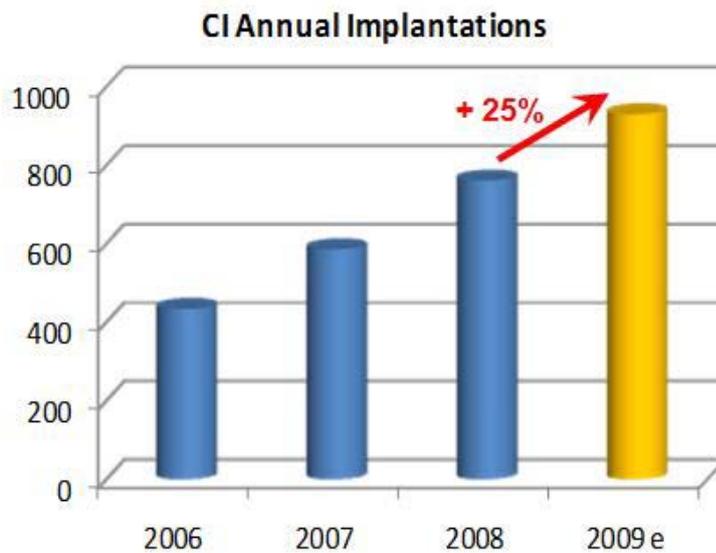


Digisonic® SP Reliability Report – March 2009

The purpose of this document is to present current information in regards to the reliability of Digisonic® SP Cochlear Implants. These data are presented over a 5 year period, from the first implantation of a Digisonic® SP cochlear implant in October 2003 to March 2009, which represent 2459 recipients located in 22 countries.

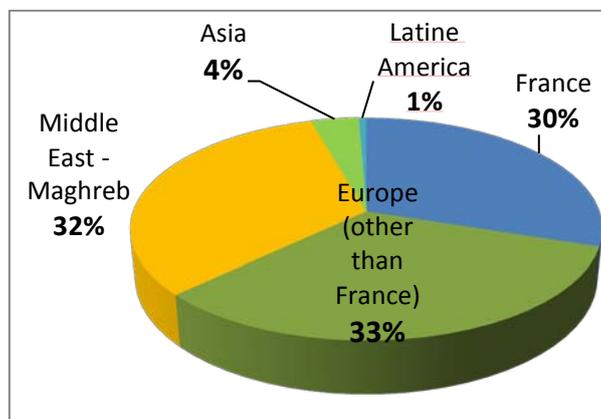
Figure 1: Trends in the number of Digisonic® SP implantations since 2003



It is to be noticed that Neurelec is steadily improving its market share. The number of implantations has significantly and continuously increased over the latest years.

Neurelec has a worldwide experience. Indeed, implantations of the Digisonic® SP system are performed in 22 countries over all continents.

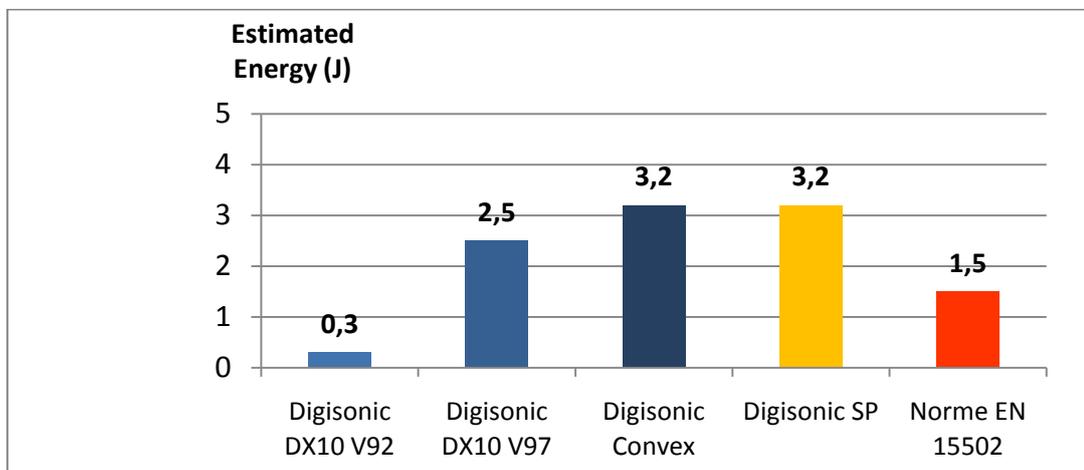
Figure 2: Geographical repartition of Neurelec's Cochlear Implants



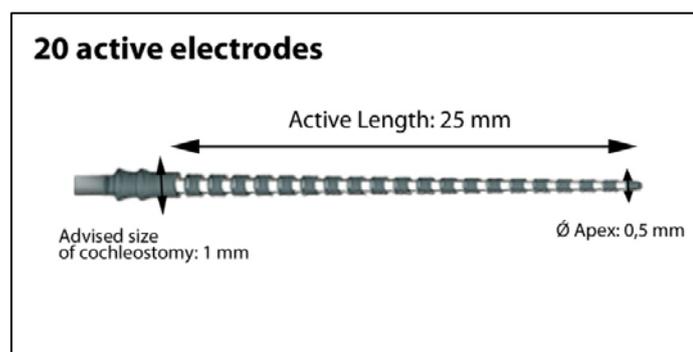
IMPORTANT FACTS:

- **A perfect control of the sealing:** Neurelec perfectly controls the closure of the ceramic case by laser welder on its production site and the sealing is guaranteed by the test of vacuum after helium gas injection in conformity with the military standards MIL STD 883.
- **Neurelec, single manufacturer to control the ceramics implant:** Ceramics allows a monobloc structure ensuring integration of all the elements making the Digisonic® SP cochlear implant the most compact implant on the market and allowing an unquestionable compatibility to MRI at 1,5 Tesla. Ceramics is a very difficult technology to implement but perfectly controlled by Neurelec. Ceramics is highly reliable and robust to the impact: **0,22% of incidents** related to an impact on the cumulated generations Digisonic® SP and Convex (>3500 patients).

Figure 3: Resistance to shock



- **A great reliability in the fixation of the implant:** Digisonic® SP uses an **innovating and unique fixation system by two screws**, making it the simplest to implant: 30% of time saved during surgery and minimization of the risk of complications.
- **An electrode array with memory of form:** Very easy to insert whatever the anatomical configurations are, this electrode array integrates 20 electrodes over an active length of 25mm. Its soft and thin termination allows a progressive, delicate and smooth insertion.

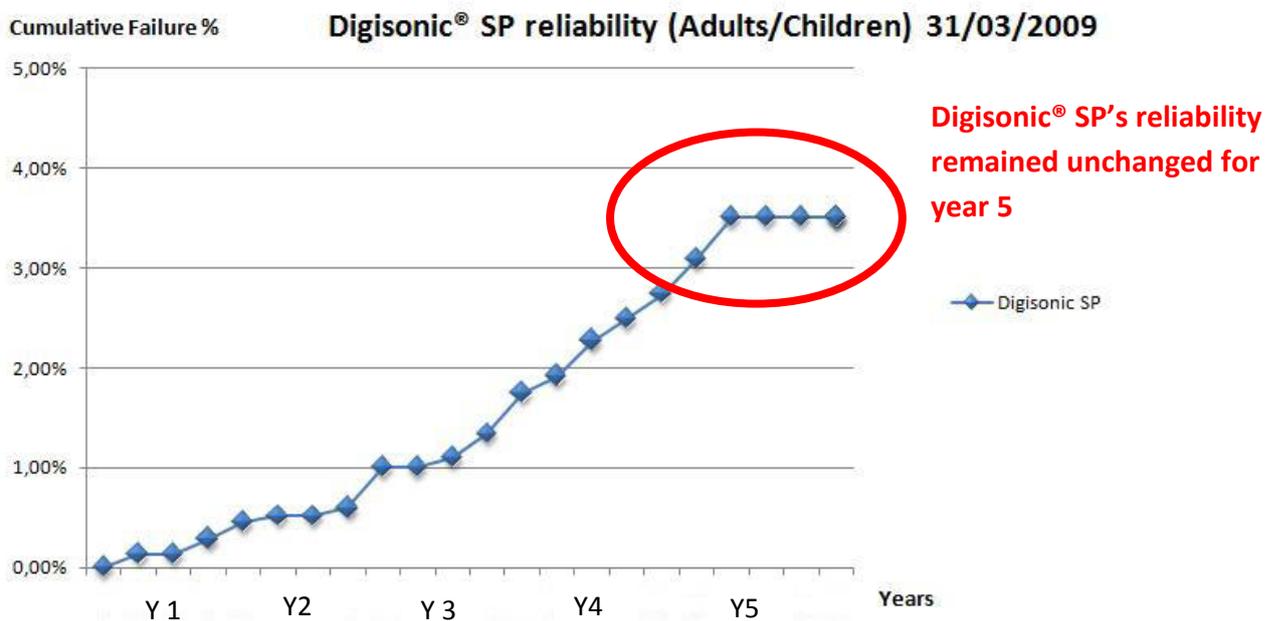


RELIABILITY AT MARCH 2009:

The reliability data for the Digisonic® SP cochlear implant on the overall population since its launching end 2003 are presented hereafter.

Implant	Number of Recipients	Duration
Digisonic® SP	2459	66 months

Figure 4: Digisonic® SP Reliability
All patients worldwide as of March 31st 2009



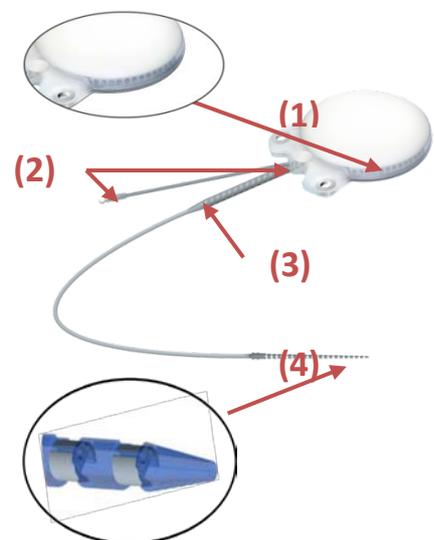
As shown above, the CSR (Cumulative Survival Rate) for Digisonic® SP cochlear implants as of March 2009 is 96,5%, meaning a Cumulative Failure rate over 66 months of 3,5% (see Figure 4).

