Reliability Report 2021

In accordance with European and Global Consensus on Cochlear Implant Failures and Explantations, ANSI/AAMI CI86 Standard

June 2021

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About Oticon Medical

Oticon Medical offers **cochlear implant solutions and bone anchored hearing systems** for different patient groups with hearing loss. All of our solutions are specialized to meet the needs of those who face the hardest hearing challenges.

The choice to have a cochlear implant is a choice for life, which is why the reliability of the CI system you choose is of the utmost importance.
At Oticon Medical we recognise this importance and strive for the best reliability coupled with the best sound experience for all our users.

The report presents the reliability data for the Neuro Zti implant and the Neuro 2 Sound Processor; key components of the Neuro System from Oticon Medical. Both exhibit the very high reliability one would expect from a company with over 100 years of research and development in hearing health.

It is Oticon Medical's aim to provide CI users with the clearest sound possible and we are well-positioned to bring the quality and technologies already widely appreciated by Oticon hearing aid users to cochlear implant development and innovation.

The Neuro CI System is available in 53 countries including the US, where FDA approval was obtained in 2021.

In addition, Neuro Zti has recently received the CE mark for extended MRI compatibility. Thanks to a unique combination of an innovative magnet and a unique fixation system, the new Neuro Zti MRI 3T is now able to withstand MRI scans up to 3T with the magnet in place.

Jes Olsen

President, Oticon Medical

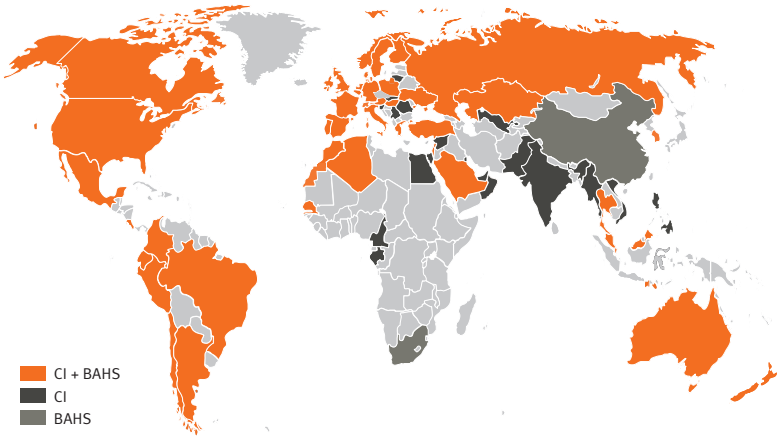
About Demant

Oticon Medical is part of the global hearing healthcare group Demant. Through multiple individual companies, the Group offers solutions and services that help people with hearing loss connect and communicate with the world around them. Our strength lies in our foundation-based ownership and the heritage of making life-changing differences. It is essential for our promise to deliver the best possible solutions for our customers that we have direct and instant access to every aspect of hearing health. For more than a century the Demant Group has played a vital part in developing innovative technologies and know-how to help improve people's hearing and health.

In every aspect, from hearing devices, hearing implants, diagnostic equipment and services, to hearing care all over the world, Demant is active and engaged. A growing business delivering high-end audio solutions for enterprise and leisure use is also a significant part of the Group.

The Demant Group operates in a global market with own companies in more than 30 countries, employs more than 16,500 employees and generates an annual revenue of DKK 15 billion. Demant is the parent company behind a number of world-renowned brands, such as Oticon, Bernafon, Sonic, Philips HearLink, Audika, Oticon Medical, MAICO, Interacoustics, Amplivox, Grason-Stadler, MedRx, Audioscan, and EPOS. The Group's products are sold in more than 130 countries where we create life-changing differences through hearing health.

Whilst Oticon Medical is an independent company within the Demant group, we work closely together with our sister companies to combine knowledge, expertise and highly advanced technology platforms to be able to offer users both the benefit of latest technology as well as valuable insights into hearing care. We work closely together and combine our knowledge, we can offer users both the benefit of the latest technology as well as valuable insights into hearing care.



Numerous tests performed to ensure high reliability

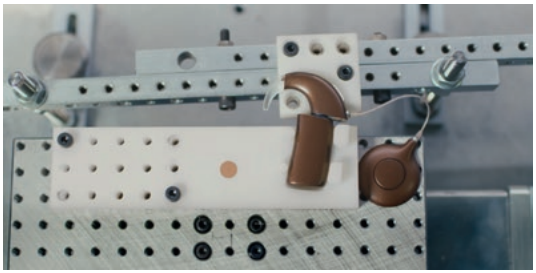
Cochlear implants help thousands of people worldwide, every day of every year.

