Symphonix

Vibrant® Soundbridge™ System

VIBRATING OSSICULAR PROSTHESIS (MODEL 502)

DEVICE DESCRIPTION

The Vibrant Soundbridge is a direct-drive, implantable middle ear hearing device intended to provide a level of useful sound perception to individuals with a sensorineural hearing loss. The Soundbridge converts environmental sound into mechanical energy that is directly transferred to the auditory ossicles. It consists of two major components: 1) the implant, called the Vibrating Ossicular Prosthesis™ (VORP™), and 2) the external amplification system, called the Audio Processor™.

The Audio Processor contains a microphone that picks up sound from the environment and converts it to an electric signal. Electronics in the Audio Processor condition the signal and transmit it across the skin to the internal receiver in the VORP. The signal is then delivered to the Floating Mass Transducer™ (FMT™) causing it to vibrate. The FMT mechanically stimulates the auditory ossicles, which the patient perceives as sound.

The VORP is surgically implanted under the skin behind the ear. The FMT is attached to the long process of the incus during the surgical procedure.

PACKAGE CONTENTS

- Vibrating Ossicular Prosthesis (Model 502)
- Patient Identification Card
- Patient Registration Card
- VORP Package Insert

INDICATIONS FOR USE

The Vibrant Soundbridge is indicated for use in adults, 18 years of age or 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.

INDIVIDUALIZATION OF TREATMENT

Specific patient selection criteria is outlined below.

- Adults, age eighteen (18) or older
- Audiologic results consistent with sensorineural hearing loss
- Pure-tone air-conduction threshold levels shall fall at or within:

Frequency (kHz)	0.5	1	1.5	2	3	4
Lower Limit	30	40	45	45	50	50
Upper Limit	65	75	80	80	85	85

- Word recognition score of 50% or better, using recorded material
- Normal middle ear anatomy
- Psychologically and motivationally suitable with realistic expectations of the benefits and limitations of the device

CONTRAINDICATIONS

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

- Conductive hearing loss
- 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

WARNINGS

1. **Magnetic Resonance Imaging (MRI):** 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.
2. **Electrosurgery:** Electrosurgical instruments are capable of producing radio frequency voltages that can directly couple the instrument tip and the implant. Monopolar electrosurgical instruments must **not** be used within the vicinity of the implant because the induced currents could cause damage to the implant or the patient's hearing.
3. **Diathermy:** 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.
4. **Electroconvulsive Therapy:** Electroconvulsive therapy must never be used on a patient with a Soundbridge because it may damage the implant or the patient's hearing.
5. The effects of **cobalt treatment, PET scans, transcranial diagnostic ultrasound,** and **linear acceleration techniques** on the implant are unknown.

Failure to follow the recommended surgical procedure for placement and stabilization of the implant increases the risk of breakage of the conductor link wires. Creating a recessed bed or well for the implant and securely stabilizing the device in place with sutures are important elements of the recommended surgical procedure.

PRECAUTIONS

1. **Ingestion of Small Parts:** The Audio Processor contains small parts that may be hazardous if swallowed.
2. **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 the patient carry their *Vibrant Soundbridge Patient Identification Card* at all times.

3. **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 the 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.
4. **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.

CLINICAL CONSIDERATIONS

Evaluation procedures should include standard audiological measures including air- and bone-conduction thresholds, immitance measures, speech recognition, hearing aid analysis, and qualitative questionnaires. Analysis of qualitative questionnaires may help to determine if a candidate's lack of perceived benefit with an acoustic hearing aid may be addressed with an implantable middle ear hearing device. Care should be taken to ensure that the patient's perceived lack of benefit from the hearing aid(s) is not attributable to poor fit or lack of function.

When clinically appropriate, the ear selected for implantation of the Soundbridge should be equal to or worse than the non-implant ear. The safety and effectiveness of bilateral implantation with the Vibrant Soundbridge has not been established.

Adverse Events: The following information considers adverse events reported on a total of 81 U.S. patients (5 patients from the feasibility study, 54 patients from the pivotal study, and 22 patients from the supplemental safety cohort). The following adverse events were reported as of May 15, 2000:

	U.S. Patients (n=81)	
Description	Reported	Unresolved
Device failure [1]	6	0
Transient facial paresis [2]	2	0
Infection [3]	1	0
Episodic dizziness [4]	2	0
Change in residual hearing [5]	2	2
Fullness sensation [6]	18	13
Perforated tympanic membrane [7]	1	0
Altered taste sensation [8]	7	2
Skin irritation [9]	2	0
Transient pain [10]	13	4
Disconnection of FMT [11]	1	0

[1] Failed devices were removed and patients successfully reimplanted. All failures occurred with a version of the device that is no longer manufactured.

[2] In both cases, the investigators reported the facial paresis as unrelated to the surgical procedure or device implantation. Both cases resolved with medical management.

