INTRODUCTION

We are pleased that you have made the decision to receive the INERAID artificial ear. You are among the first to have a device that is on the leading edge of a new technology to aid the profoundly deaf.

The INERAID artificial ear is a result of nearly a decade of research at the University of Utah and Symbion, Inc. Our goal is to produce a prosthesis which will restore partial hearing to those suffering from sensorineural deafness. We hope the performance of the artificial ear is such that you will have an improved quality of life.

You received one part of the INERAID artificial ear, the electrode assembly, during surgery several weeks ago. Since that time you have been tested to determine the characteristics of your electrodes. Based on this information the enclosed sound processor has been tuned specifically for you.

This handbook reviews some of the things you have already learned in addition to giving you some new information. It explains the components of the artificial ear and suggests a method for connecting them together to help you establish a simple routine. One section reminds you how to adjust the controls so you can receive maximum benefit from the sound processor. Battery replacement, safety features and pedestal hygiene are also covered. The section on hearing with the INERAID artificial ear gives you the opportunity to learn some of the experiences other patients have had. The guidelines in the care and maintenance section will help you keep your artificial ear in good working order. The Symbion, Inc. policy statement tells you what to do in the event you have problems with any part of the artificial ear. Please study this handbook before you begin using your new sound processor. The information may help you avoid any unnecessary problems.

The components of the INERAID artificial ear. From top to bottom: the sound processor, the percutaneous pedestal with electrode array, the ear hook assembly and the cable.
COMPONENTS

The major components of the INERAID artificial ear are the implanted electrode assembly, the ear hook assembly and the sound processor. The ear hook is connected to the sound processor by a cable. The cable has a break-away safety connector which will disconnect the sound processor from the ear hook should the cable become entangled.

Sounds entering the microphone (which is located in the ear hook) are changed to electrical energy and conveyed through the cable to the sound processor. The sound processing electronics convert sounds into electrical stimuli which are sent to the appropriate electrode implanted in the cochlea. This information is transmitted by the auditory nerve to the brain.

GETTING STARTED

You have been shown how to connect the sound processor to the ear hook and the percutaneous pedestal. This guideline will help you remember what you need to do. Inspect the different components before connecting them together to make sure everything is in order. Check to see that the sound processor is turned off to prevent a sudden noise when it is initially "plugged in."

Practice connecting the ear hook to the percutaneous pedestal until it feels comfortable. The plastic prongs help guide the connector in the correct orientation. One of the pins is a small silver guide pin which will allow the connector to go in only one way. It should go together very easily. If you have any problems have a friend help you.

**You can damage the pedestal if you force the connection.**

**NOTE:** Do not attempt to insert the connector if the pins are bent.

Although you may be able to find an assembly method that is easier for you, the following is suggested.

1. Make sure the sound processor is OFF.
2. Connect the cable to the ear hook and fit the hook over your ear.
3. Connect the ear hook to the percutaneous pedestal connector.

4. Turn the sound processor on and adjust the volume and sensitivity controls to the most desirable settings.

The sound processor may be worn on your belt or carried in a pocket. The cable may be hidden under a shirt or sweater. Some patients have found that it is easy to carry the sound processor in a case strapped over their shoulder. Try wearing it different ways to learn what is best for you. Make sure you can easily adjust the controls as needed for various environmental conditions.

**ADJUSTING CONTROLS**

The controls are located on the top panel of the sound processor.

The ON/OFF and VOLUME are combined in one control. To turn the sound processor on, you simply turn the knob clockwise. The volume increases the further you turn the knob clockwise. If the volume is too high, sounds will be louder but distorted making it more difficult to tell the difference between similar sounding words. Be sure to turn the sound processor off when you are not using it. If the sound processor is left on, it will continue to drain power from the battery even when it is not connected to the ear hook and percutaneous pedestal.