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.

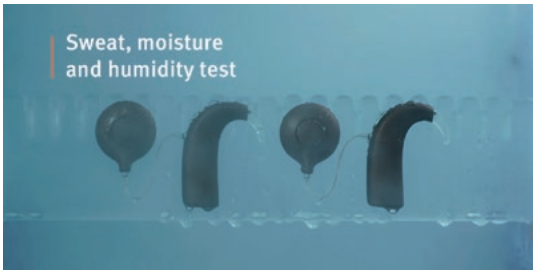
That's why our products live up to the highest quality standards, in compliance with hundreds of international requirements.

To simulate patient's active lives, our cochlear implants systems undergo hundreds of different tests. These tests include shock resistance, bending, stretching, exposure to extreme temperature and humidity conditions. These tests are performed thousands of times on the implant and the sound processor and also on all accessories and spare parts. For instance, one of these tests evaluates the number of times the battery compartment of the sound processor can be removed and replaced and still remain safe and usable. The requirements states the device must support it over 6,000 times. Oticon Medical sound processor does!

Implant impact test



Sound processor battery compartment test – 6,000 cycles



Sound processor sweat, moisture and humidity test

How this report has been made

As a cochlear implant manufacturer, we report implant failures in accordance with the principles described in the European and Global Consensus on Cochlear Implant Failures and Explantations.[1]

Oticon Medical aims to be transparent and clear in our reporting and have therefore added the Cumulative Survival Percentage that includes accident-related issues.

This means we have reported failures not only strictly related to the implant but also to external causes like trauma.

For the sound processors, the data in the report follow the ANSI/AAMI CI 86 standards: Cochlear implant systems: Requirements for safety, functional verification, labeling and reliability reporting.

Implant reliability

I'm much more relaxed now during conversations since I got my Neuro CI. I simply get much more out of it without the extra effort"

Kim, Denmark, cochlear implant user

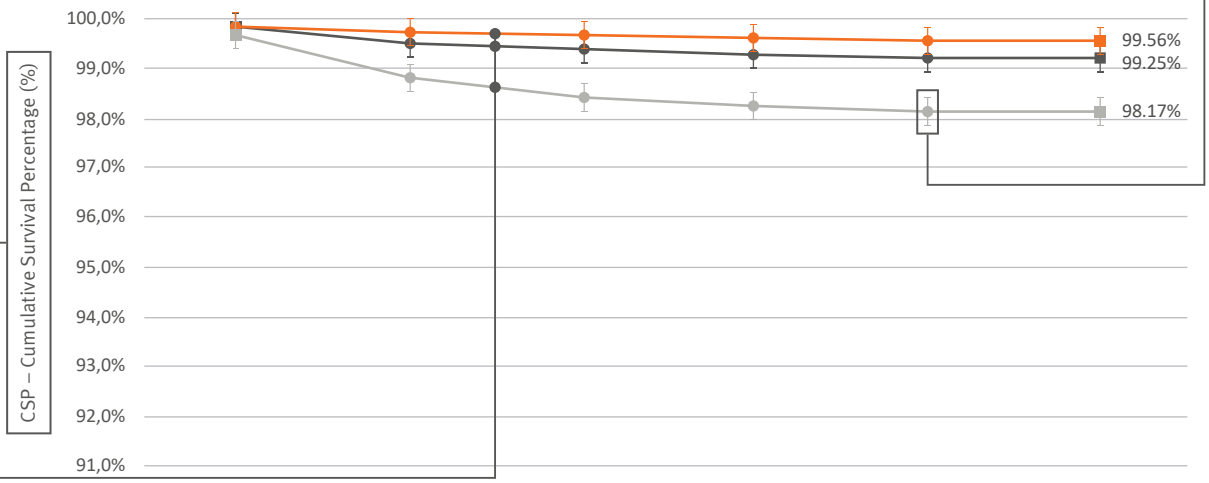
How to read this report

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[1]



	1 year	2 years	3 years	4 years	5 years	6 years
Combined adults & children	99.84%	99.52%	99.40%	99.31%	99.25%	99.25%
Adults (+18y)	99.88%	99.73%	99.68%	99.62%	99.56%	99.56%
Children (-18y)	99.70%	98.82%	98.46%	98.23%	98.17%	98.17%

Curves

3 CSP curves are reported – one for adults, one for children (below 18 years old) and one combined – all including accident-related issues.

