

# 2018 Global Implant Reliability Report



Advanced Bionics

A Sonova brand





**Anthony G., 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.

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## **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<sup>1</sup> and the principles outlined in the *European & Global Consensus on Cochlear Implant Failures and Explantations*.<sup>2</sup>

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.

Reporting Principle	Advanced Bionics Commitment
Report all device failures in adherence to the global standard as defined by ISO 5841-2:2014. <sup>1</sup>	
Report to the seven principles of best practice reporting as outlined in the European & Global Consensus on Cochlear Implant Failures and Explantations. <sup>2</sup>	 AB provides this for you while others may not
Sample size and time period are specified for each reported implant.	 AB provides this for you while others may not
AB differentiates all implant and electrode types with unique model numbers and they all gain independent FDA and CE mark regulatory approval.	 AB provides this for you while others may not
AB reports on specific device information (for example, HiRes 90K Vendor A and Vendor B devices) and will continue to do so.	 AB provides this for you while others may not
Reports show separate data for adults and children.	 AB provides this for you while others may not
95% confidence intervals are clearly and visually indicated for every graph.	 AB provides this for you while others may not
All failures are counted that occur any time after wound closure.	
Actual CSR values <sup>3</sup> presented for all implants, all generations, no computer-generated modeling data are used.	 AB provides this for you while others may not
Accident related device failures are included in our standard CSR calculations.	 AB provides this for you while others may not



## 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.

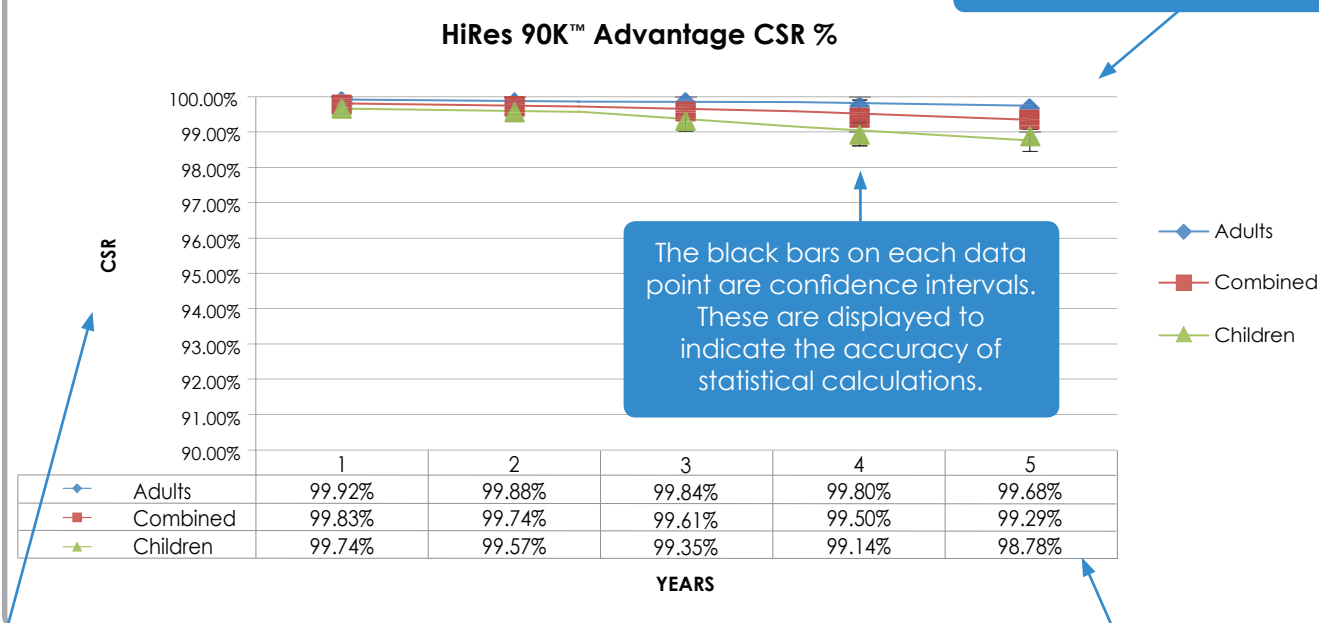
**Number of registered HiRes 90K Advantage implants as of June 1, 2018**

Adults	Children	Combined
13,637	13,627	28,406*

*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.



### 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.



## Exhaustive Testing and Complete Reporting for Greater Implant Success: The AB Difference

Every implant recipient and their hearing needs are unique. Finding the right solution can take 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.

All hearing healthcare professionals should be aware of this variability so they can select the most reliable products for their patients’ needs — whether it’s for better hearing at home, at work, in the classroom, on the phone or on the ball field.

