CAUTION: FEDERAL (U.S.) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

NOTE: Ototronix strongly recommends the completion of a MAXUM training course before performing these procedures.

A successful fitting of the MAXUM System requires an accurate deep-canal impression be taken. All clinicians involved in these procedures should not attempt this type of fitting unless they have completed a MAXUM training course.

ONLY THE IMPRESSION MATERIAL SUPPLIED BY OTOTRONIX SHOULD BE USED FOR DEEP PERITYMPANIC IMPRESSIONS.
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The MAXUM System is an electromagnetic, partially implanted, middle ear hearing device. The MAXUM System consists of a permanent ossicular implant magnet and an external digital sound processor that is worn in the external ear. The device is provided with specialized surgical instruments for the proper insertion and placement of the implant.

The MAXUM IPC System with a digital processor consists of a permanent ossicular implant magnet and an Integrated Processor and Coil (IPC). The IPC houses an electromagnetic coil and the external sound processor.

The Sound Processor in the IPC receives sound, amplifies it, and sends electrical signals to the coil at the tip of the device. This coil changes the sounds to electromagnetic signals, which cause the implant to vibrate. These vibrations travel through the cochlea, stimulating the hair cells and nerves that send impulses to the brain that are interpreted as speech or sounds.

Figure 1: Principles of Operation
Indications for Use

The MAXUM Systems are 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.

Contraindications

The MAXUM Systems are contraindicated for subjects who have:

- Conductive hearing loss
- Retrocochlear or central auditory disorder
- Active middle ear infections
- Tympanic membrane perforations associated with recurrent middle ear infections
- Disabling tinnitus

Magnetic Resonance Imaging (MRI) examinations are contraindicated for patients implanted with the MAXUM. Patients implanted with a MAXUM System should not undergo an MRI examination, enter a room where MRI exams are performed, or get close to other strong magnetic fields.

If a patient has a medical or occupational need to be exposed to strong magnetic fields such as a need for MRI examinations or working with MRI equipment, contact Ototonix at 877-410-4327.

Nickel Sensitivity: MAXUM Implant Assembly, Split Coil versions (P/N M220L and M220R) are contraindicated for patients with foreign body sensitivity to metals containing nickel. Where material sensitivity is suspected, appropriate tests should be conducted prior to implantation. (MAXUM Implant Assembly, Full Coil versions (P/N M210L and M210R) do not contain nickel and this contraindication does not apply.)
MAGNETIC RESONANCE IMAGING (MRI) EXAMINATIONS

MRI is contraindicated for patients implanted with the MAXUM. Patients implanted with a MAXUM System should not undergo an MRI examination, enter a room where MRI exams are performed, or get close to other strong magnetic fields. The effects of these exams on the implant are unknown.

If an MRI is necessary, the implant should be removed and re-implanted after the exam.

ELECTROCONVULSIVE THERAPY

Electroconvulsive therapy is contraindicated for patients implanted with the MAXUM. Electroconvulsive therapy must never be used on a patient with a MAXUM System implant because it may damage the implant or the patient’s hearing.

Diathermy

Diathermy is contraindicated for patients implanted with the MAXUM. Diathermy must never be applied over the implant because the high currents induced into the implant may damage the implant or the patient’s hearing.

ELECTROSURGERY

Electrosurgical instruments are capable of producing electromagnetic fields 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 may damage the implant or the patient’s hearing.

COBALT TREATMENT, PET SCANS, TRANSCRANIAL DIAGNOSTIC ULTRASOUND, OR LINEAR ACCELERATION TECHNIQUES

The effect of cobalt treatment, PET scans, transcranial diagnostic ultrasound, and linear acceleration techniques on the implant are unknown. Before undergoing any of these procedures, MAXUM System users should consult their physicians about the potential risks.

MAGNETIC SURGICAL INSTRUMENTS

If other surgeries are to be performed in the middle ear space of the implanted ear, avoid using magnetic (ferric) instruments. Such instruments will attract the implant, and may damage the implant or the patient’s hearing.
ELECTROMAGNETIC COMPATIBILITY
The MAXUM Systems have been found to comply with the test requirements of EN60601-1-2, Electromagnetic Compatibility for Medical Devices. Compliance indicates the system is reasonably protected from harmful interference in a typical medical installation. However, these devices may be affected by systems that produce, utilize, or radiate radio frequency energy. If your MAXUM System appears to be affected, try the following solutions to resolve the problem:

- Reorient and/or relocate the interfering device.
- Increase the separation between the MAXUM System and the interfering device.

If these solutions do not resolve the problem, please inform your hearing health care professional, your physician or contact Ototronix at (877) 410-4327.

ANTI-THEFT DETECTORS AND AIRPORT SECURITY DEVICES
Anti-theft detectors found in retail stores, public libraries, etc., and airport security devices produce electromagnetic fields. Some MAXUM System users may hear distorted sounds when passing through or near one of these devices. Testing with the MAXUM has indicated that the device is not damaged by these systems.

Do not stand near or lean against anti-theft devices in doorways of department stores and libraries. Anti-theft devices in stores and libraries are safe, providing you walk through them at a normal pace. When passing through an anti-theft system, walk though the center of the gates. If only one gate is present stay as far away as possible from it.

If scanning with a hand held metal detector is necessary at airport security stations, warn the security personnel that you have an implanted medical device. Ask them not to hold the metal detector to the device any longer than absolutely necessary. You may wish to ask for an alternate form of personal search.
RADIO FREQUENCY IDENTIFICATION (RFID) SYSTEMS
RFID is a technology that uses radio waves to exchange data between a reader and an electronic tag attached to an object. RFID Systems are used currently in keyless entry systems, passports and identification, retail sales and asset management, toll roads and many others.

The MAXUM Systems are reasonably protected from harmful interference from RFID Systems. Some MAXUM System users may hear distorted sounds when passing through or near one of these devices. Testing with the MAXUM has indicated that the device is not damaged by these systems.

It is recommended that you keep a separation distance of 6 inches (15 cm) between your MAXUM and items thought to contain RFID systems.

CELL PHONE COMPATIBILITY
Some hearing device users have reported buzzing sounds when they are using cell phones, indicating that the cell phone and hearing device may not be compatible. According to the ANSI C63.19 standard (ANSI C63.19-2006 American National Standard Methods of Measurement of Compatibility Between Wireless Communications Devices and Hearing Aids), the compatibility of a particular hearing device and cell phone can be predicted by adding the rating for the hearing device immunity to the rating for the cell phone emissions. For example, the sum of a hearing device rating of 2 (M2) and a telephone rating of 3 (M3) would result in a combined rating of 5. Any combined rating that equals at least 5 would provide “normal use”; a combined rating of 6 or greater would indicate “excellent performance.”

