



The Listen for Life Center
at Virginia Mason

Cochlear Implant Program

Doing More With Your Hearing



The Northwest's Comprehensive Hearing Center

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If you feel you, your child, or a family member may benefit from a cochlear implant, please contact us to schedule an appointment.

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Cochlear Implant Program
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Lindeman Pavilion, Level 10
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Getting Started

Thank you for your interest in The Listen For Life Center at Virginia Mason's Cochlear Implant Program. The purpose of this information booklet is to help you understand the option of cochlear implantation for those struggling with significant hearing loss. Please read through this booklet to learn more about the ear and our hearing system, cochlear implantation technology, important issues related to cochlear implants, and if an evaluation is appropriate for you or your family member.

Deciding To Move Forward

Is a cochlear implant right for you or your child? Only a comprehensive evaluation from a cochlear implant team can determine this. Please contact The Listen For Life Center to schedule an initial consultation with both the audiologist and the surgeon.

Please review this informational booklet before your initial consultation appointment and if you have access to the internet, it is highly recommended that you review the websites for the cochlear implant devices offered at The Listen For Life Center.

Cochlear Americas: www.Cochlear.com
Advanced Bionics: www.bionicear.com
Medel Corporation: www.Medel.com

Please contact us to schedule your appointments or to answer any of your questions.

The Listen For Life Center at Virginia Mason®

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We look forward to meeting you,

The Listen For Life Center Team at Virginia Mason®

About The Listen for Life Center at Virginia Mason®

Hearing loss changes the way we enjoy the everyday sounds of life and can alter the way we experience the world around us. A sense of frustration can result when conversations with family and friends becomes a challenge or when a phone call is no longer an option for fear of not hearing the caller. For someone with a hearing loss, their view of the world is dramatically changed.

The Listen For Life Center at Virginia Mason® serves individuals with hearing loss from infancy through adulthood. The most advanced application of leading edge technologies, medical and surgical treatments and oral based rehabilitation therapy are brought together – all in one location. There are one-in-four families in the Northwest region who live with a loved one's hearing loss, The Listen for Life Center is dedicated to helping these families.

We offer comprehensive services, designed to help improve the quality for life both for individuals who suffer from hearing loss and their family members.

Services For Children

- Pediatric Cochlear Implant Program
- Pediatric Hearing Evaluations
- Universal Newborn Hearing Screening (UNHS)
- Hearing Aid Evaluations, Fittings and Follow-up
- Pediatric (Re)habilitation and Outreach Services
- BAHA (Bone Anchored Hearing Aid) services



Services For Adults

- Adult Cochlear Implant Program
- Adult Hearing Evaluations
- Hearing Aid Evaluations, Fittings and Follow-up
- Rehabilitative and Educational Services for Adults
- BAHA (Bone Anchored Hearing Aid) services



Access to Advanced Technology

As new technologies emerge in the field of cochlear implants, we are dedicated to providing our patients with the system that best fits their needs and lifestyle. By providing our patients with technology from the three available FDA approved cochlear implant manufacturers (Cochlear Americas, Med El Corporation, and Advanced Bionics), our patients are ensured that they will have all available technology to choose from.

The Listen For Life Center Difference

Expertise You Can Trust

The Listen For Life Center at Virginia Mason operates the largest cochlear implant center in the Pacific Northwest, treating more people than any other center in the region.



Dr. Seth R. Schwartz, MD, MPH, serves as the Medical Director for The Listen For Life Center. He received his medical degree from Yale University and his Masters in Public Health from the University of Washington. Before coming to Virginia Mason, Dr. Schwartz was a staff Otolaryngologist at Alaskan Native Medical Center in Anchorage Alaska. He also completed a fellowship in Otology/Neurotology at Auckland City Hospital in New Zealand in 2005. Dr. Schwartz is actively involved in research regarding hearing loss, cochlear implants and hearing reconstructive surgery.