[3] Stitch abscess at the inferior aspect of the incision resolved by removing the stitch and prescribed topical and oral antibiotics.

[4] Post operative bouts of episodic dizziness resolved without medical intervention.

[5] See Clinical Study Results section of the package insert for further information.

[6] Perception of this fullness sensation does not affect the individual's ability to use the Vibrant Soundbridge.

[7] The tympanic membrane was perforated during the implantation procedure. The perforation was repaired by using fascia.

[8] Altered taste sensation can be related to the severing or irritation of the chorda tympani nerve during the implantation procedure. Resolution occurred spontaneously without treatment or surgical intervention.

[9] A mild skin irritation over the magnet attachment site was resolved through the use of a weaker strength magnet and/or topical medication.

[10] Reports of transient post surgery pain resolved spontaneously without treatment or surgical intervention.

[11] Post operatively the device did not activate. During the successful revision surgery, the investigator noted that the FMT had not been in contact with the ossicular chain.

Possible Adverse Events: These additional events are known to be possible adverse events associated with middle ear surgery.

- Implant patients are exposed to the normal risk of surgery and general anesthesia. Major ear surgery may result in numbness, swelling, or discomfort around the ear, the possibility of facial paresis, disturbance of balance or taste, or neck pain. If these occur, they are usually transient and resolve within a few weeks of surgery.

Clinical Study Summary: Clinical results for safety and effectiveness of the Vibrant Soundbridge were assessed in fifty-four (54) pivotal study patients by comparing preoperative results with an acoustic hearing aid in the ear to be implanted to post operative results with the Soundbridge. One (1) patient's device did not activate. Thus, there were fifty-three (53) pivotal study patients evaluated for effectiveness. The clinical study results are summarized below. Refer to the section entitled **Clinical Study Results** for detailed information, including descriptive statistics, regarding the data supporting the safety and effectiveness profile of the Vibrant Soundbridge.

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. Forty-nine (92% or 49/53) patients completed the test requirements for this study endpoint.
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 when compared to the patients' own hearing aids.
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.

Clinical Study Results: Clinical results for safety and effectiveness of the Vibrant Soundbridge were assessed in fifty-four (54) pivotal study patients by comparing preoperative results with an acoustic hearing aid in the ear to be implanted to post operative results with the Soundbridge. One (1) patient's device did not activate. Thus, there were fifty-three (53) pivotal study patients evaluated for effectiveness. The number of patients supporting each clinical result vary since data are based upon the number of pivotal study patients who completed all test requirements for a particular study endpoint. Detailed information, including descriptive statistics, regarding the data supporting the safety and effectiveness profile of the Vibrant Soundbridge is provided below.

1. Fifty-one patients (51/53 or 96%) had no change (≥ 10 dB) in the Pure Tone Average (PTA) of 500, 1000, and 2000 Hz. One patient (1/53 or 2%) experienced a change in PTA of 12 dB (decreased) and one patient (1/53 or 2%) experienced a change in PTA of 18 dB (decreased).

   The change in average residual hearing for many patients (39/53 or 74%) measured at 250, 500, 1000, 2000, 4000, 6000, and 8000 Hz was less than or equal to 5 dB, as illustrated in Figure 1. Few patients (7/53 or 13%) had a decrease in unaided hearing threshold after implantation of greater than 10 dB at 1000, 2000, or 4000 Hz, and few patients (6/53 or 11%) had a decrease in unaided hearing threshold of greater than 15 dB at 250, 500, 6000, or 8000 Hz.

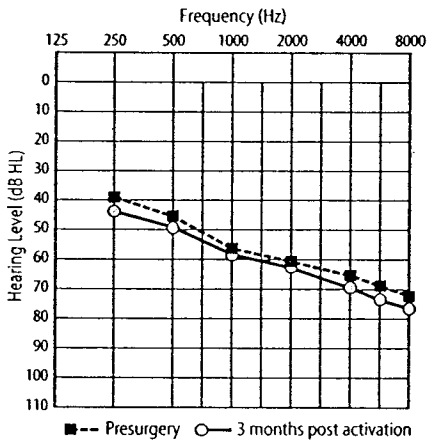

Figure 1. A comparison of mean residual hearing thresholds at presurgery and at 3 months post activation (n=53).

2. Patient reports of improved sound clarity and overall sound quality with the Vibrant Soundbridge are based upon three subscales of the Hearing Device Satisfaction Scale (HDSS). Results are illustrated in Figure 2. Forty-two patients (42/49 or 86%) expressed satisfaction in clearness of sound and tone with the Vibrant P Soundbridge compared to fifteen patients (15/49 or 31%) who expressed satisfaction in the clearness of sound and tone of their own hearing aids. Three patients (3/53 or 6%) were dissatisfied or very dissatisfied with the clearness of sound and tone of the Soundbridge. Forty-four patients (44/47 or 94%) improved their satisfaction rating of overall sound quality when using their Vibrant P Soundbridge compared to their own hearing aids. Forty-three patients (43/49 or 89%) improved their satisfaction rating of sound quality of their own voice when using their Vibrant P Soundbridge compared to their own hearing aids.