**But no matter what other companies do, we at Advanced Bionics adhere 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 all their life’s moments and milestones. It’s why we perform an exhaustive analysis on ALL returned devices, including a full diagnostic assessment of device hermeticity (the ability to retain an air-tight seal). 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 specify additional testing or analysis to determine the root cause.\*

### Have Questions? Contact Us.

We’re committed to providing 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](mailto:hear@AdvancedBionics.com). You can also visit [AdvancedBionics.com](https://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 that 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.

**Preston L.**, AB Recipient pictured with his brother



# HiRes™ Ultra Cochlear Implant

The Industry's Most Flexible and Durable  
High-Performance Implant



The HiRes™ Ultra implant is the newest member of the HiRes implant family and features advanced sound processing circuitry to provide unsurpassed programming flexibility, nearly unlimited ways to deliver sound and full upgradeability for access to tomorrow's innovations — without the need for additional surgery.

The thinner profile of the HiRes Ultra implant makes it suitable for all ages, while its durable construction provides the highest-rated resistance to impact in the industry,<sup>4</sup> which allows for fully uncompromised living. Improved MRI compatibility allows for state of the art medical care.

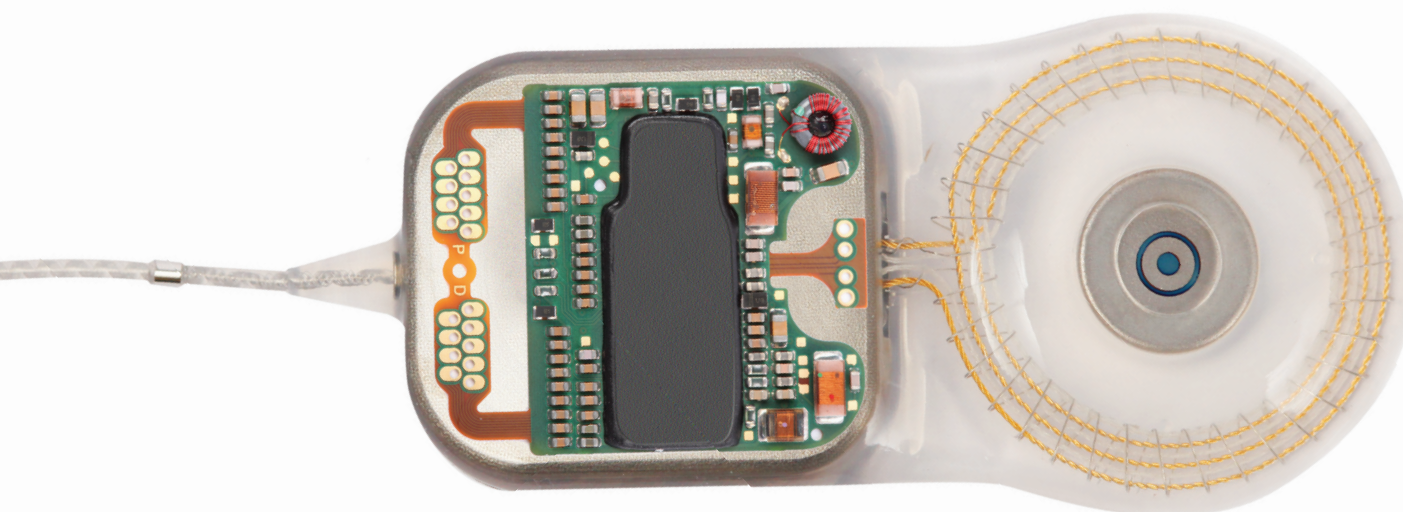
The HiRes Ultra offers a thin, discreet design suitable for adults and children alike. It is compatible with a 3T MRI procedure and it is designed to exceed the industry standards for impact resistance, offering peace of mind whilst enjoying life's adventures.

### Number of registered HiRes Ultra cochlear implants as of June 1, 2018

Adults	Children	Combined
3,807	1,565	5,481*

*Date of first commercial introduction: 2016*

Years	1
<b>Adults</b>	<b>99.91%</b>
95% Upper CI	100.00%
95% Lower CI	99.79%
<b>Combined</b>	<b>99.91%</b>
95% Upper CI	100.00%
95% Lower CI	99.79%
<b>Children</b>	<b>99.90%</b>
95% Upper CI	100.00%
95% Lower CI	99.69%







Did you know that AB offers options for you to keep both of your ears working together and contributing to your hearing experience? The Naída CI sound processor works together with another Naída CI sound processor, a hearing aid or a wireless CROS microphone.

**Jessica P., AB Recipient**

# Previous-Generation Implant Data

## HiRes 90K™ Advantage Cochlear Implant

The HiRes 90K Advantage implant features the same advanced sound processing circuitry as the HiRes Ultra implant but offers the ability to create a greater depth bone bed for securing the implant. It also provides a choice of available electrode options. It has mechanical improvements over the HiRes 90K implant.