Daniel M. Zeitler, MD, FACS joined The Listen for Life Center team in 2015 after relocating to Seattle from Denver, CO where he practiced for 4 years. He received his medical degree with honors from New York University and stayed in New York City to complete his General Surgery internship and residency in Otolaryngology/Head and Neck Surgery at New York University. He then went to Miami where he completed a fellowship in Otology/Neurotology at the University of Miami Ear Institute in 2011. Dr. Zeitler is actively involved in clinical research regarding expanding criteria for cochlear implantation and optimizing outcomes with cochlear implants.

Working closely with the physicians is a highly skilled multi-disciplinary team of Audiologists and Customer Service Representatives. The team's dedication and superior patient care set it apart from other programs in the region.

The Ear and Hearing System

Anatomy Of The Ear

Outer Ear: Helps us to tell where sound is coming from (localization) and funnels sound into the ear canal (the part where ear wax can collect).

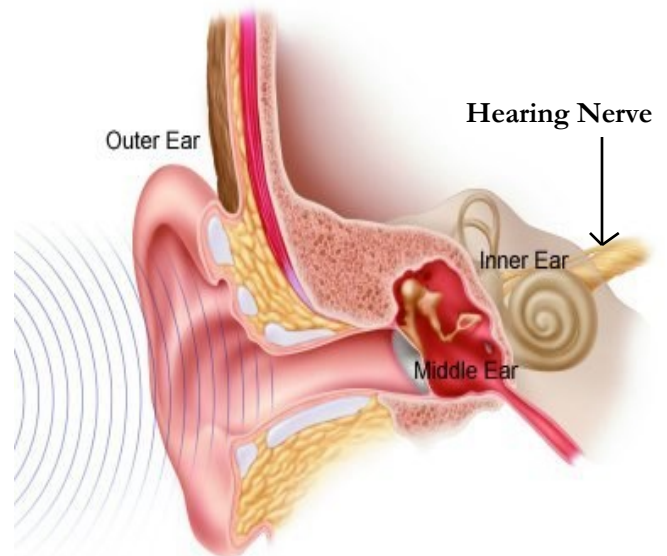
Middle Ear: The ear drum (or tympanic membrane) is tight, like the skin of a drum. It turns sound waves into mechanical vibration and moves a chain of 3 small bones (hammer, anvil and stirrup). These bones pass vibrations on to the inner ear.

Inner Ear (cochlea): This snail-shaped, fluid filled structure contains very sensitive cells called hair cells, or “cilia”. These hair cells play a very important part in helping us to hear by transmitting the stimulation from the inner ear to the hearing nerve.

The Hearing (Auditory) Nerve: Receives information from the moving inner ear hair cells . The information is taken to the brain for processing via the hearing/auditory nerve.

How We Hear

1. Sound travels down the ear canal and vibrates the ear drum.
2. The ear drum is tight and vibrates when sound hits it.
3. This vibration is passed down the chain of bones to the inner ear (cochlea)
4. The vibrations make the fluid and other structures in the cochlea move.
5. Hair cells are then moved and make tiny electrical signals which are picked up by the auditory nerve. Hair cells at the beginning of the cochlea send high pitch sound information and hair cells at the tip or end of the cochlea send low pitch information.
6. This stimulation is passed up the hearing nerve to the brain.
7. The brain interprets the stimulation as sound, and hearing has occurred.



Types of Hearing Loss

Conductive Hearing Loss: Occurs when sound is not conducted properly through the outer and/or middle ear systems. Conductive hearing loss usually involves a reduction in hearing level, or the ability to hear soft sounds. This type of hearing loss often can be corrected through medicine or surgery.

Sensorineural Hearing Loss: Occurs when there is damage to the inner ear (cochlea) or to the hearing/auditory nerve pathways from the inner ear to the brain. Sensorineural hearing loss involves a reduction in hearing level and also can affect speech understanding or the ability to hear clearly. Hearing aids and cochlear implants are two common treatment options.

Mixed Hearing Loss: Sometimes a sensorineural hearing loss occurs in combination with a conductive hearing loss. In other words, there may be damage in the outer or middle ear *and* in the inner ear or auditory nerve.