The immunity of the MAXUM has been found to be M4. While this rating system was created for acoustic hearing aids, the equipment performance measurements, categories and system classifications are based upon the best information available but cannot guarantee that all users will be satisfied.

NOTE: The performance of individual hearing aids may vary with individual cell phones. Therefore, if you are purchasing a new phone, be sure to try it with your MAXUM prior to purchase. For additional guidance, please ask your cell phone provider for the booklet entitled “Hearing Aid Compatibility with Digital Wireless Cell Phones.”
PATIENT SELECTION

Specific patient selection criteria is outlined below:

- Adults, 18 years of age or older
- Sensorineural hearing loss
- Pure tone air-conduction threshold levels shall fall at or within:

<table>
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<tr>
<th>Frequency (kHz)</th>
<th>0.25</th>
<th>0.5</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>6</th>
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<td>0</td>
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<td>35</td>
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<td>40</td>
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<td>Upper Limit</td>
<td>50</td>
<td>60</td>
<td>70</td>
<td>75</td>
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- Word recognition scores of 60% or better
- Normal middle ear anatomy
- Psychologically and motivationally suitable candidate with realistic expectations of the benefits and limitation of the device

The patient must be made aware of the Contraindications and Warnings associated with the MAXUM System. Ensure that the patient has reviewed and understands these Contraindications and Warnings prior to proceeding.

Ear Impression

The next step in determining patient candidacy requires taking a deep ear impression (See MAXUM DEEP EAR IMPRESSION) in order to determine if the ear canal meets the minimum requirements for manufacture of the IPC. The minimum measurements of the canal area to accommodate the IPC are:

- 3 mm canal diameter from the second bend of the canal to the medial end
- 4 mm in width at the canal aperture (canal opening)
- 20 mm length from aperture to the medial end of the canal

Upon determination of patient candidacy, the surgical procedure can be scheduled. The magnet comes in Right and Left ear configurations.
Ear selection should be based on the following criteria which are listed in order of decreasing importance:

1) Poorer ear by air conduction threshold, 5 dB or greater average difference 500-4000 Hz
2) Poorer ear by speech recognition scores, 8% or greater difference
3) Poorer ear by SRT, 5 dB or more difference
4) Symmetrical ears/ear not used for telephone chosen
5) Symmetrical ears/patient preference
MAXUM DEEP EAR IMPRESSION

Performed by Physician assisted by Clinician

Precautions

Proper fitting of this hearing device requires the taking of deep canal impressions. Clinicians should not attempt this type of fitting unless they have completed the Ototronix training course and developed the necessary skills needed to make this type of impression safely. ONLY THE IMPRESSION MATERIAL SUPPLIED BY OTOTRONIX SHOULD BE USED FOR DEEP PERITYMpanic IMPRESSIONS. Many impression materials have a shore value too high to use safely for these very deep fittings and could damage the skin of the ear canal.

About the MAXUM Impression

It is critical to obtain an accurate and complete deep ear impression including landmarks of the Tympanic Membrane in order to manufacture the IPC. These landmarks include the surface of the TM, umbo, and malleus and are used to position the coil.

This necessitates taking a deep ear impression that contacts the tympanic membrane surface without the use of an otoblock. For this use, a specialized impression set and procedure have been developed. The physician and assistant (usually the audiologist or hearing instrument specialist) perform the deep ear impression procedure using a topical anesthetic and an otologic microscope.

The deep ear impression should be taken a minimum of 7 days prior to surgical implantation. Ototronix will release the implant after receipt and approval of the deep ear impression.

Most of the items needed for the deep ear impression are provided in the Clinician’s Set available through Ototronix.

Other materials provided by the clinic:

Topical anesthetic
Otologic microscope
Nasal speculum
Removal Tool (e.g. non-cutting cerumen curette)
Procedure

1. The physician examines the canal and tympanic membrane of the ear to be implanted and cleans the canal walls. Removal of any cerumen or epithelial debris is performed. (A perforation in the tympanic membrane is a contraindication, preventing the procedure.) The physician medically clears the patient for the deep ear impression.

2. The patient is placed in a prone position for examination and anesthetizing of the ear canal. Components should be assembled and the Impression Placemat reviewed. The topical anesthetic solution is removed from the ear canal. Almond oil is liberally applied into the ear canal from single-use applicator bottle. A cotton swab is dipped in the oil in the ear canal and used to lubricate the helix, concha, and tragal areas of the ear. The clinician covers the patient’s ear with a paper towel. The patient is instructed to turn his/her head in a dependent position to allow the oil to drain from the ear canal. It is important to retain a liberal amount of oil coating the canal walls and tympanic membrane. The impression gun, impression cartridge, and extended tubing should be assembled. Some impression material should be expressed prior to administering to ensure proper mixing before inserting the tubing tip into the patient’s ear.

3. **Solo technique:** Using visualization, the clinician inserts the tubing attached to the impression cartridge down the ear canal without contacting the TM. The clinician squeezes the trigger of the cartridge injection tool to begin the flow of impression material, using the tube to direct the filling of the ear canal and concha, taking care to keep the tube tip immersed in the impression material.

   **Two person technique:** Using microscopic visualization, the clinician utilizes a nasal speculum to hold the ear canal open for the insertion of the tubing attached to the cartridge injection tool down to the TM. The trained assistant squeezes the trigger of the cartridge injection tool to begin the flow of impression material while the clinician uses the tube to direct the filling of the ear canal and concha, taking care to keep the tube tip immersed in the impression material.

   **For both options:** (If the tube is pulled above the surface of the impression material, an air bubble or void may develop.) Avoid allowing the impression material to be in contact with contaminants including vinyl or latex gloves.
The patient should be instructed to open and close mouth at least every 30 seconds during the curing. A timer should be set for 8 minutes. Setup time is at least eight minutes and the earmold impression material should no longer feel sticky (tacky) to the touch. The impression is carefully removed from the ear canal by gently separating the impression from the helix and tragal area with an impression removal tool such as non-cutting Buck cerumen curette. The helix area of the impression can be gently twisted forward as the impression is gradually and slowly lifted out of the ear canal. It helps to have the patient open and close his or her jaw during extraction.