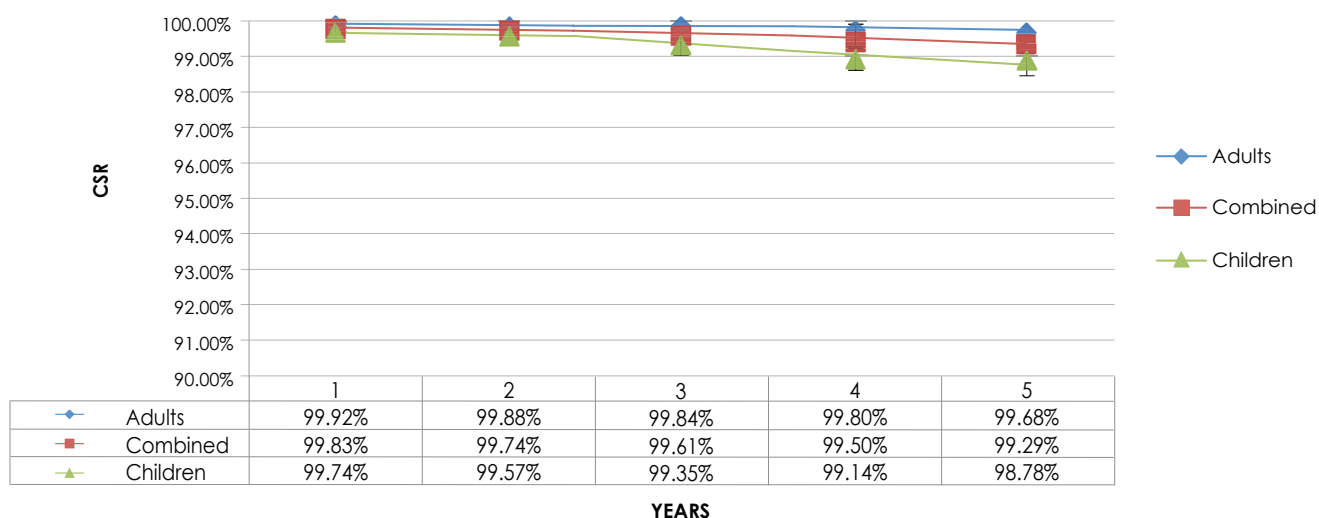


**Number of registered HiRes 90K Advantage implants as of June 1, 2018**

Adults	Children	Combined
13,637	13,627	28,406*

*Date of first commercial introduction: 2012*

**HiRes 90K™ Advantage CSR %**





# HiRes 90K™ Cochlear Implant

The HiRes 90K implant, the precursor to the HiRes 90K Advantage implant, has had some variants during its production. The variant currently available is termed the HiRes 90K (Vendor A Post-Mod) implant and benefits from some manufacturing modifications.

