

Oticon Medical

Moving from the Softband to the Ponto Implant



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MEDICAL

This booklet was created in collaboration with Dr. Laurie Mauro, AuD, from Children’s Hospital of Philadelphia (CHOP). We would like to express our thanks and gratitude to Children’s Hospital of Philadelphia for their contributions, partnership and expertise in helping to develop this informational booklet for your convenience.

Moving from the Softband to the Ponto Implant

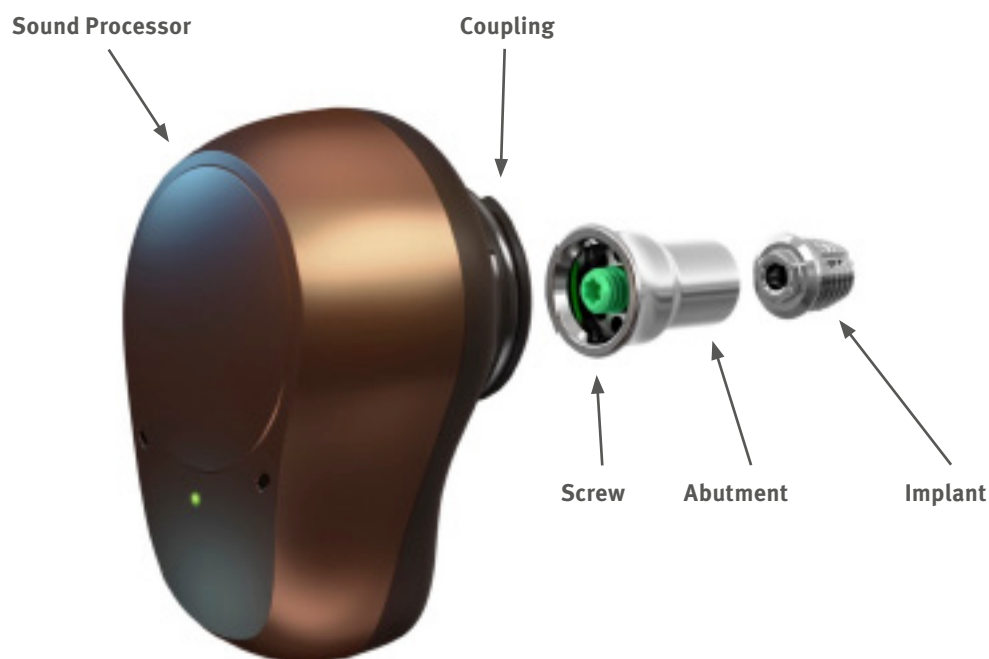
Throughout this journey to better hearing for your child you have had to make many decisions. Now, as you prepare to start the process of transitioning from a Softband to the Ponto Implant you likely have additional questions and concerns. The process may seem overwhelming, and no parent likes to consider a surgical procedure for their child. However, the benefits that they gain from the technology can provide comfort and motivation for you to proceed. We will be with you and your child every step of the way.

At what age should this transition begin? Your audiologist and surgeon will provide guidance on when the time is right to proceed from a Softband to the Ponto Implant. Children five years and older are approved under the Food and Drug Administration (FDA) guidelines for the Minimally Invasive Ponto Surgery (MIPS) procedure.

However, there are many factors that your child's surgeon will consider prior to moving towards the implant such as bone thickness, etiology of hearing loss, skull size, and their overall health.

As a reminder, a bone conduction system works by bypassing the middle and outer ear where the hearing loss is occurring and sends a vibrant and robust sound signal directly to the inner ear using bone conduction. The sound vibrations are captured by the sound processor microphone and sent through the skin to the implant located in the skull bone, then on to the inner ear. A bone conduction device is a stable, long-term solution for the treatment of a conductive, mixed, or unilateral hearing loss.

Up until this point your child has been using the Ponto Sound Processor on a Softband, but there are many reasons why proceeding to the implant is the preferred solution. Throughout the next several pages you will learn more about why Direct Sound Transmission provides improved sound quality and the surgical options for receiving the implant.



The Ponto™ System consists of a small titanium implant, an abutment, and a Ponto sound processor [see illustration above]. The implant is carefully implanted in the bone behind the ear. The abutment is then attached to it and allowed to protrude through the skin as an anchor for the sound processor.

Is there a difference between Skin Transmission versus Direct Sound Transmission?

