



Vibrant® Soundbridge™ System

PATIENT INFORMATION GUIDE

Patient Information

This booklet is intended to provide information about the Vibrant Soundbridge and to increase your understanding of this implantable middle ear hearing device. In the Patient Information Guide, we have responded to questions frequently asked by Soundbridge candidates. We encourage you to write down additional questions when reading this booklet and discuss them with your surgeon or audiologist.

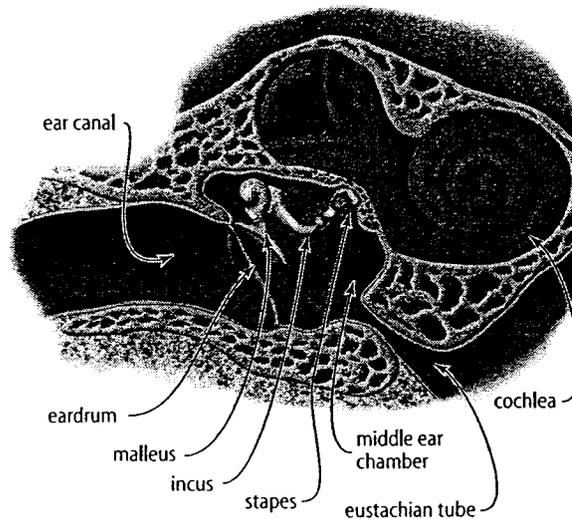
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How We Hear and How the Ear Works

The human ear consists of three parts: the outer ear, the middle ear, and the inner ear. The outer ear includes the visible part of the ear (pinna) and the ear canal. Sound waves travel down the ear canal to the eardrum and then the middle ear.

The middle ear is an air-filled space separated from the outer ear by the eardrum. The middle ear contains three small bones that make up the ossicular chain: the malleus, incus, and stapes (commonly known as the hammer, anvil, and stirrup). These bones form a mechanical bridge from the eardrum to the inner ear. When sound waves reach the eardrum, they cause vibrations across the ossicular chain.



The portion of the inner ear responsible for hearing is called the cochlea. It is fluid-filled and has thousands of tiny hair cells. The vibrations from the ossicular chain create movement in the fluid of the cochlea stimulating the hair cells. These hair cells connect to nerve fibers and send electrical pulses to the brain, which are then interpreted as sound.

Hearing Impairment

Hearing loss is primarily divided into two categories: conductive and sensorineural. Conductive hearing loss results from diseases or disorders limiting the transmission of sound through the outer or middle ear. This hearing loss can usually be treated with medication or surgery.

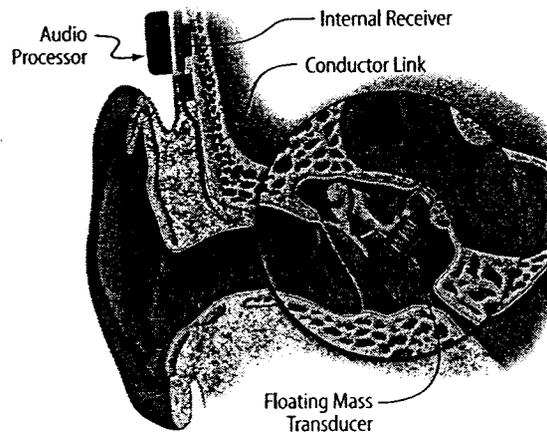
Hearing loss for most adults is sensorineural. Sensorineural loss affects the inner ear and/or neural pathways. In these cases, sound is normally transmitted through the outer and middle ear, but the inner ear is less efficient in transmitting the sound. This is usually due to damage to the hair cells lining the cochlea or in the nerve fibers carrying the signal to the brain. The result is an impaired ability to hear sound and understand speech. Sensorineural hearing loss is often initially treated with a hearing aid, with varying degrees of success.

The Vibrant Soundbridge and How It Works

The Vibrant Soundbridge produces vibrations within the middle ear, mimicking the natural hearing process. These vibrations are amplified to compensate for the loss in sensitivity of the inner ear.

The Vibrant Soundbridge consists of both external and internal devices. The external device, called the Audio Processor, is held onto the head and underneath the hair with a magnet. It contains the microphone, the battery, and electronics that convert sound to a signal that is transmitted to the internal receiver of the Soundbridge. Because the potential consequences of Magnetic Resonance Imaging (MRI) or other strong magnetic fields have **not** been determined with the Soundbridge, implanted patients should **not** be subjected to MRI, and should **not** enter an MRI Suite or come into close proximity to other sources of strong magnetic fields.