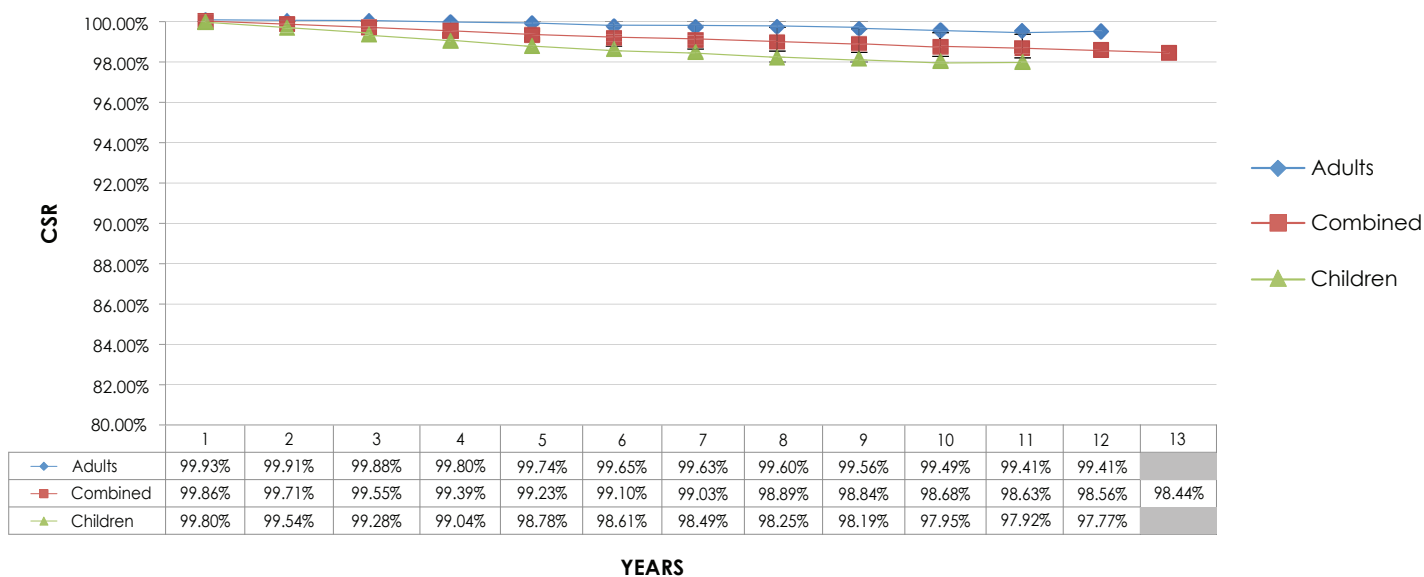


Number of registered HiRes 90K (Vendor A Post Mod) implants as of June 1, 2018

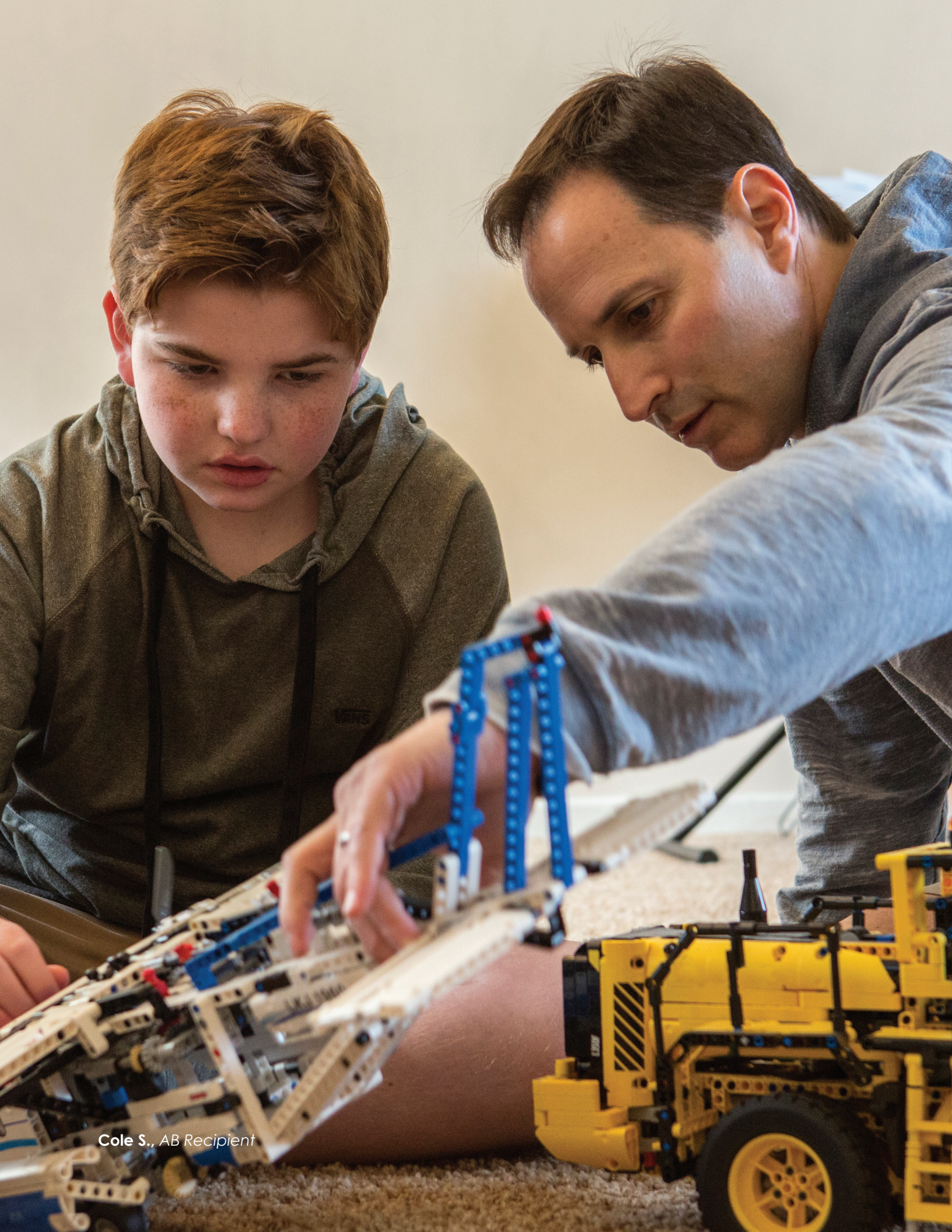
Adults	Children	Combined
29,535	36,944	68,211*

