DIGISONIC®SP / IMPLANT

RELIABLE • UNIQUE • HIGH-PERFORMANCE COCHLEAR IMPLANT SYSTEM
More than a cochlear implant manufacturer, Neurelec is committed to supplying you with the best in research and development and service to enable people affected by severe to profound perceptive deafness to communicate, to exchange ideas, to live normally, and to do a lot more than hear. The Digisonic® SP implant is the 3rd generation of cochlear implants from Neurelec. The company has benefited from its manufacturing experience since 1986 in implantable medical devices and in neurostimulation. The core of the Digisonic® SP implant integrates an ultra-high-performance set of electronics enclosed in a convex ceramic casing, a strong material that is recognized for its high resistance to shocks. A partner for life, Neurelec has designed the Digisonic® SP implant to be compatible with all future signal processing technologies and sound processors.
NORMAL FUNCTIONING OF HEARING.

THE OUTER EAR
The auricle captures the sound to send to the auditory canal.

THE MIDDLE EAR
The sound is mechanically spread by sound waves, which cause the eardrum and the ossicular chain to vibrate.

THE INNER EAR
The vibrations then propagate in the liquid contained in the cochlea and cause the hair cells to move. The hair cells then emit electrical signals to transmit the sound message to the auditory nerve.

DEAFNESS
When one or more parts of the normal hearing path is damaged, the transmission of sound information then becomes defective, causing a lowering of hearing potential. The worse the sound transmission, the greater the degree of deafness.

WHY A COCHLEAR IMPLANT?
A cochlear implantation is necessary when patients do not gain sufficient benefit from their hearing aids. A cochlear implant is generally recommended for patients who have severe to profound perceptive deafness on both sides and are unable to communicate any longer with standard hearing aids.
Hearing
WITH THE NEURELEC
DIGISONIC®SP COCHLEAR IMPLANT SYSTEM

To restore hearing, it is necessary to capture the sound, to process it to make it audible and comfortable, and to send it directly to your auditory nerve without passing through the normal hearing route.

(1) The behind-the-ear processor captures the sound, digitizes it, and sends it via an antenna to the implant receiver, situated under the skin at the level of the temporal bone.

(2) The Digisonic®SP cochlear implant is an implantable auditory prosthesis that can substitute for the failed cochlea, which is the cause of most major perceptive deafness:

• The Digisonic®SP implant transforms the digital information into an electric signal, which will be sent to the electrode array inserted in the cochlea.

• The electrodes corresponding to the sound signal frequency stimulate the auditory nerve, which transmits the sound to the brain.
CRySTALiS PURiTy — high PRECiSioN SigNAL PRoCESSiNg

To make hearing an exceptional sound experience, Neurelec has developed CRySTALiS signal processing. Before the sound reaches your cochlea, CRySTALiS captures the high definition signal, then analyses and synthesizes the sound for a faithfully restored sound environment. The CRySTALiS sound quality is so exceptional that for the first time CRySTALiS signal processing combined with the latest generation behind the ear processor enables you to hear weak sounds and understand low levels of speech... A way to experience the world of sound in all its dimensions!

EXPLoRE ThE World of Sound
WITH THE DIGISONIC® SP IMPLANT

To improve the quality of life of persons suffering from severe to profound deafness, to guarantee richer and more precise hearing, while at the same time minimizing energy consumption and the size of the implant — these are the major challenges faced by the Digisonic®SP implant.
TO Highlight SOUNDS WITH A GENTLE STIMULATION THAT CONSUMES VERY LITTLE ENERGY

The 20 stimulating electrodes of the Digisonic® SP implant allow a very precise stimulation of the auditory nerve at an optimal speed of a maximum 24,000 pulses per second. This stimulation speed is intended to transmit essential information to you while reducing the energy consumption of the implant. As a result, the behind the ear device that is paired with the Digisonic® SP implant consumes only two Zinc-Air batteries for a battery life of 3 to 4 days (it is also possible to use 2 rechargeable batteries).
Cochlear implantation today is a routine surgery, but it is still essential to minimize the incision, to reduce the length of the surgery, to avoid the movement of the implant, and to assure its robustness. With its unique structure and system of fixation, the Digisonic®SP implant has been designed in an innovative manner for your safety.

