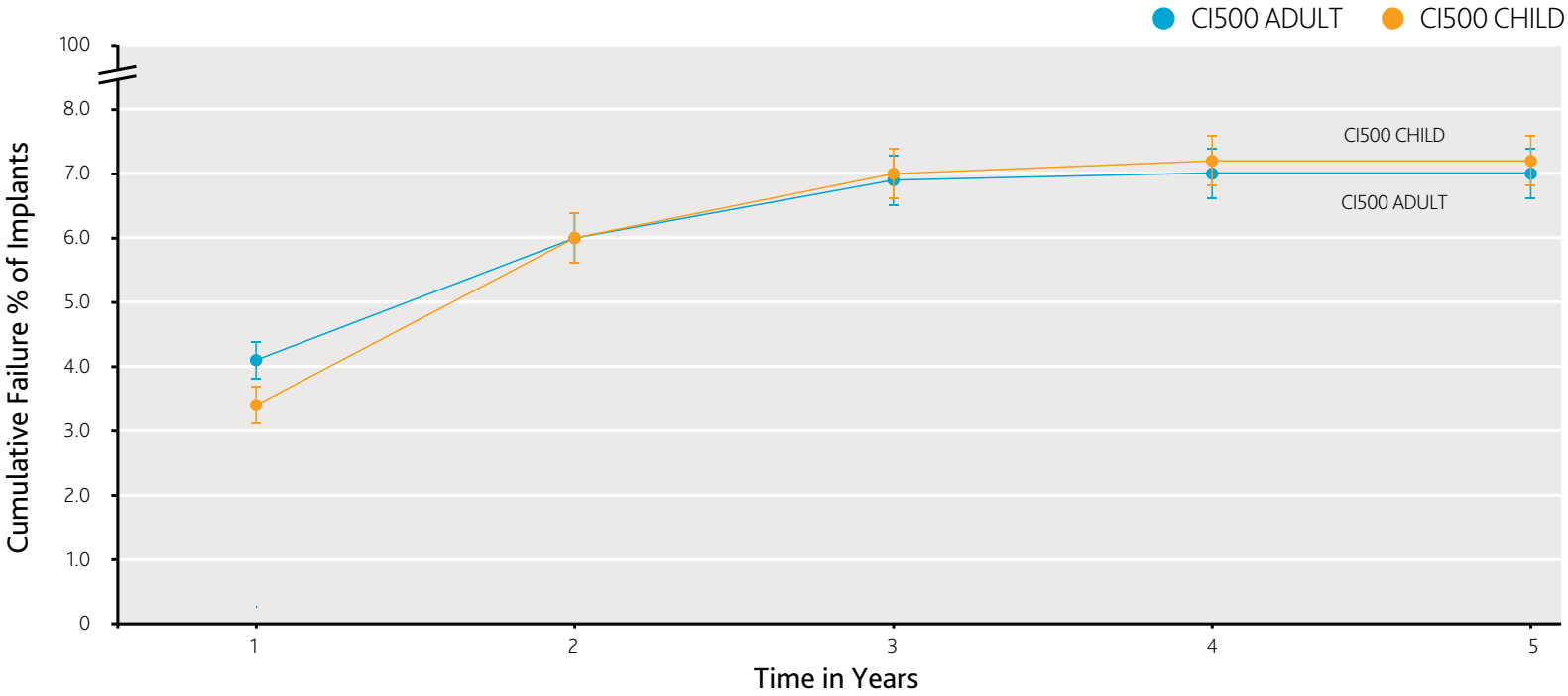
Cumulative Survival Percentage (CSP)

YEARS	1	2	3	4	5
CI500 Adult	95.9	94.0	93.1	93.0	93.0
CI500 Child	96.6	94.0	93.0	92.8	92.8

Cumulative Failure Percentage (CFP)

YEARS	1	2	3	4	5
CI500 Adult	4.1	6.0	6.9	7.0	7.0
CI500 Child	3.4	6.0	7.0	7.2	7.2

CI500 Reliability



REGISTERED IMPLANT DATA FOR ADULT AND CHILD AS AT 24 FEBRUARY 2014

Full Compliance with International Reporting Standards

In 2005, a Consensus Statement on 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[ii,iii] 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 compliance with the Consensus Statement.

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[i].	YES	All device failures are reported to the competent authority. Cochlear uses the applicable definitions, categorisation scheme and calculation procedures of ISO 5841-2:2000[i]. All device failure modes are included.
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.	YES	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).	YES	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.	YES	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.	YES	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.	YES	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[ii, iii].
Device survival time starts to count with closure of the wound intraoperatively.	YES	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** 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

** Implanted in some countries.

REFERENCES

i - 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.

ii - European Consensus Statement on Cochlear Implant Failures and Explantations. Otol Neurotol. 26: 1097-1099, 2005.

iii - 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.

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Hear now. And always

As the leading global expert in implantable hearing solutions, Cochlear is dedicated to bringing the gift of sound to people all over the world. For over thirty years, Cochlear has pioneered this technology, helping more than a quarter of a million people reconnect to their families and friends.

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 of hearing science.

For our customers, that means access to our latest technologies throughout their lives, and the ongoing support they need.

That is why seven out of ten people worldwide who choose a cochlear implant choose Cochlear as their hearing partner.

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