*Last year of distribution<sup>5</sup>: Still available in select markets*

HiRes 90K™ Vendor A Post Mod CSR %







Cole S., AB Recipient



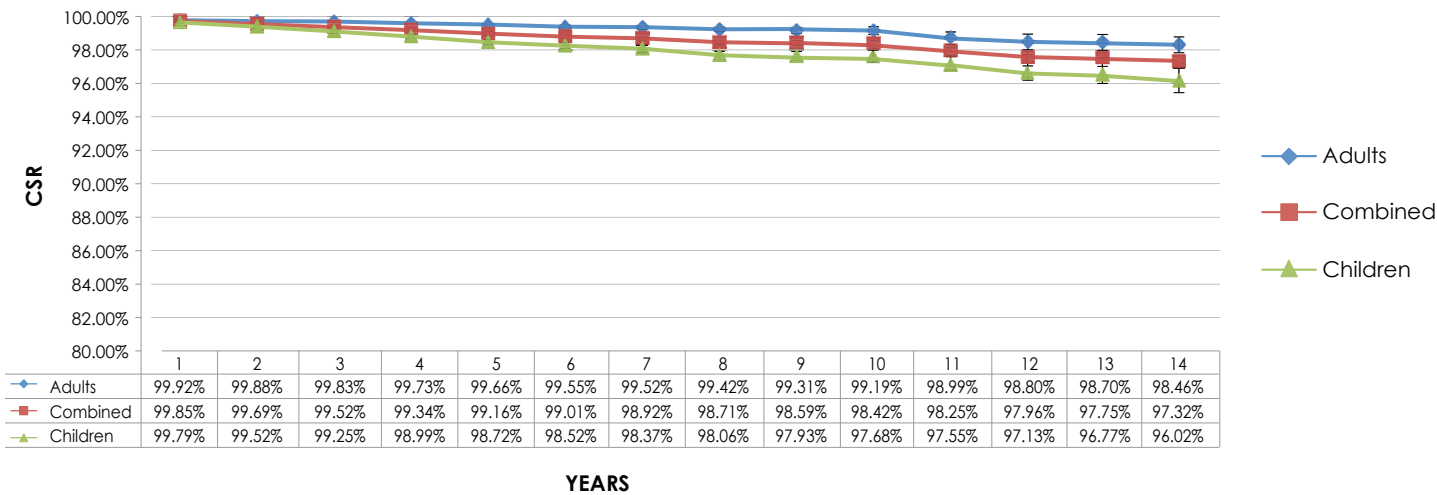
# HiRes 90K Vendor A – All CSR %

Number of registered HiRes 90K (Vendor A All) implants as of June 1, 2018

Adults	Children	Combined
30,980	38,034	70,764*

Last year of distribution<sup>5</sup>: Still available in select markets

HiRes 90K™ Vendor A - All CSR %

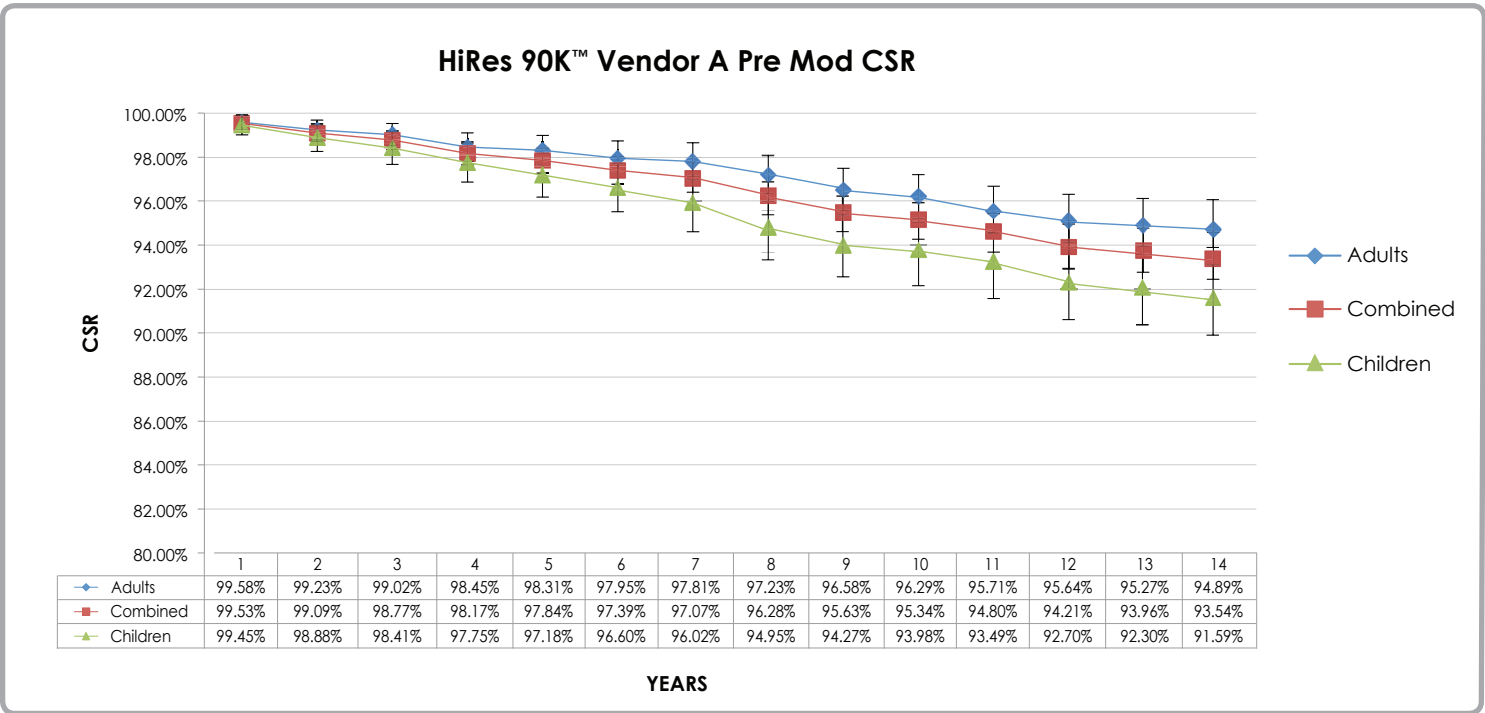


