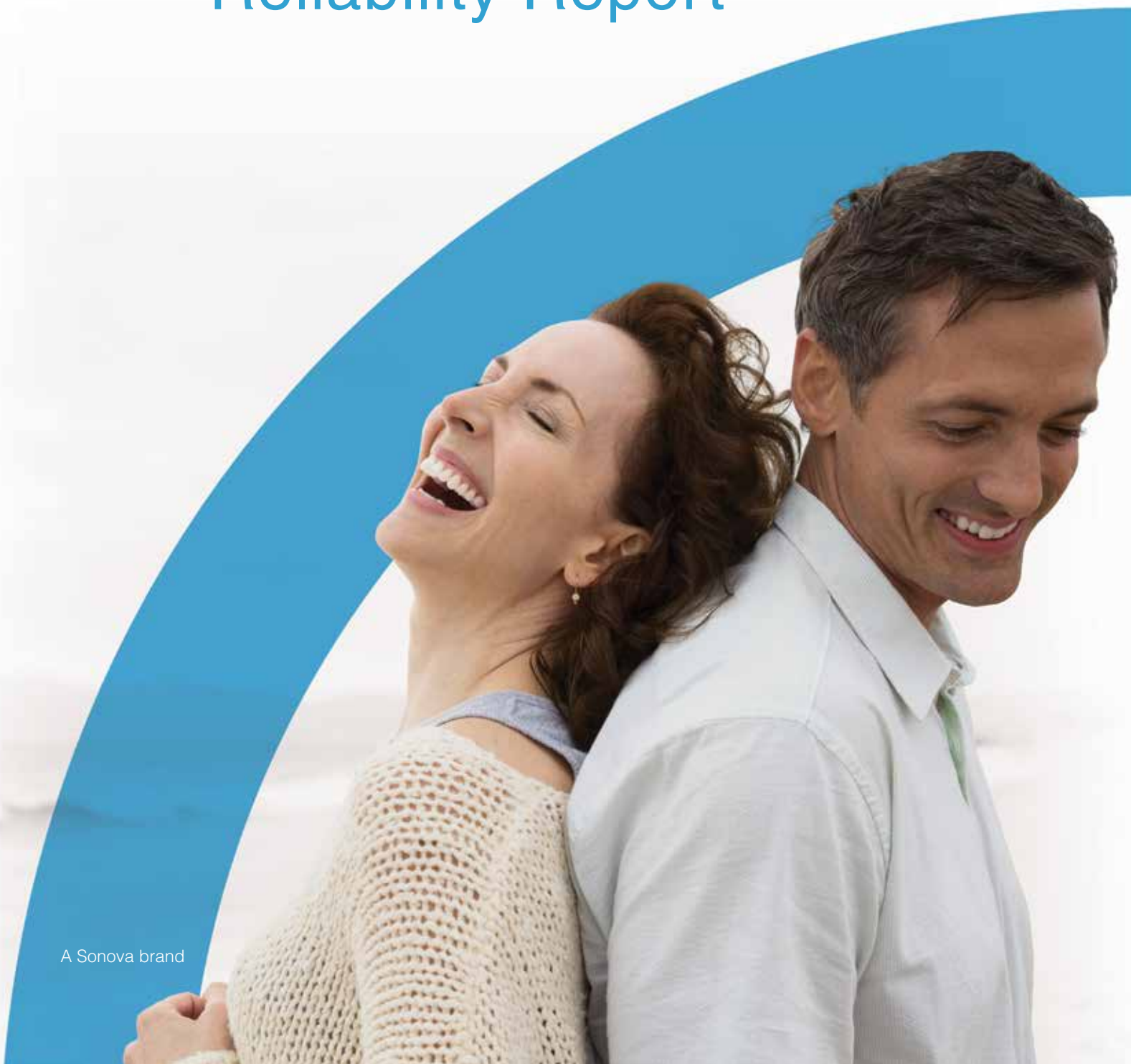
ADVANCED BIONICS
POWERFUL CONNECTIONS

2019 Global Implant Reliability Report



A Sonova brand

> My parents originally chose AB because of it's **dependability, ongoing research to upgrade and the support team** behind AB (BEA) to help us through the process. When I was older, I chose to go bilateral and stay with AB for the same reasons. I saw that over the years with AB that they are **dedicated to their product and are continually striving for ways to help their customers hear better** through different sound strategies and processor upgrades.
>
> — Alexandra L., AB Recipient

Our Mission

RELIABLE, HIGH-QUALITY HEARING SOLUTIONS FOR A LIFETIME OF BETTER HEARING

At Advanced Bionics, we're dedicated to providing the highest quality hearing products and comprehensive, custom services so everyone can experience the joy of hearing and stay connected to the sounds, people and activities they love.

Our commitment to providing the best and most reliable hearing performance possible for our implant recipients drives everything we do. And the trust they place in us to deliver it inspires us to act with integrity and transparency as we design, test and build durable, future-proof products that work for them throughout their entire lives.

TRANSPARENT REPORTING ON IMPLANT RELIABILITY

As part of our commitment to providing clear and accurate information, Advanced Bionics reports all device failures in adherence to the global standard as defined by ISO 5841 – 2:2014[1] and the principles outlined in the *European & Global Consensus on Cochlear Implant Failures and Explantations.*[2]

Even though all manufacturers adhere to these standards, other manufacturers may report using different definitions of what constitutes a device failure, and therefore not include the same types of information in their reliability statistics.

Advanced Bionics is committed to providing patients and professionals with the most complete reports on all of our returned devices --with data presented clearly and transparently, so they can make the most informed decisions about their hearing needs.

IMPORTANT TIPS FOR READING THE TABLES AND GRAPHS IN THIS REPORT

The number of registered users are shown for adults, children and as a combined number. This does not represent all devices sold/implanted.

* The combined number also includes any registered users that we do not have date of birth information.