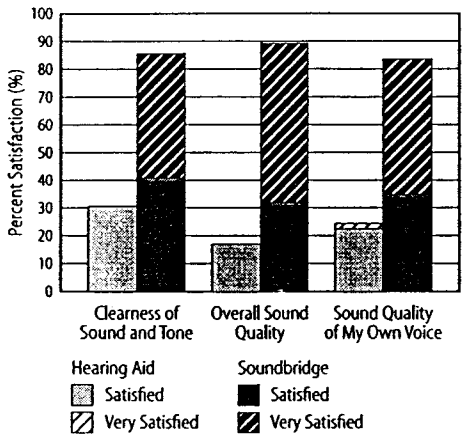

Figure 2. HDSS results: sound clarity and quality measures.

3. Patient reports of better overall fit and comfort with the Vibrant Soundbridge are based upon one subscale of the HDSS. Forty-eight patients (48/49 or 98%) expressed satisfaction with the overall fit and comfort of the Soundbridge. For the eleven (11) patients who were dissatisfied with the overall fit and comfort of their own hearing aids, all eleven patients (11/11 or 100%) were satisfied with the Vibrant Soundbridge.
4. Patient reports of reduction in acoustic feedback with the Vibrant Soundbridge are based upon one subscale of the HDSS. Of the thirty-two (32) patients who reported acoustic feedback with their own hearing aids, thirty-one patients (31/32 or 97%) reported no acoustic feedback with their Vibrant Soundbridge.
5. The Vibrant Soundbridge demonstrated a statistically significant increase in functional gain from 500 Hz through 6000 Hz when compared to a patient's presurgery aided condition.

   With the Vibrant P Soundbridge, there was a statistically significant increase in functional gain at 1000 Hz at $p < 0.01$, and for the frequencies of 2000 Hz, 3000 Hz, 4000 Hz, and 6000 Hz at $p < 0.001$, compared to the patients' own hearing aid, as illustrated in Figure 3.

   At 500 Hz most (43/53 or 81%) patients had a functional gain that was equal (within 5 dB) or increased from the functional gain of the patient's own hearing aid. At 1000 Hz most (44/53 or 83%) patients had a functional gain that was equal (within 5 dB) or increased from the functional gain of the patient's own hearing aid. At 2000 Hz most (52/53 or 98%) patients had a functional gain that was equal (within 5 dB) or increased from the functional gain of the patient's own hearing aid. At 4000 Hz most (48/53 or 91%) patients had a functional gain that was equal (within 5 dB) or increased from the functional gain of the patient's own hearing aid. At 6000 Hz most (47/53 or 89%) patients had a functional gain that was equal (within 5 dB) or increased from the functional gain of the patient's own hearing aid. At 8000 Hz most (13/13 or 100%) patients had a functional gain that was equal (within 5 dB) or increased from the functional gain of the patient's own hearing aid.

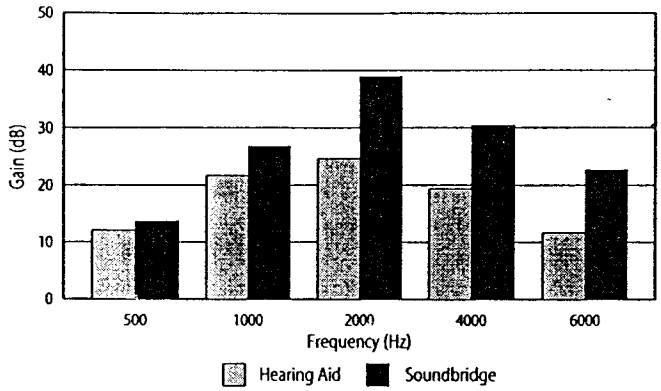

Figure 3. Functional Gain for presurgery hearing aid and 3 months post activation for the Vibrant P Soundbridge (n=53).

With the Vibrant D Soundbridge, functional gain was significantly increased ($p < 0.001$) for the frequencies of 500 Hz, 1000 Hz, 2000 Hz, 3000 Hz, 4000 Hz, and 6000 Hz, compared to the patients' own hearing aid, as illustrated in Figure 4.

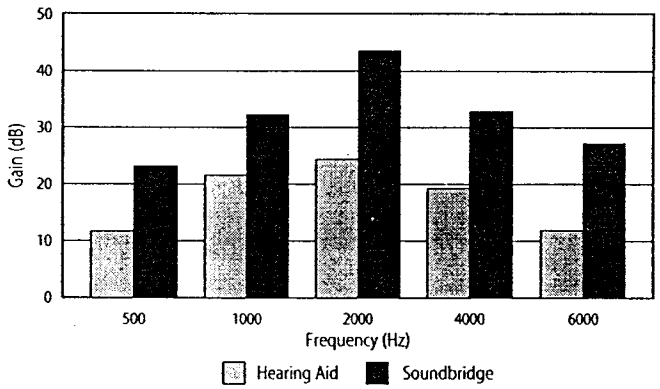

Figure 4. Functional Gain at presurgery hearing aid and 6-week evaluation for the Vibrant D Soundbridge (n=50).