Detailed CSP

Detailed CSP are given for each year after implantation

**Device survival time begins with closure of the wound.*

Reliability data

Figures at a glance

Neuro Zti

99.25%

after 6 years

Including accident-related issues
combining EVO and Classic

Digisonic SP

95.67%

after 16 years

Including accident-related issues
combining EVO and Classic

Data as june 30th 2021

Neuro Zti implant

Proven to be a trustworthy implant

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 has the **smallest surgical footprint**[2] thanks to its unique rigid structure[2] 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**[2] that aims at making the implant stable without the need for bone bed drilling, therefore making it a **proven and reliable system,**[3, 4, 5] **saving precious time in the operating room.**[2]

Thanks to the unique loudness coding in duration and the OM pulse shape, the **Oticon Medical stimulation** approach has been developed to deliver precise stimulation and clear sound in a way that respects the natural physiology of the auditory system.

In addition, Neuro Zti has recently received the CE mark for extended MRI compatibility*. Thanks to a unique combination of an innovative magnet and a unique fixation system, the new Neuro Zti MRI 3T is now able to withstand MRI scans up to 3T.

This technology shows high resistance to demagnetization, allowing patients to safely undergo multiple MRI examinations with no head bandage requirements. For professionnals, longer scan durations and no head position restrictions also make it an easy and flexible option.

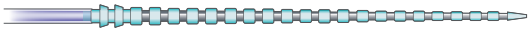
3T

**Subject to local availability according to local regulatory standards*

Electrode arrays

The Neuro Zti cochlear implant features two kinds of electrode arrays – Classic and EVO – both composed of 20 platinum iridium full-band electrodes.

The CLASSIC electrode array has a stiff profile proving greater insertion forces to support some compromised cochlear patency insertions.

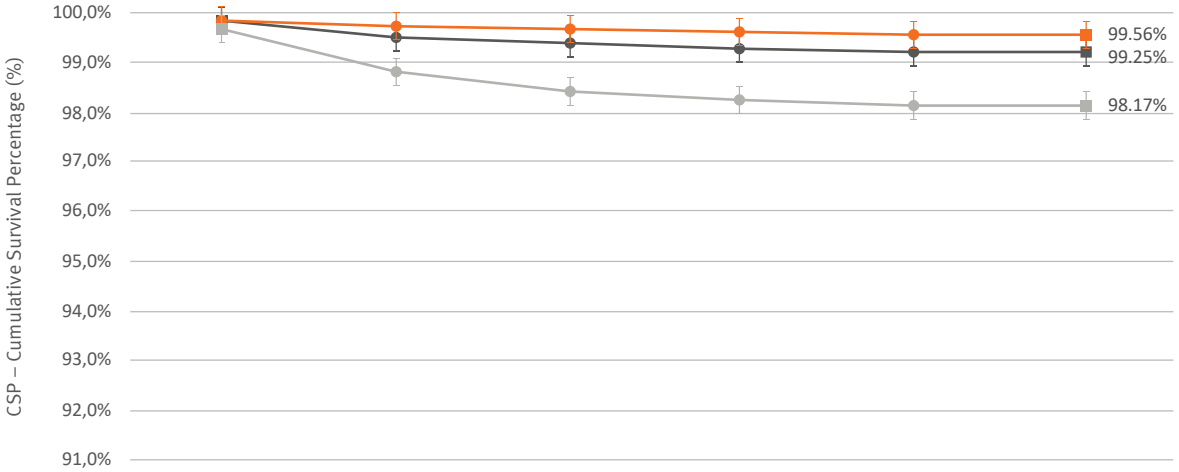


Neuro Zti CLA

The EVO electrode array has been designed for soft surgery[6,7] and is mainly used for normal cochleas insertions, also when surgeons want to preserve fragile cochlea's structure, and reduce the risk of trauma.[6,7,8]

Neuro Zti EVO

Neuro Zti – Classic & EVO



	1 year	2 years	3 years	4 years	5 years	6 years
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Adults (+18y)	99.88%	99.73%	99.68%	99.62%	99.56%	99.56%
Children (-18y)	99.70%	98.82%	98.46%	98.23%	98.17%	98.17%