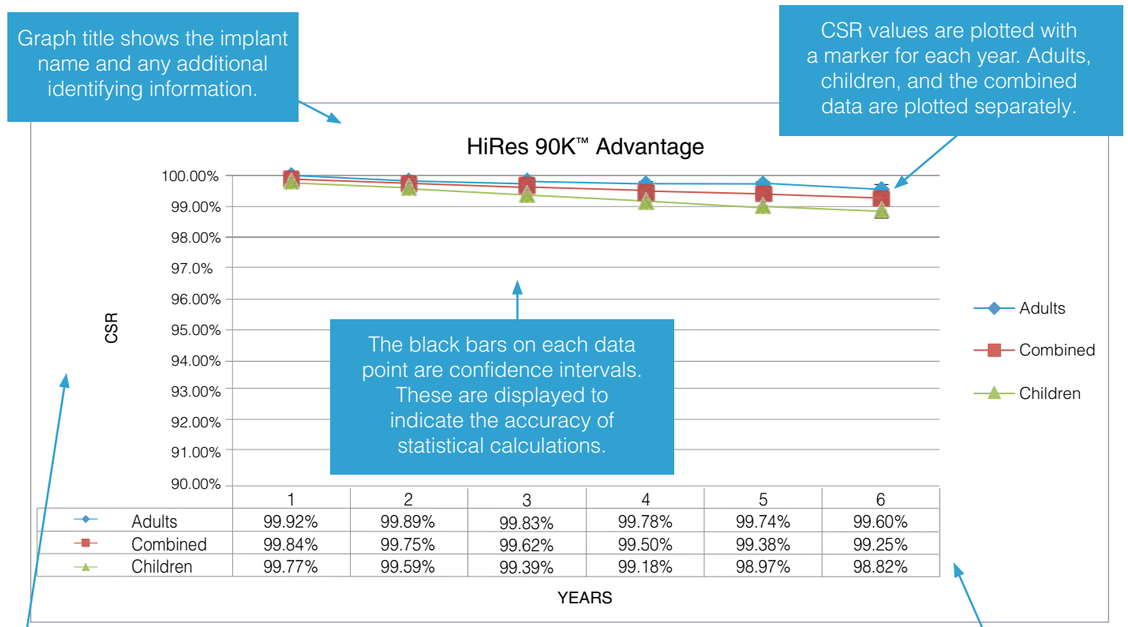
Number of registered HiRes 90K Advantage implants as of July 15, 2019

ADULTS	CHILDREN	COMBINED
14,531	16,643	32,745*

Date of first commercial introduction: 2012

Graph title shows the implant name and any additional identifying information.

CSR values are plotted with a marker for each year. Adults, children, and the combined data are plotted separately.



	1	2	3	4	5	6
Adults	99.92%	99.89%	99.83%	99.78%	99.74%	99.60%
Combined	99.84%	99.75%	99.62%	99.50%	99.38%	99.25%
Children	99.77%	99.59%	99.39%	99.18%	98.97%	98.82%

The black bars on each data point are confidence intervals. These are displayed to indicate the accuracy of statistical calculations.

What does CSR mean?
Cumulative survival rate (CSR) shows the percentage of implants that are still functional after the time in years indicated in the table and on the graph.You may also see this described as Cumulative Survival Percentage.

Detailed CSR percentages are shown for each year in the table. Results are broken up into adults, children, and shown as a combined total.

REPORTING PRINCIPLES	ADVANCED BIONICS COMMITMENT	ADVANCED BIONICS	MED EL[5]	COCHLEAR[4]	OTICON[6]
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].	Accident related device failures are included in our standard CSR calculations.	✔	?	✔	✔
Extensive failure analysis including hermeticity on all medical and non-medical returns.	Hermeticity is specifically measured on every implant return.	✔	?	?	?
Manufacturers 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.	Sample size and time period are specified for each reported implant.	✔	✗	✔	✗
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).	Actual CSR values are presented for all generations of all implants. No computer-generated modeling data is used.	✔	✗	✔	✗
The complete data set of the "mother" product should always be supplied when presenting data on subsequent device modifications.		✔	✗	✔	✔
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.	AB differentiates all implant and electrode types with unique model numbers and they all gain independent FDA and CE mark regulatory approval.	✔	?	✔	✔
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 1000 units) should be provided.	Reports show separate data for adults and children.	✔	✗	✔	✗
Device survival time starts to count with closure of the wound intraoperatively.	All failures are counted that occur any time after wound closure.	✔	?	✔	?

Finding the right solution for your hearing needs takes careful research. But since every cochlear implant manufacturer has a different approach to the evaluation of explanted and returned devices (as well as their reliability reporting practices), it can be difficult to get truly accurate, “apples-to-apples” product comparisons.

Advanced Bionics adheres to the most stringent testing and reporting standards because we’re committed to making sure our recipients get the most reliable solution for hearing through life’s moments. It’s why we perform an exhaustive analysis on ALL returned devices. And whenever a reported device issue can’t be confirmed or replicated, we employ a cross-functional team of engineers to review the case and determine the root cause.

HAVE QUESTIONS? CONTACT US.

We’re committed to providing both our users and hearing healthcare professionals with all the information they need to thoroughly and accurately evaluate clinical device benefits to make sure their patients get the right implant for their needs.