At 500 Hz most (46/50 or 92%) patients had a functional gain that was equal (within 5 dB) or increased from the functional gain of the patient's own hearing aid. At 1000 Hz most (49/50 or 98%) patients had a functional gain that was equal (within 5 dB) or increased from the functional gain of the patient's own hearing aid. At 2000 Hz most (50/50 or 100%) patients had a functional gain that was equal (within 5 dB) or increased from the functional gain of the patient's own hearing aid. At 4000 Hz most (47/50 or 94%) patients had a functional gain that was equal (within 5 dB) or increased from the functional gain of the patient's own hearing aid. At 6000 Hz most (43/50 or 86%) patients had a functional gain that was equal (within 5 dB) or increased from the functional gain of the patient's own hearing aid. At 8000 Hz most (13/13 or 100%) patients had a functional gain that was equal (within 5 dB) or increased from the functional gain of the patient's own hearing aid.

6. Patient's perceived benefit in many listening situations with the Vibrant Soundbridge is based upon subjective reporting using the Profile of Hearing Aid Performance (PHAP), Cox and Gilmore, 1990. Additionally, patients' improved satisfaction rating of the effectiveness of the Vibrant Soundbridge in background noise compared to their own hearing aids is supported by one subscale of the HDSS.

With the Vibrant P Soundbridge, the patients as a group reported significant improvement with the Soundbridge compared to their own hearing aids on all seven subscales of the PHAP, as illustrated in Figure 5.

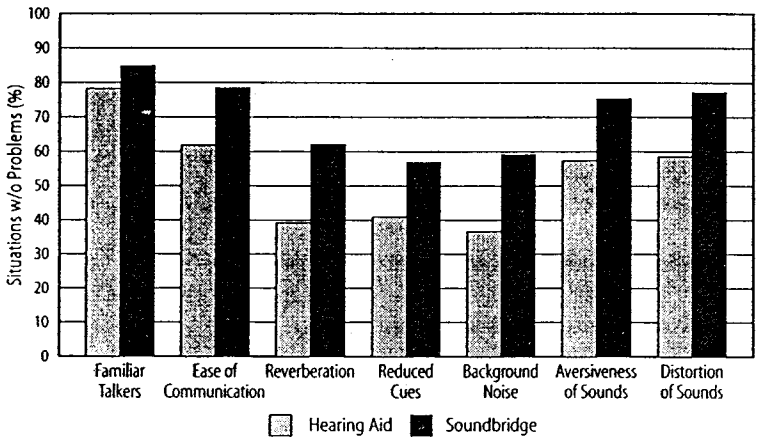

Figure 5. Mean PHAP responses at presurgery and 3 months post activation for the Vibrant P Soundbridge (n=51).

For individual patient analysis on the PHAP with the Vibrant P Soundbridge, significant improvement was based upon comparison to critical difference scores at a 95% confidence interval, as described below:

Familiar Talkers: 8 out of 51 patients (16%)
Ease of Communication: 14 out of 51 patients (27%)
Reverberation: 24 out of 51 patients (47%)
Reduced Cues: 20 out of 51 patients (39%)
Background Noise: 27 out of 51 patients (53%)
Aversiveness of Sounds: 13 out of 51 patients (25%)
Distortion of Sounds: 15 out of 51 patients (29%)

With the Vibrant D Soundbridge, the patients as a group reported significant improvement with the Soundbridge compared to their own hearing aids on all seven subscales of the PHAP, as illustrated in Figure 6.

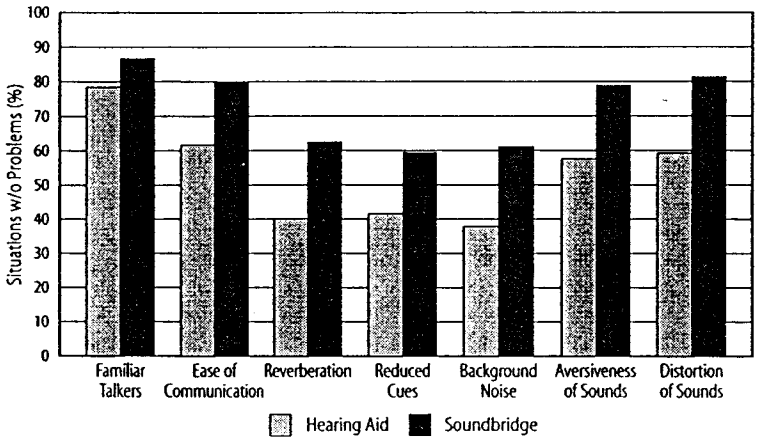

Figure 6. Mean PHAP responses at presurgery and 6-week evaluation of the Vibrant D Soundbridge (n=50).

