

2016 Mid-Year Cochlear Implant Reliability Report



A Sonova brand



Advanced Bionics



Our Mission

At **Advanced Bionics** we are dedicated to improving lives by developing technologies and services that help our recipients achieve their full potential.

Our commitment to putting **patients first** and providing the best possible hearing performance remains at the forefront of all that we do.

The trust patients place in us inspires us to act with **integrity and transparency** as we **strive for excellence** each and every day in all that we do.

The Industry's Most Transparent Reporting

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 5841-2:2014¹ and the principles outlined in the European & Global Consensus on Cochlear Implant Failures and Explantations².

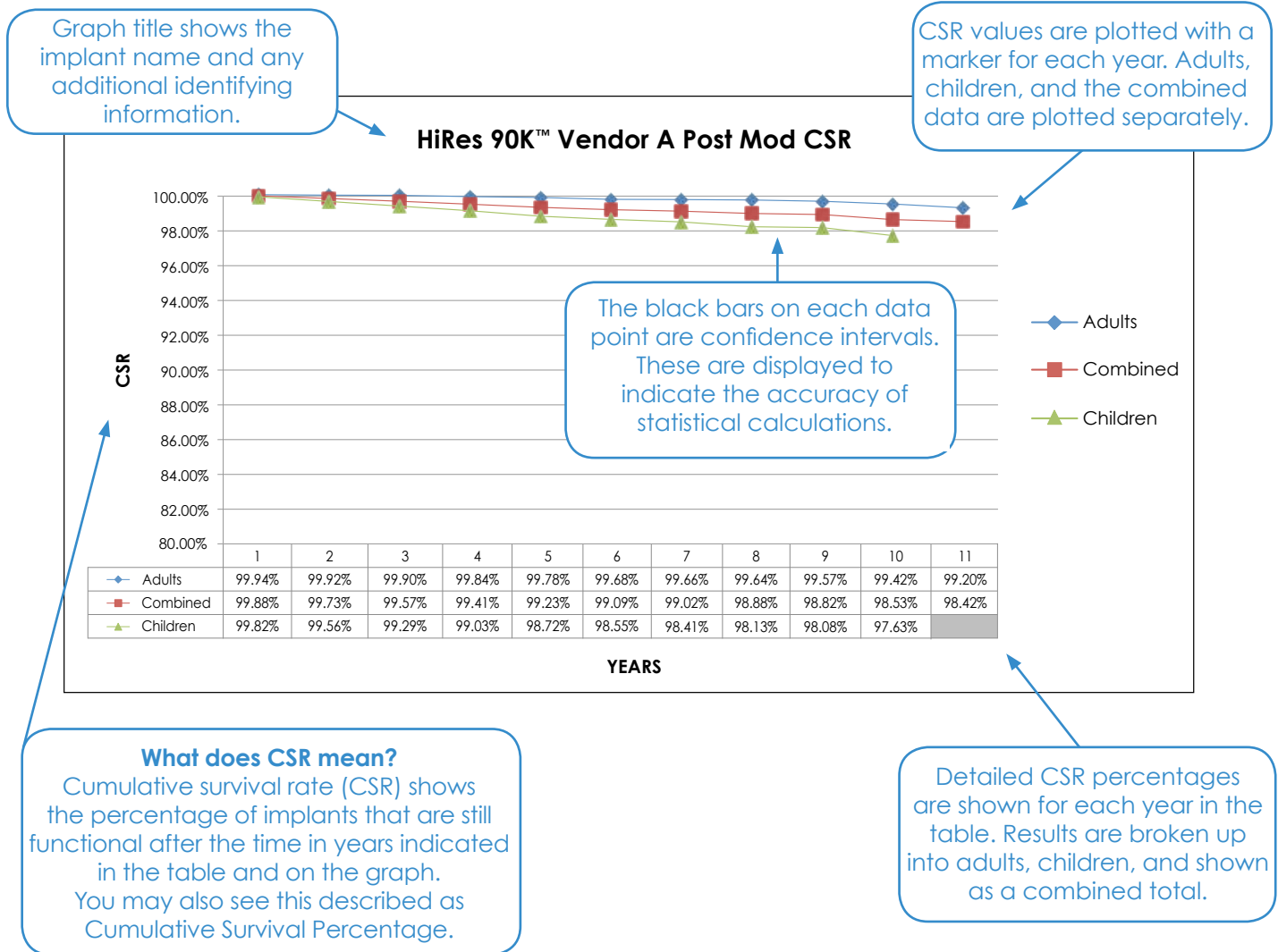
Even though all manufacturers adhere to these standards, other manufacturers may report using different definitions of what constitutes a device failure, and therefore not include the same types of information in their reliability statistics.

Additionally, AB provides data for different iterations of implants in a series both "pre" and "post" modification, while other manufacturers may only present their data "post" modification, leaving out important information for the earlier, pre-modification version.

Advanced Bionics is committed to providing patients and professionals with the most complete reports, in an easy-to-interpret format, with data presented clearly and transparently.

Your Life. **Our Commitment.**TM

Important Tips for Reading the Graphs in this Report



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.



