Oticon Medical offers bone anchored hearing systems and cochlear implant solutions for different patient groups with hearing loss. All of our solutions are specialised to meet the needs of those who face the hardest hearing challenges.
A solid group, for a patient lifelong support

The Demant Group is a global market leader in hearing healthcare. We develop, manufacture and sell products and equipment that help people with hearing loss connect and communicate with the world around them. We focus on four business activities: Hearing Devices, Hearing Implants, Diagnostic Instruments and Personal Communication.

Demant is the parent company behind the commercial successes of such world-renowned brands as Oticon, Bernafon, Sonic, Audika, Oticon Medical, Interacoustics, Grason-Stadler, MedRx and Sennheiser Communications. William Demant Foundation holds the majority of shares in Demant A/S, providing stability and strength for the long haul.

The Demant Group operates in a global market with companies in more than 30 countries, employs more than 14,000 staff and generates annual revenue of EUR 1.9 billion. Our products are sold in more than 130 countries where we create life-changing differences through hearing health.

As a member of one of the world’s largest groups of hearing health care companies, Oticon Medical is uniquely positioned with access to a comprehensive global distribution set-up and efficient shared services.
Cochlear implants you can trust

Cochlear implants help thousands of people worldwide, every day of every year.

At Oticon Medical, we understand that if patients use a cochlear implant, they need to be able to rely on its performance – for work, for play, for staying in touch – for life.

That’s why our products live up to the highest quality standards, respecting hundreds of international requirements.

To simulate patients’ active lives, our cochlear implants undergo over 50 different tests. As an example of this extensive program, the implants undergo impact tests, a pillow test with 36,500 cycles, sweat, moisture and humidity tests as well as drop tests from multiple directions.

All for one reason: So we can be sure our cochlear implant systems can withstand the wear and tear of the user’s daily life.
How this report has been made

As a cochlear implant manufacturer, we report device failures in accordance with the International Standard ISO 5841-2:2014\(^1\) and the principles described in the European and Global Consensus on Cochlear Implant Failures and Explantations\(^2\).

We want to be transparent and clear in our report and have therefore added the Cumulative Survival Percentage that includes the accident-related issues.

This means we have reported failures not only strictly related to the implant but also to external causes like trauma.
Our Implants
Neuro Zti
A safe and reliable solution

The Neuro Zti cochlear implant is the result of more than 25 years’ experience in cochlear implant development, manufacturing know-how and material science expertise.

It is the most compact implant on the market thanks to its unique rigid structure made of zirconia and titanium. This enables it to absorb the high impacts encountered in daily life.

Neuro Zti also features a unique screw fixation system that aims at making the implant stable without the need for bone bed drilling, therefore making it a proven and safe system and saving precious time in the operating room.

In addition, a recent independent study confirms that thanks to the rigid structure and the screw fixation system, Neuro Zti prevents pain and magnet dislocation during MRI exams using the most common equipment with the magnet in place.
Digisonic SP

The Digisonic® SP implant features a unique monobloc design with the magnet and the receiver in a single unit. The implant’s structure, combined with an exclusive screw fixation system, removes the need to drill a bone bed during surgery. The implant is simply slid under the skin and then fixed in place, so surgical incision is minimised and surgery is less invasive, which helps facilitate healing and make the procedure less traumatic for the patient.
Electrode arrays

The Neuro Zti and the Digisonic SP cochlear implants feature two kinds of electrode arrays – Classic and EVO – both composed of 20 platinum iridium full-band electrodes that enable the entire sound spectrum to be stimulated.

The CLASSIC electrode array has an optimised stiffness profile that makes it compatible with typical and difficult insertions. It is straight with a shape-conforming structure and has dimensions that facilitate deep cochlear insertion.

The EVO electrode array is designed to preserve the fragile structures of the cochlea, particularly important when there is residual hearing. Its smooth surface, small diameter, thin end and flexibility are designed to ensure a smooth, trauma-free insertion so that the cochlear structures are preserved.
Reliability data

Figures at a glance

**Neuro Zti**
- 99.70% after 4 years
- Including accident-related issues combining EVO and Classic

**Digisonic SP**
- 97.05% after 14 years
- Including accident-related issues combining EVO and Classic

*Data as of June 30th 2019*
How to read this report

CSP – Cumulative Survival Percentage
Cumulative percentage of functioning devices over a given period of time after implantation

95% confidence interval
The CSP curves report the 95% confidence interval to indicate the statistics’ accuracy as required by the European and Global Consensus on Cochlear Implant Failures and Explantations

Curves
2 CSP curves are reported – one excluding accident-related issues and – for the sake of transparency and clarity – one including them