For individual patient analysis on the PHAP with the Vibrant D Soundbridge, significant improvement was based upon comparison to critical difference scores at a 95% confidence interval, as described below:

Familiar Talkers: 9 out of 50 patients (18%)
Ease of Communication: 15 out of 50 patients (30%)
Reverberation: 24 out of 50 patients (48%)
Reduced Cues: 18 out of 50 patients (36%)
Background Noise: 28 out of 50 patients (56%)
Aversiveness of Sounds: 21 out of 50 patients (42%)
Distortion of Sounds: 17 out of 50 patients (34%)

The results from the HDSS subscale for background noise supported the PHAP results reported above. Forty-three patients (43/49 or 88%) improved their satisfaction rating of the effectiveness of the Soundbridge in background noise compared to their own hearing aids.

7. Patients' satisfaction in reduced maintenance issues with the Vibrant Soundbridge due to cerumen and moisture accumulation is based upon one subscale of the HDSS. Forty-five patients (45/46 or 98%) expressed satisfaction with cleaning and maintenance issues with the Vibrant P Soundbridge, such as those due to cerumen and moisture accumulation. For the fourteen (14) patients who were dissatisfied with cleaning and maintenance of their own hearing aids, all fourteen patients(14/14 or 100%) were satisfied with the Vibrant Soundbridge.
8. Speech perception results are based upon testing of the Vibrant Soundbridge and the patients' own hearing aid in a controlled soundfield environment (i.e., NU-6 word scores, SPIN-low predictability word scores) and upon the Soundbridge Hearing Aid Comparison Questionnaire (SHACQ), a non-validated assessment tool developed by Symphonix Devices, Inc. The SHACQ was administered to patients post operatively on a one-time basis.

Speech perception testing in a controlled environment demonstated equivalent group mean results between the Vibrant Soundbridge and the patients' own hearing aid. However, as reported on the SHACQ, when listening to speech, the Vibrant Soundbridge was preferred over the patients' own hearing aids in various listening

situations. Thirty-three patients (33/43 or 86%) preferred the Vibrant Soundbridge compared to their own hearing aids when listening to speech outdoors. While listening to speech in quiet environments, forty-one patients (41/43 or 95%) preferred the Vibrant Soundbridge compared to their own hearing aids. While listening to speech in a restaurant, thirty-five patients (35/40 or 88%) preferred the Vibrant Soundbridge compared to their own hearing aids. Thirty-eight patients (38/44 or 86%) preferred the Vibrant Soundbridge over their own hearing aids when listening to speech on the television. While listening to speech on the radio, thirty-five patients (35/40 or 88%) preferred the Vibrant Soundbridge over their own hearing aids.

Storage, Handling and Sterilization

Store the VORP at temperatures between -40 and +65 °C (-40 and +149 °F). A "use by" date is printed on the device packaging. Expired product should be returned to Symphonix Devices. The VORP itself is not subject to aging.

Handle the VORP package with care. Damage to the outer storage package may rupture the inner sterile tray.

The VORP is supplied sterile. Before opening the sterile package, inspect it carefully. If the sterile package is broken, return the device to Symphonix Devices.

This device is intended for single patient use only. Do not reuse or sterilize.

Information for Use and Recommended Training

Surgeons should be experienced in middle ear surgery including mastoidectomy and posterior tympanotomy. It is recommended that surgeons receive specific training regarding implantation of the Vibrant Soundbridge. It is strongly recommended that a surgeon work closely with an audiologist when selecting candidates to be implanted and during the post operative management of patients. Surgeons should refer to the *Vibrant Soundbridge Reference Manual for Surgeons* for specific instructions for use.