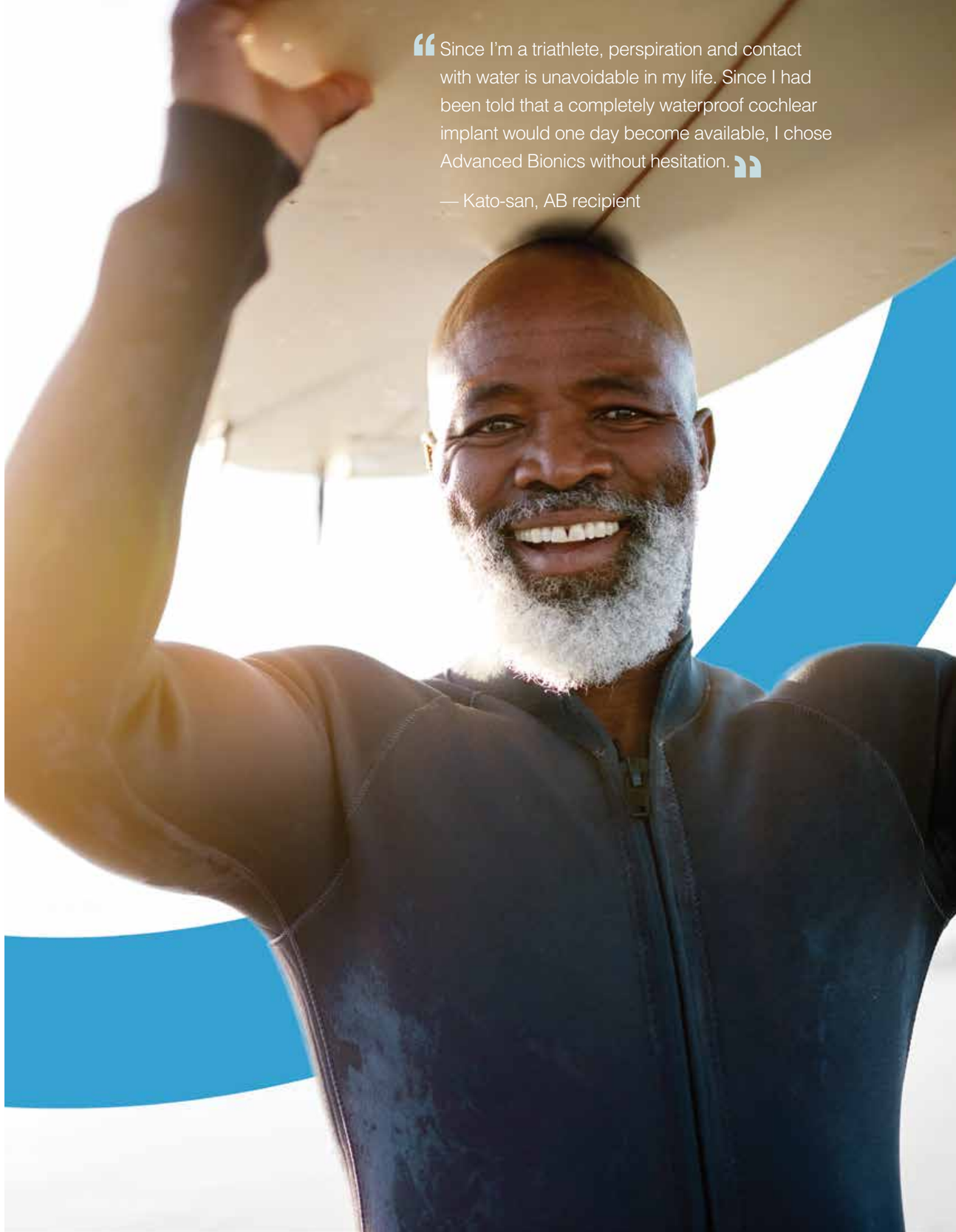
Our representatives are always available for questions, troubleshooting, and device testing consultation — for both implant recipients and professionals.

Contact us by emailing *hear@AdvancedBionics.com*. You can also visit *AdvancedBionics.com* for more information.

*NOTE: This level of documentation is required by the U.S. cochlear implant standard, AAMI CI86/Ed. 1, *Cochlear Implant Systems: Requirements for Safety, Functional Verification, Labeling and Reliability Reporting.*

did you know?...

MADE IN AMERICA! ALL OUR COCHLEAR IMPLANTS AND SOUND PROCESSORS ARE MADE IN THE UNITED STATES.



HiRes™ Ultra 3D Cochlear Implant

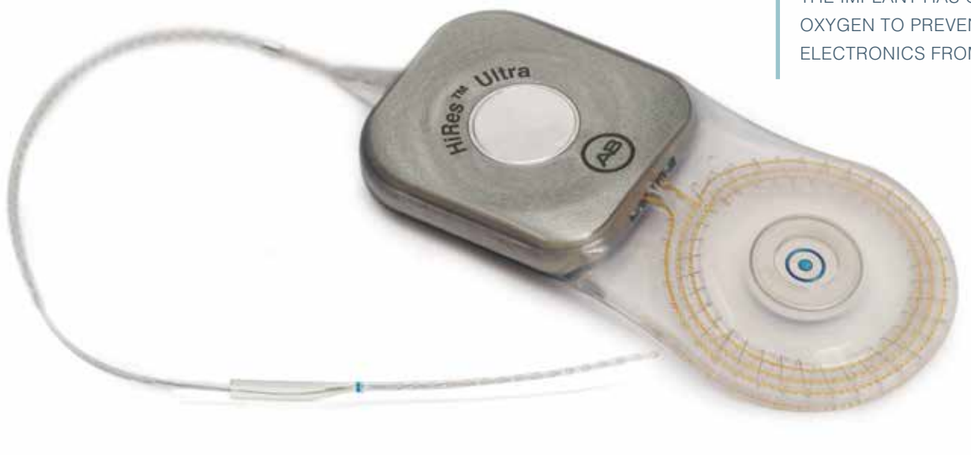
HASSLE FREE, PAIN FREE MRI, UNINTERRUPTED HEARING

The HiRes Ultra 3D implant is the newest member of the HiRes implant family. It is one of the first cochlear implants that allows users access to a MRI without head bandaging or magnet removal surgery. It's highly likely that everyone will get an MRI at some time in their life[7] and we know that 70% of recipients experience pain[8] when undergoing an MRI normally. The HiRes Ultra 3D was created in order to address this important clinical need and provides our recipients with access to a pain-free and hassle-free MRI experience.

> In the case that a child needs an MRI, now or in the future, we don't have to sacrifice their early access to sound. We can start their hearing journey during a pivotal language learning time while still keeping other medical needs in mind.
>
> — Kelley D., AuD, Pediatric Ear, Nose and Throat of Atlanta

HiRes™ Ultra Cochlear Implant

THE INDUSTRY'S MOST FLEXIBLE AND DURABLE HIGH-PERFORMANCE IMPLANT



did you know?...

THE IMPLANT HAS ONLY 0.0001% OXYGEN TO PREVENT THE ELECTRONICS FROM OXIDIZING.