Bone anchored hearing devices can be placed into two broad categories: either they deliver sound via **Skin Transmission**, where the vibrating unit is placed on top of the skin and the sound vibrations must pass through the skin and are attenuated before they reach the bone, or via **Direct Sound Transmission**, with sound vibrations going directly to the bone and then on to the inner ear. Up to this point your child has been using a non-surgical Skin Transmission solution (e.g., a Softband). A Softband is necessary for young children to have early access to sound until they have reached the necessary age for a Direct Sound Transmission solution, which requires a surgical procedure.

The Ponto Implant is a percutaneous solution where the processor sends sound information through the skin to an implanted vibrating unit in direct contact with the bone. This solution is recommended to provide the Direct Sound Transmission necessary to expand your child's hearing outcomes.

Clinical evidence comparing patient outcomes between a skin transmission device and a direct transmission device indicates there is a significant difference. It has been shown that hearing thresholds obtained with Direct Sound Transmission solutions are about 5-20 dB lower (better) between 600 and 6000 Hz, and speech reception thresholds are also 4-7 dB lower (better) than with conventional devices.^{1,4} Beyond this fact, research shows that by choosing Direct Sound Transmission, such as a Ponto percutaneous solution, children can learn faster.

A research study by Andrea Pittman (2019)³ found that using Direct Sound Transmission can increase the learning speed in children by 2.5 times when compared to a Skin Transmission solution. This study is the first to show the influence of different sound transmission pathways on the essential domain of auditory learning with the effects of Direct Sound Transmission clear — children learn new words faster.



The implant and surgical approaches

The Ponto Implant is a small titanium implant that is embedded into the bone behind your child's ear. The Ponto Implant has been uniquely designed for implant stability with its wide design and OptiGrip geometry, it has a proven 98% survival rate.



Osseointegration

After implant placement, the titanium implant will become integrated with the bone through a process known as osseointegration. This process can take several months. During this time, the bone will gradually form and harden around the implant. It is after this process that your child will return to the audiologist for the fitting of the Ponto Sound Processor onto the abutment. The Softband will no longer be necessary for sound transmission. Your child will be able to benefit from the direct sound transmission provided by the implant. This will open up access to improved sound quality.

Linear incision with tissue preservation

This approach requires a small straight incision behind the child's ear. The surgeon will place the implant either along the incision line or slightly to the side of the incision depending on their preference. The surgeon will use additional techniques to preserve the surrounding tissue for faster healing process.



“The procedure itself is fairly small... Within 24 hours after the first surgery, he did not need any pain relief, and the following day we were in the park and he was playing around on the zip wires.”

— Louise, mother of Ruben

Watch Video:

<https://www.oticonmedical.com/us/bone-conduction/meet-other-users/users-tell-their-story/bahs/reuben>



The MIPS procedure

A small procedure with huge benefits – the Minimally Invasive Ponto Surgery (MIPS)

The MIPS technique is a suture-free procedure with a unique approach to tissue preservation that is completed in approximately 15 minutes. It is truly minimally invasive because the soft tissue excised exactly matches the shape of the percutaneous abutment. All preparations for the implant installation are done through this circular incision, eliminating the need for sutures, and thinning of the soft tissue. This procedure has revolutionized the industry by offering patients a less-invasive approach to better hearing with a Ponto device. This new procedure offers the advantages of a simple, safe, and easy surgery with huge benefits.

As a parent you can have peace of mind that the clinical evidence gathered over the past 10 years suggests that 98% of adults and children report an improvement in their quality of life after Ponto surgery. Additionally, there are minimal complications reported. In fact, no skin-related aftercare treatment was required for 95% of follow-up visits.² These outcomes are meant to ease any concerns you may have about the upcoming procedure for your child.

Regardless of the type of procedure used to place the tiny implant into bone behind your child's ear, surgeons may choose to do a single-stage procedure or a two-stage procedure.

Single-stage surgery

Surgeons will consider a single-stage surgery for children with normal bone quality and a bone thickness above 4 mm (typically 12 years or older) if age, development status and other known factors have been considered and found suitable. In a single-stage surgical procedure, the implant and abutment placement, as well as the skin preparation, are carried out in

the same procedure. The sound processor is then generally fitted 3 months after surgery.