Know the Truth, Understand the Transparency

At Advanced Bionics we strive to not only provide reliable implants, but we also provide clear, complete reporting, and respond to any issues that may arise quickly, with transparency, and with the patient's best interest in mind.

Reporting Principle	Advanced Bionics Commitment
Report all device failures in adherence to the global standard as defined by ISO 5841-2:2014 ¹ .	<input checked="" type="checkbox"/>
Report to the seven principles of best practice reporting as outlined in the European & Global Consensus on Cochlear Implant Failures and Explantations ² .	<input checked="" type="checkbox"/> AB provides this for you while others may not
Sample size and time period are specified for each reported implant.	<input checked="" type="checkbox"/> 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.	<input checked="" type="checkbox"/> AB provides this for you while others may not
Reports show separate data for adults and children.	<input checked="" type="checkbox"/> AB provides this for you while others may not
95% confidence intervals are clearly and visually indicated for every graph.	<input checked="" type="checkbox"/> AB provides this for you while others may not
All failures are counted that occur any time after wound closure.	<input checked="" type="checkbox"/>
Actual CSR values ³ presented for all implants, all generations, no computer-generated modeling data are used.	<input checked="" type="checkbox"/> AB provides this for you while others may not



Know AB, Know the Difference

Reliability is important.

When choosing a cochlear implant you want to make sure that your device is reliable and will stand up to your active lifestyle. At AB, reliability is the priority in everything we do. At two years the HiRes 90K™ Advantage implant has a 99.79% CSR.

We strongly believe that hearing healthcare professionals, recipients, and cochlear implant candidates should be aware of the important differences in reporting, as the consensus statement can allow for variability between manufacturers. CSR can only be effectively used to compare implants when data is provided by all manufacturers following the same reporting principles.

In addition to providing complete CSR data, AB is the only company that performs a comprehensive failure analysis on every device explanted and in the Failure Analysis Report provided to the center clearly indicate the root cause of the failure and whether the device is counted against the CSR.

Have Questions? Need More Information? Contact Us.

AB steadfastly supports hearing healthcare professionals in their evaluation of clinical benefit provided by a device. Company representatives remain readily available for questions, troubleshooting assistance, and device testing for both recipients and professionals. Contact AB by calling 866.844.4327, emailing hear@AdvancedBionics.com, or visiting AdvancedBionics.com.



At AB our **consistent innovation** and **cutting-edge technology** reinforces our commitment to you.

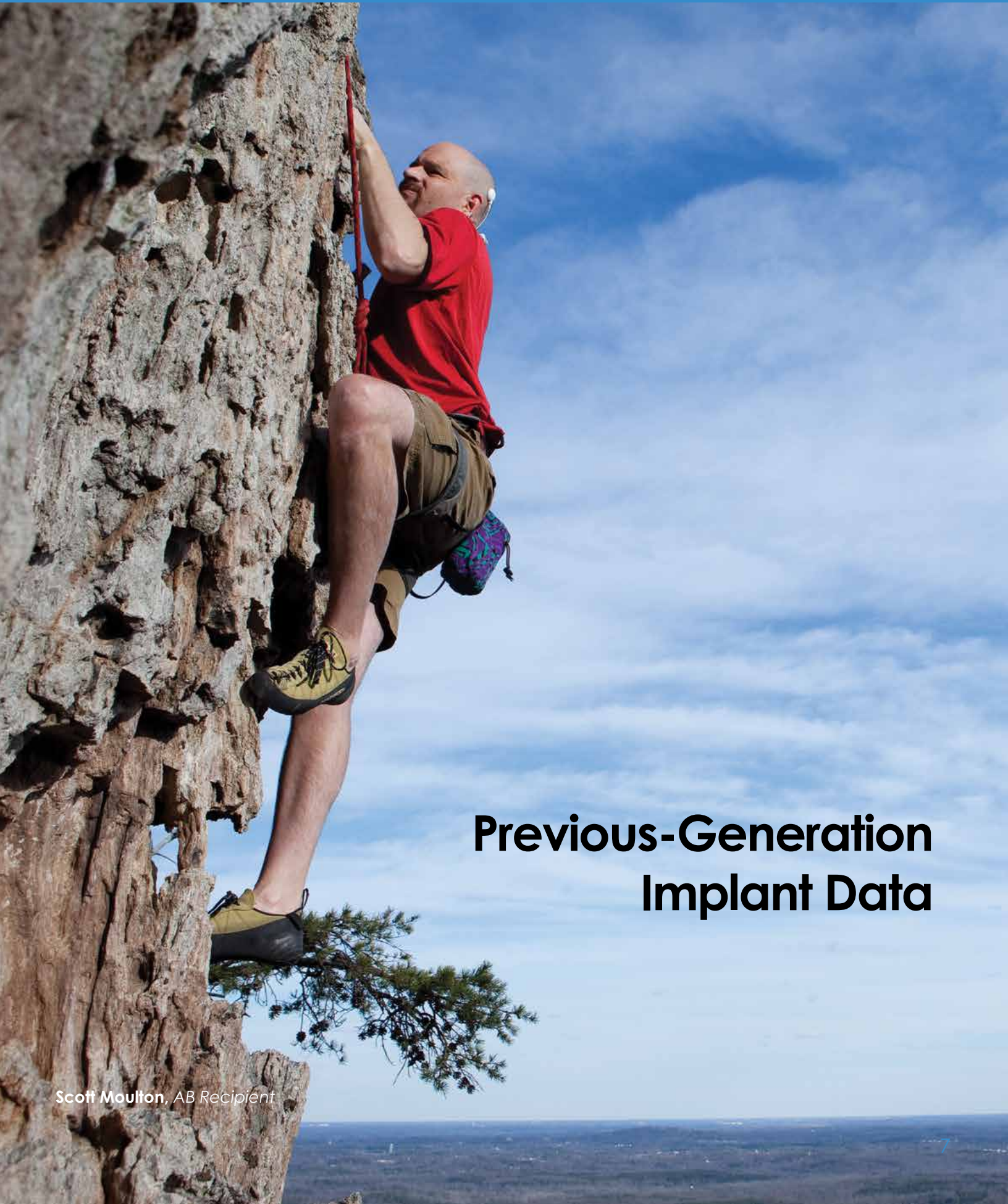
Choose AB and we promise to grow with you, providing new technology, industry-leading advancements, and **continued reliability and transparency.**