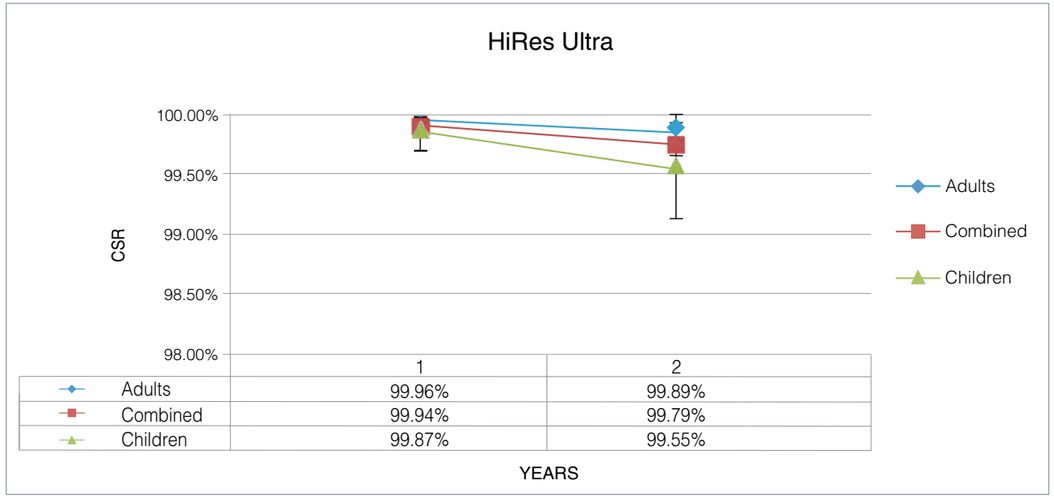
The HiRes Ultra offers a thin, discreet design suitable for adults and children. It is designed to exceed industry standards for impact resistance, offering users greater peace of mind while wearing their implant. The HiRes Ultra is also upgradeable and offers access to newer innovations without the need for surgery. It is MR conditional and can be used in both a 1.5T and 3T MRI procedure.

> "I was deaf for 7 months before surgery and activation — having had "normal" hearing before. The implant restored the previous "hearing" life that I had before my sudden deafness. It made an enormous difference in quality of life on all levels. Miracles are commonly described as making the blind see, the lame walk and the deaf hear. The implant has been a miracle in my life."
>
> — Bill S., AB Recipient

Number of registered HiRes Ultra cochlear implants as of July 15, 2019

ADULTS	CHILDREN	COMBINED
5,903	2,819	9,021*

Date of first commercial introduction: 2016



> The AB cochlear implant has given me an opportunity to live life to its fullest. Because of my CI, I can more fully participate in my children's lives and enjoy the sounds of their childhood.
>
> — Scott H., AB Recipient

PREVIOUS-GENERATION IMPLANT DATA

HiRes 90K™ Advantage Cochlear Implant

The HiRes 90K Advantage implant offers users access to some of the best sound processing technology available. It also offers surgeons the ability to create a deeper bone bed in order to secure the implant. Available with a variety of electrode options, the HiRes 90K advantage offers mechanical improvements over the HiRes 90K implant. It's been approved for MRI and can undergo 1.5T MRI scans with the magnet removed.

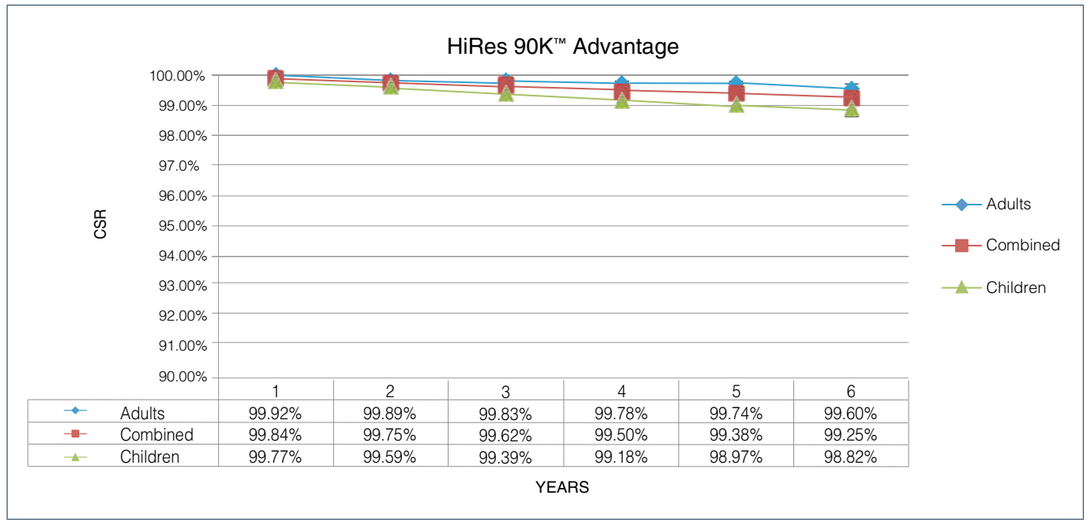
did you know?...

LASER TECHNOLOGY IS EXTENSIVELY USED TO MANUFACTURE THE IMPLANTS FROM RAW MATERIALS TO FINAL PACKAGING..

Number of registered HiRes 90K Advantage implants as of July 15, 2019

Adults	Children	Combined
14,531	16,643	32,745*

Date of first commercial introduction: 2012



	1	2	3	4	5	6
Adults	99.92%	99.89%	99.83%	99.78%	99.74%	99.60%
Combined	99.84%	99.75%	99.62%	99.50%	99.38%	99.25%
Children	99.77%	99.59%	99.39%	99.18%	98.97%	98.82%

HiRes 90K™ Cochlear Implant

The HiRes 90K implant, the precursor to the HiRes 90K advantage implant, offers users access to advanced sound processing technology. It's been approved for MRI and can undergo 1.5T MRI scans with the magnet removed. The HiRes 90K implant has had manufacturing modifications—the version that is currently available is termed the HiRes 90K (vendor A post-mod) implant.