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

Symphonix Devices, Inc.
2331 Zanker Road
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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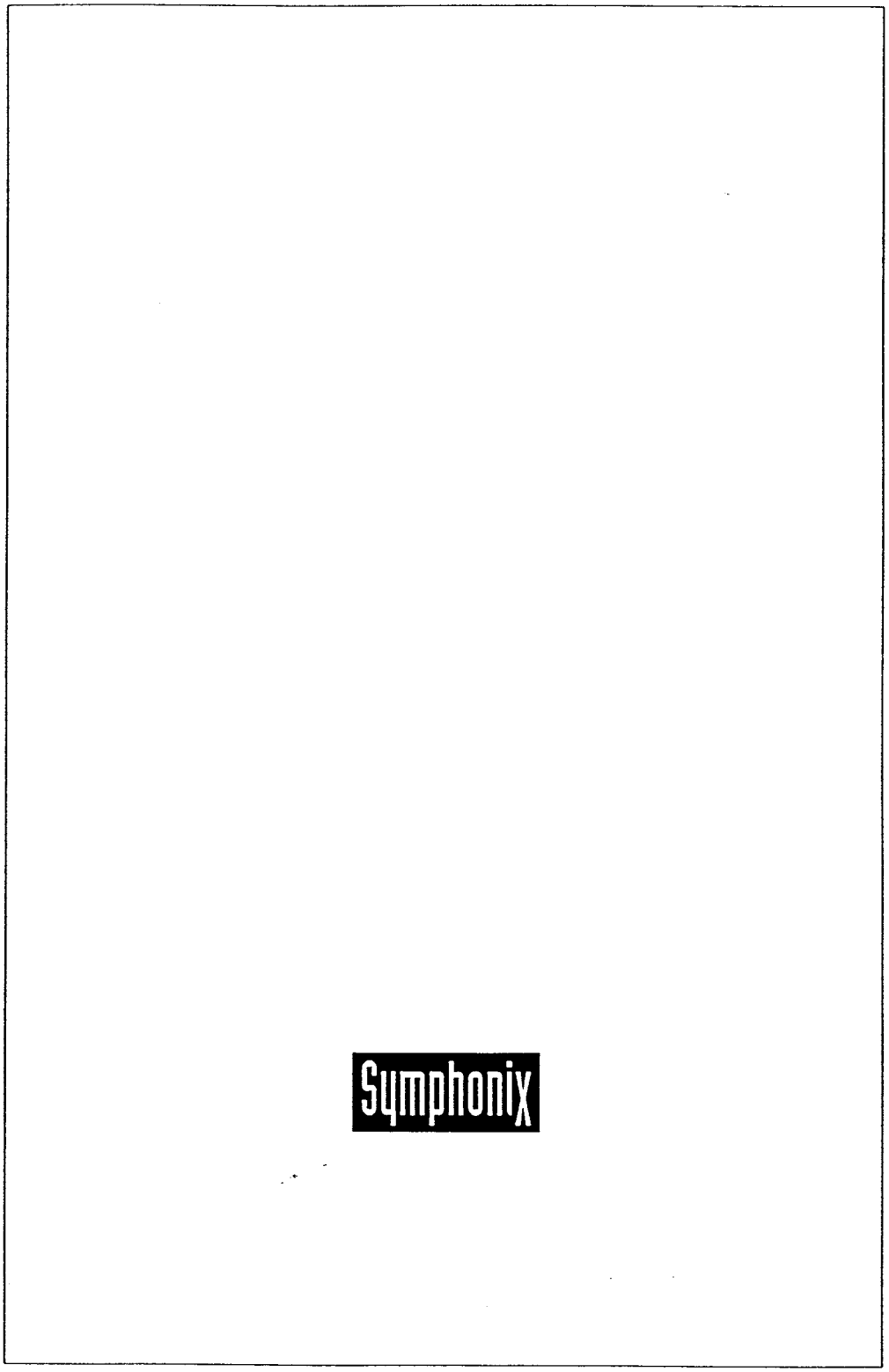
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Vibrant® Soundbridge™ System

Patient

USER MANUAL

User Manual: Front Cover

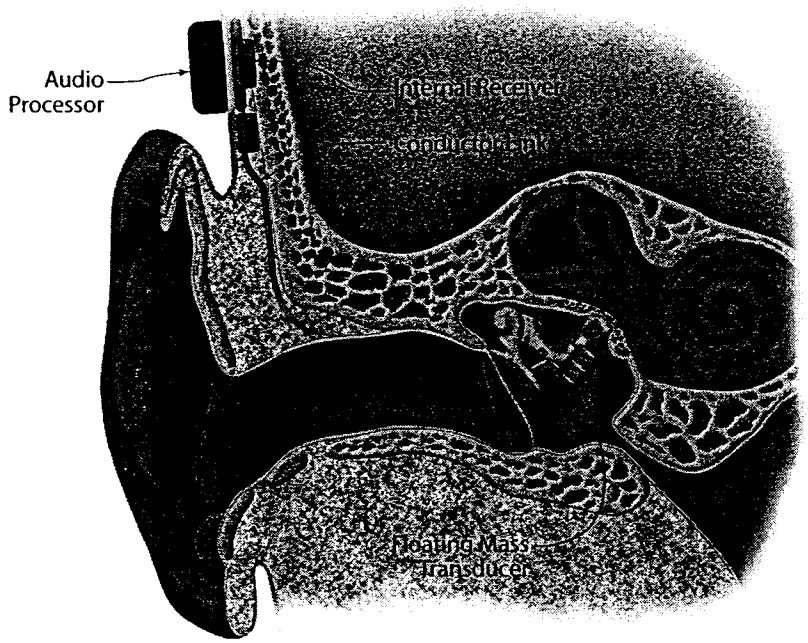
Contents

This manual covers operational and maintenance aspects of the Vibrant Soundbridge. It is intended to augment information provided by your doctor or audiologist.