**LESS INVASIVE SURGERY. THANKS TO AN ULTRA-COMPACT MONOBLOC STRUCTURE**

Inserting the Digisonic®SP is quick and simple, thanks to the monobloc structure associated with a unique system of fixation using self-tapping screws:

- Unlike most cochlear implants on the market, which have a two-part structure and a separate magnet, this surgery does not require any milling of the bone.
- The implant is simply slid under the skin.
- The incision is minimal, contributing to easy scar healing and reduction of the risk of post-operative infection.
- Because of the monobloc structure, the area of the peeled off skin is much smaller than in other implants, and scar healing is therefore faster and the operation less traumatic.

**BRAND A**
Dim.: 33.6 x 23.7 mm

**BRAND B**
Dim.: 45.7 x 25.4 mm

**BRAND C**
Dim.: 50.5 x 23.5 mm

**BRAND D**
Dim.: 56 x 28 mm
SIMPLE AND STABLE PLACEMENT OF THE IMPLANT... THANKS TO A Unique SYSTEM OF FIXATION.

The migration of the implant can be the cause of explantation or a revision surgery to reposition the implant. Fixation is therefore a major element in the surgical procedure.

The Digisonic® SP is the first monobloc implant that integrates a fixation system with 2 titanium self-tapping micro-screws (1); it does not require milling of the bone or a suture to position the implant. The flexibility of the silicon mounting tabs allows perfect adjustment to the shape of the head.

MRI WITH NO Worries

It is possible that you or your child will one day need to have an MRI* exam. Since the interaction of the magnetic resonance with the magnet in your implant might change the performance of your implant or have a significant impact on the quality of the MRI image, the generation of Digisonic® SP implants is designed to be compatible** with MRI exams at 1.5 Tesla***.

* Magnetic Resonance Imaging.


*** It is recommended that you contact the Neurelec customer service or your Neurelec distributor before any MRI exam and follow their recommendations.

Get more information on medical exams by consulting our Internet site: www.neurelec.com (section “Advice and Assistance”).
The characteristics of the Digisonic®SP implant (monobloc structure and fixation system) simplify the act of surgery. By eliminating milling, the average time of a procedure is shorter and the surgery is less invasive.

**According to a study** conducted on the screw fixation system, the unique surgical technique of the Digisonic®SP implant significantly reduces operating time.

*Multi Center evaluation of the Digisonic®SP cochlear implant fixation system with titanium screws on 156 patients (Guevara Nicolas M.D, Sterkers Olivier M.D., Ph.D, Bébèlar Jean-Pierre M.D., Meller Renaud M.D., Magnan Jacques M.D., Mosnier Isabelle M.D., Amstutz Isabelle M.D., Lerosey Yannick M.D., Triglia Jean-Michel M.D., Roman Stéphane M.D., Gahide Ivan M.D.).*
A Design AND MATERIALS
DESIGNED TO RESIST SHOCKS

The robustness of the Digisonic®SP implant is assured by a convex ceramic capsule. Ceramic material has shown very high resistance to shocks over the past 30 years in use in implantable prostheses in the medical field. Neurelec has increased the resistance of the ceramic receptor by giving it a convex form, which tends to dissipate the shock waves and thus reduce the impact at the point of contact. Finally, a silicon casing covers the receptor to provide the best possible defense against shocks (conforms to standard EN 45502-2-3).
AN ELECTRODE ARRAY **Easy**

TO INSERT

Thanks to the deep insertion (26 mm) of the electrode array into the cochlea, the 20 platinum-iridium electrodes of the Digisonic®SP allow stimulation of the complete sound spectrum.