What is a Cochlear Implant?

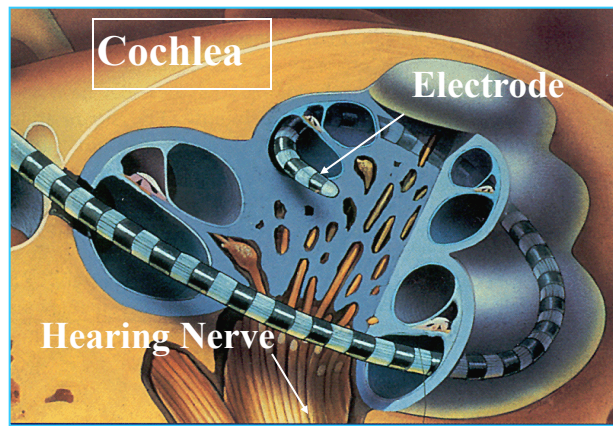
A cochlear implant is a safe, reliable, and effective treatment for severe-to-profound hearing loss in adults and children. Designed to allow implant users to hear sounds as they occur, a cochlear implant can enhance communication abilities with better hearing and speaking potential for implant recipients. The device consists of an internal implant and an externally worn speech processor. The external speech processor comes in a body-worn style or an ear level style (pictured below).



1. Sound is picked-up by a microphone.
2. Sound is sent from the microphone to a speech processor.
3. The speech processor analyzes and digitizes the sound into coded signals.
4. Coded signals are sent to the transmitter coil via radio frequency.

5. The transmitter coil sends the code across the skin to the internal implant.
6. The internal implant converts the code to electrical signals.
7. The signals are sent to the electrodes to stimulate the remaining nerve fibers.
8. The signals are recognized as sounds by the brain, producing a hearing sensation.

Each speech processor is programmed to meet the users individual hearing needs. Different speech coding strategies emphasize different pitch, loudness, and timing cues. The brain receives the information within microseconds of the microphone picking up sound, so sound is heard as it occurs.



View of an internal electrode array inside the cochlea.

Overview Of The Available Technology

A cochlear implant system consists of an internal implant and an externally worn speech processor. The external speech processor comes in a body-worn style or an ear level style. There are three manufacturers of cochlear implant systems approved by the Federal Drug Administration (FDA). The Listen For Life Center offers all three manufacturers at our Center.

Cochlear Americas: Additional information available at www.cochlear.com

Nucleus Freedom Cochlear Implant



Nucleus CP910 Processor



Remote Assistant



Medel Corporation: Additional information at www.medel.com

Concert Cochlear Implant



OPUS 2 Speech Processor



Fine Tuner



Advanced Bionics: Additional information at www.bionicear.com

HiRes 90K



Naida Behind-The-Ear Style



Neptune Body Worn Style



Is A Cochlear Implant Right For Me Or My Child?

There are many different factors to consider when deciding if you or your child is should be evaluated for a cochlear implant. Various audiological, medical and psychological factors are taken into consideration. Please see below:

Children: 12 months to 17 years.

Does your child have:

- Profound sensorineural hearing loss in both ears (12 months-24 months)?
- Severe-to-profound sensorineural hearing loss in both ears (older than 24 months)?
- Lack of progress in development of auditory skill with hearing aids?
- Receive little or no benefit from hearing aids?
- High motivation and realistic expectations from family?
- Other existing medical conditions that won't interfere with cochlear implant procedure?

Adults: 18 years and over.

Do you:

- Have a severe-to-profound sensorineural hearing loss in both ears?
- Receive little or no useful benefit from hearing aids?
- Struggle with conversation even with your hearing aids on?
- Have difficulty understanding on the telephone even with hearing aids?
- Have a desire to be part of the hearing world?

How are Hearing Aids and Cochlear Implants Different?