4. Examine the impression to verify adequacy of canal size and the depth to the tympanic membrane. A cast of the tympanic membrane should be seen on the medial end of the impression and the landmarks of the handle of the malleus and umbo clearly identifiable. If the impression is not deep enough or has voided area(s) produced by air/oil bubbles, Step 3 of this impression procedure should be repeated. Either an adequate impression is obtained or it is determined the canal size is inadequate in size or shape to accommodate the IPC. The Impression Template (provided in the Clinician’s Kit) is used to measure the dimensions of the impression. The minimum measurements of the canal area to accommodate the IPC are:

- 3 mm in canal diameter from the second bend of the canal to the medial end
- 4 mm in canal aperture width (canal opening)
- 20 mm for length from aperture to the medial end of the canal

5. Following the ear impression procedure, the clinician should visually inspect the ear canal and TM to ensure the health and integrity of those structures. Impressions should be sent to Ototronix for release of the implant after receipt and approval of the deep ear impression.
Surgical Factors

The surgical approach for implanting the internal portion of a MAXUM System is common otological surgery practice, and the implantation protocol has been standardized. The surgical protocol is designed to properly position and to maximize the stability of the implant.

Correct, stable attachment of the implant by the surgeon involves securing the Wireform Attachment Ring of the implant around the incudostapedial joint, obtaining proper axial alignment with the ear canal, and securing the implant in that orientation while minimizing disturbance to middle ear mucosa in order to minimize scar tissue formation. Scar tissue formation is variable and is influenced by the surgical procedure, placement of the implant in proximity to bony or soft tissue structures, and patients’ individual responses to surgery and healing. Scar tissue has the potential of attaching to the implant itself and pulling the implant out of its intended position. Scar tissue may be more pronounced in some patients than in others. However, the formation of a foreign body granuloma, since it is a pathological response to healing, may be preventable by minimizing contamination from foreign materials, such as talcum powder from gloves.

The placement site for the MAXUM implant, the incudo-stapedial joint, was originally selected not only for function but also for stability and safety and remains the preferred placement for this application. Incudostapedial positioning also provides the best site for minimizing movement of an implant by scar tissue retraction. Healing of an implant site without attachment of the implant to adjacent structures is important for both stability and maintenance of axial alignment with the electromagnetic coil of the IPC. The MAXUM implant’s placement on the incudo-stapedial joint provides the optimal position for an implant, i.e., farther away from soft tissues than any other site on the ossicular chain.

Figure 2: Implant
Surgical Preparation

GENERAL
The clinic chart, including audiogram, is carefully checked to verify identifying information, such as the name of the patient, the correct ear for surgery, allergies, and any systemic history of importance. Ensure that the correct implant is available for surgery (implant for left ear or right ear). The Implant packaging clearly identifies Left or Right.

PREOPERATIVE MEDICATION
Oral sedation, using a combination of atropine, a barbiturate, and an analgesic, is given 30-45 minutes prior to the surgical procedure. Intravenous access is achieved and a lactated ringer’s solution started to maintain patency.

Note: If a patient appears to be frightened or anxious, a 5 mg dose of diazepam can be administered intravenously prior to the first injection of local anesthetic. Trained operating room personnel, utilizing EKG and continuous pulse oximetry, monitor the patient’s cardiopulmonary status throughout the surgical procedure. If necessary, this dose of diazepam can be supplemented at 2.5 mg increments until a total dose of 10 mg has been delivered for an adult.

SURGICAL SITE PREPARATION
The ear is prepared with a povidone-iodine solution, or its equivalent, 20 minutes prior to the surgical procedure. The ear canal is filled with prep solution and the surrounding scalp scrubbed prior to draping. At the onset of the surgical procedure, the prep solution is removed by irrigating the ear with liberal amounts of sterile water. The patient’s hair need not be shaved but is retracted out of the surgical field.
SUGGESTIONS FOR POSITIONING THE PATIENT

The patient may be positioned on the surgical table with the table reversed so that the patient’s head is on the foot end of the table. This position allows the surgeon to have more room for his legs when seated. It is highly desirable that the table have automatic controls, which allow it to move in three dimensions: table up/down, side/side rotation, and head up/down. Controls are placed so that the buttons are easily palpable by the surgeon through the drapes.

The patient’s head is positioned on a small, two-inch thick flat foam pillow with a three-inch neck roll, which stabilizes the head comfortably. The patient’s head should rest near the end of the table, and the patient’s arm nearest the surgeon should be extended towards the knee in order to bring the shoulder down out of the surgical field, thereby increasing access to the ear.

The patient is draped in the usual fashion with a complete body drape followed by a regional ear drape, leaving only the external ear exposed. A canopy is created over the patient’s head utilizing a semicircular gooseneck “ether screen” which is positioned lateral to, and in front of, the head. This allows the monitoring nurse to see the patient’s face throughout the surgical procedure and provide reassurance as needed.

The suction tubing is connected to the surgeon-controlled variable foot pedal suction device (Hough-Cadogan foot pedal). The foot pedal is placed conveniently on the floor beneath the surgeon’s foot. This variable suction system allows the surgeon to control suction intensity throughout the surgical procedure. The surgical microscope should be lightweight, finely balanced, and maneuverable, outfitted with a 200 mm or 225 mm lens for middle ear surgery.

In order to prevent foreign body granuloma formation, it is extremely important for the surgeon’s hands to be thoroughly washed after being gloved to remove all traces of talcum powder, lint and fibers that could contaminate the instruments, the implant or the wound.
Surgical Procedure

ANESTHESIA

Local anesthetic is preferred for all patients except unusually tense individuals. In these occasional situations a general anesthetic may be preferable. The local anesthetic solution is composed of 2% lidocaine hydrochloride (Xylocaine) with 1:30,000 epinephrine and hyaluronidase (Wydase) added for enhancing tissue penetration. (Typically, 14 cc of 2% lidocaine solution is mixed with 0.5 cc of 1:1000 epinephrine and 0.5 cc of hyaluronidase.) The mixture is introduced through a 1 ml Luer-Lok syringe firmly attached to a 1½-inch 27-gauge needle. The initial injection is made in the soft tissues of the cartilaginous ear canal superiorly and inferiorly just medial to the conchal cartilage.