Two-stage surgery

Children with expected soft/poor bone quality or thin bone are indicated for a two-stage surgical procedure, with a prolonged osseointegration period of 3 to 6 months or more between the two stages. The implant is placed, and a cover screw connected to it in the first stage. After 3 to 6 months the second stage is performed, including removing the cover screw, connection of the abutment and skin preparation. The exact time required for osseointegration is based on the surgeon's assessment of the bone depth and quality during the first stage of the surgical procedure. The sound processor can then be fitted after the soft tissue has healed from the second surgery.

The healing period

Upon completing the procedure, your child's surgeon will place a healing cap over the implant site. The healing cap will remain in place for approximately seven days. When the healing cap has been removed, your child's skin may still be very sensitive. We advise that you treat the area around the abutment gently. During this period clean your child's abutment using a non-alcoholic wet wipe until your physician indicates that the area has healed, and at that time further instructions will be provided.

Once your child's skin has completely healed, it is important to continue the recommended skincare routine daily to avoid any build-up of debris around the abutment. The process is just as easy as brushing your teeth. Wash the abutment area with warm water every day. After you have cleaned the area, use a cotton swab or a soft cleaning brush to clean gently around and inside the abutment. Additional care instructions can be found on our website, www.oticonmedical.com/us.

MRI safe

The Ponto Implant and abutment are MRI conditional. This means that a patient with a Ponto Implant and abutment can have an MRI safely by adhering to the manufacturer guidelines. These guidelines can be found in the Ponto Instructions for Use document,⁵ and a copy should be provided to the radiologist prior to the scheduled scan. The sound processor, which attaches to the abutment, must be disconnected since it is not MRI safe.



Does insurance cover the surgical procedure?

Bone conduction hearing implants may be covered by your private insurance company and/or other public insurance companies (i.e., Medicaid). The Oticon Medical Insurance Support Team will assist you with everything: verification of benefits; submitting paperwork to insurance providers; and requesting and receiving pre-authorization for the procedure. We do this in a confidential and private manner to protect your healthcare information through each step of the process.

Below are some commonly asked questions regarding insurance services.

1. How do I contact the Oticon Medical Insurance Support Team?

You can call the Oticon Medical Insurance Support Team directly at **1.855.400.9761** or **insuranceservices@oticonmedical.com**.

2. How do I submit paperwork to the Oticon Medical Insurance Support Team?

If you need to submit any paperwork to our team, please send via mail or fax as listed below. Please be sure that all documents include your name and contact information and are sent to the attention of the Insurance Support Team.

Oticon Medical
580 Howard Avenue
Somerset, New Jersey 08873
Phone: 1.855.400.9761
Fax: 1.888.683.8736
Email: **insuranceservices@oticonmedical.com**

3. How long does a request for Prior Authorization take?

A request for prior authorization can take anywhere from 4–6 weeks (or less). However, it depends on the insurance plan. Insurance Support does not control the timeframe of how long it takes for a plan to make a decision. We strictly request the approval and await a decision. Once approved or denied, Insurance Support notifies all parties that a decision has been reached.

4. My insurance carrier denied my prior approval request. What can be done?

As part of our services, Oticon Medical will request a prior approval from a patient's insurance plan. Insurance Support is not responsible for the decision of the insurance carriers. If a request is denied, the patient has the right to an appeal. Please contact **insuranceservices@oticonmedical.com** for additional questions or assistance regarding an appeal.

References

¹ Håkansson, B., Tjellstrom, A., Rosenhall, U. (1984) Hearing thresholds with direct bone conduction versus conventional bone conduction. Scand Audiol 13: 3–13.

² Lagerkvist, H, et al. (2020). Ten years' experience with the Ponto bone anchored hearing system – a systematic literature review (under review).

³ Pittman, A. L. (2019) Bone conduction amplification in children: Stimulation via a percutaneous abutment vs. a transcutaneous Softband. Ear Hear.

⁴ Verstraeten, N., Zarowski, A. J., Somers, T., Riff, D. and Offeciers, E. F. (2009). Comparison of the audiologic results obtained with the bone anchored hearing aid attached to the headband, the testband, and to the “snap” abutment Otol. Neurotol 30: 70–75.

⁵ Ponto 4 Instructions for Use 197425 UK/2020.11

“I cannot say enough good things about how easy Oticon Medical made the process for me. Once we determined that I would be able to get the new device, the upgrade process was very simple and quick!”

– Katie

Watch Video:

<https://www.oticonmedical.com/us/bone-conduction/meet-other-users/users-tell-their-story/bahs/katie>

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 part of the Demant group, a global leader in hearing healthcare with 14,500 people in over 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 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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