Jessica Parekh, AB Recipient

Introducing the New HiRes™ Ultra Cochlear Implant



The HiRes Ultra is our latest implant based on the advanced sound processing circuitry found in the HiRes 90K™ Advantage cochlear implant, now featured in a thin and discreet implant package with greater MRI compatibility. We will begin reporting on this device once we have a sufficiently large implanted population.



Previous-Generation Implant Data

Scott Moulton, AB Recipient



HiRes 90K™ Advantage Implant

the industry's most reliable implant

The HiRes 90K™ Advantage implant features the most advanced sound processing circuitry in the world. The sophisticated design of all implants in the HiRes 90K family provides unsurpassed programming flexibility, nearly unlimited ways to deliver sound, and full upgradeability for access to tomorrow's innovations without surgery.

HiRes 90K Advantage Implant Reliability

The HiRes 90K implant from Advanced Bionics remains the most durable in the industry. The data below indicates the real-world reliability from HiRes 90K recipients across the globe.

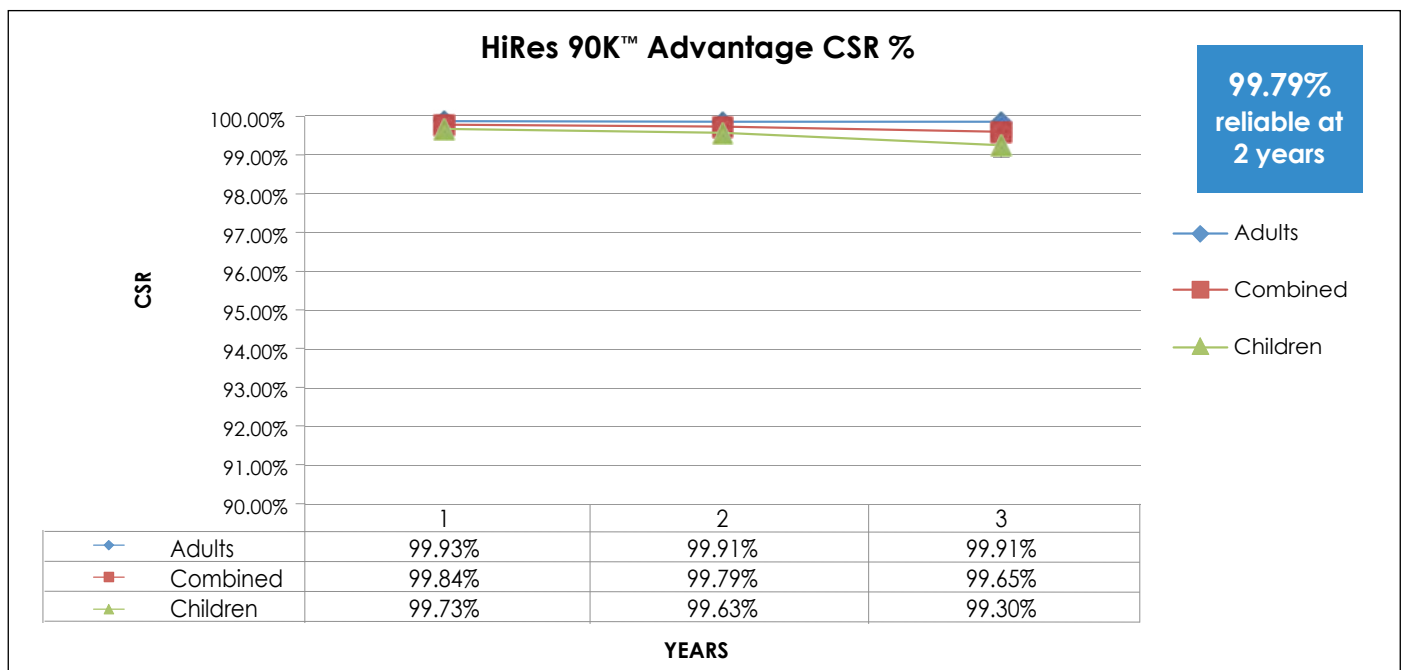


Number of registered HiRes 90K Advantage implants as of July 1, 2016

Adults	Children	Combined
9,792	8,715	19,150*

Date of first commercial introduction: 2012

This is AB's latest implant⁴





Dedicated to putting patients first, AB's rigorous and responsive Quality Assurance System is designed to protect recipients by ensuring exceptionally high product reliability, swiftly identifying any potential issue, and by employing appropriate corrective actions. AB has consistently demonstrated an unparalleled commitment to recipients by taking firm and decisive action when issues have arisen.

