Reliability Report
H1 2017

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MEDICAL

About Oticon Medical

Oticon Medical offers **bone anchored hearing systems** and **cochlear implant solutions,** which address the needs of different patient groups. Our solutions benefit people with hearing loss, specialised to meet the needs of those who face the hardest hearing challenges.

Our history of innovation

Our desire to improve comes from a strong history of product innovation.

Our more than 100 years of history within hearing means we have built up significant knowledge and understanding of core technologies within advanced sound processing, coding strategies, micro mechanics, integrated circuit design, software design, wireless connectivity, audiology and hearing performance.

Add to that three decades of hearing implant experience, where we continue to develop and improve the most minimally invasive implant systems and innovative time-saving and safe surgical procedures, and you have **a powerhouse within hearing performance.**

Cochlear implants patients can rely on

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, each one repeated thousands and thousands of times.**

Scan the QR code to see why you can rely on Oticon Medical's implantable hearing solutions

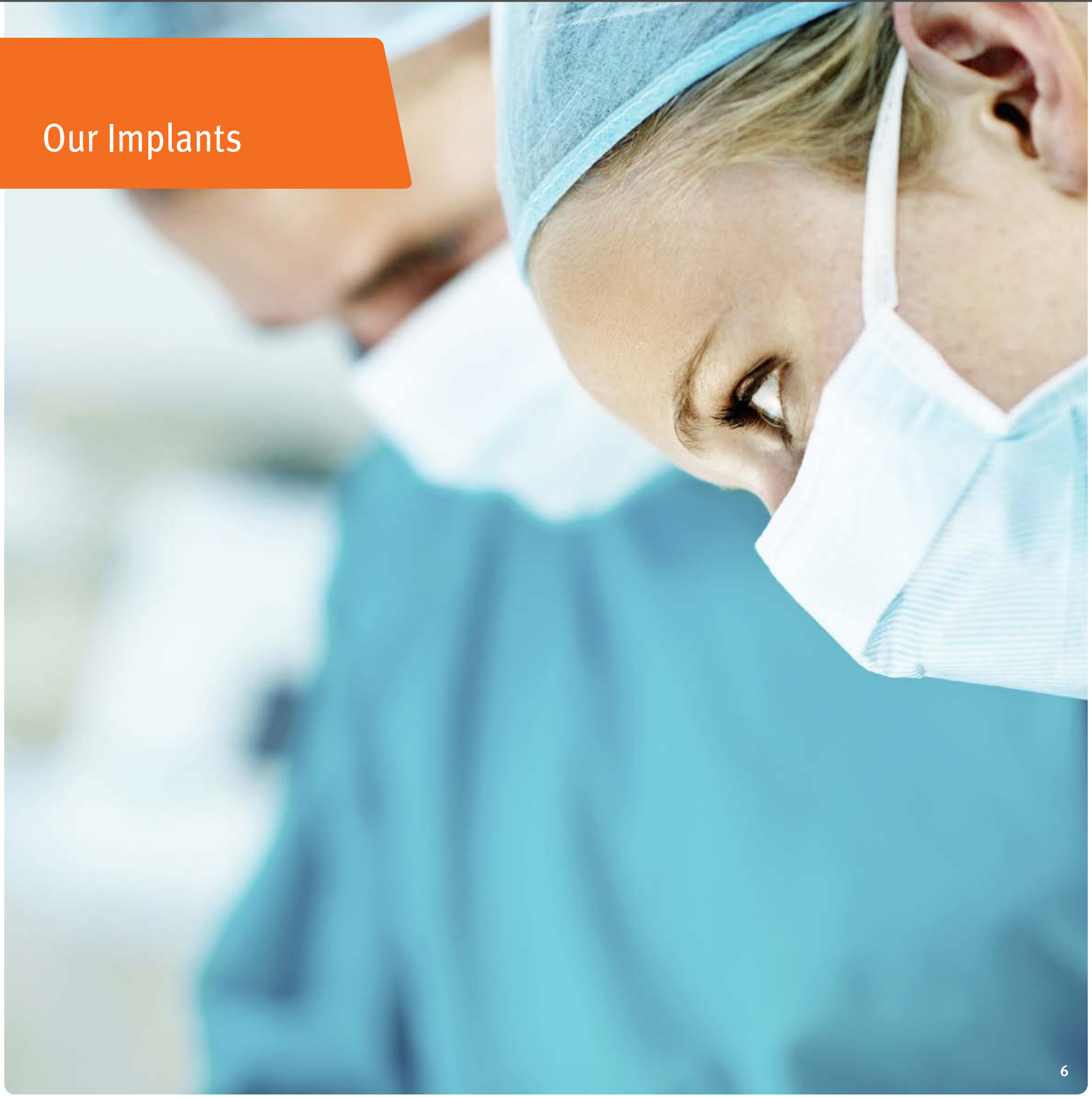
How this report has been made

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].

The founding philosophy at Oticon Medical is "People First". That's why we want to be transparent and clear in our report and add 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

Designed for safe and simple surgery

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** providing a powerful future-proof electronic platform that enables you to enjoy the wide variety of sound in your life today and in the future.

The Neuro Zti implant receiver is made of zirconia and titanium — two materials that are widely used in the medical field because of their biocompatibility. In addition, these innovative materials enable an **implant design that is small, highly robust and able to absorb impacts encountered in daily life.**

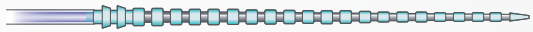
Digisonic SP

The Digisonic® SP implant features a unique monobloc design with the magnet and the receiver within a single unit. The implant's structure, combined with an exclusive screw fixation system, does away with 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 render 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.

