Cochlear implant technology helped thousands of people worldwide. Most users wear their systems throughout the entire day. At Oticon Medical, we know that any device failure impacts our patients and their families; it disrupts school or work routines, creates frustration and may precipitate a decline in personal performance. That is why we work so hard to produce the most reliable devices possible.

As a cochlear implant manufacturer, we report device failures in accordance with the International Standard ISO 5841-2:2000 & the principles described in the European & Global Consensus on Cochlear Implant Failures & Explantations.

Note: Oticon Medical imposes a strict report policy as part of its quality commitment by counting all devices removed for reasons other than medical necessity as failures, including the loss of clinical benefit. All registered recipients worldwide are included.
HOW TO READ OTICON MEDICAL RELIABILITY REPORT?

In accordance with the International Standard ISO 5841-2:2000 & the principles described in the European & Global Consensus on Cochlear Implant Failures & Explantations, Oticon Medical uses the appropriate standard method to communicate device reliability, by showing:

1/ For implant:

- **The Cumulative Survival Percentage (CSP):** percentage of devices that remain functioning over a given period of time after implantation.
- **The Cumulative Failure Percentage (CFP):** percentage of devices that are no longer functioning over a certain period of time.

\[
\text{CSP (in \%) } = \frac{\text{[Devices that are still functioning for X years]}}{\text{[All devices implanted for X years]}} \times 100
\]

\[
\text{CFP} = [100-\text{CSP}]
\]
HOW TO READ OTICON MEDICAL RELIABILITY REPORT?

2/ For sound processor:

- **The Monthly Service Rate (MSR):** the qualitative characteristics and reliability of our sound processors are monitored by the MSR. It reflects the percentage of devices that are returned for service each month. Loaners and order mistakes are excluded.

\[
\text{MSR (in \%)} = \frac{\text{[Number of monthly returns]}}{\text{[Cumulative number of sound processors delivered]}} \times 100
\]
The **Neuro cochlear implant system** has been available on the market since **November 2015**. Due to the relatively short time on the market, the Neuro system reliability data can only be presented in the next Reliability Report update.

Oticon Medical’s **first cochlear implant system combines best of hearing instrument and cochlear implant technologies**.

The Neuro system consists of an innovative new implant, and a unique approach to sound processing:

- **The Neuro Zti implant** is ultra-thin and compact to make surgery as simple and safe as possible. The implant is robust and reliable, and can be adapted for high tesla scanning, such as MRI. The Neuro Zti features an entirely new internal chip design that is flexible and powerful enough to work in combination with present and future advanced sound processors from Oticon Medical.

- **The Neuro One sound processor** uses Oticon’s advanced Inium chip platform with a number of automatic features and innovative sound processing - also called Coordinated Adaptive Processing. The end goal is to empower users to achieve better understanding and take an active part in conversations wherever they go.
Digisonic® SP implant has been available on the market since **March 2006**.

Digisonic® SP EVO implant has been available on the market since **January 2013**.

Digisonic® SP cochlear implants are designed for **minimal invasive surgery** and to **preserve cochlear structures**:

- Compact and safe design
- Unique fixation system
- Atraumatic electrodes

<table>
<thead>
<tr>
<th>ELECTRODE ARRAY</th>
<th>Digisonic® SP</th>
<th>Digisonic® SP EVO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of active electrodes</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td>Active length</td>
<td>25 mm</td>
<td>24 mm</td>
</tr>
<tr>
<td>Insertion length</td>
<td>26 mm</td>
<td>25 mm</td>
</tr>
</tbody>
</table>
| Type of electrode array  | Active area: 0,39 mm² to 0,77 mm²
                          Diameter at apex: 0,5 mm
                          Diameter at base: 1,07 mm | Active area: 0,39 mm² to 0,52 mm²
                          Diameter at apex: 0,4 mm
                          Diameter at base: 0,5 mm |

<table>
<thead>
<tr>
<th>Number of registred implants 31 December 2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Digisonic® SP</td>
</tr>
<tr>
<td>Digisonic® SP EVO</td>
</tr>
</tbody>
</table>
DIGISONIC® SP COCHLEAR IMPLANT

Cumulative Survival Percentage as of end December 2015.

<table>
<thead>
<tr>
<th>YEAR</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>DIGISONIC® SP CSP (%)</td>
<td>99.52</td>
<td>98.93</td>
<td>98.37</td>
<td>97.96</td>
<td>97.63</td>
<td>97.39</td>
<td>97.34</td>
<td>97.26</td>
<td>97.23</td>
<td>97.21</td>
</tr>
</tbody>
</table>

Because sound matters

Oticon Medical
Cumulative Failure Percentage as of end December 2015.

<table>
<thead>
<tr>
<th>YEAR</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>DIGISONIC® SP CFP (%)</td>
<td>0.48</td>
<td>1.07</td>
<td>1.63</td>
<td>2.04</td>
<td>2.37</td>
<td>2.61</td>
<td>2.66</td>
<td>2.74</td>
<td>2.77</td>
<td>2.79</td>
</tr>
</tbody>
</table>
DIGISONIC® SP EVO COCHLEAR IMPLANT

Cumulative Survival Percentage as of end December 2015.

<table>
<thead>
<tr>
<th>YEAR</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>CSP (%)</td>
<td>99.88</td>
<td>99.82</td>
<td>99.82</td>
<td>99.82</td>
</tr>
</tbody>
</table>

Because sound matters
**DIGISONIC® SP EVO COCHLEAR IMPLANT**

Cumulative Failure Percentage as of end December 2015.

<table>
<thead>
<tr>
<th>YEAR</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.12</td>
<td>0.18</td>
<td>0.18</td>
<td>0.18</td>
</tr>
</tbody>
</table>

**DIGISONIC® SP EVO CFP (%)**

![Cumulative Failure % graph](image-url)
The Saphyr® neo collection sound processor has been available on the market since September 2013.

The Saphyr® neo collection sound processor offers advanced sound processing and is designed to improve user comfort.

- Significant\(^{(1)}\) improvement of speech understanding in noise
  Voice Track\(^{TM}\) & Crystalis\(^{XDP}\)
- Comfortable and intuitive
- Wireless capabilities

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Bergeron, F., Hotton, M., Millette, I., Lamothe, J., Bussières, R., Côté, M., Philippon, D. 2014. Speech recognition with the most recent technologies from the four major cochlear implant manufacturers; an update.

13\(^{th}\) International conference on cochlear implants and other implantable auditory technologies, June 18th-21st 2014, Munich, Germany.
• **Monthly Service Rate (%)**: an average percentage calculated for the period between September 2013 and end of December 2015, i.e. after **21 months on the market**.

![Chart showing Saphyr® neo collection average MSR based on 21 months on the market](chart.png)
Because Sound Matters

Oticon Medical is a global company in implantable hearing solutions, dedicated to bringing the magical world of sound to people at every stage of life. As a member of one of the world’s largest groups of hearing health care companies, we share a close link with Oticon and direct access to the latest advancements in hearing research and technologies. Our competencies span more than a century of innovations in sound processing and decades of pioneering experience in hearing implant technology.

By working collaboratively with patients, physicians and hearing care professionals, we ensure that every solution we create is designed with user needs in mind. We share an unwavering commitment to provide innovative solutions and support that enhance quality of life for people wherever life may take them. Because we know how much sound matters.
REFERENCES


European Consensus Statement on Cochlear Implant Failures and Explantations, Otology & Neurotology, 2005 Nov; 26:1097-1099