HiRes 90K Implant Reliability

The HiRes 90K™ implant is the most durable device on the market when it comes to impact trauma. This means you or your child can partake in sports and activities with the confidence that your implant will stand up to the challenge of your active lifestyle.

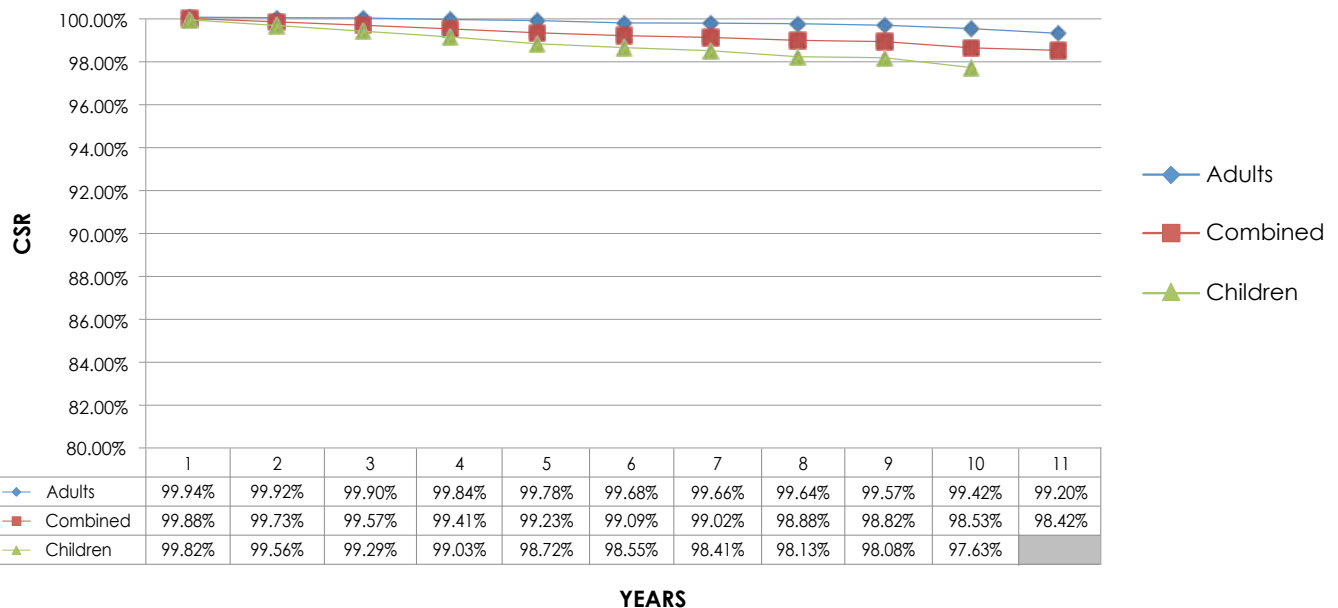
Our stringent quality system allows AB to react quickly and with the recipient's best interest in mind.