2015
First implantation
99.25%
Including accident-related issues

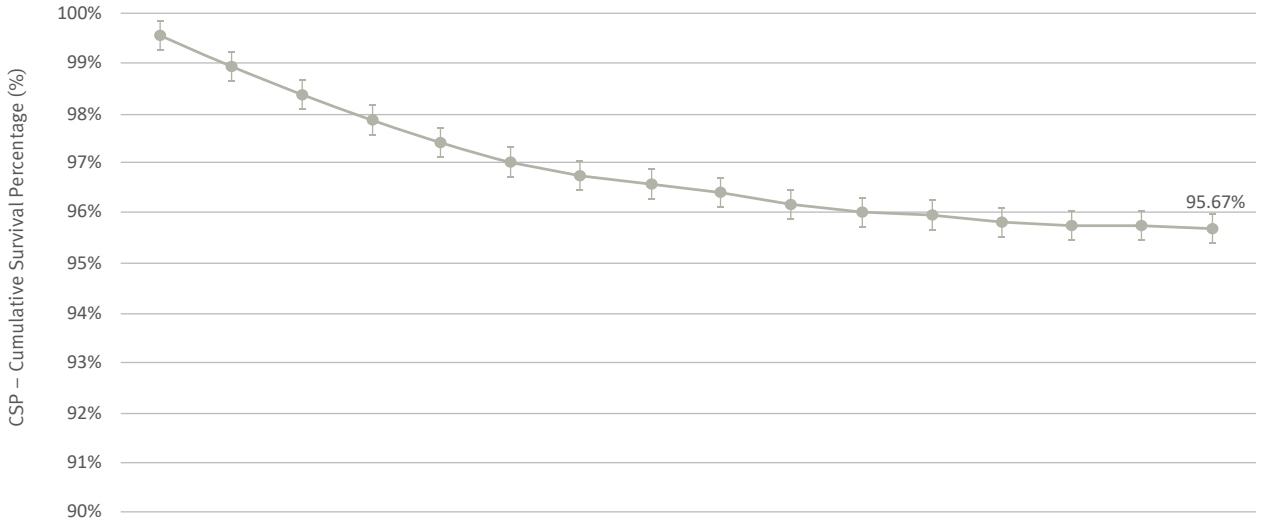
Data as june 30th 2021
Confidence intervals smaller than 0.1% may not be clearly visible in the graphs.

Digisonic SP implant

In 2005, the Digisonic® SP implant revolutionized the cochlear implant market thanks to its 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 Digisonic SP range has been discontinued in 2020. In accordance with the European consensus, Oticon Medical keeps on reporting its reliability over time.

Digisonic SP



	1 year	2 years	3 years	4 years	5 years	6 years	7 years	8 years	9 years	10 years	11 years	12 years	13 years	14 years	15 years	16 years
Combined adults & children	99,56%	98,97%	98,37%	97,85%	97,39%	97,02%	96,74%	96,58%	96,39%	96,17%	96,02%	95,94%	95,81%	95,76%	95,70%	95,67%

2006
First implantation
96.67%
Including accident-related issues

Data as of june 30th 2021

Sound processor reliability

I started noticing some sounds straight away. At first it was the sound of drawers being closed and cars in the street, then I started being able to hear the sound of my children's voices."

Mette, Denmark, cochlear implant user

The Neuro 2 sound processor commercialized in 2018 is the smallest sound processor on the market.[2] It is sweeping up prizes in the cochlear implant industry due to its groundbreaking design.

