Advanced Bionics

2014 Cochlear Implant Device Reliability Report

Credibility in Reporting

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The Industry's Most Conservative Reporting

As part of AB's commitment to providing clear and accurate information, this reliability report for cochlear implant devices presents current data on past generations of AB cochlear implants for reference.

Like all cochlear implant manufacturers, AB is compliant to the industry reliability standard.[1] Going far beyond the required compliance, AB adheres to the most conservative interpretation of the industry reliability standard, counting all devices removed for nonmedical reasons as failures according to global consensus.[2,3] AB's cumulative survival rate (CSR) includes all "soft" failures,[4,5] in situ failures, and electrode issues amongst its classifications for implant failures that other manufacturers may exclude in their reporting. This stringent reporting is not practiced by the other cochlear implant manufacturers. Hearing healthcare professionals, patients, and cochlear implant candidates should be aware of this important difference in reporting standards.

AB steadfastly supports hearing healthcare professionals in their evaluation of clinical benefit provided by a device. Company representatives remain readily available for troubleshooting assistance and device testing.

Only when the data is provided by all manufacturers with the same stringency in reporting can CSR be effectively used to compare implants. AB is committed to providing a timely Failure Analysis Report for every device explanted, clearly indicating the root cause of the failure and whether the device is counted against the CSR.

The Industry's Most Reliable Implant*

AB cochlear implants that are implanted today demonstrate industry-leading reliability.

By continuously monitoring manufacturing processes and integrating feedback from recipients and professionals, AB's robust Quality Assurance System responds quickly to any issues, complaints, or suggestions that can lead to improvements in quality and reliability.

HiRes 90K™ Advantage Implant Reliability

The HiRes 90K Advantage implant contains a mechanical design improvement over the original HiRes 90K implant. The main change is a reinforcement of the antenna coil, prompted by our internal Quality Assurance System identifying a potential failure mode from impact trauma. The Advantage Implant at the 1-year CSR level is currently at 99.81%.[6]

HiRes 90K™ Implant Reliability

Available since 2005, the HiRes 90K implant, also known as the HiRes 90K Vendor A Post-Mod implant, features a proven reliable design. Below are the CSR values for the last eight years containing data for over 30,000 devices.

Years Implanted	1	2	3	4	5	6	7	8
CSR Value	99.83%	99.59%	99.33%	99.05%	98.79%	98.59%	98.40%	98.09%

*For Supplier A

Dedicated to putting patients first, AB's rigorous and responsive Quality Assurance System is designed to protect our patients 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 our patients by taking firm and decisive action when issues have arisen.

As a result of this incomparable commitment to patients 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. Of the more than 28,000 implanted HiRes 90K devices produced at that time, only two (0.007%) explanted devices were confirmed to have this issue and to date, no further devices have been affected. All HiRes 90K devices manufactured since this date have a manufacturing improvement in place.

During the lifetime of a product, there are opportunities to address known failure modes and to improve the manufacturing process. Prior to the modifications to the HiRes 90K implant, the HiRes 90K Vendor A Pre-Mod device was manufactured. The CSR data for this variant is given below.

Years Implanted	1	2	3	4	5	6	7	8	9	10
CSR Value	99.45%	98.66%	98.02%	97.02%	96.34%	95.66%	95.10%	94.29%	93.64%	93.23%

The Industry's Experience with Hermeticity

Maintaining hermeticity of the implant and preventing ingress of moisture has been a historical issue for cochlear implant manufacturers.[7-9]

Over two and a half years into the lifecycle of the HiRes 90K implant, the company identified internal moisture issues resulting from feedthrough components manufactured by one of two approved suppliers ("Vendor B")[10] and promptly initiated a voluntary recall of all affected devices. AB immediately ceased the use of that vendor component and stopped distribution of impacted devices, which resolved the issue. No such issues have occurred in components manufactured by the other approved supplier ("Vendor A"). Since then, AB has manufactured HiRes 90K devices with feedthrough components provided exclusively by Vendor A.

HiRes 90K™ Vendor B Implant Reliability

Years Implanted	1	2	3	4	5	6	7	8	9
CSR Value	96.85%	88.63%	81.77%	76.38%	72.34%	69.24%	66.09%	63.84%	61.81%

The Industry's Strongest History in Durability

The HiRes 90K device is the toughest device on the market when it comes to impact trauma, which is a concern of every parent. Patients also continue to benefit from the reliability and durability of AB's previous-generation CII and Clarion 1.2 Implants. The mechanical stability of the CII implant represents the culmination of several generations of improvements in Ceramic Injection Molding technology of the earlier C1.2 implants.

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Clarion II (CII) Implant Reliability

Years Implanted	1	2	3	4	5	6	7	8	9	10	11	12
CSR Value	99.39%	98.96%	98.44%	98.14%	97.76%	97.26%	96.88%	96.54%	96.24%	96.05%	95.86%	95.75%

Clarion C1.2 Implant Reliability

Years Implanted	1	2	3	4	5	6	7	8
CSR Value	98.86%	97.89%	96.29%	94.32%	92.38%	90.60%	89.14%	87.28%

Years Implanted	9	10	11	12	13	14	15	16
CSR Value	86.03%	84.40%	83.30%	82.50%	81.81%	81.05%	80.27%	79.38%

Commitment to Our Patients

AB remains committed to putting our patients first. The reliability and robustness of the current HiRes 90K™ Advantage implant is a testament to our Quality Assurance System and our continuous device improvements. AB already has the industry's highest impact resistance for the HiRes 90K implant; the mechanical improvements of the Advantage implant are a further enhancement to the most reliable implant in the industry.

The high-quality HiRes 90K implant family delivers the industry's most advanced technology with a reliable design that is Built Kid Tough™. Patients can have peace of mind choosing AB for hearing their world.

References

1. ISO 5841-2 (2000) 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. Battmer RD, Backous DD, Balkany TJ, et al. (2010) International classification of reliability for implanted cochlear implant receiver stimulators. *Otology and Neurotology*, 31(8):1190-1193.
4. A "soft" failure is an uncommon event where a device malfunction is suspected based upon user performance/adversive symptoms, but cannot be proven through in vivo tests or evaluation of the explanted device.
5. Balkany TJ, Hodges AV, Buchman CA, et al. (2005) Cochlear implant soft failures consensus development conference statement. *Otology and Neurotology*, 26:815–818.
6. All CSR data contained in this report is valid as of May 2, 2014.
7. Cochlear™ Nucleus® Reliability Report 438388 ISS2 APR13
8. Goldman Sachs Global Investment Research. Cochlear Ltd. (COH.AX) A$62.42: Device failures spike in February to new monthly record. April 9, 2012.
9. FDA Warning Letter to Med-El. November 16, 2004. Accessible at http://www.fda.gov/ICECI/EnforcementActions/ WarningLetters/2004/ucm146926.htm
10. Auditory Reliability Report. 2007. Advanced Bionics, LLC, Valencia, California.

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