The SENSITIVITY control regulates the quietest sound you can hear provided the volume control is set to an adequate level. The most sensitive setting is obtained when you turn it fully clockwise. This allows more sound in. When you turn the knob counter-clockwise it reduces the amount of sound that comes in. This will help you focus on speech in a noisy environment. For example, if you are in a restaurant and want to avoid the distraction of people talking at another table, adjust the sensitivity control counter-clockwise. You will learn how to adjust this control to reach maximum benefit in a variety of situations. The best hearing occurs at a narrow range between too much noise and no sound at all.
The MICROPHONE JACK allows you to use the optional microphone in addition to the microphone located in the ear hook. You may find this feature helpful when there is a lot of background noise or if you are some distance from the speaker. For example, if you are in a lecture hall you can put the microphone near the speaker. This will block out much of the background noise so you can hear the speaker more clearly.

BATTERY

The sound processor is powered by one 9 volt transistor battery. Depending upon how long the sound processor is used each day and the volume setting required, the battery will last four to six days. Alkaline batteries are higher quality so they will last longer.

The volume gradually gets weaker as the battery gets lower. For satisfactory use you should change the battery when you notice the volume decreasing. You may find it to your advantage to carry a spare battery with you. Do not carry your battery in a pocket with keys, change or other metal objects. This may cause the new battery to lose its charge.

There are inexpensive battery testers available at electronic stores. You may wish to use one to determine if a battery is still good. If the battery does not have enough power for the INERAID sound processor you may be able to use it for something else. Many radios and battery operated toys will work with a battery that does not have enough charge to operate the sound processor satisfactorily.

To replace the battery, open the compartment on the top panel of the sound processor by sliding the cover in the direction of the arrow. (See photo on previous page.) Remove the used battery (it is not a rechargeable battery). Insert the new battery as shown in the picture. You will know if you put the battery in the wrong way because the compartment will not close unless you force it.

If a dead battery is left in the sound processor for several days it may release corrosive fluids which can damage the sound processor. Of course you will not have this problem if you are using the sound processor on a daily basis.
Batteries hold their charge better when stored in a cool location. Many people keep them in a refrigerator. You will be able to save money on batteries if you buy them in bulk quantities.

SAFETY FEATURES

The INERAID artificial ear has been designed with safety features to protect you. If the cable becomes entangled the break-away safety connector will quickly disconnect the sound processor from the ear hook. This will eliminate any excessive tension on the tissues surrounding the percutaneous pedestal.

The electrical circuitry in the sound processor has been specifically designed to prevent electrical discharge. However, if this did happen you would hear a loud sound and could quickly pull the break-away connector to disconnect the sound processor from the pedestal.

If there is a loud noise in the environment the electronics will automatically shut it out to prevent too much stimuli from reaching your auditory nerve. This may result in a second of silence. You may think the sound processor has a short in it since the sound will go off briefly and then return. Please remember that this is merely a safety feature. We call this the A.G.C. (Automatic Gain Control).

PEDESTAL HYGIENE

It's important to keep the area surrounding the pedestal clean. The otologist suggests cleaning it with cotton swabs dipped in a solution of equal parts of water and hydrogen peroxide for at least six weeks after surgery. He also prescribes an antibiotic ointment for the incision area (unless you are allergic to antibiotics).

Your pedestal may become infected in the future. Sometimes glasses or goggles straps rub the pedestal and irritate the area. One patient experienced a problem with an ingrown hair. A minor infection should clear up in 24 to 48 hours when treated with a topical antibiotic. If the infection does not heal in this time you should visit your physician. Early treatment will clear up a problem before it has the chance to develop into a serious complication.
Hearing with the INERAID Artificial Ear

Patients involved in the program have related the following advice and experiences. These comments are shared here to help you know what to expect as you use your sound processor. The INERAID artificial ear is still a new device and we are continuing to learn about it. Your experiences could be entirely different than those other patients have had.

Your initial attempts at communicating with the INERAID artificial ear may not be as promising as you had hoped. Be patient with yourself and do not expect to recognize environmental sounds immediately. You have been in a world without sound for quite some time and it will take you a while to adjust. Compare hearing again to being in a dark room for several hours and walking out into blinding sunlight. At first you need to squint and your eyes may feel irritated. After a short time your eyes adjust.