CONTINUOUS IMPROVEMENT ON DESIGN:

Neurelec continuously commits to provide the best solutions to patients and professionals using Digisonic® SP cochlear implant. This is why constant improvements are implemented on our devices.

Since March 2006, Neurelec applied the following upgrades to the Digisonic® SP Cochlear Implant:

- (1) Reinforcement of the junction electrode wires/feed-through
- (2) Strengthening of ground electrodes
- (3) Reinforcement of the extension capacity (flexibility) of the lead; junction between the receiver and the electrode array
- (4) Integration of a soft and thin tip on the electrode array



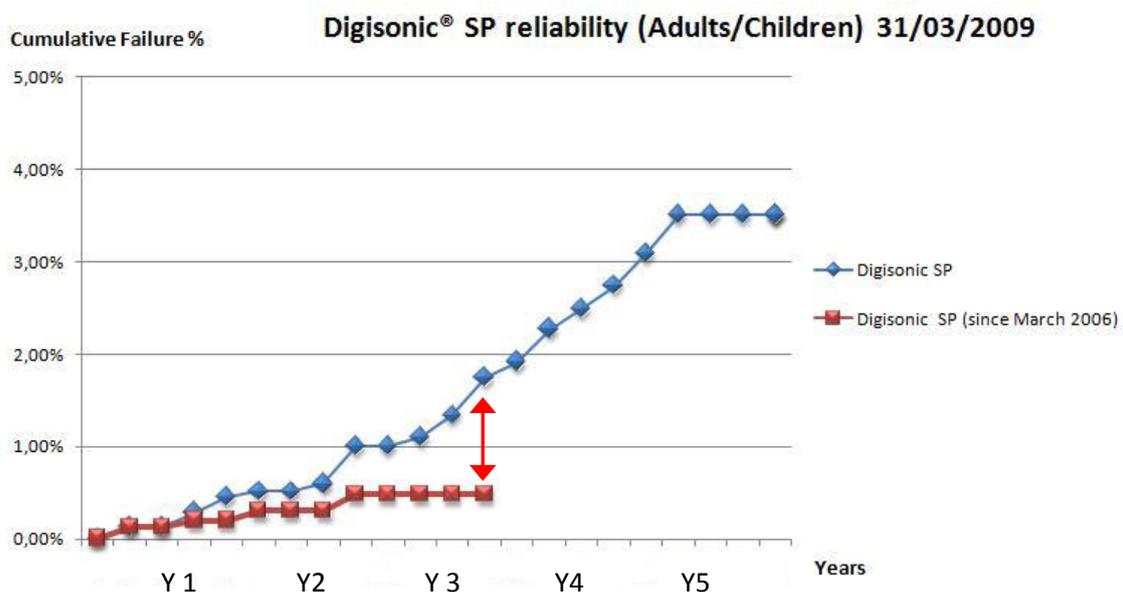
The impact of these improvements is directly perceptible over the cumulated survival rate of the Digisonic® SP cochlear implant which demonstrate a stable curve from the 5th year (see Figure 4).

For a better interpretation of the impact of these improvements, the data of cumulated reliability since October 2003 and since the application of the improvements above are presented in parallel:

Implant	Number of recipients	Duration	Cumulative failure percentage at 37 months
Digisonic® SP	2459	66 months	1,75 %
Digisonic® SP after revisions of March 2006	1777	37 months	0,48%

Figure 5: Comparison between Digisonic® SP Reliability after improvements on the design

All patients worldwide as of March 31st 2009 vs. all patients implanted after March 2006



It is to be noticed that improvements permitted to decrease the Cumulative Failure Rate from 1,15% to **0,48% after 37 cumulative months**. Neurelec commits to design for reliability.

Understanding this reliability report:

This document aims to objectively inform professionals about the reliability of Neurelec's cochlear implants.

The Cumulative Failure Rate (CFR) is an appropriate method to report reliability as it indicates the percentage of systems that are no longer functioning over a certain period of time. CFR data are shown in graphs and tables in this document.

In accordance with international standards, Neurelec also communicates on the Cumulative Survival Rate (CSR); the likelihood of devices to function over time. The CSR is simply 100%-CFR. CSR data are also shown in this document underneath the CFR table.

Important facts:

- This report complies with the International Standard ISO 5841-2 (for cardiac pacemakers) and the Principles of Reporting on Device Failure described in the European Consensus Statement on Cochlear Implant Failures and Explantations.
- All device failures are reported in the calculation of the CSR.
- Neurelec includes in this report all categories of device failures (impact, hermeticity, electronic, electrode array, other, no cause determined). Failures related to loss of clinical benefit are also reported.
- Device survival time starts to count with closure of the wound intraoperatively.

**Neurelec regularly communicates on the reliability of its products
during international conferences and on its website
www.neurelec.com**