For some people, hearing aids are not enough to provide them with sound awareness, and potential improvements in speech understanding. Hearing aids and cochlear implants differ in a number of key ways:

1– Hearing aids amplify sound and continue to utilize the remaining hearing. A cochlear implant, on the other hand, bypasses the outer ear, middle ear and most of the inner ear by changing speech and other sounds into electrical energy that is used to stimulate surviving hearing nerve fibers in the inner ear (cochlea).

2– Cochlear implants have both an internal device and an external speech processor. Placement of the internal device requires a surgical procedure. A hearing aid on the other hand, has only an external device and does not require surgery.

3– Hearing aids are appropriate when the degree of hearing loss is in the mild, moderate, moderately-severe and possibly severe range. Patients are only considered for a cochlear implant when the hearing loss is within the severe and/or profound hearing loss range and they struggle with communication even with the use of appropriately fit hearing aids. It is very important to remember that candidacy for a cochlear implant is dependent on various medical, audiological and psychological considerations.

Determining Candidacy..... Then What?

Determining Candidacy

The goal of a thorough medical and audiological work-up is to determine what will provide the best hearing for you or your child. For some individuals, appropriately selected and fit hearing aids will provide better hearing than what a cochlear implant will provide. Appointments with the Listen For Life Center's cochlear implant team are necessary before a recommendation can be made to proceed with implantation. The following are specific steps that take place in the candidacy evaluation process:

- Complete Hearing Evaluation – An audiologist will conduct a complete hearing test. For children, multiple appointments may be necessary to obtain accurate results.
- Hearing Aid Evaluation – Your current hearing aids will be evaluated to verify proper function. Once the best instrumentation is determined for your hearing loss, speech perception testing while wearing hearing aids is performed to help determine the actual benefit received. For children, this would be done in conjunction with intensive hearing evaluations.
- Counseling Sessions – The audiologist and the surgeon will discuss device benefits, limitations and expectations with the potential cochlear implant candidates and his or her family. The cochlear implant team will help you decide which device is likely to be most appropriate for you or your child.
- Medical Assessment – The medical work-up typically includes a CT scan and/or MRI and an exam with an Otologist and recommendations for pneumococcal vaccine. For some, balance testing and/or a psychological evaluation is needed.
- Pneumococcal Vaccination – This vaccination will be administered by our nurse should you choose to do so. The CDC and FDA recommend getting the pneumococcal vaccination prior to cochlear implant surgery. Please see the additional information on the bottom of page 12.

After Surgery

- Medical Follow-up after Surgery - An appointment with the surgeon or a doctor in your local area is needed within the first week following surgery. The purpose is to check the surgery site.
- Speech Processor Fitting and Programming – After the surgical area is allowed to heal for 1 week, the patient will begin a series of visits to The Listen For Life Center for the fitting and programming of the speech processor. Patients are seen at 1-week, 1-month, 3-months, 6-months and 12-months after the initial activation of the device.
- Evaluation of Cochlear Implant Performance - Cochlear implant performance is obtained by measuring sound awareness at various pitches, speech understanding in quiet, and in noise. Tracking cochlear implant progress with formal testing allows the programming audiologist to make specific adjustments based on test results. It also allows comparisons to performance before implantation and to past evaluation sessions. These visits also occur at 1-month, 3-months, 6-months and 12-months post activation, prior to the programming session.
- Aural Rehabilitation – Since each recipient has different communication abilities and needs, recipients will progress at different rates. Audiologists work to strengthen patients current hearing skills through auditory training, communication strategies and counseling.

Potential Benefits of Cochlear Implantation

There are two areas to discuss when looking at one's hearing potential with a cochlear implant. These include medical and biological factors that are unique to each patient, and the technology available (cochlear implant system) to maximize one's hearing potential. Research indicates that the technology from the three cochlear implant systems available today is similar and there are no significant differences in expected performance. The device chosen will not guarantee a given level of performance with a cochlear implant because there are many medical and biological factors that can affect how well someone can hear and understand sound.