Number of registered HiRes 90K (Vendor A Post Mod) implants as of July 1, 2016

Adults	Children	Combined
25,277	30,087	56,583*

Last year of distribution⁴: Still available in select markets

HiRes 90K™ Vendor A Post Mod CSR





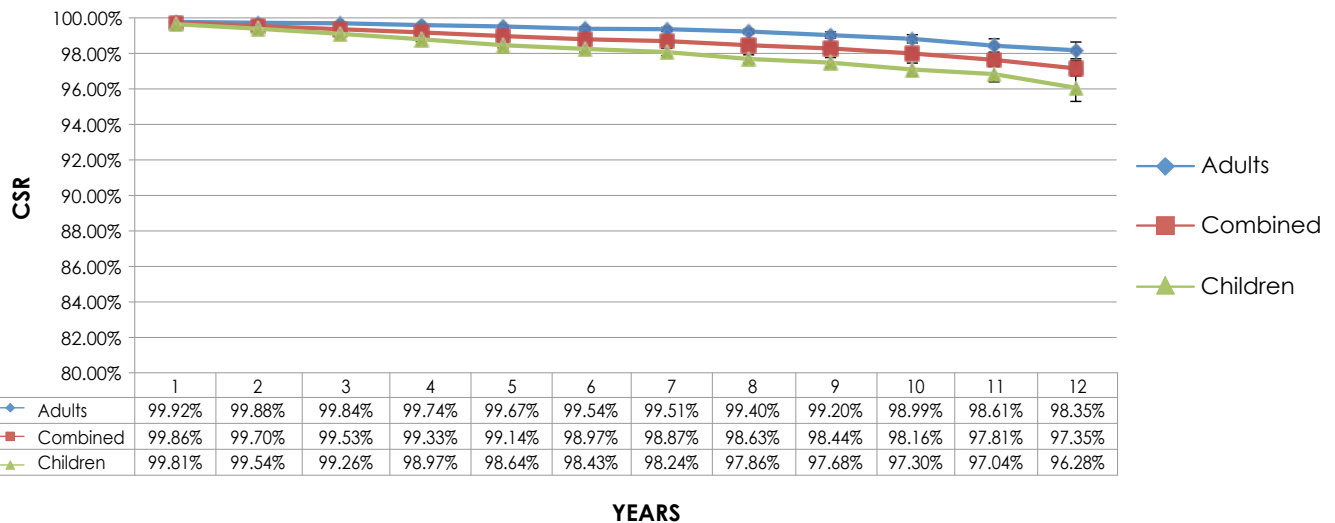
HiRes 90K Vendor A – All CSR %

Number of registered HiRes 90K (Vendor A All) implants as of July 1, 2016

Adults	Children	Combined
26,720	31,177	59,135*

Last year of distribution⁴: Still available in select markets

HiRes 90K™ Vendor A - All CSR %



Superior Quality System



Dedicated to putting patients first, AB's rigorous and responsive Quality Assurance System is designed to protect recipients by ensuring exceptionally high product reliability, swiftly identifying any potential issue, and by employing appropriate corrective actions.

AB has consistently demonstrated an unparalleled commitment to recipients by taking firm and decisive action when issues have arisen. As a result of this incomparable commitment to recipients and a superior quality system, AB instituted a voluntary recall in November 2010 after becoming aware of a rare issue with the HiRes 90K cochlear implant. AB initiated the recall with only two devices out of 28,000 confirmed to have this issue. AB continues to track this data and out of more than 50,000 implants, there are still only two confirmed instances of this issue.

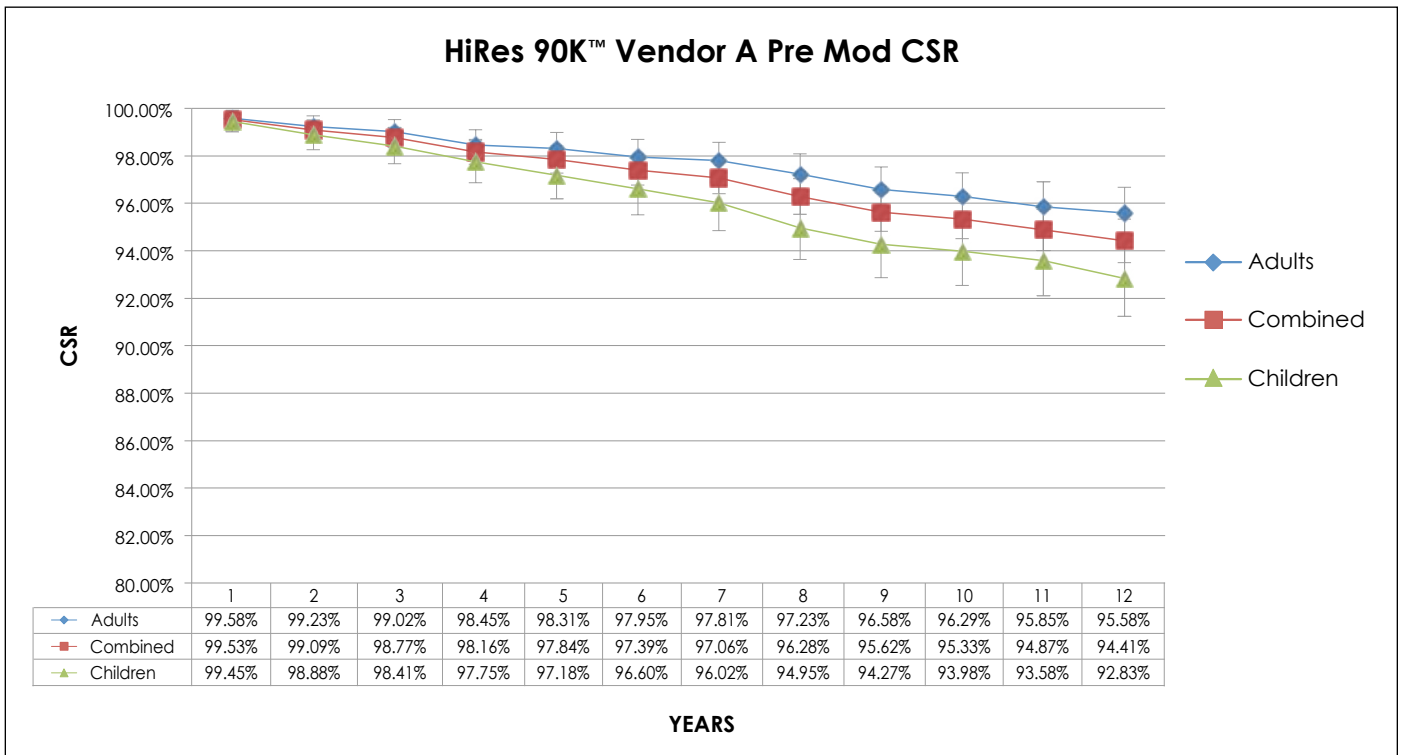


HiRes 90K Vendor A Pre Mod CSR %

Number of registered HiRes 90K (Vendor A Pre Mod) implants as of July 1, 2016

Adults	Children	Combined
1,443	1,090	2,552*

Last year of distribution⁴: 2010



Advanced Bionics provides industry-leading implants that are built to last, providing recipients with a robust solution for hearing in any environment, anywhere.