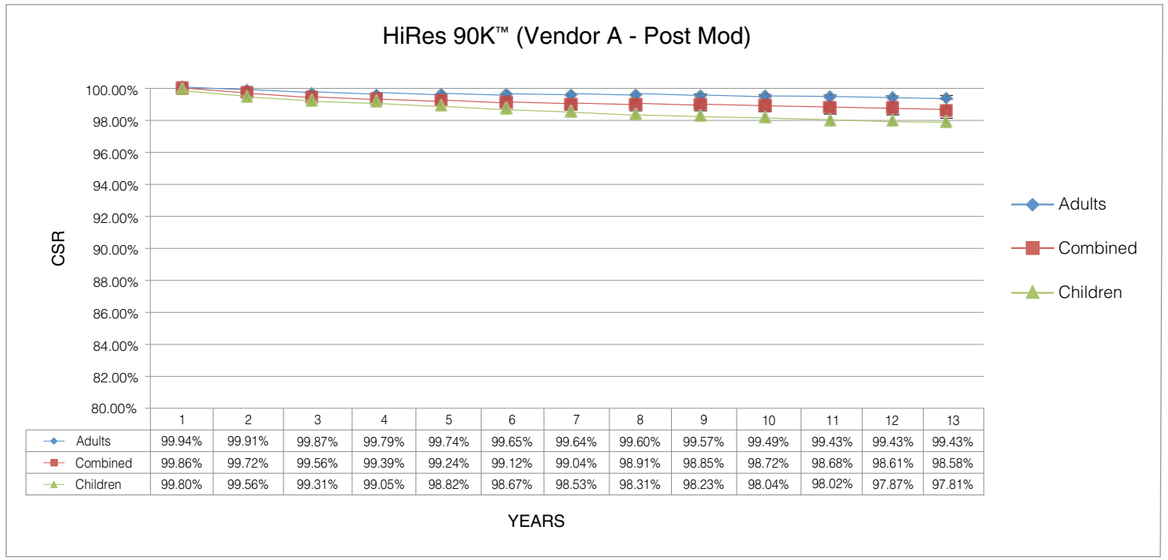
did you know?...

AB IS PART OF THE SONOVA GROUP OF COMPANIES. TOGETHER WITH OUR SISTER COMPANY, PHONAK, WE HAVE COMBINED TO BRING STATE-OF-THE-ART SOLUTIONS FROM THE HEARING AID FIELD TO COCHLEAR IMPLANT USERS.

Number of registered HiRes 90K (Vendor A Post Mod) implants as of July 15, 2019

Adults	Children	Combined
30,618	41,120	73,878*

Last year of distribution[9]: Still available in select markets



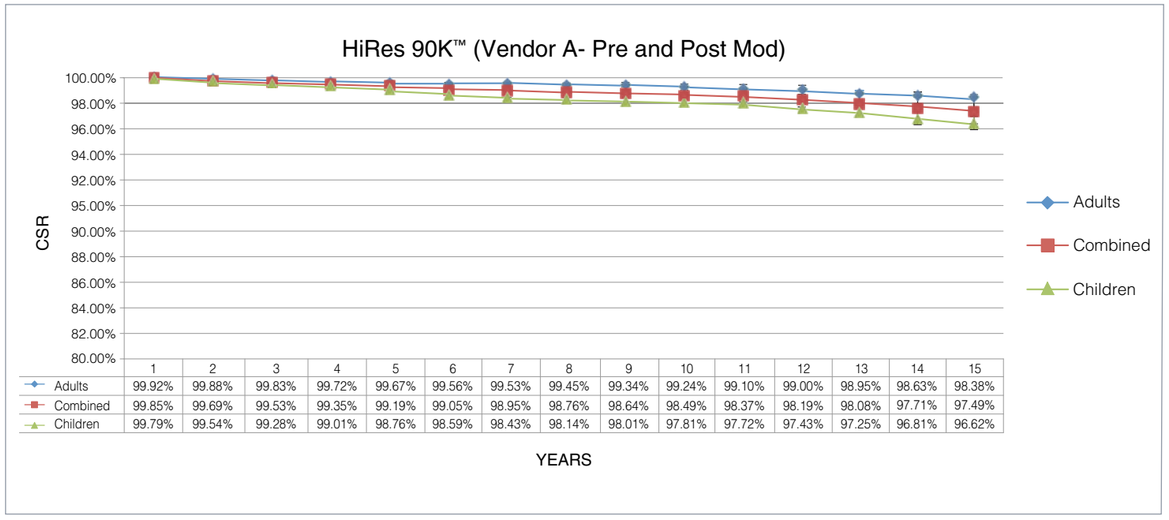
	1	2	3	4	5	6	7	8	9	10	11	12	13
Adults	99.94%	99.91%	99.87%	99.79%	99.74%	99.65%	99.64%	99.60%	99.57%	99.49%	99.43%	99.43%	99.43%
Combined	99.86%	99.72%	99.56%	99.39%	99.24%	99.12%	99.04%	98.91%	98.85%	98.72%	98.68%	98.61%	98.58%
Children	99.80%	99.56%	99.31%	99.05%	98.82%	98.67%	98.53%	98.31%	98.23%	98.04%	98.02%	97.87%	97.81%