The implanted or internal device, called the Vibrating Ossicular Prosthesis (VORP), consists of the internal receiver, conductor link, magnet, and the Floating Mass



Transducer (FMT). A signal from the Audio Processor is transmitted through the skin to the internal receiver. This electrical signal then travels down through the conductor link to the FMT. The FMT is attached to the incus, one of the three small bones of the middle ear. The FMT converts the signal to mechanical vibrations that move the the middle ear bones (ossicles), mimicking the normal hearing process.

The Vibrant Soundbridge Is Not a Hearing Aid Nor a Cochlear Implant

Hearing aids amplify sound. The Soundbridge converts sound waves to mechanical vibrations inside the middle ear. The ear canal remains completely open when a Soundbridge is used. This reduces or eliminates problems associated with blocking the ear canal such as occlusion effect, physical discomfort, and maintenance problems. The Audio Processor of the Vibrant Soundbridge can be worn discretely, hidden under the individual's hair.

The Vibrant Soundbridge is intended to address a different type of hearing loss than cochlear implants. A cochlear implant is intended for people with severe to profound hearing loss. The Vibrant Soundbridge is intended for people with moderate to severe hearing impairment that have tried using a conventional hearing aid without satisfactory results.

Indications for Use, Patient Evaluation, and Surgery

Indications for Use

The Vibrant Soundbridge is intended for adults, 18 years of age and older, who have a moderate to severe sensorineural hearing loss and desire an alternative to an acoustic hearing aid. Prior to receiving the device, it is recommended that an individual have experience with appropriately fit hearing aids.

Patient Evaluation

If you are interested in the Vibrant Soundbridge, you will need to undergo a series of audiological tests and a medical examination to determine if you are a candidate for the device. The audiological tests assess your type of hearing impairment and level of hearing loss.

Surgery

The purpose of the surgical procedure is to implant the internal components of the Soundbridge: the internal receiver, conductor link, and Floating Mass Transducer (FMT). A small section behind your ear will be shaved and an incision made. The incision is approximately 3 1/2 to 4 inches long. The internal receiver is placed under the skin in the area behind your ear. The FMT is attached to one of the bones of the middle ear called the incus. The surgery typically takes about two hours and is performed under general anesthesia. Your surgeon can more fully advise you on the details of the surgery.

Surgical Risks

The risks of the Soundbridge surgery include many of the same risks associated with other surgeries involving general anesthesia. Middle ear surgery may also result in numbness, irritation, swelling, and discomfort near the ear. Many of these symptoms may be only temporary and resolve in the months following surgery. Your surgeon can more fully discuss these risks with you in greater detail.

What Happens After Surgery

Most Soundbridge patients carry on their normal activities within a few days after surgery, but physical exertion should be minimized for several weeks. Complete healing around the implant area and middle ear differs among patients, but most patients completely heal within two months. Approximately two months after surgery, you will be fitted with the Audio Processor and the Soundbridge activated.

Vibrant Soundbridge Benefits

The Soundbridge offers a safe and effective alternative to acoustic hearing aids for patients with moderate to severe sensorineural hearing loss. Leading hearing treatment centers in the United States and Europe participated in clinical studies of the Vibrant Soundbridge with adult patients. Patients using the Vibrant Soundbridge experienced many benefits. Please see Appendix A for additional information on the clinical studies.

One very important benefit of the Soundbridge was that most patients experienced no change in their unaided hearing after surgery. They also obtained a significant improvement in clarity and overall sound quality compared to their hearing aid. Patients reported improved clearness of sound and improvement in their own speech and tone.

Another major improvement reported by Soundbridge patients was in the overall fit and comfort with the device. Unlike with a conventional hearing aid, there is nothing that needs to be put in the ear canal with the Soundbridge.

Nearly every patient in the United States clinical trial experienced no acoustic feedback or whistling with the Soundbridge.

Patients also perceived a major benefit of the Soundbridge in many listening situations compared to their hearing aids. Some of these situations included entertainment settings such as television, movies, radio, and theater. They also reported a significant improvement in satisfaction when in environments with background noise. However, there was no significant difference in performance between the Soundbridge and an acoustic hearing aid in word recognition scores when patients were tested in a controlled soundfield environment.

Although patients participating in the clinical studies of the Vibrant Soundbridge experienced some of the above benefits, there are no definitive tests which can be administered prior to implantation that can accurately predict the degree of benefit you may receive from the Soundbridge.

Contraindications

A Soundbridge is not indicated for individuals with the following conditions:

- Conductive hearing loss
- Lesion of the auditory nerve or brainstem (retrocochlear) or central auditory disorder
- Active middle ear infections
- Tympanic membrane perforations associated with recurrent middle ear infections
- A skin or scalp condition that may preclude attachment of the Audio Processor



The Audio Processor can usually be hidden by the patient's hair.