Detailed CSP
Detailed CSP are given for each year after implantation

<table>
<thead>
<tr>
<th>Year</th>
<th>CSP (excluding accident-related issues)</th>
<th>CSP (including accident-related issues)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 year</td>
<td>99.85%</td>
<td>99.69%</td>
</tr>
<tr>
<td>2 years</td>
<td>99.74%</td>
<td>99.28%</td>
</tr>
<tr>
<td>3 years</td>
<td>99.38%</td>
<td>98.66%</td>
</tr>
<tr>
<td>4 years</td>
<td>99.13%</td>
<td>98.41%</td>
</tr>
<tr>
<td>5 years</td>
<td>99.02%</td>
<td>98.31%</td>
</tr>
<tr>
<td>6 years</td>
<td>98.97%</td>
<td>98.20%</td>
</tr>
<tr>
<td>7 years</td>
<td>98.97%</td>
<td>98.20%</td>
</tr>
</tbody>
</table>
### Neuro Zti – Classic & EVO

**2015**

**First implantation**

**99.70%**

Including accident-related issues

---

**Data as of June 30th 2019**

*For statistical purposes data reported on the Neuro Zti cochlear implant combine the EVO and the Classic version*

<table>
<thead>
<tr>
<th>CSP – Cumulative Survival Percentage (%)</th>
<th>1 year</th>
<th>2 years</th>
<th>3 years</th>
<th>4 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>CSP (excluding accident-related issues)</td>
<td>99.91%</td>
<td>99.77%</td>
<td>99.72%</td>
<td>99.70%</td>
</tr>
<tr>
<td>CSP (including accident-related issues)</td>
<td>99.91%</td>
<td>99.77%</td>
<td>99.72%</td>
<td>99.70%</td>
</tr>
</tbody>
</table>
Digisonic SP – Classic

CSP – Cumulative Survival Percentage (%)

<table>
<thead>
<tr>
<th>Year</th>
<th>CSP (excluding accident-related issues)</th>
<th>CSP (including accident-related issues)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 year</td>
<td>99.74%</td>
<td>99.65%</td>
</tr>
<tr>
<td>2 years</td>
<td>99.45%</td>
<td>99.18%</td>
</tr>
<tr>
<td>3 years</td>
<td>99.13%</td>
<td>98.63%</td>
</tr>
<tr>
<td>4 years</td>
<td>98.80%</td>
<td>98.17%</td>
</tr>
<tr>
<td>5 years</td>
<td>98.57%</td>
<td>97.80%</td>
</tr>
<tr>
<td>6 years</td>
<td>98.38%</td>
<td>97.51%</td>
</tr>
<tr>
<td>7 years</td>
<td>98.24%</td>
<td>97.32%</td>
</tr>
<tr>
<td>8 years</td>
<td>98.14%</td>
<td>97.18%</td>
</tr>
<tr>
<td>9 years</td>
<td>98.04%</td>
<td>97.08%</td>
</tr>
<tr>
<td>10 years</td>
<td>97.94%</td>
<td>96.98%</td>
</tr>
<tr>
<td>11 years</td>
<td>97.85%</td>
<td>96.88%</td>
</tr>
<tr>
<td>12 years</td>
<td>97.83%</td>
<td>96.86%</td>
</tr>
<tr>
<td>13 years</td>
<td>97.83%</td>
<td>96.86%</td>
</tr>
<tr>
<td>14 years</td>
<td>97.83%</td>
<td>96.86%</td>
</tr>
</tbody>
</table>

2006
First implantation

96.86%
Including accident-related issues

Data as of June 30th 2019
Digisonic SP – Evo

CSP – Cumulative Survival Percentage (%)

1 year | 2 years | 3 years | 4 years | 5 years | 6 years | 7 years
---|---|---|---|---|---|---
CSP (excluding accident-related issues) | 99.85% | 99.74% | 99.38% | 99.13% | 99.02% | 98.97% | 98.97%
CSP (including accident-related issues) | 99.69% | 99.28% | 98.66% | 98.41% | 98.31% | 98.20% | 98.20%

2013
First implantation
98.20%
Including accident-related issues

Data as of June 30th 2019
References

3. Oticon Medical CI Unique – Jan 2019 (the Oticon Medical Unique logo Indicates an Oticon Medical unique technology or accessory in the CI industry at the time of this publication)
4. M81371UK, Neuro System Insert version A 2016, reporting the results of the survey “Surgical Procedure Questionnaire, Neuro Zti Cochlear Implant” M80798
5. Data on file at Oticon Medical (Mechanical Overall Feature Doc-00060923
7. Oticon Medical Reliability report 2019. Data as of june 30th 2019
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 part of the Demant group, a global leader in hearing healthcare with 14,500 people in over 130 countries, we have access to one of the world’s strongest research and development teams, the latest technological advances and insights into hearing care.

Our competencies span more than a century of innovations in sound processing and decades of pioneering experience in hearing implant technology. We work collaboratively with patients, physicians and hearing care professionals to ensure that every solution we create is designed with users’ 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.