Siobhan Davis, AB Recipient



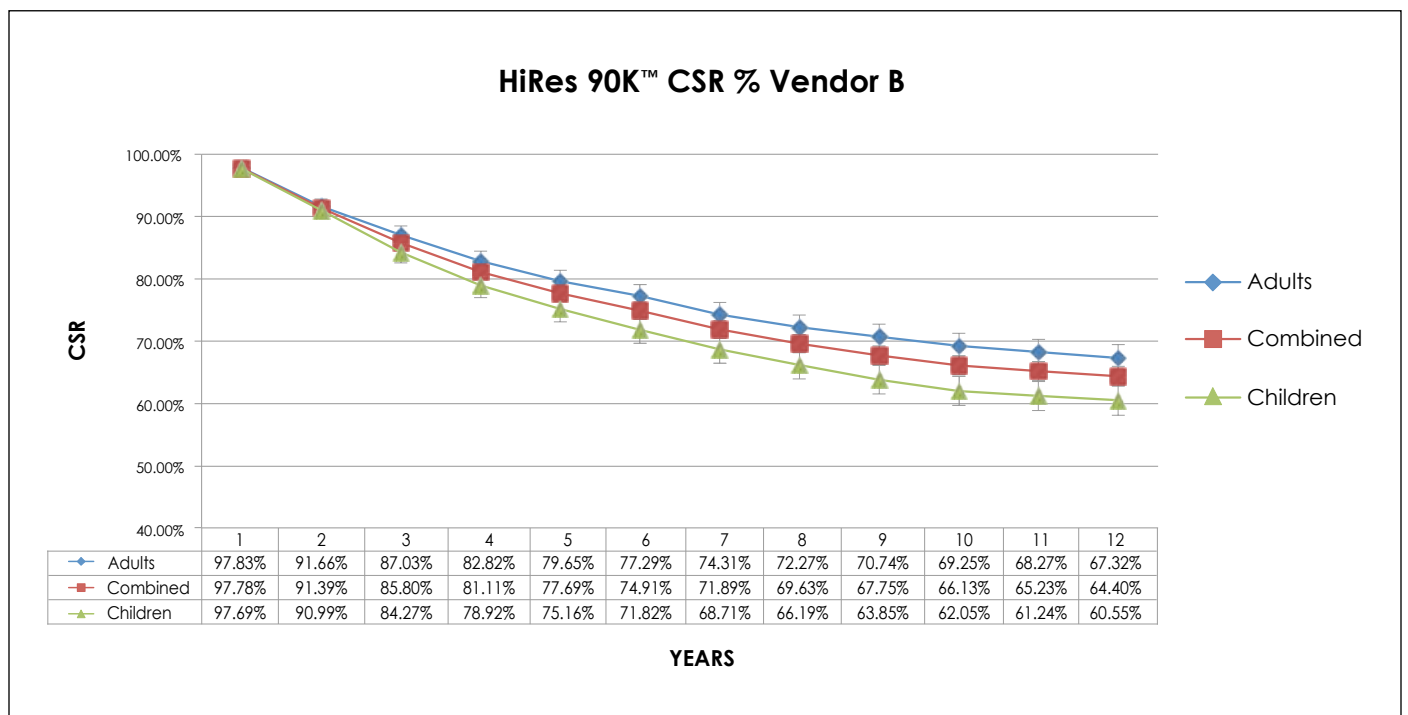
HiRes 90K Vendor B CSR %

Number of registered HiRes 90K (Vendor B) implants as of July 1, 2016

Adults	Children	Combined
2,199	1,837	4,066*

Last year of distribution⁴: 2006

Putting Recipients First: Implant Voluntarily Recalled in 2006



Edward Freeman, AB Recipient

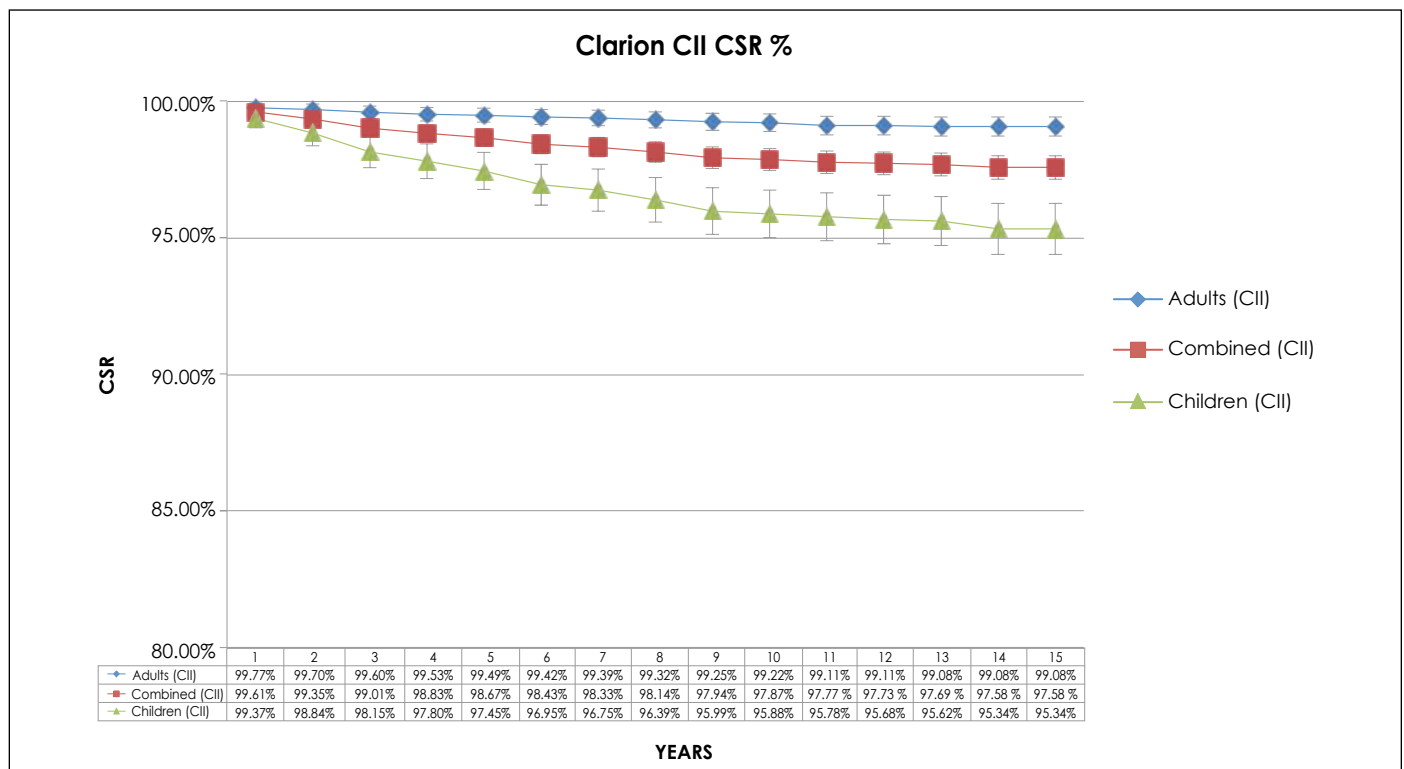
Clarion Family of Implants Reliability

Advanced Bionics recipients continue to benefit from the reliability and durability of the Clarion™ Series of implants. The CII implant represents the culmination of several generations of improvements to the ceramic injection molding technology used in the C1.2 implants.

Number of registered CII implants - July 1, 2016

Adults	Children	Combined
2,987	2,079	5,107*

Last year of distribution⁴: 2004



Did you know?

AB uses actual CSR values to provide the most accurate reporting. Other manufacturers may use a computer model instead to report failures.