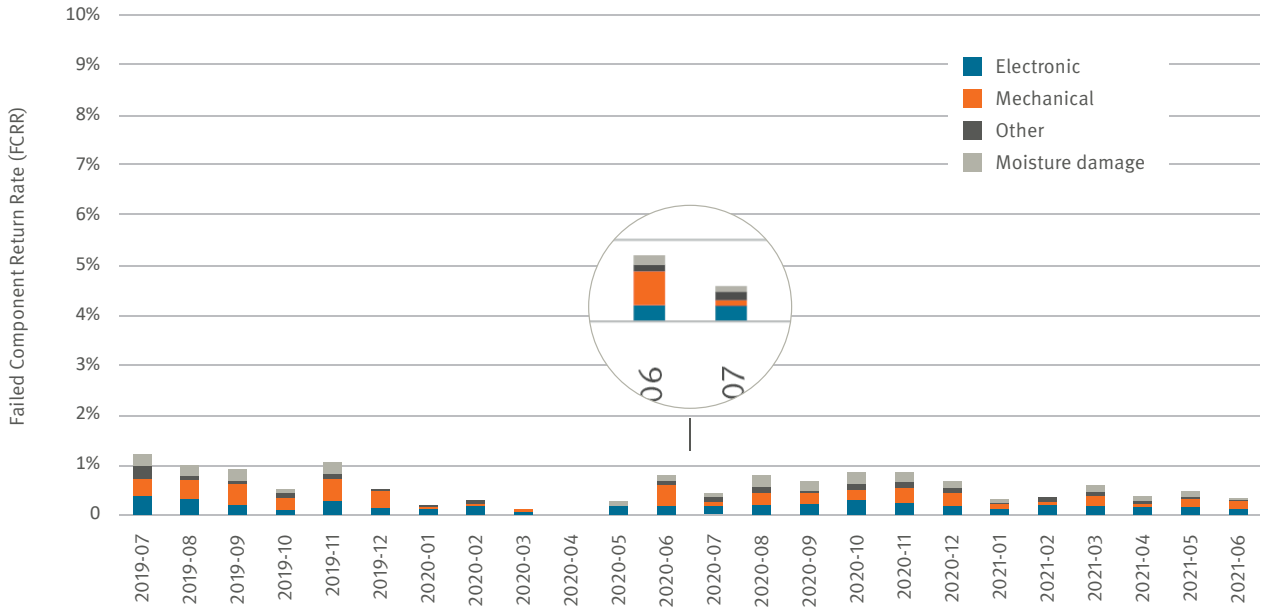
How to read the sound processor data

Electronic failure

A functional failure of the electronics or the electronic assembly.

Other/unknown failure

Failures that don't fit in the other categories (e.g. firmware failures).



Mechanical failure

A functional failure resulting from physical damage caused by mechanical stress, chemical exposure, or ultraviolet (UV) exposure that is a result of normal use.

Moisture damage failure

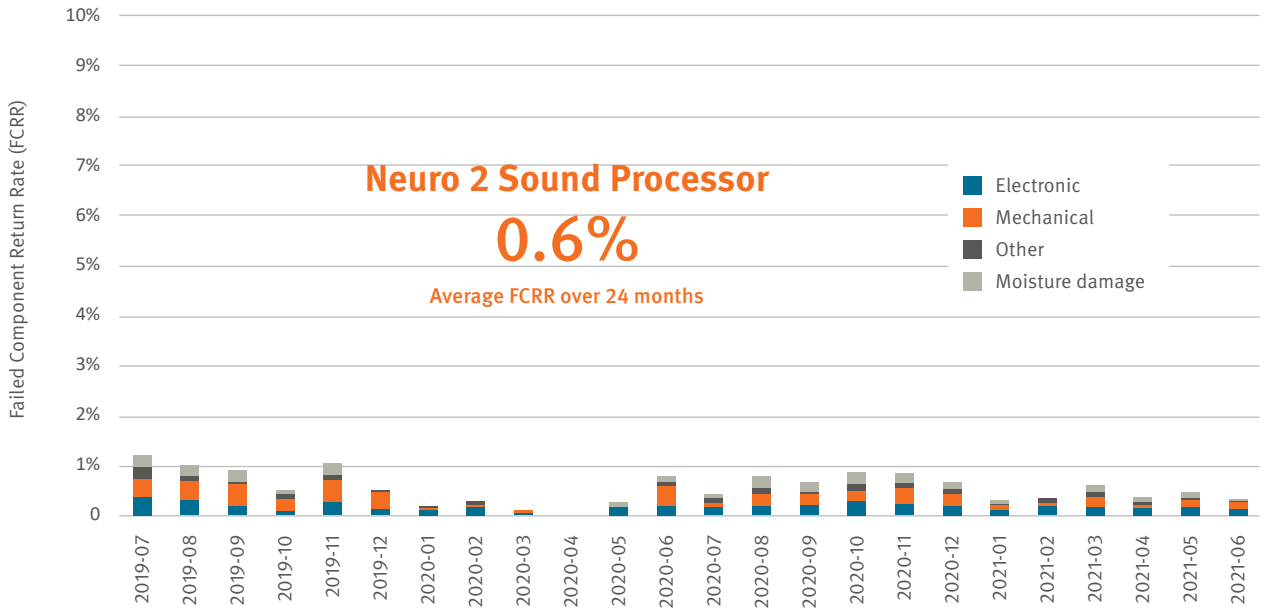
A functional failure that is a result of moisture ingress. This category excludes corrosion and other similar damage unless it results in a functional failure.