# HiRes 90K Vendor A Pre Mod CSR %

Number of registered HiRes 90K (Vendor A Pre Mod) implants as of June 1, 2018

Adults	Children	Combined
1,445	1,090	2,553*

Last year of distribution<sup>5</sup>: Still available in select markets





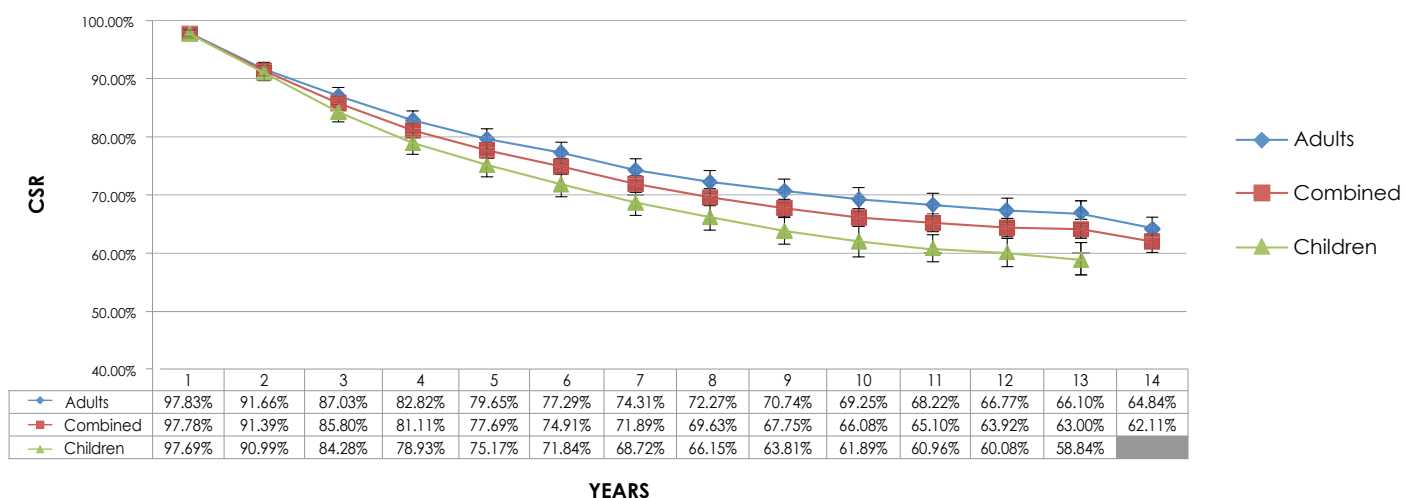
## HiRes 90K Vendor B CSR %

Number of registered HiRes 90K (Vendor B) implants as of June 1, 2018

Adults	Children	Combined
2,199	1,838	4,066*

Last year of distribution<sup>5</sup>: 2006 (Implant Voluntarily Recalled in 2006)

HiRes 90K™ CSR % (Vendor B)