Possible Adverse Events

Surgery of the middle ear involves manipulation of the fragile ossicular bones (malleus, incus, and stapes) and exposes the inner ear to the risk of surgical trauma. Serious complications may arise either during or after surgery that may result in irreparable damage to your ear structure causing irreversible partial or total loss of hearing. Additional surgery may be required to correct these conditions, if possible.

Complications that may occur include, but are not limited to: sensorineural or conductive deafness due to trauma during surgery; granular inflammatory lesions; device displacement after surgery due to the development of scar tissue; vertigo; damage to the incus; the implant may not function; and infection after surgery. It is also possible that the device could cause a significant loss in residual hearing.

Warnings and Precautions

The following section describes warnings and general precautions that apply to your Vibrant Soundbridge. Read the information carefully and ask your surgeon or audiologist if you have any questions.

Always inform any physician you are visiting for medical treatment that you have a Soundbridge implanted. He or she may not know that you have an implant and this information may affect your treatment.

Warnings:

Magnetic resonance imaging (MRI): Because the potential consequences of being subjected to MRI or other strong magnetic fields have **not** been determined, patients implanted with the Vibrant Soundbridge should **not** be subjected to MRI, and should **not** enter an MRI Suite or come into close proximity to other sources of strong magnetic fields.

Electrosurgery: Electrosurgical instruments are capable of producing radio frequency voltages from the instrument tip that can directly interact with the implant. Monopolar electrosurgical instruments must **not** be used within the vicinity of the implant. The induced currents could cause damage to the implant or the patient's hearing.

Diathermy: The application of heat for treatment or ablation of tissue (diathermy) must never be applied over the implant because the high currents induced into the implant could cause damage to the implant or the patient's hearing.

Electroconvulsive therapy: Electroconvulsive therapy must never be used on a patient with a Soundbridge because it may cause damage to the implant or the patient's hearing.

The effects of imaging studies such as *cobalt treatment, PET scans, transcranial diagnostic ultrasound, and linear acceleration techniques* on the implant are unknown.

Precautions:

The Audio Processor contains complex electronic parts. These parts are durable, but must be treated with care. The Audio Processor must never be disassembled by anyone other than authorized service personnel or the warranty will be void. The magnet compartment must only be opened by a qualified audiologist. All sound adjustments shall only be made by a qualified audiologist.

The Audio Processor is specifically adjusted for each individual user. Never exchange your Audio Processor with another Soundbridge user.

When stored do not allow your Audio Processor to be exposed to temperatures outside the range of -40 to 149 °F. Exposure of the Audio Processor to temperatures outside this range can potentially damage the individual components and render the device inoperable. When wearing your Audio Processor, care should be taken not to expose the device to temperatures outside the range of 32 to 113 °F. Exposure of the Audio Processor to temperatures outside this range may result in distortion of sound, reduced output levels, and shorter battery life. The effects are temporary and the Audio Processor should return to normal operation when the device is back in the range of 32 to 113 °F.

Ingestion of small parts: The Audio Processor contains small parts that may be hazardous if swallowed.

Theft and metal detection systems: Commercial theft detection systems and metal detectors produce strong electromagnetic fields. Patients with an implant should be advised that passing through security metal detectors may activate the detector alarm. For this reason, it is advised that patients carry their Vibrant Soundbridge *Patient Identification Card* at all times.

Use of Audio Processor: Patients should only use the Audio Processor that has been specifically programmed for them by their clinician. Use of a different Audio Processor may cause distorted or uncomfortably loud sounds.

Cleaning external parts: The outside of the Audio Processor can be cleaned with a cloth slightly dampened with rubbing (isopropyl) alcohol. Regular cleaning will prevent a build-up of dirt.

Avoid water damage: Protect the Audio Processor from water or perspiration. The warranty is void when damage is caused by moisture. Never bathe or shower while wearing the Audio Processor. If you are playing a sport or you are in a situation where you will perspire a lot, wear a sweat band to absorb moisture near the Audio Processor. Use of *Dri-Aid* after exposure to moisture may help.

Dirt Damage: Avoid getting sand or dirt into any part of the Audio Processor. If the Audio Processor is not working, return it to your audiologist or Symphonix Devices for repair or replacement.

Interference: Cellular telephones and strong magnetic sources, such as high voltage power lines or transformers, may interfere with the operation of the Audio Processor. As a result, you may experience interference or distorted sound when in close proximity to a mobile phone or strong magnetic source. If this occurs, you should move away from the source.

Range of benefits: The Vibrant Soundbridge does not restore normal hearing and benefits may vary from one patient to another. There appears to be little correlation between degree of benefit obtained from an implant and the cause or degree of hearing impairment. There are no definitive tests which can be administered prior to implantation that estimate the degree of benefit a patient may receive.