The next injection is given superiorly in the area of the vascular strip. A final injection is given inferiorly in the external canal at the junction of the thick skin at the external orifice and the thinner skin of the external canal. Excellent blanching caused by subperiosteal infiltration will be seen advancing towards the tympanic membrane. The total amount of anesthetic solution used ranges from 0.6 ml to 1.0 ml (Figure 3).
INCISION AND ELEVATION OF THE TYMPANOMEATAL FLAP

The tympanomeatal flap created during this procedure is identical to the technique utilized during stapedectomy or endaural tympanoplasty. The incision is made with a Rosen knife in a semilunar fashion with the limbs of the incision closer to the tympanic membrane superiorly and inferiorly. The arch of the incision is brought out laterally approximately 8 mm from the tympanic membrane (Figure 4).

The tympanomeatal flap is elevated superiorly to the notch of Rivinus (12 o’clock position) and inferiorly to the 6 o’clock position. A commercially-prepared No. 3 long-fiber cotton ball is placed against the tympanomeatal flap. This is very helpful in maintaining a dry field, protecting the flap, and assisting with flap elevation. Once the tympanic membrane annulus is identified, it is elevated out of the sulcus tympanicus and the middle ear space entered (Figure 5).
EXPOSURE OF THE OVAL WINDOW NICHE

Occasionally it will be necessary to remove bone from the posterosuperior canal wall to properly visualize the stapes and to minimize the formation of synechiae between the scutum and the implant. A serrated curette is engaged along the bony margin at the notch of Rivinus, and bone removal is performed until the pyramidal process and posterior crus of the stapes can be visualized. Care is taken to avoid trauma to the chorda tympani nerve. Bone chips are then removed from the field (Figure 6). Several drops of local anesthetic are instilled into the middle ear at this point to provide additional topical anesthesia and hemostasis.

EVALUATION OF THE OSSICULAR CHAIN

The oval window niche and ossicular chain are now evaluated. Cicatricial tissue around the incus and stapes are removed. The mobility of the ossicular chain should be assessed, and the position of the facial nerve confirmed. The location of the promontory in relationship to the incudostapedial joint and undersurface of the manubrium should be assessed. The attachment ring is designed so that the implant can be rotated into several positions, #1, #2, or #3 or any point in between (see Figure 7). Anatomical variations may preclude placing the implant in some positions. Usually the most preferable position is near #3.
 INSERTION OF THE IMPLANT

Several factors should be considered prior to insertion of the implant into the middle ear. The distance between the implant cylinder and the IPC as well as the orientation between the coil and magnet are critically important in optimizing performance of the MAXUM System. The strength of an electromagnetic field relates exponentially with the cube of the distance between the coil and implant magnet. The implant is designed with the attachment ring positioned off-center near the base of the magnet cylinder. This arrangement brings the cylinder as close as possible to the undersurface of the tympanic membrane while minimizing the chance of contact with the middle ear promontory. A safe reference point is a position in which the magnet cylinder does not project laterally beyond the long process of the incus (Figure 9).
The strength of the electromagnetic field is also dependent upon the alignment between the coil and implant cylinder. Optimal alignment is in the d plane. Any rotation of the implant away from axial alignment with the coil can significantly reduce gain. The implant has been designed with a 30 degree angle between the attachment ring and the cylinder in order to allow optimal alignment. This angle should never be altered because proper alignment might be disturbed and the integrity of the attachment ring compromised by excessive torque applied to it.

The implant should not be handled directly by the surgeon’s gloves since contamination of the implant by powder may occur. MAXUM surgical instruments are provided for the purpose of facilitating instrumental retrieval of the implant from its package and its handling during insertion. It is suggested that the implant be removed from its package using the MAXUM Cylinder-holding Forceps. Use of this instrument will prevent accidental dropping of the implant. Once removed from the packaging, the long end of the implant will then be accessible for grasping by either of two methods: first, by using the MAXUM Insertion Instrument with suction controlled by a foot pedal or second, by using the MAXUM Cylinder-holding Forceps. Both the forceps and the suction insertion instrument are designed to engage the long end of the magnet cylinder.

The implant is introduced into the middle ear and around the incudostapedial joint with the surgeon’s dominant hand. The opening in the coil is placed around the joint from the posterior side (Figure 10). A speculum holder may be utilized to stabilize the speculum during this part of the procedure, but this is usually not necessary.
Method A, continued

USE OF THE MAXUM INSERTION INSTRUMENT

When the non-magnetic, suction foot pedal-controlled MAXUM Insertion Instrument is used, the implant is held by suction in a properly-positioned alignment. It is then carried into the surgical field. Using the Insertion Instrument, the attachment ring is moved into position around the joint ensuring that the ring encircles the stapedial head (Figure 11).

Whether the Insertion Instrument or the Cylinder Holding Forceps are used, great care should be taken not to violate mucous membrane surfaces more than is absolutely necessary. This will minimize the chance of scar tissue formation.

ALTERNATIVE USE OF THE MAXUM CYLINDER-HOLDING FORCEPS

An alternative method of Wireform Attachment Ring insertion is the use of a non-magnetic MAXUM Cylinder-holding Forceps, either straight or angled (Figure 12). This delicate non-magnetic forceps has a smooth, open mouth that allows it to encircle and hold the magnet cylinder firmly without damage to its surface. The attachment ring should not be grasped by the forceps directly as this may damage its integrity. After grasping the implant magnet cylinder by the lateral end, the implant is introduced into the ear, and the attachment ring is aligned parallel to the incudostapedial joint. The ring is then moved into the joint space until it is surrounding the incudostapedial joint.
CLOSING OF THE SPLIT COIL

The implant is placed inferior and preferably posterior to the I-S joint (see page 19 for positioning discussion) and the split coil is rested over the stapedial tendon and under the long process or the incus (Figure 13). When positioned properly, the distal tip of the split coil should be visible anterior of the stapes. Once the implant is in place, the coil of the MAXUM implant must be closed. This is achieved by exposing the loop to a temperature above its transition point. At this temperature, the coil will close to its intended shape. We recommend the use of the low temperature heating devices SMart® Thermal Handle and SMart® Thermal Tip and Drape available from Gyrus ENT. These hearing devices have been tested with the wireform coil and are listed in List of Accessories, Reference Item #14 on page 32. Place the heating device approximately 0.5 mm from the open split coil (Figure 14). Activate the heating device to cause the open split coil to close. Testing has shown that the heating element reaches stable temperatures above the split coil transition point within three seconds. If the implant is not fully closed do not continue heating but rather reconsider heating device placement. Visually examine the implant to ensure that the coil is fully closed (Figure 11). Do not crimp the coil manually. Care should be taken to avoid contact between the heated tip and surrounding anatomy.