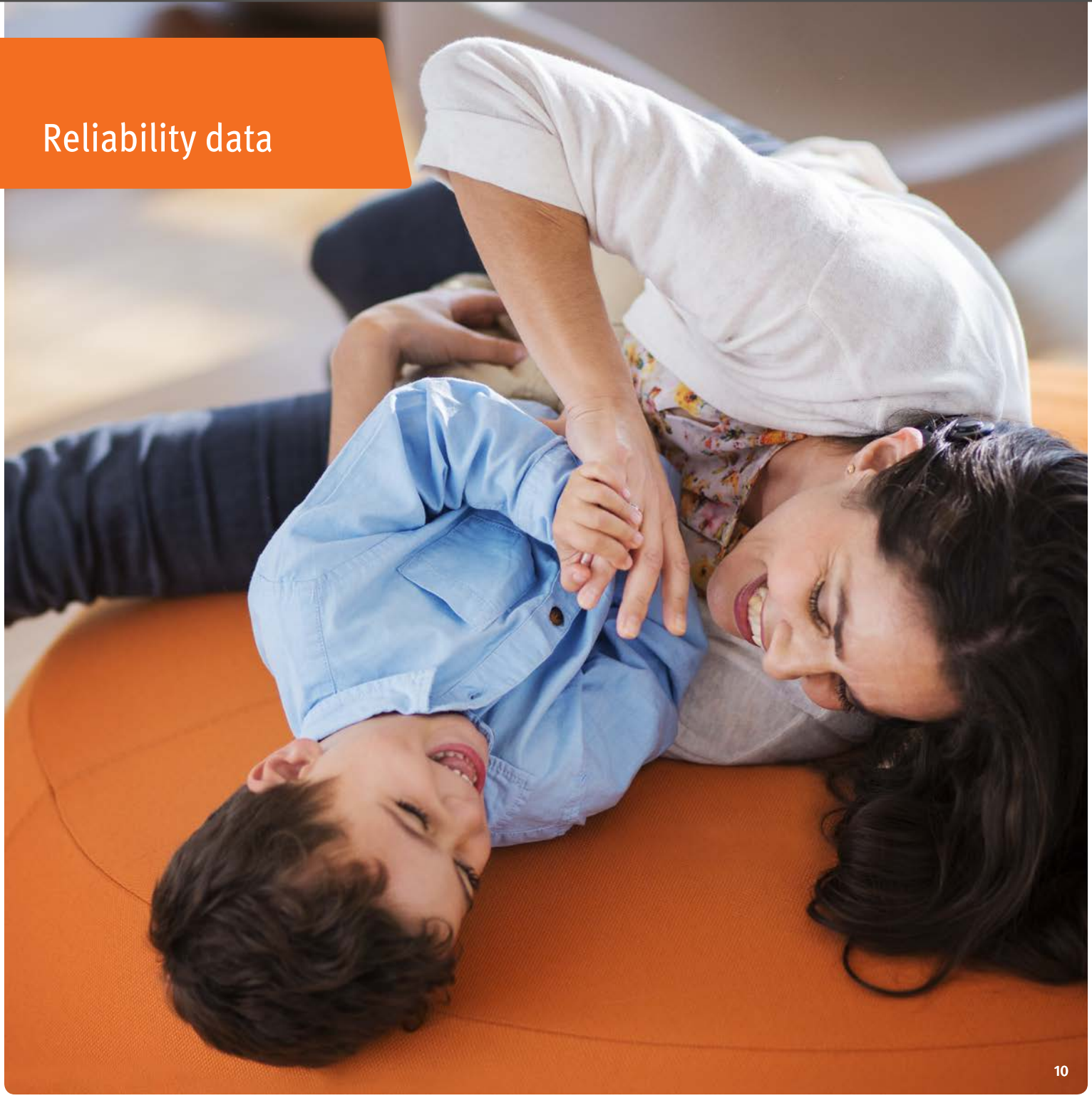


Neuro Zti CLA

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.

Neuro Zti EVO

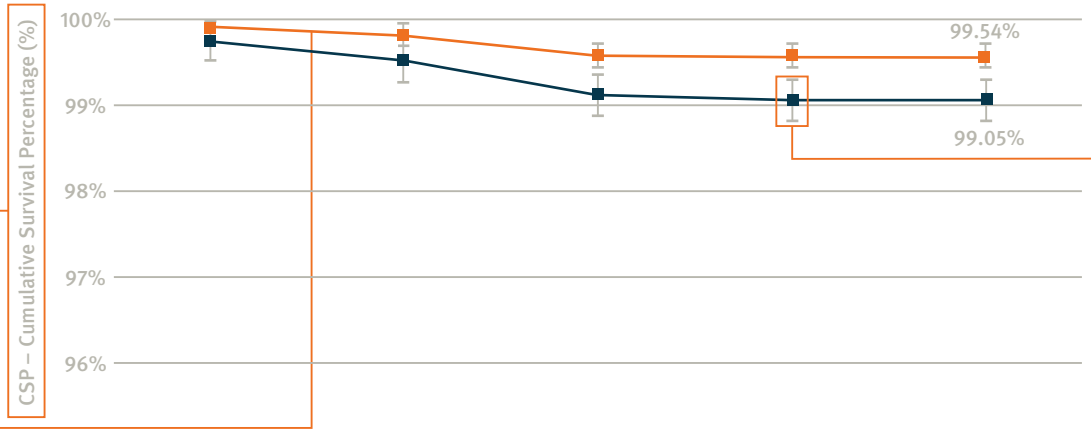
Reliability data



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[2]



	1 year	2 years	3 years	4 years	5 years
CSP (excluding accident-related issues)	99.91%	99.82%	99.59%	99.54%	99.54%
CSP (including accident-related issues)	99.75%	99.50%	99.10%	99.05%	99.05%