Introduction to Your Vibrant Soundbridge

The Vibrant Soundbridge consists of an external portion and an internal portion. The external portion is called the Audio Processor.™ This is the portion of the Soundbridge that remains outside the body. It contains the microphone, the battery, and the electronics to convert sound to a signal that is transmitted to the internal portion of the Soundbridge. The Audio Processor is held onto the head with a magnet. Because the potential consequences of Magnetic Resonance Imaging (MRI) or other strong magnetic fields have **not** been determined with the Vibrant 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 portion of the Soundbridge consists of the internal receiver, the conductor link, and the Floating Mass Transducer™ (FMT™). A signal from the Audio Processor, the external portion of the Soundbridge, is transmitted across the skin to the internal receiver. The internal receiver then, via the conductor link, relays the signal to the FMT. The FMT converts the signal to vibrations. These vibrations move the bones of the middle ear similar to normal hearing.



The implanted portion of the Soundbridge is not operated directly by the user and has no specific maintenance requirements. The user does have operational and maintenance responsibility for the Audio Processor. You should read this manual carefully and completely so that you can be familiar with the operation and maintenance of your Audio Processor.

Indications for Use

The Vibrant Soundbridge is indicated for use in adults, 18 years of age or 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.

Operation of the Audio Processor

The Vibrant Soundbridge is activated when the Audio Processor is placed over the receiving coil of the implant.

The Audio Processor has no user controls. The Audio Processor continues to transmit sound information even when it is not attached to your head. To extend battery life, the battery door should be opened whenever the Audio Processor is not attached to your head. This disconnects the battery from the Audio Processor and turns off the electronics.

Storage: When not attached, your Audio Processor should be kept in the storage box provided. You should open the battery compartment door to extend battery life.

If you live in a humid climate or perspire heavily, the Audio Processor should be placed in a drying container when not worn. One brand of drying container is *Dri-Aid*. It is available from a pharmacy or hearing aid dispenser. Your audiologist can tell you where it may be obtained in your locality. Drying containers remain effective for a limited period depending on the humidity in your area. Follow the instructions provided with the container for reactivation and disposal.

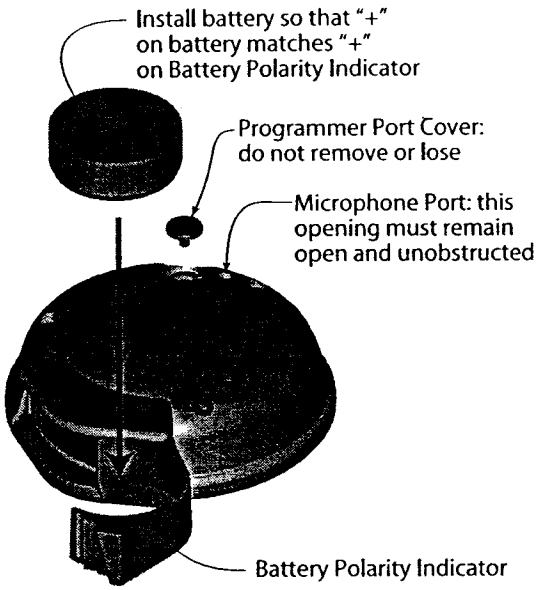
Checking battery status: The Audio Processor is designed to have a battery life of approximately one week. This is based on an "on" time of 16 hours a day at an average volume level.

The battery life of the Audio Processor may vary depending on programmed settings, environment, and hours of use. You should replace the battery regularly (for example, every Monday morning) or when the sound level of your Soundbridge drops off dramatically. The reduction or lack of sound output is the only indication that the battery needs to be replaced.

Changing the battery:

1. Open the battery compartment door and remove the old battery. It may be helpful to ease the battery out of the battery compartment door (battery polarity indicator) with the tip of a pen. ENSURE THAT THE BATTERY

DOOR IS FULLY OPEN. DO NOT FORCE THE BATTERY FROM THE COMPARTMENT DOOR. EASE IT OUT GENTLY. DO NOT ATTEMPT TO FORCE THE BATTERY DOOR PAST THE POINT OF RESISTANCE.



2. Take a new battery from the battery package, remove the tab to activate battery, and install the new battery in the Audio Processor battery compartment door, as shown in the illustration. If the battery does not slide in smoothly, it may be backwards. DO NOT FORCE THE BATTERY INTO THE COMPARTMENT DOOR. Check to see that the smaller end of the battery is being inserted into the door first.
3. Once the battery is seated, close the door completely to activate the electronics, and replace the Audio Processor over the implant.

WARNING: Only use size 675 zinc–air batteries. Use of batteries of other sizes, voltages, or power levels may cause irreparable damage to the Audio Processor and void the warranty.

Spare battery: It is recommended that you keep a spare battery with you, but it must be carried in its original packaging or other container that will keep it clean and away from metal. Be sure not to pull the activation tab from a battery until just prior to inserting it in the Audio Processor.