The Listen For Life Center's cochlear implant team will determine if you or your child is a candidate for a cochlear implant. If candidacy is confirmed, we expect that a cochlear implant will provide greater benefit than hearing aids. Cochlear implant patients should expect to make continual progress compared to hearing aids. The degree of benefit and how rapid a person makes progress depends upon many medical and biological factors.

Medical and biological factors that can influence one's hearing potential:

- How long (in years) has the hearing loss been present
- How old were you or your child when the hearing loss began
- Use of hearing aids prior to implantation
- Access to sound during the critical language learning period (typically before age 5)
- How old you or your child is at time of implantation
- The status of the inner ear and hearing nerve
- Did you or your child have meningitis prior to implantation
- Other related medical conditions

Range of benefits with cochlear implants

- Detection of every-day sounds, such as a door bell, birds singing and voices
- Environmental awareness and a better connection to the sounds around you
- Improvements in communication through hearing and speech reading
- Limited speech understanding without speech reading in quiet listening situations
- Speech understanding in quiet listening situations
- Limited speech understanding in mild background noise listening situations
- The ability to hear on the telephone
- The ability to listen to and appreciate music



Surgery Expectations and Potential Risks of Implantation

A Typical Surgery Experience

Cochlear implantation takes between 60 and 90 minutes in duration and is performed on an outpatient basis. This means that an overnight hospital stay is usually not required.

The incision needed for cochlear implantation at The Listen For Life Center is minimally invasive with little to no-hair shaving. Facial nerve monitoring is performed to reduce the chances of affecting the facial nerve. In some cases, an X-ray is performed following placement of the electrode into the cochlea to confirm proper placement prior to completing surgery. For some patients, neural response measures are obtained to help assist in the programming of the cochlear implant device. Most patients return to regular activities within 2-3 days following surgery.



Our Surgical Team

Going the Extra Mile

The pre-operative, operative and post-operative staff at Virginia Mason Medical Center are trained on how to effectively communicate with a patient with hearing loss. Sign language or foreign language interpreters are provided to patients and families who request them. Parents typically are invited to initially accompany their children into surgery to calm fears. Finally, due to patient's dependence on speech reading, the operating room staff have a "wear no-mask" policy in place prior to the point that patients are put under anesthesia. This helps both adults and children ease their fears while in the operating room.

Potential Risks and Complications with Cochlear Implantation:

- During surgery any remaining hearing in the implanted ear will most likely be lost.
- Due to the close location of the facial nerve, there is a remote possibility that temporary or permanent facial paralysis may occur after surgery.
- There is a slight risk that the patient may experience taste disturbances (commonly described as a metallic taste) following implant surgery.
- There is the risk that the surgical site may become infected, which in very rare cases may require an additional surgery and possible removal of the device.
- The patient may have some temporary balance and dizziness following implant surgery.
- Tinnitus (ringing in the ear) is considered unpredictable following implant surgery. It may worsen in the implant ear, or it may decrease in loudness for those who have tinnitus prior to implant surgery.
- The patient may experience pain at the wound following surgery; this is usually temporary.
- Risk of device failure

Pneumococcal Vaccine for Meningitis

Preparation for cochlear implant surgery includes proper vaccination against bacterial meningitis. Meningitis is a bacterial infection that can be serious if not treated quickly and is a common cause of deafness. The best prevention of meningitis includes an understanding of meningitis and a vaccination called the "pneumococcal vaccine." For more information, please visit the Food and Drug Administration (FDA) website at www.fda.gov. The Listen For Life Center's team will provide you with current vaccination recommendations if you or your child are considered for cochlear implantation and will be able to administer it the day of your evaluation.

Cost and Financial Considerations

Cost

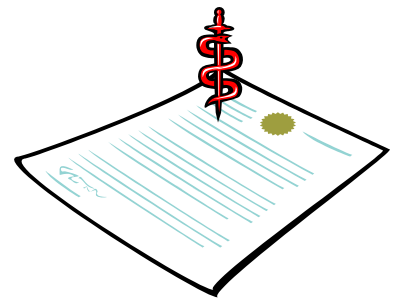
The estimated total cost associated with the pre-operative work-up, device hardware, surgery and post-operative programming and rehabilitation is approximately \$50,000-\$60,000.