Frequently Asked Questions

Are any activities restricted because of the Vibrant Soundbridge?

While the Vibrant Soundbridge does not impose restrictions on most daily activities, precautions must be taken. You should remove the Audio Processor prior to bathing, showering, and swimming. Sports such as tennis, golf, skiing, and running may necessitate the need to support the Audio Processor with a headband or to remove the device during these activities. It is recommended that you remove the Audio Processor prior to going to bed. This allows the skin underneath the device to be exposed to air.

Can a hearing aid be worn in the implanted ear immediately after surgery?

No. A hearing aid is not to be used immediately after surgery in the implanted ear because the surgical site needs to heal and the ear canal needs to return to its normal size. Once your surgeon has checked your surgical site and determined that appropriate healing has occurred, you may resume use of a hearing aid until the Vibrant Soundbridge is activated.

Is the Vibrant Soundbridge difficult to operate or manipulate?

No. Once the Audio Processor is placed on the head and fitted, no further manipulation is required. Each night, you should remove the Audio Processor from your head and open the battery compartment. This allows moisture in the compartment to escape and will lengthen battery life. The battery should be replaced approximately every week.

Will the Vibrant Soundbridge be upgraded in the future?

The Vibrant Soundbridge uses state-of-the-art design. New advances in sound processing are constantly being developed. The Vibrant Soundbridge, with its semi-implantable design, may be able to take advantage of these future design improvements without further surgery by simply upgrading your Audio Processor. This capability to upgrade the technology without further surgery is a significant benefit of the system.

How do I get a Vibrant Soundbridge?

A final determination of implant eligibility is made following a series of patient selection evaluations. These include both medical and audiological assessments, performed by audiologists and surgeons.

What if the device breaks and is in need of repair?

If the Audio Processor appears to be faulty and the problem cannot be resolved by changing the battery, you should contact your audiologist or implant center. Your clinician might require you to return to the clinic for evaluation of the problem.

How long does the Soundbridge last?

The Soundbridge has been designed to last a long time. The materials used in its construction are biocompatible and durable. Symphonix warrants that the internal device will be free from defects in workmanship and materials for a period of 5 years from the date of implantation and the Audio Processor will be free from defects in workmanship and materials for one year from the initial fitting. However, despite conservative design and careful quality control and inspection, an internal device failure could occur. If the implant fails, it may be necessary to surgically remove the Soundbridge. Each case, however, must be individually evaluated by the implant surgeon to determine the possibility of successful device replacement. See the *Vibrant Soundbridge System User Manual* for a complete description of warranty terms and conditions.

Appendix A: Clinical Studies Information

Clinical results for safety and effectiveness of the Vibrant Soundbridge were assessed in fifty-three (53) U.S. patients by comparing preoperative results with an acoustic hearing aid in the ear to be implanted to post operative results with the Soundbridge. The clinical results are summarized below.

1. For most patients, the Vibrant Soundbridge did not significantly affect residual hearing; however, a small percentage (4% or 2/53) of patients experienced a decrease in residual hearing.
2. Based upon subjective responses, when comparing the Vibrant Soundbridge to their own hearing aids, a majority (86% or 42/49) of patients reported significantly improved sound clarity and overall sound quality.
3. Patients reported that the Vibrant Soundbridge provided better overall fit and comfort compared to their own hearing aids.
4. The Vibrant Soundbridge significantly reduced acoustic feedback.
5. The Vibrant Soundbridge provided equal or increased functional gain when compared to the patients' own hearing aid.
6. The Vibrant Soundbridge significantly improved patients' perceived benefit in many listening situations, such as: familiar talkers, ease of communication, reverberation, reduced cues, background noise, aversiveness of sound, and distortion of sound.
7. The Vibrant Soundbridge reduced maintenance issues due to cerumen and moisture accumulation.
8. Speech perception testing in a controlled soundfield environment (i.e., NU-6 word scores, SPIN-low predictability word scores) demonstrated **equivalent group mean** results between the Vibrant Soundbridge and the patients' own hearing aid. However, when listening to speech, the Vibrant Soundbridge was preferred over the patients' own hearing aid in various listening situations.

For additional clinical studies information, please contact:

Symphonix Devices, Inc.
San Jose, CA 95131-1109
(800) 833-7733

For further information regarding the use of this Symphonix product, or to report any problems, please contact:

Symphonix Devices, Inc.
Customer Service
San Jose, CA 95131-1109
or call
(800) 833-7733

CAUTION: Federal (or United States) law restricts this device to sale by or on the order of a physician or audiologist.

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