Neuro 2 Sound Processor

Neuro 2 Sound Processor – Failed Component Return Rate

Fail Mode	July 19	Aug 19	Sep 19	Oct 19	Nov 19	Dec 19	Jan 20	Feb 20	Mar 20	April 20	May 20	Jun 20
Electronic	0.4%	0.3%	0.2%	0.1%	0.3%	0.1%	0.1%	0.2%	0.0%	0.0%	0.2%	0.2%
Fault-free*	0.5%	0.5%	0.2%	0.4%	0.5%	0.3%	0.3%	0.2%	0.2%	0.0%	0.2%	0.3%
Mechanical	0.4%	0.4%	0.4%	0.2%	0.4%	0.4%	0.1%	0.0%	0.1%	0.0%	0.0%	0.4%
Moisture damage	0.2%	0.2%	0.2%	0.1%	0.2%	0.0%	0.0%	0.0%	0.0%	0.0%	0.1%	0.1%
Other	0.3%	0.1%	0.1%	0.1%	0.1%	0.0%	0.0%	0.1%	0.0%	0.0%	0.0%	0.1%

Fail Mode	July 20	Aug 20	Sep 20	Oct 20	Nov 20	Dec 20	Jan 21	Feb 21	Mar 21	Apr 21	May 21	Jun 21
Electronic	0.2%	0.2%	0.2%	0.3%	0.2%	0.2%	0.1%	0.2%	0.2%	0.2%	0.2%	0.1%
Fault-free*	0.3%	0.5%	0.3%	0.3%	0.4%	0.2%	0.1%	0.2%	0.2%	0.2%	0.1%	0.2%
Mechanical	0.1%	0.2%	0.2%	0.2%	0.3%	0.3%	0.1%	0.1%	0.2%	0.1%	0.2%	0.1%
Moisture damage	0.1%	0.2%	0.2%	0.2%	0.2%	0.1%	0.1%	0.0%	0.1%	0.1%	0.1%	0.0%
Other	0.1%	0.1%	0.0%	0.1%	0.1%	0.1%	0.0%	0.1%	0.1%	0.1%	0.0%	0.0%



** Fault-free fail mode is a returned device that is found to be fully functional. The device condition might reflect normal wear and tear, such as minor mechanical damage (including scratches, cracks, and discoloration), corrosion, and/or moisture damage that did not result in a functional failure.*

References

1. European consensus statement on cochlear implant failures and explantations. Otol Neurotol. 2005 Nov;26(6):1097-9.
2. Oticon Medical CI Unique, sept 2020, version G (DOC-00067651).
3. Data on file at Oticon Medical (Mechanical Overall Feature Doc-00060923.
4. Titanium Grade 2 = ISO 5832-2 (2018) / ASTM F 67 (2013) and Titanium Grade 5 = ISO 5832-3 (2016) / ASTM F 136 (2013).
5. Oticon Medical Reliability report 2021. Data as of june 30th 2021.
6. Sipari et al., Cochlear Implantation With a Novel Long Straight Electrode: the Insertion Results Evaluated by Imaging and Histology in Human Temporal Bones, Otology & Neurology, 2018.
7. Martins et al., Evaluation of intracochlear trauma caused by insertion of cochlear implant electrode arrays through different quadrants of the round window, Biomed Res Int, 2015.
8. Wanna GB, O'Connell BP, Francis DO, Gifford RH, Hunter JB, Holder JT, Bennett ML, Rivas A, Labadie RF, Haynes DS., Predictive factors for short- and long-term hearing preservation in cochlear implantation with conventional-length electrodes. Laryngoscope. 2017 Jun 22. doi: 10.1002/lary.26714. [Epub ahead of print].

Notes

Because sound matters

Oticon Medical is a global company in implantable hearing solutions, dedicated to bringing the power of sound to people at every stage of life. As part of the Demant group, a global leader in hearing healthcare with more than 16,500 people in over 30 countries and users benefitting from our products and solutions in more than 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 have a strong passion to provide innovative solutions and support that enhance quality of life and help people live full lives – now and in the future.
Because we know how much sound matters.

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