If using the MAXUM Insertion Instrument, the suction holding the implant may be released by lifting the foot off the suction foot pedal.

If using the Cylinder-holding Forceps, the forceps are then opened to release the implant.

End of instructions specific to Method A. Please proceed to page 28 to continue with the surgical implant procedure instructions.
Hough Attachment - Method B

Alternatively, this Method B developed for the full coil implant may be used (model numbers M210L and M210R). This technique involves the separation of the incudostapedial joint and the insertion of a full coil MAXUM implant. This method may also be used for split coil implants (model numbers M220L and M220R) in closed configuration.

SEPARATION OF THE INCUDOSTAPEDIAL JOINT

The incudostapedial joint capsule mucosa is delicately incised superficially with the MAXUM Incudostapedial Joint Knife-Sickle (Figure 15). The joint separation is completed either with this sickle knife or the MAXUM Incudostapedial Joint Knife-Round. The initial pressure in making this incision should always be made in an anterior direction with the stapedius tendon acting as a strut to hold the stapes securely stable in its position. This will minimize the likelihood of damage to the superstructure of the stapes (Figure 16).

OPENING THE JOINT SPACE FOR INTRODUCTION OF THE IMPLANT

The next step is the separation of the joint space enough so that the Wireform Attachment Ring of the implant (attachment ring) can be inserted and positioned to encircle the incudostapedial joint. The lenticular process of the incus must be lifted laterally away from the head of the stapes. This can be accomplished by lifting the long process of the incus laterally using a MAXUM Right Angle Hook (Left or Right) (Figure 17).
INSERTION OF THE IMPLANT

Several factors should be considered prior to insertion of the implant into the middle ear. The distance between the implant cylinder and the IPC as well as the orientation between the coil and magnet are critically important in optimizing performance of the MAXUM System. The strength of an electromagnetic field relates exponentially with the cube of the distance between the coil and implant magnet. The implant is designed with the attachment ring positioned off-center near the base of the magnet cylinder. This arrangement brings the cylinder as close as possible to the undersurface of the tympanic membrane while minimizing the chance of contact with the middle ear promontory. A safe reference point is a position in which the magnet cylinder does not project laterally beyond the long process of the incus (Figure 18).

The strength of the electromagnetic field is also dependent upon the alignment between the coil and implant cylinder. Optimal alignment is in the co-axial plane. Any rotation of the implant away from axial alignment with the coil can significantly reduce gain. The implant has been designed with a 30 degree angle between the attachment ring and the cylinder in order to allow optimal alignment. This angle should never be altered because proper alignment might be disturbed and the integrity of the attachment ring compromised by excessive torque applied to it.

Figure 18: Optimal alignment, close to TM, off promontory
The implant should not be handled directly by the surgeon’s gloves since contamination of the implant by powder may occur. MAXUM surgical instruments are provided for the purpose of facilitating instrumental retrieval of the implant from its package and its handling during insertion. It is suggested that the implant be removed from its package using the MAXUM Cylinder-holding Forceps. Use of this instrument will prevent accidental dropping of the implant. Once removed from the packaging, the long end of the implant will then be accessible for grasping by either of two methods: first, by using the MAXUM Insertion Instrument with suction controlled by a foot pedal or second, by using the MAXUM Cylinder-holding Forceps. Both the forceps and the suction insertion instrument are designed to engage the long end of the magnet cylinder.

The implant is introduced into the middle ear and into the incudostapedial joint with the surgeon’s dominant hand while the incus is suspended with the Right Angle Hook held by the non-dominant hand. A speculum holder may be utilized to stabilize the speculum during this part of the procedure, but this is usually not necessary.

**USE OF THE MAXUM INSERTION INSTRUMENT**

When the non-magnetic, suction foot pedal-controlled MAXUM Insertion Instrument is used, the implant is held by suction in a properly positioned alignment. It is then carried into the surgical field. Using the Insertion Instrument, the attachment ring is moved into position around the joint. (Figure 19). Once the ring encircles the stapedial head, the suction holding the implant is released by lifting the foot off the suction foot pedal. The incus is then released allowing the long process of the incus to rejoin the stapedial head through the attachment ring.

Figure 19: MAXUM Insertion Instrument
ALTERNATIVE USE OF THE MAXUM CYLINDER-HOLDING FORCEPS

An alternative method of Wireform Attachment Ring insertion is the use of a non-magnetic MAXUM Cylinder-holding Forceps, either straight or angled. This delicate non-magnetic forceps has a smooth, open mouth that allows it to encircle and hold the magnet cylinder firmly without damage to its surface. The attachment ring should not be grasped by the forceps directly as this may damage its integrity. After grasping the implant magnet cylinder by the lateral end, the implant is introduced into the ear, and the attachment ring is aligned parallel to the incudostapedial joint. The ring is then moved into the joint space until it is surrounding the incudo-stapedial joint. The forceps are then opened to release the implant (Figure 20).

Whichever method is used, great care should be taken not to violate mucous membrane surfaces more than is absolutely necessary. This will minimize the chance of scar tissue formation.

The lateral suspension of the incus is then gradually released until the lenticular process of the incus is returned back to its normal joint position against the head of the stapes (Figure 21). Due to the normal elastic (memory-like) spring of the incus, the joint surfaces of the incus and stapedial head are reunited. The lenticular surfaces of the incus and head of the stapes will reappose inside the attachment ring, allowing firm reunion with fibrous tissue and surrounding mucous membrane. The attachment ring is examined microscopically to verify that it is completely encircling the head of the stapes.

End of instructions specific to Method B.
IMPLANT ALIGNMENT

The attachment ring is then adjusted (by moving the ring slightly in a clockwise or counterclockwise direction) so that the magnetic cylinder is axially aligned with the ear canal. Care should also be taken to make sure that the promontory does not come into contact with the undersurface of the implant cylinder as this increases the risk of synechiae formation and may diminish implant performance.

It is essential that only provided MAXUM nonmagnetic instruments, such as the MAXUM Right Angle Hooks or the MAXUM Right Angle Pick, be used in the middle ear following implant insertion in order to avoid implant displacement. (See List of Accessories in this manual for a complete listing of instruments specially designed for use with the MAXUM implant.)