Kerun Bindra, AB Recipient



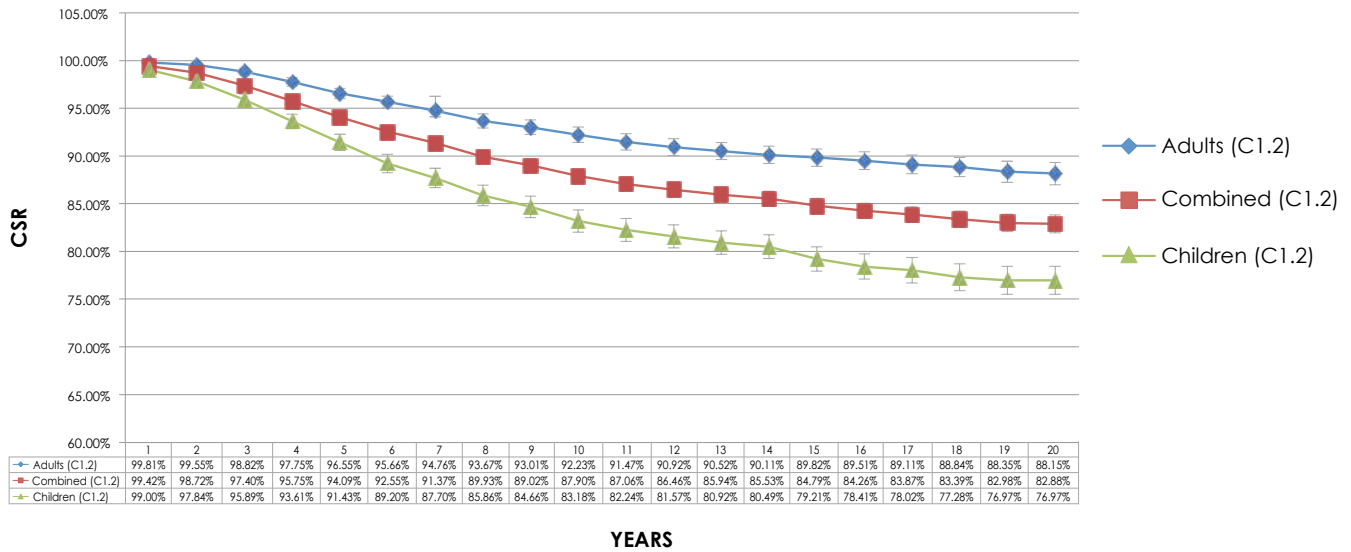
Clarion 1.2 (C1.2) Implant Reliability

Number of registered C1.2 implants - July 1, 2016

Adults	Children	Combined
4,289	4,132	8,476*

Last year of distribution⁴: 2004

Clarion C1.2 CSR %



Scott Moulton, AB Recipient



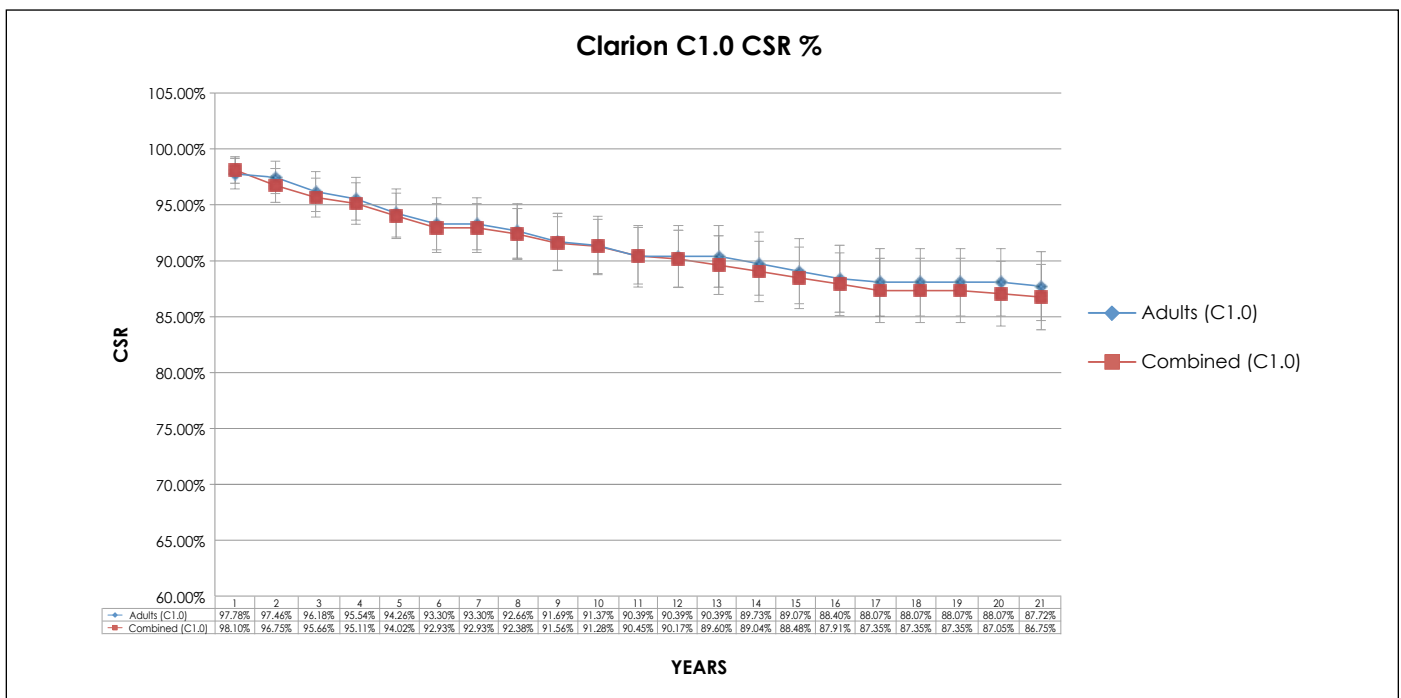
Clarion 1.0 (C1.0) Implant Reliability

As the number of children implanted with the C1.0 is well below a level required for statistical analysis, the data will be included with the adult data and presented as a combined CSR but not presented separately. The confidence intervals has also been set to 90% as the implanted population is low.

Number of registered C1.0 implants - July 1, 2016

Adults	Children	Combined
315	50	369*

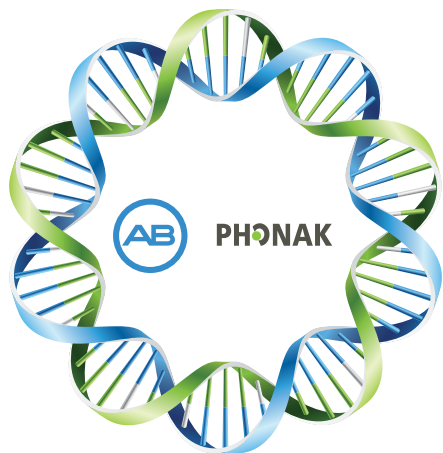
Last year of distribution⁴: 2004



Hear Your Best with AB

AB is the company that recipients and professionals can trust for the best possible hearing performance.





The Power of Two Working Together as One

The innovation DNA of AB and Phonak have combined to deliver performance technologies that will change the way you hear.

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

*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 Neurotology, 26(6):1097-1099.
3. All CSR data contained in this report is valid as of July 1, 2016.
4. 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.