Due to the structure of its memory shape and its optimal dimensions, the Digisonic®SP electrode array is recognized by many professionals as the simplest to handle, even in case of anatomic complications. The ease of use of the electrode array of the Digisonic®SP implant favors a natural positioning inside the cochlea.

(1) Streamlined edge of the electrode array to allow easy insertion into the cochlear spiral.

(2) The cone-shaped structure at the base of the electrode array eases closing the cochleostomy, thus minimizing the risks of infection.
DIGISONIC® SP EVO: a Gentle INSERTION WITH THE EVO ELECTRODE-ARRAY

The smooth surface, extremely reduced diameter and flexibility of the EVO electrode-array makes it possible to insert it into a natural position inside the cochlea while protecting the internal structures of the cochlea.

The Digisonic® SP Evo cochlear implant is compatible with the various surgical techniques practiced. Its special characteristics make it perfectly suitable for conservative and less invasive surgical procedures, such as cochlear implantation with residual hearing preservation. Extremely thin and flexible, the Evo electrode array is very easy to insert in the cochlea, and no force is needed*.


(1) Smooth and thin (0.4mm at the apex) electrode-array to preserve the cochlear structures as much as possible.

(2) The base of the electrode-array is cone-shaped to help seal off the opening of the cochleostomy, thus minimizing the risk of infection.
When one’s sight is corrected (myopia, presbyopia, etc.), it seems normal to correct both eyes to improve one’s vision. Just as seeing with two eyes allows one to see better, to hear with two ears allows one to have a more natural restoration of sound, better comprehension of words amidst noise, and a better local placement of sounds.
THE DIGISONIC® SP BINAURAL IMPLANT SYSTEM: A SINGLE IMPLANT, A SINGLE PROCESSOR, ONE Binaural SOUND... NEVER SEEN BEFORE!!

THE DIGISONIC® SP BINAURAL IMPLANT: AN ALTERNATIVE TO BILATERAL IMPLANTATION IN ADULTS

Today, Neurelec is the only manufacturer of cochlear implants to offer you an implant capable of giving you binaural hearing in the simplest and most economic form possible. On the basis of the Digisonic® SP, the Digisonic® SP Binaural implant has two electrode arrays designed to stimulate each cochlea.

With the Digisonic® SP Binaural Implant, Expand Your Field of Hearing Quite Simply

The sound processor analyses the signal coming from its own microphone and from the contralateral* microphone. The signal sent in each cochlea is thus perfectly synchronized and does not entail any time lag in perception.

* Side opposite of the implanted receiver.

WITH THE DIGISONIC® SP BINAURAL IMPLANT, EXPAND YOUR FIELD OF HEARING QUITE SIMPLY

Thanks to the contralateral microphone, the Digisonic® SP Binaural implant improves spatial localization, give excellent stereophonic sound, and provides better comprehension of words against a noisy background. A clinical study confirmed the Digisonic® SP Binaural implant performances are equivalent, if not higher, to bilateral cochlear implantation outcomes*. Using a simplified system for which you have only one operation to undergo and only one processor to maintain, the Digisonic® SP Binaural implant has been developed to offer the most natural hearing.


N.B.: The Digisonic®SP Binaural implant is for adults only.
Neurelec today offers two designs for behind the ear processors adapted to individual preferences: ◆, the 4th generation processor with an integrated induction loop (Telecoil), and the Digi SP’K, a micro behind the ear processor with integrated induction loop and remote battery designed to adapt to very small ears (children, adults).
DIGI SP’K, THE SMALLEST EAR CONTOUR ON THE MARKET

Made of anodized aluminum, the Digi SP’K micro-BTE processor is unchallenged as the smallest on the market. Thanks to its reinforced connections, it is particularly well adapted to resist the hectic life-style of young children while maintaining their structure. Powered by a simple standard or rechargeable AA battery, the Digi SP’K has an exceptional battery life of 6 days, based on its settings. What’s more, with its integrated induction loop and its auxiliary socket for multiple uses (audio cable, FM system, etc.), the Digi SP’K offers a wide palette of new possibilities for young children or to anyone preferring the micro-contour option with remote battery.