It is very important that proper alignment of the magnet be achieved. This is accurately accomplished by the following:

- The surgeon looks straight down the external ear canal. This will be the same axis as will be occupied by the external ear canal mold post-operatively. The magnet cylinder can then be moved so that the flat end of the cylinder is seen “head on”. When the cylinder is in the optimal position, the sides of the cylinder will be obscured evenly by the flat surface end of the cylinder. The surgeon’s line of vision will thus be exactly in the same alignment as will be the IPC coil that will be placed post-operatively (Figure 22).
Utilizing the nonmagnetic MAXUM Gentle Curved Pick, small pieces of Gelfoam soaked with Physiosol (balanced physiologic salt solution) are inserted to form a temporary resorbable wet cast around the implant. Within a few minutes during the postoperative period, the Gelfoam will contain a blood clot. This not only maintains the position of the implant, but also provides a nutritional cast for enhancement of mucous membrane healing during the postoperative period (Figure 23). If anatomically indicated, Gelfilm™ (solid gelatin sheet) can be cut into tiny slivers to cover any other areas denuded of mucous membrane. These materials will be resorbed slowly (approximately 6-8 weeks) holding the implant in position until it is permanently attached and preventing the formation of scar bands. The authors recommend that synthetic materials, such as sialastic sheeting, not be used in the middle ear.

UNUSUAL ANATOMICAL CONSIDERATIONS

When a high promontory is encountered the implant cylinder may be rotated either anteriorally (toward position #1 of Figure 7) or posteriorally (toward position #3 of Figure 7) in relationship to the promontory to reduce the risk of post-operative fixation. If the implant cylinder touches or closely approaches the underneath surface of the tympanic membrane, extrusion of the implant or perforation of the tympanic membrane may occur. To minimize the likelihood of these occurrences, a small cap of tragal or conchal cartilage should be interposed between the implant and tympanic membrane. The cylinder should not project laterally beyond the lateral surface of the incus’ long process.
CLOSURE

The tympanomeatal flap is replaced using a nonmagnetic instrument, such as the MAXUM Derlacki Mobilizer, so that the incision lines are reapproximated. (Figure 24) Gelatin sponge strips soaked with Physiosol are placed over the incision lines, and an expandable cellulose wick (Pope Oto-Wick) is placed in the ear canal. A cotton ball is then applied to the ear canal. No other head dressing is needed.

Figure 24: Tympanomeatal Flap Replaced
Post-Operative Care

The patient is discharged the day of surgery and a follow-up appointment arranged in one week. A written instruction card, “Post-operative Precautions for MAXUM Users” is provided to the patient outlining special precautions and routine care guidelines. (A sample of this card is shown in the section titled “Post-Operative Instructions for MAXUM Users” of this Surgeon’s Manual.)

Prophylactic antibiotics are not routinely recommended postoperatively, but the patient is instructed to report fever >99.5, purulent otorrhea, worsening discomfort, progressive hearing loss, or dizziness/vertigo. During the first post-operative visit, one week following surgery, the Oto-Wick is removed from the ear canal and the ear inspected. Care should be taken to avoid placing a suction or other metal otologic instrument into the ear canal medial to the bony/cartilaginous junction unless that instrument is nonmagnetic.

Special precautions are taken to minimize the likelihood of implant displacement during the healing period (8 weeks post operatively). Patients are cautioned to avoid blowing their nose and are told to sneeze with their mouth open. Contact sports are forbidden during this time.

Routine audiometry is performed at the second post-operative visit, eight weeks following surgery. The status of the ear canal and tympanic membrane are re-evaluated at this time, and the remainder of the gelatin packing is removed from the ear canal. It is safe to use magnetic instruments in the ear canal during this and subsequent visits.
List of Accessories for Implanting the MAXUM System

1. Insertion Instrument (non-magnetic)
2. Right Angle Pick
3. Gentle Curved Pick (non-magnetic)
4. Derlacki Mobilizer (non-magnetic)
5. Incudostapedial Joint Knife, Sickle
6. Incudostapedial Joint Knife, Round (sharp, fine, 1/3 mm) (non-magnetic)
7. Right Angle Hook, right (turned 90° right) (non-magnetic)
8. Right Angle Hook, left (turned 90° left) (non-magnetic)
9. Suction Luer Lock Device, 22 Gauge
10. Suction Luer Lock Device, 20 Gauge
11. Cylinder-holding Forceps (straight) (non-magnetic)
12. Cylinder-holding Forceps (angled) (non-magnetic)
13. Straight Holding Forceps, Flat (non-magnetic)
14. Heating Device for use with MAXUM Split Coil (model numbers M220L and M220R): Ototronix does not supply the heating device required for closing the Split Coil implant. Recommended heating device is the SMart® Thermal Handle and SMart® Thermal Tip and Drape available from Gyrus ENT (Catalog No. 7013-1012 & 7013-1013).
Post-Operative Instructions for MAXUM Users

1. Do not exercise or move your head quickly for the first two weeks post-operatively.
2. Do not engage in vigorous exercise or contact sports, such as basketball, football, soccer, hockey, etc., for three months.
3. Do not wear the IPC in the ear canal when engaging in contact sports at any time.
4. Do not blow your nose for three weeks. Any accumulation in the nose may be drawn back and expectorated through the mouth.
5. Keep your nose and mouth open while sneezing.
6. Flying is permissible after one week, but only on commercial airlines for the first month.
7. Do not blow on musical instruments for three weeks.
8. Change cotton in ear daily for one week. Use only sterile cotton. Wash your hands for 2 to 3 minutes with soap and water before touching your ear. If necessary, the external ear may be cleansed with cotton dampened with rubbing alcohol.
9. Do not wash your hair or get water in the ear for one week post-operatively and keep water out of the ear canal for three weeks. A cotton plug placed in the canal and covered with Vaseline will prevent water entering the ear while washing the face or taking a shower.
10. Do not use Q-tips to clean your ear.
11. Do not be concerned with your hearing. It is very normal for the hearing to regress a few hours after surgery. It will be very distorted and poor for some time. Do not be discouraged over this. Often the hearing will be poor initially but will continue to improve for many weeks after surgery.
12. Call your physician if you develop a cold or have an elevation in temperature above normal. Please call if you should have excessive pain or dizziness during the first few weeks following surgery. Call if there is excessive pain or drainage. (A small amount of bloody drainage on the cotton the first few days after surgery is not unusual.)
13. No swimming for two months. Avoid diving until advised.
14. Later, when you are using your MAXUM device, report to your doctor any swelling or pain you experience in the external ear canal.
15. Schedule an appointment to have your pack removed as instructed by your physician.
CLINICAL CONSIDERATIONS

Evaluation procedures should include standard audiometric measures including air and bone-conduction thresholds, immittance measures, speech recognition, and hearing aid evaluation. Additionally, qualitative (subjective) 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 subject’s perceived lack of benefit from the hearing aid(s) is not attributable to poor fit or lack of function. The ear selected for implantation of the MAXUM System should be equal to or worse than the non-implant ear. The safety and effectiveness of bilateral implantation and implantation in pregnant women, nursing mothers, children, or those with unilateral hearing impairment has not been established.