Fitting the Audio Processor to the Implant

The magnetic force that holds your Audio Processor to the implant is adjustable by the audiologist. If wearing the Audio Processor causes redness to the skin or discomfort, or if the Audio Processor seems to fall off excessively, return to the audiologist to have the magnet adjusted. This adjustment must be made by your audiologist.

Hair trimming: Occasionally you may need to trim or shave your hair to about 1/4 inch in the area immediately over the implant. The patch of trimmed hair can be easily concealed by the remainder of your hair.

Warnings and Precautions

The following section describes warnings and general precautions that apply to your Vibrant Soundbridge. Read the following material carefully. If you have any questions, consult the surgeon that performed your implant surgery.

Always inform any physician that you are visiting for medical treatment that you have a Soundbridge implanted. He or she may not be aware that you have an implant, and this knowledge 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 (e.g., cautery devices, electrical scalpels or scissors) 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 the patient carry their Vibrant Soundbridge Patient Identification Card at all times.

Use of Audio Processor: You should only use the Audio Processor that has been specifically programmed for you by your 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 you may receive.

Troubleshooting

Other than replacing the battery, there are no user serviceable features on the Audio Processor. If changing the battery does not correct a particular problem, return to the audiologist who fit your Audio Processor for advice.

- If sounds are uncomfortably loud, remove the Audio Processor and consult your audiologist.
- If the housing of the Audio Processor becomes damaged, contact your audiologist.
- If the sound seems to be quieter as time passes, the microphone port may be dirty. Contact your audiologist for inspection and possible cleaning.

Registration and Warranty

Registration: Registration Cards are packed separately with the implant and the Audio Processor. The purpose of these registration cards is to maintain traceability of both devices and to secure warranty rights. These cards should already have been sent to Symphonix Devices by the surgeon and the audiologist.

Also provided is a *Patient Identification Card* which you should carry at all times. This card will identify to emergency medical personnel that you have a Soundbridge implanted.

Warranty: Symphonix Devices, Inc., ("the Company") warrants to the purchaser of the Vibrant Soundbridge ("Soundbridge") that the implant (Vibrating Ossicular Prosthesis™ or "VORP™") will be free from defects in workmanship and materials for a period of five (5) years from the date of implantation, subject to the terms and conditions stated below. The Company warrants to the purchaser of the Soundbridge that the Audio Processor will be free from defects in workmanship and materials for a period of one (1) year from the date of initial fitting, subject to the terms and conditions set forth below.

For the period of time set forth above, if a returned VORP is found by the Company to have failed due to defect in materials or workmanship, full credit of the original purchase price will be given against the purchase price of a replacement VORP implanted in the original user. For the period of time set forth above, if a returned Audio Processor is found by the Company to have failed due to defect in materials or workmanship, the Company will replace or repair of the Audio Processor at its discretion.

The Company makes no representation or warranty that the VORP or Audio Processor, in the environment of the human body, will not fail or that the human body will not react adversely to the implantation of the VORP. Suitability of the Soundbridge for any particular patient is a matter of medical

judgment, and the Company makes no representation or warranty of fitness for a particular purpose. The warranty and credit allowances specified herein constitute the sole and exclusive express warranty of the Company and are in lieu of all other warranties, except warranties implied by law. Any such implied warranty, including that of merchantability, is limited to the duration of the express warranty herein. In no event shall the Company be liable for incidental or consequential damages, including, but not limited to, medical expenses. Some state laws do not allow the exclusion or limitation of incidental or consequential damages, so the above limitations may not apply to you. This warranty gives you specific legal rights and you may also have other rights under local law.

PROVISIONS APPLICABLE TO CANADA ONLY:

Legislation in some provinces provides for certain additional warranties or remedies other than stated herein, and to the extent that the same may not be waived, the limitations and exclusions set out above may not apply to you. This warranty gives you specific legal rights, and you may also have other rights which vary from province to province.

Any exclusion or limitation stated above that is contrary to the laws of any jurisdiction shall be deemed void and of no effect in that jurisdiction.

TERMS AND CONDITIONS OF WARRANTY:

1. Neither the VORP or the Audio Processor shall be subjected at any time to temperatures outside the range of -40 to 149 °F.
2. The VORP must not be implanted after the "Use Before" date marked on the package.
3. Both the Audio Processor and VORP Patient Registration Cards must be completed and returned to the Company in order to obtain warranty rights.
4. A VORP returned for a claim under the terms of this warranty must be returned to the Company within 30 days of removal from the patient together with a written report detailing the circumstances of the removal.
5. The Company shall examine any returned items and determine whether credit is due under the terms of this warranty. No credit allowance will be given when the Company finds evidence of improper handling or material alteration of any returned item.
6. Any returned items shall become property of the Company.
7. The warranty applies only for a VORP or Audio Processor replacement in the original patient.
8. No person has authority to bind the Company to any representation or warranty contrary to or in addition to this warranty.

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.

Symphonix

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