HIRES 90K — ALL VENDOR A CSR%

Number of registered HiRes 90K (Vendor A All) implants as of July 15, 2019

Adults	Children	Combined
32,068	42,211	76,432*

Last year of distribution[9]: Still available in select markets



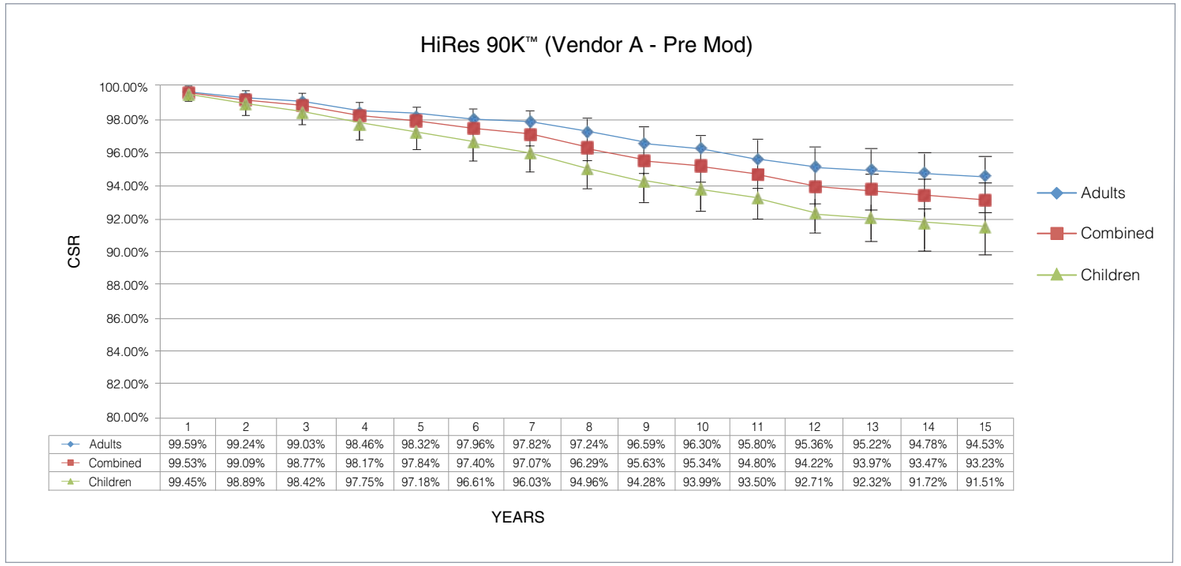
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Adults	99.92%	99.88%	99.83%	99.72%	99.67%	99.56%	99.53%	99.45%	99.34%	99.24%	99.10%	99.00%	98.95%	98.63%	98.38%
Combined	99.85%	99.69%	99.53%	99.35%	99.19%	99.05%	98.95%	98.76%	98.64%	98.49%	98.37%	98.19%	98.08%	97.71%	97.49%
Children	99.79%	99.54%	99.28%	99.01%	98.76%	98.59%	98.43%	98.14%	98.01%	97.81%	97.72%	97.43%	97.25%	96.81%	96.62%

HIRES 90K — VENDOR A PRE MOD CSR%

Number of registered HiRes 90K (Vendor A Pre Mod) implants as of July 15, 2019

Adults	Children	Combined
1,450	1,092	2,555*

Last year of distribution[9]: Still available in select markets



	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Adults	99.59%	99.24%	99.03%	98.46%	98.32%	97.96%	97.82%	97.24%	96.59%	96.30%	95.80%	95.36%	95.22%	94.78%	94.53%
Combined	99.53%	99.09%	98.77%	98.17%	97.84%	97.40%	97.07%	96.29%	95.63%	95.34%	94.80%	94.22%	93.97%	93.47%	93.23%
Children	99.45%	98.89%	98.42%	97.75%	97.18%	96.61%	96.03%	94.96%	94.28%	93.99%	93.50%	92.71%	92.32%	91.72%	91.51%

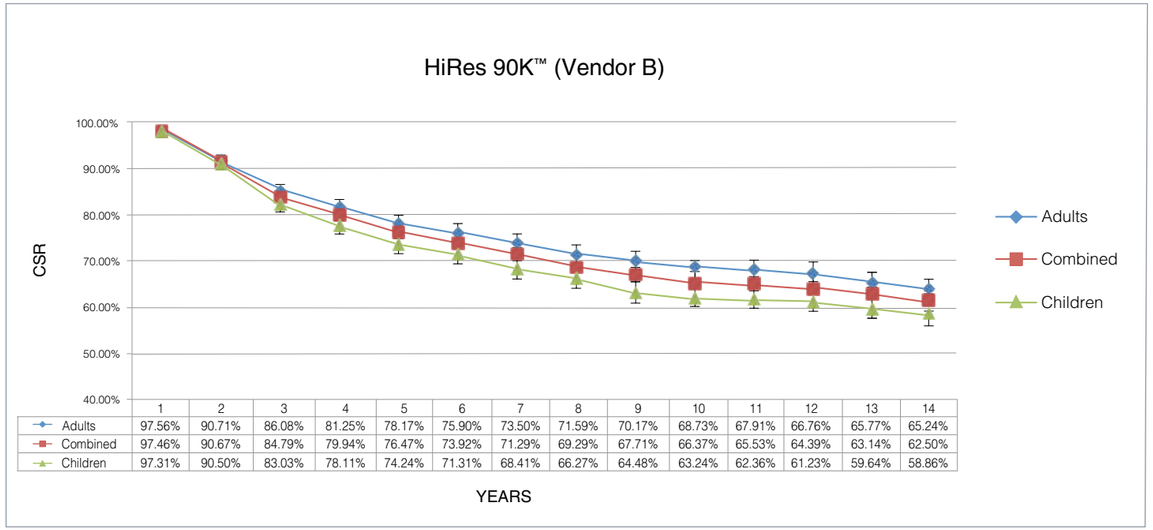
> I chose AB after extensive research as I felt their CI and processor technology would deliver the best sound quality. As a musician, sound quality is important. AB's CI system allows me to hear the subtle differences in pitch and tone that I was missing with my hearing aids. AB was also appealing to me as they are based in the US and put significant effort in developing and improving CI technology.
>
> — Joshua T., AB Recipient

HIRES 90K — VENDOR B CSR%

Number of registered HiRes 90K (Vendor B) implants as of July 15, 2019

Adults	Children	Combined
2,204	1,836	4,065*

Last year of distribution[9]: 2006 (Implant Voluntarily Recalled in 2006)



	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Adults	97.56%	90.71%	86.08%	81.25%	78.17%	75.90%	73.50%	71.59%	70.17%	68.73%	67.91%	66.76%	65.77%	65.24%
Combined	97.46%	90.67%	84.79%	79.94%	76.47%	73.92%	71.29%	69.29%	67.71%	66.37%	65.53%	64.39%	63.14%	62.50%
Children	97.31%	90.50%	83.03%	78.11%	74.24%	71.31%	68.41%	66.27%	64.48%	63.24%	62.36%	61.23%	59.64%	58.86%