It will take several days to a few weeks for you to become accustomed to auditory stimuli. Begin by using the sound processor daily for several short periods in a familiar environment. Practice adjusting the controls until you are comfortable with them. Increase the amount of exposure time every day and try using the sound processor in a new setting. At first the volume may seem very loud, as you continue to use the device this problem will disappear. Listening intently is an exercise and will make you tired—you may even experience a mild headache. Periods of rest without the artificial ear will eliminate this problem.

You may learn to recognize sounds more quickly if you have family members or friends drill you. Ask them to point out one sound at a time and learn what it is. For instance, a companion can knock on the door, turn on the water or drop a ball on the ground until you are able to identify these sounds without looking.

Gradually, you will be able to recognize more sounds and become accustomed to listening to things around you. Some stimuli, such as a garage door opening or a clanging cash register, may be too noisy at first. If a certain noise bothers you, turn the sound processor off while you are exposed to it. Once you get used to hearing again you probably won't need to do this.

After you feel comfortable with environmental sounds you may enjoy a word game. Pick a subject and have a friend say related words for you to repeat. For example, you may choose the subject “camping.” Your friend may say words such as sleeping bag, campfire, marshmallow, back pack, tent, or mosquito. Stay with subjects both of you are familiar with.

You may be able to understand speech through speech reading, context and the sound produced by the artificial ear. It is important to face the speaker so you can continue using your speech reading skills. Some sounds are easier to hear because they are a better frequency and have more intensity. For example, b and d sounds are easier to identify than s and v sounds. Listen for key words to help you with the context. You are likely to feel frustrated if you try to grasp every word. You may find that it is easier to understand people you have been communicating with on a regular basis than someone you do not see very often. Remember that practice is essential. Your efforts will be rewarding if you concentrate on listening for 30 minutes or more every day.

Background noise may interfere with your ability to understand the person you are talking to. Adjust the sensitivity control to reduce the background noise so you can hear more clearly. You may need to ask the person to speak more distinctly and slowly. He may be tempted to shout but encourage him to talk in a normal voice. With practice you will learn to block out most common background noise so it does not distract you. Remember that in some situations background noise (such as heavy traffic) makes understanding speech difficult even for people with normal hearing.

Your own voice may not seem as natural to you as other people’s voices. Even if you had normal hearing, your voice would sound different to you than it does to someone else. This is because we all hear our own voices through bone conduction as well as air conduction. If your voice seems softer or
**TROUBLE SHOOTING CHECK LIST**

<table>
<thead>
<tr>
<th>PROBLEM</th>
<th>CHECK THE FOLLOWING</th>
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<tbody>
<tr>
<td>NO VOLUME</td>
<td>a) volume control</td>
</tr>
<tr>
<td></td>
<td>b) sensitivity control</td>
</tr>
<tr>
<td></td>
<td>c) all connectors</td>
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<tr>
<td></td>
<td>d) replace the battery</td>
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<tr>
<td></td>
<td>e) change the cable</td>
</tr>
<tr>
<td>CRACKLE SOUND</td>
<td>a) pedestal</td>
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<tr>
<td></td>
<td>b) earhook</td>
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<tr>
<td></td>
<td>c) sound processor connector</td>
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<td></td>
<td>d) change the cord</td>
</tr>
<tr>
<td></td>
<td>e) change the environment</td>
</tr>
<tr>
<td>VOLUME LOSS</td>
<td>a) volume control</td>
</tr>
<tr>
<td></td>
<td>b) sensitivity control</td>
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<td></td>
<td>c) battery</td>
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<td>d) cold sound processor</td>
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<td></td>
<td>e) hot sound processor</td>
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<td></td>
<td>f) earhook</td>
</tr>
<tr>
<td></td>
<td>g) are you tired or upset</td>
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<tr>
<td>HOLLOW SOUNDS</td>
<td>a) pedestal connection</td>
</tr>
<tr>
<td></td>
<td>b) earhook connection</td>
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<tr>
<td></td>
<td>c) sound processor connection</td>
</tr>
<tr>
<td>ON/OFF/ON</td>
<td>a) loud noise activated the A.G.C. (sometimes this is normal)</td>
</tr>
<tr>
<td></td>
<td>b) change earhook</td>
</tr>
<tr>
<td></td>
<td>c) internal problem</td>
</tr>
<tr>
<td>PEDESTAL CONNECTION</td>
<td>a) wrong alignment</td>
</tr>
<tr>
<td></td>
<td>b) pins bent</td>
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<tr>
<td></td>
<td>c) damaged pinsaver</td>
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<tr>
<td>BUZZ SOUND</td>
<td>a) change cord</td>
</tr>
<tr>
<td></td>
<td>b) internal problems</td>
</tr>
<tr>
<td>INFREQUENT STATIC</td>
<td>a) oscillation of the sound processor (sometimes normal)</td>
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</tbody>
</table>