Unique with its butterfly bio-design, sàphyr® is a behind the ear processor that is light, comfortable, ergonomic, and perfectly adapted to bilateral transplantation. It comes in a variety of satin-finish colors, and will blend with your hair. Precious, sàphyr® is a high technology product manufactured of very precise components. Thanks to the CRYSTALIS signal processing, sàphyr® offers a pure sound and excellent results even for low sounds. Essential, sàphyr® is easy to use for high-definition hearing, made simply with only 2 standard or rechargeable zinc-air batteries. Thanks to the integration of the Telecoil, the auxiliary socket, and the possibility of setting 4 independent programs, sàphyr® was designed to enhance your auditory potential — meetings, theatre halls, telephone, noisy and calm sound atmospheres, music, etc. From now on it’s simple with Neurelec.
## THE DIGISONIC® SP IMPLANT RANGE

### Indications
- **Digisonic® SP Binaural**: Normal or partially ossified cochlea
- **Digisonic® SP ABI**: Binaural implantation
- **Digisonic® SP EVO**: Brainstem implantation
- **Digisonic® SP Normal or partially ossified cochlea**

### MECHANICAL PROPERTIES

<table>
<thead>
<tr>
<th>Dimensions</th>
<th><strong>Digisonic® SP Binaural</strong></th>
<th><strong>Digisonic® SP ABI</strong></th>
<th><strong>Digisonic® SP EVO</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Diameter 30.2 mm - Thickness: from 4.9 to 5.75 mm</td>
<td>20</td>
<td>2 x 12</td>
<td>15</td>
</tr>
<tr>
<td>Weight</td>
<td>10.5 g</td>
<td>10.5 g</td>
<td>10.5 g</td>
</tr>
</tbody>
</table>

### STIMULATION CAPACITY

<table>
<thead>
<tr>
<th>Stimulation mode</th>
<th><strong>Digisonic® SP Binaural</strong></th>
<th><strong>Digisonic® SP ABI</strong></th>
<th><strong>Digisonic® SP EVO</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Balanced biphasic stimulation</td>
<td>24 000 pps maximum</td>
<td>24 000 pps maximum</td>
<td>24 000 pps maximum</td>
</tr>
</tbody>
</table>

### SAFETY

<table>
<thead>
<tr>
<th>Surgery</th>
<th><strong>Digisonic® SP Binaural</strong></th>
<th><strong>Digisonic® SP ABI</strong></th>
<th><strong>Digisonic® SP EVO</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Small cochleostomy (1 mm in diameter)</td>
<td>Small cochleostomy (1 mm in diameter)</td>
<td>Small cochleostomy (1 mm in diameter)</td>
<td>Small cochleostomy (1 mm in diameter)</td>
</tr>
<tr>
<td>MRI compatibility</td>
<td>1.5 Tesla</td>
<td>1.5 Tesla</td>
<td>1.5 Tesla</td>
</tr>
<tr>
<td>Operating pressure</td>
<td>Absolute pressure of 3 bars (corresponding to a diving depth of 20 meters)</td>
<td>Absolute pressure of 3 bars (corresponding to a diving depth of 20 meters)</td>
<td>Absolute pressure of 3 bars (corresponding to a diving depth of 20 meters)</td>
</tr>
<tr>
<td>Receiver</td>
<td>Receiver hermetically sealed by laser in ceramic shell containing all the critical components</td>
<td>Receiver hermetically sealed by laser in ceramic shell containing all the critical components</td>
<td>Receiver hermetically sealed by laser in ceramic shell containing all the critical components</td>
</tr>
<tr>
<td>Ground electrodes</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>