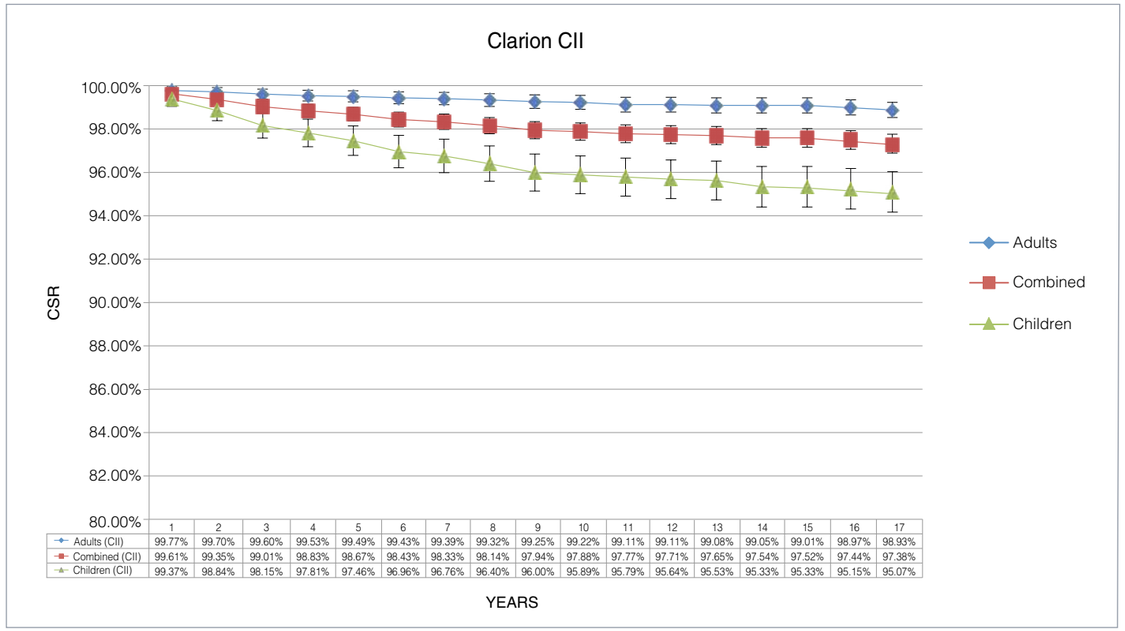
THE CLARION FAMILY OF IMPLANTS

The CII implant provided the basis for the technology behind our latest series of implants and continues to provide access to the latest innovations in sound processing strategies and sound processors. It benefits from the generational improvements to the ceramic injection molding technology used in the earlier C1.2 implants.

Number of registered CII implants - July15, 2019

Adults	Children	Combined
2,998	2,085	5,109*

Last year of distribution[9]: 2004



	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
Adults (CII)	99.77%	99.70%	99.60%	99.53%	99.49%	99.43%	99.39%	99.32%	99.25%	99.22%	99.11%	99.11%	99.08%	99.05%	99.01%	98.97%	98.93%
Combined (CII)	99.61%	99.35%	99.01%	98.83%	98.67%	98.43%	98.33%	98.14%	97.94%	97.88%	97.77%	97.71%	97.65%	97.54%	97.52%	97.44%	97.38%
Children (CII)	99.37%	98.84%	98.15%	97.81%	97.46%	96.96%	96.76%	96.40%	96.00%	95.89%	95.79%	95.64%	95.53%	95.33%	95.33%	95.15%	95.07%

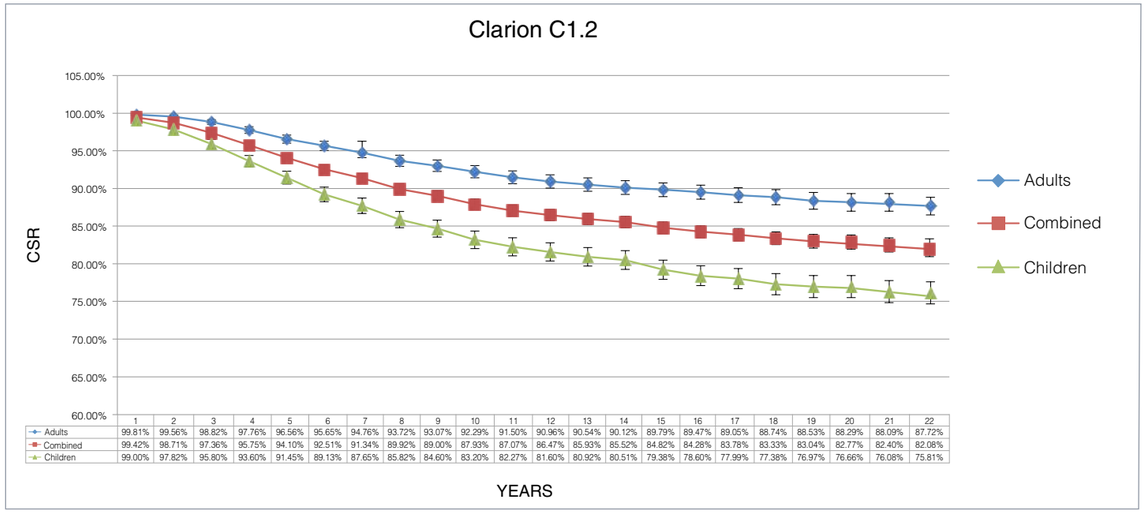
> My CI has truly gave me my life back in so many ways. It saved my job, helped me to reconnect with friends and family, get back into the social world and stop hiding from people and conversations. With “Clear Voice,” I am hearing music again and back out dancing!
>
> — Deborah S., AB Recipient