Adverse Events—MAXUM System (BTE) Study

Summarized in Table 1 are the adverse events reported on a total of 103 subjects reported as of April 4, 2001. Four (4) subjects were reported as having serious adverse events, all of which were determined by a physician to be “definitely” unrelated to the device. The events included a cardiovascular disorder, carcinoma, and two (2) deaths.

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<th>Description</th>
<th>No. Reported</th>
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<tr>
<td>Infection</td>
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<tr>
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<td>0</td>
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<td>Transient Balance Involvement</td>
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<td>5</td>
</tr>
<tr>
<td>Tympanic Membrane Damage</td>
<td>6</td>
<td>5</td>
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</table>
Investigator reported abnormal ear sensation consisting of fullness; event resolved during the normal healing period after implant.

Engineering analysis determined these events to be associated with the Printed Circuit Board (PCB) assembly operation. The operation has been modified and validated. Low levels of EMI have been found to be dependent upon the location and strength of the electromagnetic source. Three events reported as unresolved were due to their intermittent nature and will be monitored by the Investigator at the subjects’ next visits.

Investigator reported middle ear effusion; event resolved during the normal healing period after implant.

Engineering analysis of the ECAs resulted in improved manufacturing processes and controls that have been implemented to eliminate systematic failures.

These events were related to the operative procedure or to the ECA fitting. In most of the cases these events resolved through longer healing periods postimplant or through ECA modifications. The Investigator is continuing to monitor the 2 subjects whose events were reported as unresolved.

Audiological data indicated that the hearing loss appears to be conductive. Investigator reported that he will continue to monitor the subject.

Each of the reported hematomas resolved through normal healing.

The infections also included Otitis Media (2) and Otitis Externa (2). Each of the reported events resolved through otologic management.

Outer ear irritation consisted of ear irritation (7), ear canal abrasion (2), ear edema (2), ear inflammation (2), and ear abrasion external (1).

The investigator reported this event as a transient neurological effect.

Processor failures were determined to be associated with the PCB assembly operation. The operation has been modified and validated. Analysis of the unresolved processor failure was in-process at the submission of this data.

Several observations of skin irritation were reported, including Eczema (2) and Pruritis (1). The investigators noted that each event was resolved.

Taste perversion 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. One case remains unresolved and will be monitored by the Investigator.

Subject medical records noted a past history of tinnitus. This case will be monitored by the Investigator.

Transient balance involvement comprised of reports of dizziness (1), nausea (1), vertigo (2), and vomiting (1). Each event resolved spontaneously.

Four reported events were resolved through surgical intervention and one event resolved without intervention. One event is not resolved and the Investigator is monitoring the subject. (Non-serious adverse events unrelated to the device are not included in Table 1. These events consisted of: Unconfirmed ECA/Sound Processor failures (16), broken ECAs due to user abuse, improper use, or adjustments that damaged the device (7), tooth disorder (1), and infection in the non-implant ear (1)).
Potential Adverse Events

Surgery of the middle ear requires manipulation of the 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 include, but are not limited to: sensorineural or conductive deafness due to trauma during surgery; granular inflammatory lesions; device displacement after surgery due to development of scar tissue; damage to the incus; non-functioning implant; and infection after surgery. Additional surgery may be required to correct these conditions, if possible. There may also be numbness, swelling or discomfort around the ear, the possibility of facial paresis, and/or the disturbance of balance or taste, but they are usually transient and resolve within a few weeks after surgery.

Implant Device Failures and Replacements

There were no implant device failures, revisions or replacements reported in the MAXUM System (BTE) study. Some failures of the external Sound Processor and Earmold Coil Assembly were noted and analyzed. Improved manufacturing processes and controls have been implemented to eliminate systematic failures.
Clinical Study Summary: MAXUM IPC System with a Digital Processor

A limited confirmatory study of the IPC with a digital processor was conducted on a subset of 10 subjects, 9 of which were from the original (BTE) study, with similar results.

Clinical Study Summary: MAXUM IPC System with an Analog Processor

A limited confirmatory study of the IPC with an analog processor was conducted on a subset of 10 subjects from the original MAXUM System (BTE) study, with similar results.

Clinical Study Summary: MAXUM BTE System

One hundred-three (103) subjects underwent the implant procedure with the MAXUM BTE System and were fit with the BTE style Sound Processor. The following clinical study summary is based on ninety-five (95) subjects who had completed 20-week assessments. The assessment compared preoperative results with an optimally fit acoustic hearing aid in the ear to be implanted to post operative results with the MAXUM System. “Optimally fit” as defined by the clinical study included insertion gain matching using National Acoustic Laboratories-Revised (NAL-R) prescriptive target ranges (+5 dB for 500, 1000, and 2000 Hz and +12 dB for 3000 and 4000Hz) and evidence of improvement in aided benefit.

Subjects were tested to find hearing thresholds, sound field thresholds, speech testing in quiet and noise, aided benefit, and subject perceptions.

All items showing improvements were determined to be statistically significant. For more detailed information about the MAXUM System (BTE), please refer to the section below on Clinical Study Results.

1. For most subjects, the change in residual hearing was not significant. Average decrease in air conduction thresholds at 20 weeks was 4.2 dB across the frequency range of 250 to 8000 Hz. Average bone conduction thresholds decreased by 1.1 dB. Few subjects (10/95 or 10.5%) had greater than 10 dB of change by air conduction. Few subjects (4/95 or 4%) had greater than 10 dB of change by bone conduction.

2. There was an average increase in functional gain of 7.9 dB with the MAXUM compared to their acoustic hearing aid. For the high frequencies of 2000, 3000, and 4000 Hz, there was an average increase in functional gain of 9.6 dB.
3. The Articulation Index score results showed an improvement of 11.9% with the MAXUM. The MAXUM System shows an improved audibility over acoustic hearing aids.