**TROUBLE SHOOTING**

The sound processor contains sensitive micro-electronic technology and should be opened and repaired only by Symbion, Inc. servicing personnel. However, there are some things you should verify before contacting Symbion, Inc.

If you do not hear anything when the sound processor is turned on make sure the battery was inserted correctly and check all the cable connections. Be sure to turn the sound processor off before you begin. If the cable has a short and you do not turn the sound processor off you may experience an uncomfortable noise. Check the cables to be certain they are properly connected but do not try to force them. If your cable has a short it will need to be replaced.

If the sound quality is normal for a few minutes then quickly deteriorates you may have bad batteries. When batteries begin to wear out they may work for a few minutes each time you switch the sound processor on and then stop. Replacing the batteries may solve this problem.

If you still cannot hear as well as usual, readjust your volume and sensitivity controls. They may not be on the best setting for the particular situation you are in. Remember, if you are in a noisy environment or are feeling tired the sound quality will not be as good as usual.

Contact your audiologist if you have any concerns. Your audiologist will check on you occasionally but you should not wait for his/her next call if you need something taken care of immediately.

**POTENTIAL ADVERSE EFFECTS**

The INERAID artificial ear is an investigational device and there may be potential adverse effects associated with its use. You have had the opportunity to review these risks thoroughly before you received the implanted electrodes. The risks are summarized here for your convenience.

**Infection**

If you contract an infection in the area of the percutaneous pedestal, there is a remote possibility...
that it could lead to meningitis. This is why it is important that you visit your physician if you suspect an infection.

**Electrical Stimulation**

Animal studies have revealed some bone growth around stimulated electrodes implanted in the cochlea. However, patients with cochlear implants have not complained of decreased hearing ability which could be attributed to bone formation.

Theoretically, electrical stimulation may result in nerve degeneration; however, this has not been measured or observed in any patients.

Less than 1% of the single-channel cochlear implant patients have reported dizziness or failure of muscular coordination when the implanted electrodes were stimulated. None of the patients using the INERAI ID artificial ear have reported this condition.

**Tinnitus**

Electrode insertion and stimulation may cause inner ear trauma which could result in tinnitus (ringing in the ears).

**Electrical Discharge**

Risk of electrical discharge has been minimized by circuit design. Many electrical components would have to fail simultaneously. If this occurs, you would hear a loud sound and should quickly pull the break-away connector to disconnect the sound processor.

**Damage to Percutaneous Pedestal**

There is the possibility that a sharp blow to your head may break the pedestal. A broken pedestal may need to be surgically removed.

**WARNINGS**

Except for changing batteries, you should not open the sound processor or attempt to alter any of the internal control settings or components. There are no user serviceable parts inside and all servicing should be referred to Symbion, Inc.

**Do not** continue to wear the artificial ear if it is not working properly. This could result in further damage.

No attachments or cables other than those provided by Symbion, Inc. should be used with the artificial ear.

The sound processor should not be used if there is obvious damage. It should not be used for anything other than its intended purpose.

**DISCLAIMER OF WARRANTIES**

The INERAI D artificial ear is a medical device which has been granted an exemption, as an investigational device, by the Food and Drug Administration. Although Symbion, Inc., the manufacturer of the INERAI D artificial ear, has utilized great care in developing and manufacturing the INERAI D artificial ear, it cannot make any warranties of any kind concerning the performance of the artificial ear because of the technically complex nature of the device, and because the performance of the device will be dependent upon the medical condition of each individual user.