CLARION 1.2 (C1.2) IMPLANT

Number of registered C1.2 implants - July 15, 2019

Adults	Children	Combined
4,311	4,146	8,497*

Last year of distribution[9]: 2004



	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22
Adults	99.81%	99.56%	98.82%	97.76%	96.56%	95.65%	94.76%	93.72%	93.07%	92.29%	91.50%	90.96%	90.54%	90.12%	89.79%	89.47%	89.05%	88.74%	88.53%	88.29%	88.09%	87.72%
Combined	99.42%	98.71%	97.36%	95.75%	94.10%	92.51%	91.34%	89.92%	89.00%	87.93%	87.07%	86.47%	85.93%	85.52%	84.82%	84.28%	83.78%	83.33%	83.04%	82.77%	82.40%	82.08%
Children	99.00%	97.82%	95.80%	93.60%	91.45%	89.13%	87.65%	85.82%	84.60%	83.20%	82.27%	81.60%	80.92%	80.51%	79.38%	78.60%	77.99%	77.38%	76.97%	76.66%	76.08%	75.81%

> Well, all my relatives, my friends, his friends, his classmates, his teachers, are surprised because thanks to the cochlear implant, he is living his life normally. He lives his life like any other child — he plays with his friends, he talks with them using the telephone, he sends them texts. They also send audio through their cell phone to each other and play — he has fun like all the other children.
>
> — Sandra O., Mother of AB Recipient

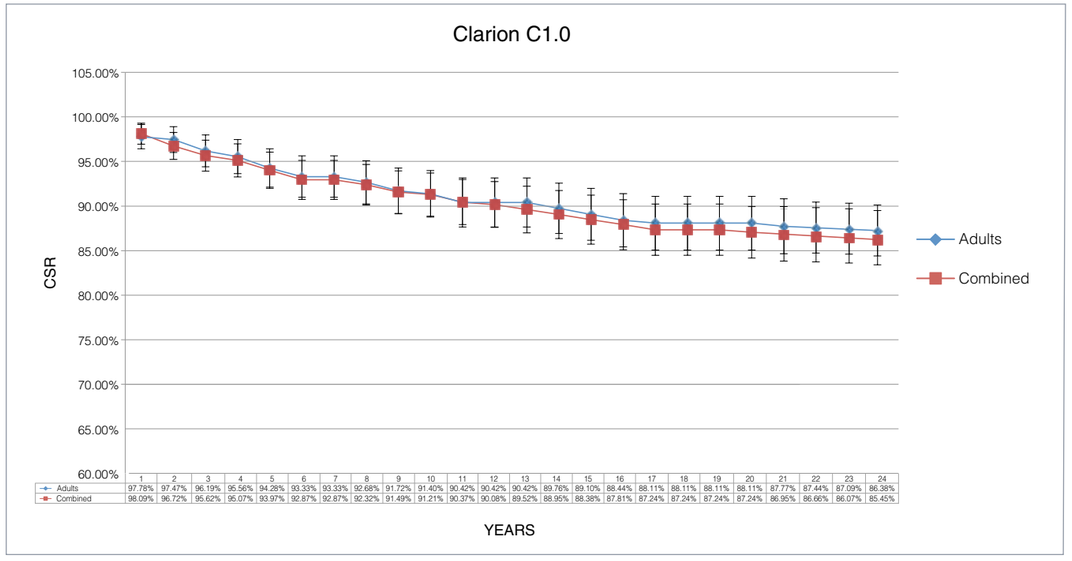
CLARION 1.0 (C1.0) IMPLANT

The C1.0 is Advanced Bionics first device, offering innovations such as independent current sources and pre-curved electrodes. As the number of children implanted is below the level required for statistical analysis, the data is included with the adult data and presented as a combined CSR. The low total population also requires the confidence intervals to be set to 90% for this group.

Number of registered C1.0 implants - July 15, 2029

Adults	Children	Combined
316	48	366*

Last year of distribution[9]: 2004



	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
Adults	97.78%	97.47%	96.19%	95.56%	94.28%	93.33%	93.33%	92.68%	91.72%	91.40%	90.42%	90.42%	90.42%	89.76%	89.10%	88.44%	88.11%	88.11%	88.11%	88.11%	87.77%	87.44%	87.09%	86.38%
Combined	98.09%	96.72%	95.62%	95.07%	93.97%	92.87%	92.87%	92.32%	91.49%	91.21%	90.37%	90.08%	89.52%	88.95%	88.38%	87.81%	87.24%	87.24%	87.24%	87.24%	86.95%	86.66%	86.07%	85.45%

To learn more about the unique advantages
of hearing with Advanced Bionics,
visit start.myabonline.com (for candidates & recipients)
or abproportal.com (for professionals),
call 866.844.4327 (HEAR),
or email hear@advancedbionics.com.

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For information on additional AB locations, please visit
advancedbionics.com/contact

AB – A Sonova brand

*Implants registered without DOB information are included in Combined data but cannot be classified as Adult or Child. Implant data also includes those implants implanted during clinical trials.

1. ISO 5841-2 (2014) Implants for surgery -cardiac pacemakers, Internatinoal Organization for Standardization (ISO), Geneva, Switzerland.
2. European Consensus Statement on Cochlear Implant Failures and Explanations. (2005) Otology and Neurology, 26(6): 1097-1099.
3. All CSR data contained in this report is valid as of July 15, 2019.
4. 2018 Cochlear Nucleus Implant Reliability report.
5. Cochlear Implant Reliability . https://www.medel.com/hearing-solutions/cochlear-implants/reliability#Our_Promise. Accessed May 30, 2019.
6. 2018 Oticon Reliability Report.
7. Todt I, Rademacher G, Grupe G, et al. Cochlear implants and 1.5 T MRI scans: the effect of diametrically bipolar magnets and screw fixation on pain. J Otolaryngol Head Neck Surg. 2018;47(1):11. Published 2018 Feb 5. doi:10.1186/s40463-017-0252-
8. Grupe G, Wagner J, Hofmann S, Stratmann A, Mittmann P, Ernst A, Todt I. [Prevalence and complications of MRI scans of cochlear implant patients: German version]. HNO. 2016 Mar;64(3):156-62. doi: 10.1007/s00106-016-0128-8. German. PubMed PMID: 26879879.
9. Dates provided are those for major markets covered by FDA and TUV regulation. HiRes™ Ultra and HiRes 90K™ Advantage implants may be pending approval in a small subset of additional regions.

027-N025-02 RevC