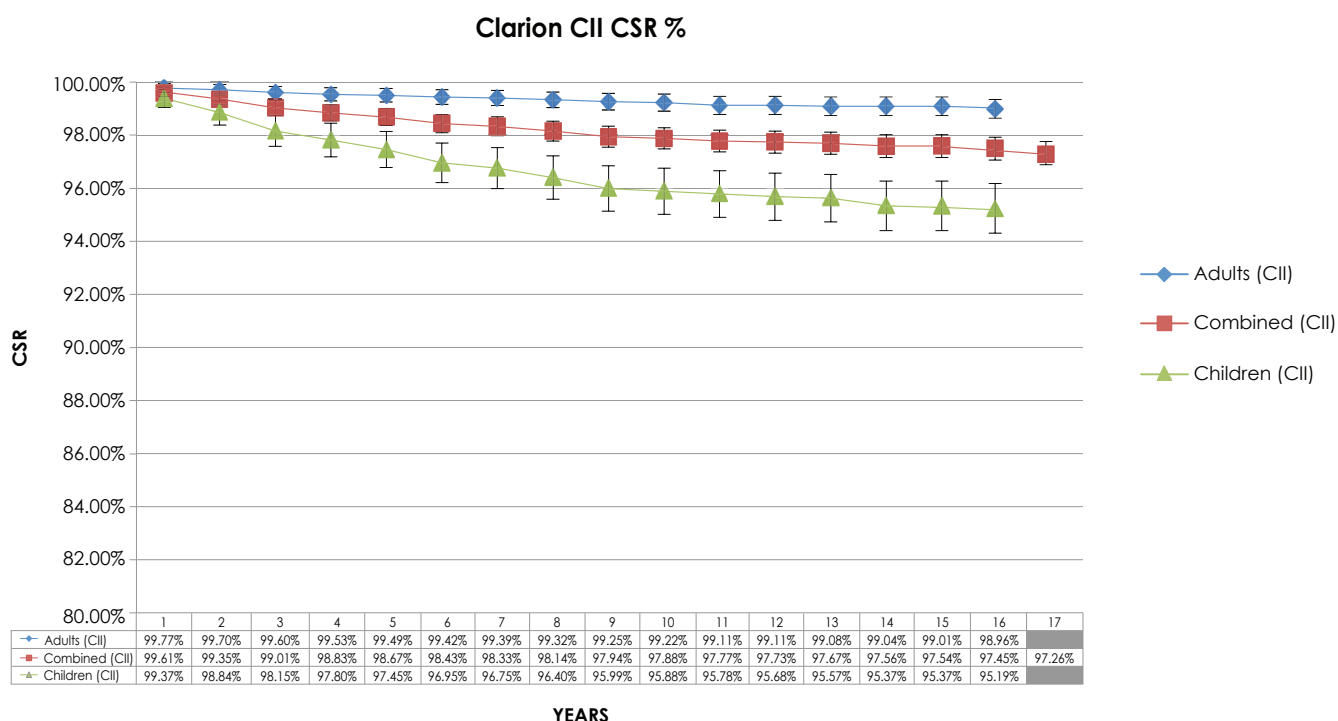
## Clarion Family of Implants

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 - June 1, 2018

Adults	Children	Combined
2,987	2,080	5,108*

Last year of distribution<sup>5</sup>: 2004



Choosing a device commits you to a lifetime with that technology — it is important that you choose a system capable of distinguishing between a drum and a flute, a high note and a low note, and the voice of a friend from that of a stranger.



