Product Overview & Technical Specifications

	Digisonic® SP	Digisonic® SP EVO	Digisonic® SP ABI
Specifications	Normal or partially ossified cochlea	Normal or partially ossified cochlea	Brainstem implantation
References	I-SP-SD	I-SP-SD-EVO	I-SP-ABI
Mechanical properties			
Dimensions	Diameter: 30.2 mm – Thickness: from 4.9 to 5.75 mm		
Weight	10.5 g		
Receiver	Titanium base – encapsulation in ceramic – silicone casing		
Stimulation capacity			
Stimulation mode	Balanced biphasic stimulation		
Rate of stimulation	19 000 pps maximum (pps: pulses per second)		
Safety			
Surgery	Minimal incision – No drilling of the temporal bone – Fixation with two self-tapping screws		
MRI compatibility	1.5 tesla – Refer to instructions		
Operating pressure	Absolute pressure of 3 bars		
Receiver	Ceramic receiver housing all vital components hermetically sealed by laser		
Ground electrodes	2		
Electrode array			
Materials	Platinum iridium, silicone		
Number of active electrodes	20	20	15
Insertion length	26 mm	25 mm	Dimensions of electrode array: 7.8 X 3 mm
Active length	25 mm	24 mm	Dimensions of electrode array: 7.8 X 3 mm
Dimensions	Active area: 0.39 to 0.77 mm² Diam. at apex: 0.5 mm Diam. at base: 1.07 mm	Active area: 0.46 to 0.60 mm² Diam. at apex: 0.4 mm Diam. at base: 0.5 mm	Surface area of each ABI electrode: 0.39 mm²
Type of electrode array	Straight with shape memory Shape at apex: thin end Shape at base: two push rings with a diam. of 1.5 mm	Straight with shape memory Smooth Shape at apex: rounded Shape at base: two push rings - 1 with a diam. of 1.5 mm - 1 with a diam. of 1.2 mm	Surface electrodes Fixation with polyester strips
Objective measurements			
	Impedance measurement – Measurement of implant power supply – Evoked auditory brainstem response (EABR) – Stapedius reflex		

Cochlear Implant System

Product Information

Digisonic® SP, Digisonic® SP EVO, Digisonic® SP ABI

The Digisonic® SP range includes the Digisonic® SP and Digisonic® SP EVO cochlear implants as well as the Digisonic® SP ABI brainstem implant. The characteristics of each implant gives surgeons the ability to select the most appropriate solution for each patient, considering their cochlear anatomy, the auditory nerve, and even the possibility for using residual hearing.

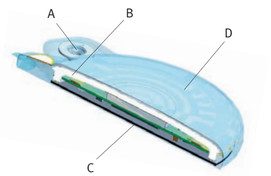
Compact design
The Digisonic® SP implant houses a magnet and a receiver within a single unit made of ceramic and titanium.
The implant's monobloc structure, combined with a screw fixation system, does away with the need to drill a bone bed during surgery. The implant is simply slid under the skin and 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.
The monobloc structure allows for:
- a minimally invasive surgical technique,
- shorter surgery time(1),
- optimised implant stability and resistance.

A unique fixation system
The Digisonic® SP includes a fixation system with two self-tapping screws(A) made of titanium that obviates the need any for drilling into the bone or suturing to secure the implant, thereby minimising the risk of migration and significantly shortens procedure time(1).
The flexibility of the silicone mounted "wings" makes it possible to adjust to different head shapes.

Reliable, resistant materials
The Digisonic® SP implant is composed of a convex ceramic shell(B) on the upper part and of a titanium base(C), all of which is enclosed in a silicone casing(D).
The convex shape helps dissipate shock waves, thereby reducing impact at the point of contact.

The Digisonic® SP implant's shock resistance has been tested to be at least 2.5 joules (*following the EN 45502-2-3:2010 standard*).

Compatible with MRI at 1.5 tesla
The Digisonic® SP generation of implants is compatible with magnetic resonance imaging (MRI) examinations at 1.5 tesla(2), MRI recommendations* must be respected.
Housing the magnet in the implant monobloc unit circumvents the risk of magnet migration after MRI examinations(3).



Indications:
Digisonic® SP and Digisonic® SP EVO: severe to profound perceptive hearing loss, with limited benefits from appropriately fitted hearing aids.

Digisonic® SP ABI: severe to profound retrocochlear perceptive hearing loss.