Insurance Coverage

Coverage for cochlear implantation is often available if the procedure is pre-authorized at the physician's request. Virginia Mason will help you to secure insurance pre-authorization for the cochlear implant process and will not proceed with the surgery and device hardware purchase without obtaining pre-authorization. Currently Medicare and Washington State Medicaid (children only as of 1.1.2011) for children do provide coverage for cochlear implantation.

Understanding your insurance coverage and potential out-of-pocket expenses can be difficult at times. It is very important to remember that pre-authorization of coverage does not guarantee that the approved service(s) will be covered at 100%. You may still have some out-of-pocket expenses and co-pay fees.

Pre-authorization is obtained for the amount of coverage under your specific insurance plan, which may include full coverage for related expenses or only partial coverage. It is important to know what coverage you have prior to undergoing surgery.



What You Need to Know About Medicare

Cochlear implants are a covered service by Medicare. No pre-authorization is necessary for surgery as long as you qualify based on audiologic and medical criteria as determined by the audiologist and doctor. **A doctor's prescription is required for every visit with the audiologist before and after surgery.** Without the prescription, the cost for the services will be billed directly to you. In addition, Medicare provides coverage for the external devices, batteries and for loss or damage once your original manufacturer's warranty expires. Please review your Medicare handbook for specifics.

Helpful Tips to Better Understand Your Coverage

Organize your insurance information

- Obtain a written copy of your insurance plan/benefit packet
- Gather insurance cards, policy and plan numbers
- Locate your plan's contact numbers and addresses

If the requested service(s) is approved:

- Make sure Virginia Mason Medical Center is the approved provider
- Find out the limitations of the approval
- If limitations do exist, find out if they can be appealed, and if so, how

If the requested service(s) is denied:

- Ask for the denial in writing. An Explanation Of Benefits (EOB) should be provided.
- Contact your insurance provider to find out the appeal process
- The Listen For Life Center can provide a letter of appeal and medical records as needed



Frequently Asked Questions

How can I or my child be evaluated for a cochlear implant?

—In order to provide proper scheduling, please contact the Listen for Life Center to schedule an initial consultation with the audiologist and doctor.

How do I know if a cochlear implant is right for me or my child?

—There are many different factors to consider when deciding if you or your child is a candidate for a cochlear implant. Various audiological, medical and psychological factors are taken into consideration. Page #9 of this packet outlines questions to ask yourself to help decide if an evaluation should be considered.



Is the cost of cochlear implantation covered by insurance?

—Coverage for cochlear implantation is often available if the procedure is pre-authorized at the physician's request and if you meet medical and audiologic criteria. Virginia Mason's insurance department will help you secure insurance pre-authorization for the cochlear implant surgery and will not proceed without obtaining approval. Currently Medicare and Washington State Medicaid (for children only) provide coverage for cochlear implantation if you meet criteria.

Will part of my hair be shaved during surgery?

—The incision needed for cochlear implantation at The Listen For Life Center is minimally invasive and requires minimal to no-shaving of the hair. In the rare case that shaving is needed, you will be informed of this prior to surgery.

How long have cochlear implants been used?

—Research on auditory nerve stimulation started in the mid 1950s in France. Early versions of today's multi-channel cochlear implant systems started in the late 1970s and became commercially available and approved by the FDA in 1985. Since then, cochlear implant technology continues to improve, resulting in expanded candidacy criteria, higher patient satisfaction and improved speech understanding.

Does The Listen For Life Center perform bilateral cochlear implants?

—Yes. The Listen For Life Center performs bilateral cochlear implantation at the request of patients. Bilateral implantation is still not recognized as a standard of care with most insurance companies. The Virginia Mason staff will do their best to provide the necessary documentation to assist your insurance company in making an informed decision. We recommend you check with your insurance company regarding your benefits and exclusions.