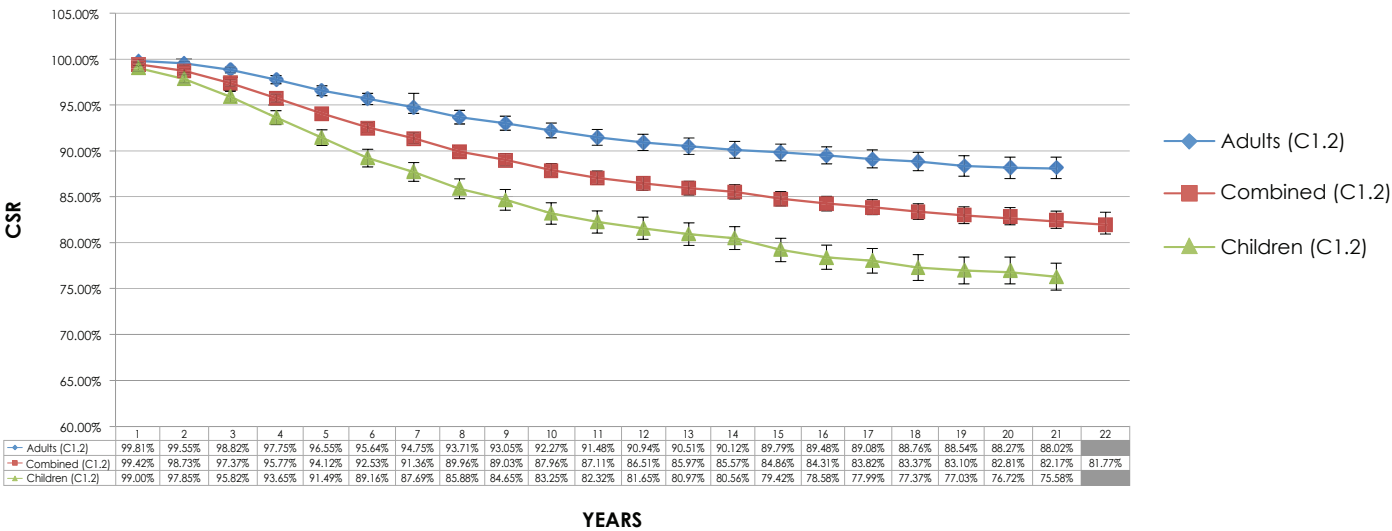
# Clarion 1.2 (C1.2) Implant

Number of registered C1.2 implants - June 1, 2018

Adults	Children	Combined
4,299	4,142	8,495*

Last year of distribution<sup>5</sup>: 2004

Clarion C1.2 CSR %



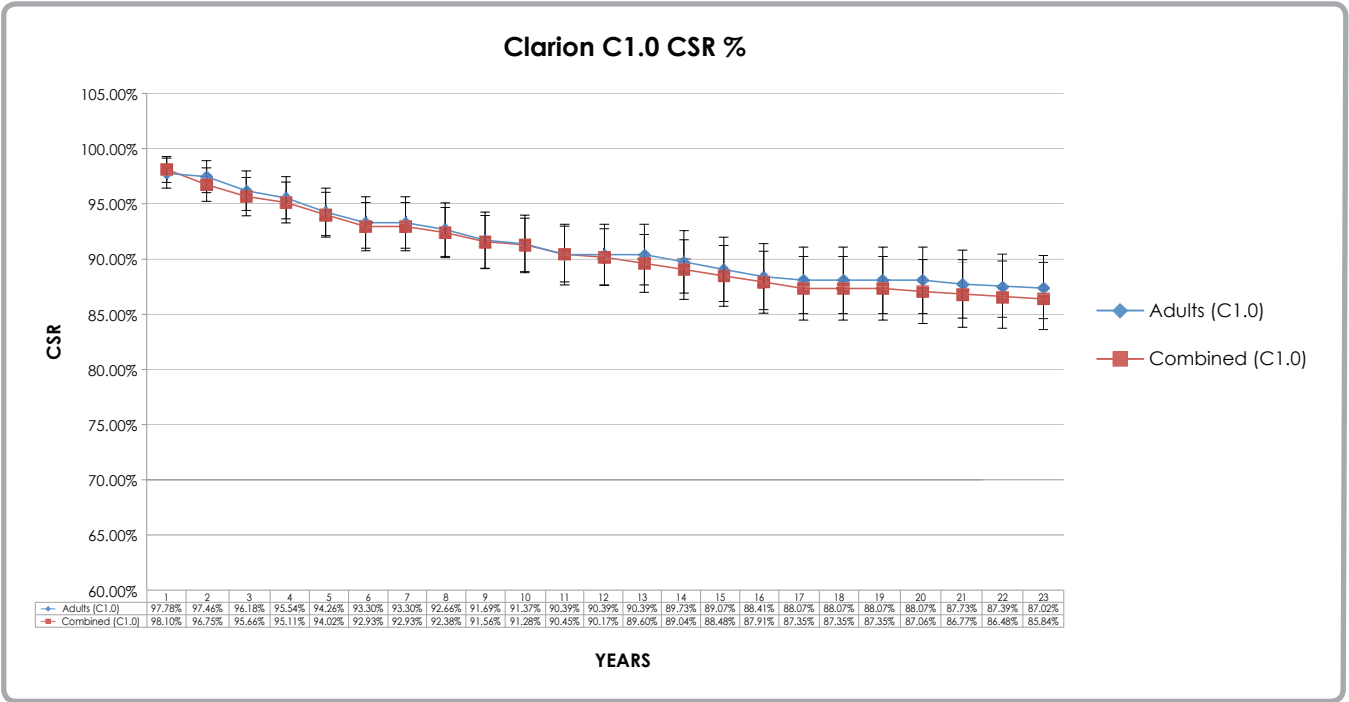
# Clarion 1.0 (C1.0) Implant

The C1.0 is Advanced Bionics first device, offering innovations such as independent current sources and pre-curved electrodes. As the number of children implant 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 - June 1, 2018

Adults	Children	Combined
315	50	369*

Last year of distribution<sup>5</sup>: 2004





To learn more about the unique advantages  
of hearing with Advanced Bionics,  
call **866.844.4327 (HEAR)**,  
email **hear@AdvancedBionics.com**,  
or visit **AdvancedBionics.com**.



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For information on additional AB locations, please visit  
[AdvancedBionics.com/contact](http://AdvancedBionics.com/contact)

\*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. International Organization for Standardization (ISO), Geneva, Switzerland.
2. European Consensus Statement on Cochlear Implant Failures and Explantations. (2005) *Otology and Neurology*, 26(6): 1097–1099.
3. All CSR data contained in this report is valid as of June 1, 2018.
4. EN 45502-2-3:2010. Active Implantable Medical Devices. Particular Requirements for Cochlear and Auditory Brainstem Implant Systems.
5. Dates provided are those for major markets covered by FDA and TÜV regulation. HiRes™ Ultra and HiRes 90K™ Advantage implants, may be pending approval in a small subset of additional regions.

The AB recipients, their family members, and friends featured in this report have not been compensated for the use of their image in this material.

Pictured on the cover:

**Charles H., AB Recipient**