Product characteristics
- Compact monobloc structure
- Built-in magnet and receiver
- Fixation system using two self-tapping screws
- Materials: ceramic, titanium, silicone
- Compatible with MRI at 1.5 tesla
- Designed for a minimally invasive surgical technique

Product range overview
- **Digisonic® SP**
  20 electrodes
  Full cochlear coverage possible
- **Digisonic® SP EVO**
  20 electrodes
  Atraumatic insertion
- **Digisonic® SP ABI**
  15 electrodes
  Brainstem implant

**A MRI examination declaration form must be completed and sent to Oticon Medical Customer Service. Refer to the user manual or contact Customer Services for further information.*

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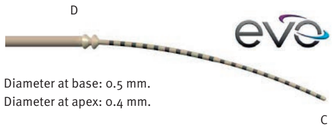
Electrode Arrays Digisonic® SP & Digisonic® SP EVO

The electrode arrays of the Digisonic® SP and Digisonic® SP EVO implants are composed of 20 platinum iridium electrodes that enable the entire sound spectrum to be stimulated.

Diameter at base: 1.07 mm.
Diameter at apex: 0.5 mm.

Reference: I-SP-SD

The Digisonic® SP electrode array possesses a shape memory structure and dimensions that make it possible to insert it deep (26 mm) into the cochlea.
The soft tip of the electrode array minimises invasion into the cochlear structures[A]. Push rings at the base of the electrode array facilitate improved array insertion as well as a hermetic sealing of the cochlea, to minimise the risk of infection[B].

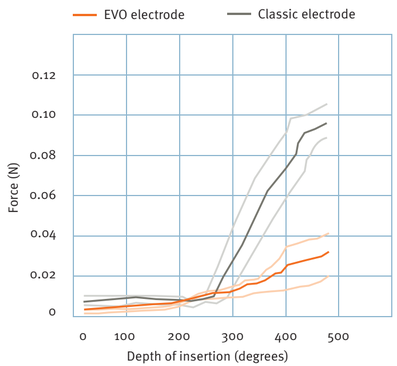


Diameter at base: 0.5 mm.
Diameter at apex: 0.4 mm.

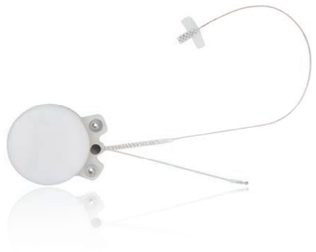
Reference: I-SP-SD-EVO

The electrode array of the Digisonic® SP EVO is designed to preserve the fragile structures of the cochlea, particularly important when there is residual hearing. Its structure is the result of an optimal compromise between rigidity, flexibility and length. Its smooth surface, small diameter, thin end[C] and flexibility ensure a smooth, trauma-free insertion so that the cochlear structures are preserved as much as possible.
Push rings at the base of the electrode array facilitate improved array insertion as well as a hermetic sealing of the cochlea, to minimise the risk of infection[D].

The specific characteristics of the Digisonic® SP EVO significantly reduce insertion forces by 32% compared with Digisonic® SP[4.] This allows insertion-induced trauma to be minimised and, thus, the cochlear structures to be preserved.



Digisonic® SP ABI Brainstem Implant



In cases of hearing loss accompanied by major lesions of the cochleae or of the auditory nerve, the cochlear implant cannot be used, and the medical team may recommend a brainstem implant.

The Digisonic® SP ABI is a brainstem implant that is designed to rehabilitate severe to profound retrocochlear hearing loss that is accompanied by major lesions of the cochleae (major cochlear malformation, complete cochlear ossification, or fracture of the petrous pyramid) or of the auditory nerve (axonal neuropathy, tumours near or on the auditory nerve such as neuromas, or complete obliteration of both auditory nerves) precluding cochlear implantation from being considered.

Digisonic® SP ABI comes with an array of 15 surface electrodes and a polyester strip placed on the cochlear nuclei of the brainstem. Each electrode stimulates a different area of the cochlear nuclei that corresponds to a frequency band of the acoustic signal processed by the external processor.

A brainstem implant provide useful auditory sensations to users, and improve quality of life by faciliting communication with family members and others[5 & 6].

Reference: I-SP-ABI

Note: Brainstem implant is not available in all countries, please contact your local Oticon Medical office or distributor to check availability.

Reliability data

Oticon Medical measures the reliability of its products in accordance with the international standard ISO 5841-2:2000 and the principles decided on in the European Global Consensus on Cochlear Implant Failures & Explantations*.

To that end, Oticon Medical uses the standard calculation method, the aim of which is to communicate the following statistics:
- Cumulative Survival Percentage (CSP): percentage of devices that are still functioning after a given period following implantation.
- Cumulative Failure Percentage (CFP): percentage of devices that are no longer functioning after a given period following implantation.

These data are available in the annual reliability report released by Oticon Medical.
Other than our own report, an independant study have showed a CSR (Cumulative Survival Rate) of 98,51% after 5 years[7].

***References:** International Organization for Standardization, International Standard ISO 5841-2 Implants for Surgery-Cardiac Pacemaker (2000).*
European Consensus Statement on Cochlear Implant Failures and Explantations, Otology & Neurotology, 2005 Nov; 26:1097-1099.

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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.