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

Figures at a glance

Neuro Zti

99.92% CSP after 2 years

Including accident-related issues
combining EVO and Classic

Digisonic SP

97.51% CSP after 12 years

Including accident-related issues
combining EVO and Classic

Data as of June 30th 2017

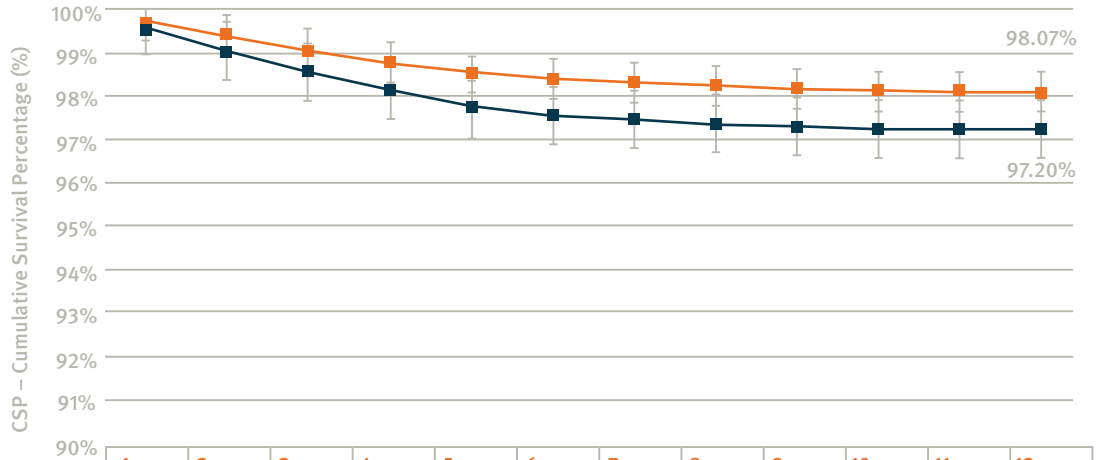
Neuro Zti – Classic & EVO

	1 year	2 years
CSP (excluding accident-related issues)	99.92%	99.92%
CSP (including accident-related issues)	99.92%	99.92%

2015
First implantation
99.92%
Including accident-related issues

Data as of June 30th 2017
For statistical purposes data reported on the Neuro Zti cochlear implant combine the EVO and the Classic version

Digisonic SP – Classic

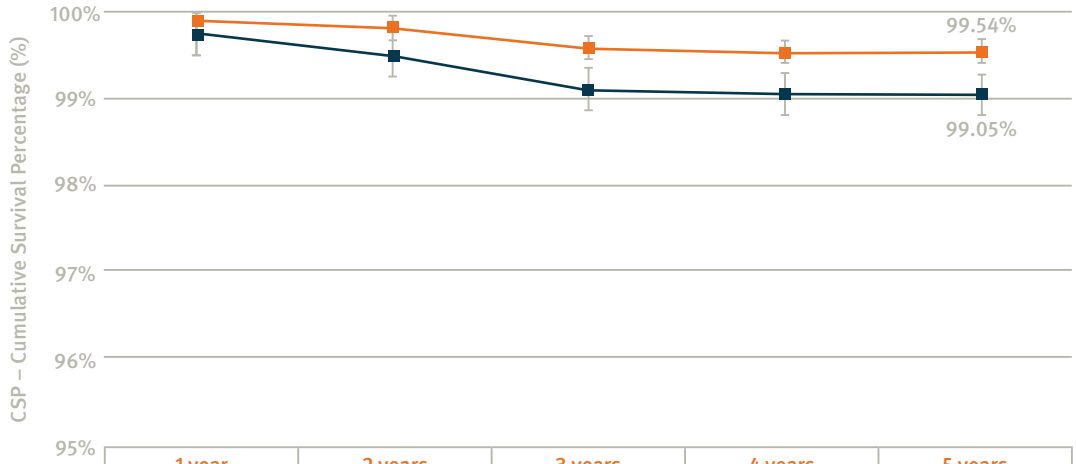


	1 year	2 years	3 years	4 years	5 years	6 years	7 years	8 years	9 years	10 years	11 years	12 years
CSP (excluding accident-related issues)	99.72%	99.38%	99.07%	98.75%	98.52%	98.38%	98.29%	98.21%	98.14%	98.08%	98.07%	98.07%
CSP (including accident-related issues)	99.59%	99.01%	98.52%	98.09%	97.75%	97.51%	97.43%	97.34%	97.27%	97.21%	97.20%	97.20%

2006
First implantation
97.20%
Including accident-related issues

Data as of June 30th 2017

Digisonic SP – Evo



	1 year	2 years	3 years	4 years	5 years
CSP (excluding accident-related issues)	99.91%	99.82%	99.59%	99.54%	99.54%
CSP (including accident-related issues)	99.75%	99.50%	99.10%	99.05%	99.05%

2013
First implantation
99.05%
Including accident-related issues

Data as of June 30th 2017

References

1. ISO 5841-2. Implants for surgery — Cardiac Pacemakers — part 2: Reporting of clinical performance of populations of pulse generators or leads. Geneva (Switzerland): International Organization for Standardization. 2014.
2. European consensus statement on cochlear implant failures and explantations. Otol Neurotol. 2005 Nov; 26(6): 1097-9

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 healthcare 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.

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