The Industry’s Most Stringent Reporting

As part of AB’s commitment to providing clear and accurate information, this reliability report presents current data on every generation of AB cochlear implants for reference when counseling your patients.

Like all cochlear implant manufacturers, AB is compliant to the industry reliability standard. 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. AB’s cumulative survival rate (CSR) includes all “soft” failures, in situ failures, and electrode issues that other manufacturers may exclude in their reporting. AB steadfastly supports hearing healthcare professionals in their evaluation of clinical benefit provided by a device. Ensuring there is no ambiguity, AB also provides a Failure Analysis Report for every explanted device clearly indicating whether the device is counted against the CSR. AB is also dedicated to delivering a complete analysis of each device within a time period averaging six weeks.

Only when the data is provided by all manufacturers with the same stringency in reporting can CSR be effectively used to compare implants.

The Industry’s Most Reliable Implant*

AB cochlear implants that are implanted today demonstrate high reliability with a 99.8% one-year CSR measured as dictated by the international standard.

HiRes 90K™ Implant Reliability*

In order to further improve device reliability, AB incorporated a number of important modifications into the manufacturing process as of February 1, 2005. AB continues to manufacture these highly reliable devices.

<table>
<thead>
<tr>
<th>Years Implanted</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td>HiRes 90K Implant Since 2005</td>
<td>99.8%</td>
<td>99.5%</td>
<td>99.2%</td>
<td>98.9%</td>
<td>98.7%</td>
<td>98.1%</td>
</tr>
</tbody>
</table>

* For Supplier A
The Industry’s Most Rigorous Quality System

Dedicated to putting patients first, AB’s rigorous and responsive Quality Assurance System is designed to ensure high product reliability, swiftly identifies any potential issue, and employs remedial corrective actions irrespective of the impact on its business.

As a result of this 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, only two (0.007%) explanted devices were confirmed to have this issue.

The Industry’s Experience with Hermiticity

Maintaining hermiticity of the implant and preventing ingress of moisture has been a historical issue for all cochlear implant manufacturers.\(^7-9\)

As previously reported by AB, over two and a half years into the lifecycle of the HiRes 90K™ implant, the company identified internal moisture issues resulting from feedthroughs manufactured by one of two approved suppliers ("Supplier B").\(^10\) No such issues occurred in components manufactured by the other approved supplier ("Supplier A"). Since then, AB has manufactured HiRes 90K devices with feedthroughs provided exclusively by Supplier A.

<table>
<thead>
<tr>
<th>Years Implanted</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supplier B</td>
<td>96.9</td>
<td>88.6</td>
<td>81.7</td>
<td>76.2</td>
<td>72.0</td>
<td>68.9</td>
<td>65.6</td>
<td>62.3</td>
</tr>
</tbody>
</table>

The Industry’s Strongest History in Durability

Patients 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.

<table>
<thead>
<tr>
<th>Years Implanted</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>CII</td>
<td>99.4</td>
<td>99.0</td>
<td>98.4</td>
<td>98.1</td>
<td>97.8</td>
<td>97.3</td>
<td>96.9</td>
<td>96.5</td>
<td>96.2</td>
<td>96.0</td>
</tr>
</tbody>
</table>

Table 3. Cumulative survival rates for the Clarion II (CII) implant in each category.

<table>
<thead>
<tr>
<th>Years Implanted</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>11</th>
<th>12</th>
<th>13</th>
<th>14</th>
<th>15</th>
</tr>
</thead>
<tbody>
<tr>
<td>CI</td>
<td>98.9</td>
<td>97.9</td>
<td>96.3</td>
<td>94.3</td>
<td>92.4</td>
<td>90.6</td>
<td>89.1</td>
<td>87.3</td>
<td>86.0</td>
<td>84.4</td>
<td>83.2</td>
<td>82.4</td>
<td>81.8</td>
<td>81.0</td>
<td>79.9</td>
</tr>
</tbody>
</table>

Table 4. Cumulative survival rates for the Clarion 1.2 (C1) implant in each category.
The Commitment to Improvement

AB remains committed to continuous device improvements. In keeping with this dedication, the new HiRes 90K™ Advantage implant features mechanical improvements to the antenna and continues to deliver superior performance and full upgradeability. AB already has the industry’s highest impact resistance for the HiRes 90K implant. This is 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 robust, reliable design that is Built Kid Tough™. Patients can have peace of mind choosing AB for hearing their world.

References

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.
6. As of May 1, 2012.
11. As of June 13, 2012