### ELECTRODE ARRAY

<table>
<thead>
<tr>
<th>Materials</th>
<th><strong>Digisonic® SP Binaural</strong></th>
<th><strong>Digisonic® SP ABI</strong></th>
<th><strong>Digisonic® SP EVO</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Platinum Iridium, silicon</td>
<td>20</td>
<td>2 x 12</td>
<td>15</td>
</tr>
<tr>
<td>Number of active electrodes</td>
<td>26 mm</td>
<td>26 mm</td>
<td>26 mm</td>
</tr>
<tr>
<td>Insertion length</td>
<td>25 mm</td>
<td>25 mm</td>
<td>25 mm</td>
</tr>
<tr>
<td>Active length</td>
<td>0.39 mm² to 0.77 mm²</td>
<td>0.39 mm² to 0.65 mm²</td>
<td>0.46 mm² to 0.60 mm²</td>
</tr>
<tr>
<td>Active area: 0.5 mm</td>
<td>Active area: 0.5 mm</td>
<td>Active area: 0.5 mm</td>
<td>Diameter at base: 0.5 mm</td>
</tr>
<tr>
<td>Diameter at apex: 1.07 mm</td>
<td>Diameter at base: 1.07 mm</td>
<td>Diameter at apex: 0.4 mm</td>
<td>Diameter at apex: 0.4 mm</td>
</tr>
<tr>
<td>Type of electrode array</td>
<td>Straight with shape memory</td>
<td>Straight with shape memory</td>
<td>Surface electrodes. Fixation with Dacron®</td>
</tr>
</tbody>
</table>

### OBJECTIVE MEASURES

<table>
<thead>
<tr>
<th>Impedance measures – implant power supply measure - EABR** - stapedius reflex</th>
<th><strong>Digisonic® SP Binaural</strong></th>
<th><strong>Digisonic® SP ABI</strong></th>
<th><strong>Digisonic® SP EVO</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Electrode array</strong></td>
<td><strong>Electrode array</strong></td>
<td><strong>Electrode array</strong></td>
<td><strong>Electrode array</strong></td>
</tr>
<tr>
<td><strong>Surface electrodes. Fixation with Dacron®</strong></td>
<td></td>
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</tr>
</tbody>
</table>

**Electrode array**

**Evoked Auditory Brainstem Responses**
DIGISONIC®SP ABI

When hearing loss is accompanied by large lesions in both cochleas or on the auditory nerve, a cochlear implant cannot be used and instead, a brainstem implant may be recommended. Type II neurofibromatosis (NF2) is a progressive, very rare, genetic disease. Neurinomas or (non-cancerous) tumors develop on the auditory nerves and therefore affect hearing. The degree of hearing loss depends on the size of the tumors on the nerves. The bigger they are, the less the patient is able to perceive sound. Unfortunately, there is no miracle cure for this disease. Removal of the neurinomas often involves ablation of the auditory nerves. To prevent total hearing loss, the medical team may recommend a brainstem implant. Digisonic® SP ABI is equipped with 15 flat stimulating electrodes that are attached directly to the brainstem. Each electrode stimulates different areas of the stem, enabling you to perceive a wide range of sounds.

WHAT ABOUT THE FUTURE TECHNOLOGIES?

Neurelec is constantly innovating, and is always improving its products, bit by bit. It is essential to develop products that for your entire life will adapt to your needs or to those of your child – medical exams, new technology...

That is why technological advances, the future generations of processors and of signal processing, will be developed to offer the best possible compatibility with the generation of Digisonic® SP implants.
SEE MORE – EXPERIENCE IN A BETTER WAY – Hear – LIVE LIFE TO ITS FULLEST

To hear is to discover the world on another day, to turn round to a bird, a plane, persons whom you wouldn’t have seen if you hadn’t heard them.

To hear is to perceive sounds, but also to comprehend the world around you, your family, your friends. To hear is to be able to partake in all this.

The world is made up of colors, shapes, materials, smells, wave sounds, tears, bursts of laughter.

LIVE IT.