4. Speech recognition in quiet showed a 5.3% improvement with the MAXUM when compared with the subjects’ Acoustic hearing aids.

5. Speech testing in noise results with the Speech Perception in Noise (SPIN) test showed no difference between the MAXUM System and acoustic hearing aids.

6. The Abbreviated Profile of Hearing Aid Benefit (APHAB) scores showed an improvement of approximately 20% across three different sub-scales with the MAXUM when compared to acoustic hearing aids.

7. When subjects compared their pre-implant acoustic hearing aid with the MAXUM in the Hough Ear Institute Profile* (HEIP) test, the results showed that:
   
   a. Out of 94 subjects responding, 84 of those subjects (89%) preferred the MAXUM in terms of overall satisfaction.

   b. Sixty-three of 94 subjects (67%) reported feedback with their acoustic hearing aids. Eight of 94 subjects (8.5%) reported feedback with the MAXUM. Out of 94 subjects responding, 93 of them (99%) preferred the MAXUM as having the least amount of feedback.

   c. Fifty of 92 subjects (54%) reported occlusion with their acoustic hearing aids. 21 of 92 subjects (23%) reported occlusion with the MAXUM.

   d. Out of 94 subjects responding, 84 of those subjects (89%) responded that they preferred the MAXUM over their acoustic hearing aids in the areas of sound quality.

   e. Twenty-one of 41 (51%) subjects reporting tinnitus pre-implant reported that their hearing aid decreased their perception of tinnitus. Twenty of 30 (67%) subjects reporting tinnitus post-implant reported that the MAXUM System decreased their perception of tinnitus.

*HEIP is a validated but not standardized questionnaire addressing the subjects’ perception of the presence of tinnitus, feedback, and occlusion as well as sound quality judgments and device preference.
Clinical Study Results: MAXUM IPC System with a Digital Processor

A limited confirmatory study of the IPC with a digital processor was conducted on a subset of 10 subjects, 9 of which were from the original (BTE) study, with similar results.

Clinical Study Results: MAXUM IPC System with an Analog Processor

A limited confirmatory study of the IPC with an analog processor was conducted on a subset of 10 subjects from the original (BTE) study, with similar results.

Clinical Study Results: MAXUM System (BTE)

One hundred-three (103) subjects underwent the implant procedure with the MAXUM System implant and were fit with the BTE style sound processor. The following clinical study summary is based on ninety-five (95) subjects who had completed 20-week assessments. The assessment compared preoperative results with an optimally fit acoustic hearing aid in the ear to be implanted to post operative results with the MAXUM System. Optimally fit, as defined by the clinical study, included insertion gain matching using National Acoustic Laboratories-Revised (NAL-R) prescriptive target ranges (±5 dB for 500, 1000, and 2000 Hz and ± 12 dB for 3000 and 4000 Hz) and evidence of improvement in aided benefit. Subjects were tested to find hearing thresholds, sound field thresholds, speech testing in quiet and noise, aided benefit, and subject’s perceptions.

RESIDUAL HEARING

For most subjects (85 of 95 or 89.5%), residual hearing with the MAXUM System was not significantly affected. Average decrease in air conduction thresholds at 20 weeks was 4.2 dB across the frequency range of 250 to 8000 Hz. Average bone conduction thresholds decreased by 1.1 dB. Few subjects (10 of 95 or 10.5%) had greater than 10 dB of change. Eight of 95 subjects (8%) experienced a change between 10 to 15 dB in hearing thresholds and 2 of 95 subjects (2%) experienced a change greater than 15 dB.
INCREASED FUNCTIONAL GAIN AND AIDED THRESHOLDS

The MAXUM System provided 7.9 dB additional functional gain when comparing the subject’s acoustic hearing aid performance to that of the MAXUM Systems at the 20 week assessment. The MAXUM demonstrated a statistically significant improvement in averaged aided sound field thresholds and functional gain from 500–4000 Hz. At 36 and 52 weeks, the additional functional gain was 7.9 dB and 7.0 dB, respectively. All three (3) time points, showed a statistically significant gain in average functional gain (each p-value < 0.05, Paired t-test).

Additional functional gain is needed to compensate for the residual hearing threshold change. Aided thresholds are improved with the MAXUM System regardless of the decrease in residual hearing. Individual results will vary.

The figure at right shows aided thresholds comparing the MAXUM to the acoustic hearing aid.

A similar analysis was performed for the high frequency average of 2000, 3000 and 4000 Hz (referred to in the protocol as the High Frequency Warble Tone Average-HFWTA of functional gain). The average improvement in the high frequency range at 20 weeks compared to performance with an acoustic hearing aid is 9.6 dB. At 36 and 52 weeks, the average improvement in HFWTA is 9.2 dB and 10.8 dB, respectively. At each of the three (3) time points, the improvement from performance with an acoustic hearing aid achieved statistical significance (each p-value < 0.05, Paired t-test).
CHANGE IN ARTICULATION INDEX

A secondary outcome measuring audibility is the Articulation Index (AI) and was assessed at pre-implant and 20 weeks. The AI was used to calculate the level of audibility based on aided hearing thresholds. The average improvement in Articulation Index scores comparing performance with the MAXUM to the acoustic hearing aid was 11.9%. The improvement was statistically significant (p-value < 0.05, Paired t-test).

SPEECH PERCEPTION RESULTS

There are two (2) additional secondary efficacy measures of performance using audiometric speech tests. These consist of the NU-6 (50-item word list) and the Speech Perception In Noise (SPIN) test. Tables 2 and 3 show the results on the aided NU-6 test and the SPIN (aided, low predictability sentences-raw scores) test. The results indicate average improvements with the MAXUM on the NU-6 performance of 5.3%, 5.0%, and 12.2% across the 20, 36, and 52-week assessments, respectively. The NU-6 improvement from the acoustic hearing aid to the MAXUM was statistically significant at the 20 and 52-week follow-ups. On average, SPIN scores were similar pre-implant and post-implant at the 20 and 36 week assessments.

The average change in SPIN aided, low predictability sentences at 20 weeks was -0.1 words. For the 36 and 52-week follow-ups, the average improvements were 0.1 words and 4.2 words. The SPIN improvement from the acoustic hearing aid to the 52-week follow-up was statistically significant (p-value = 0.0135, Paired t-test).
IMPROVEMENTS IN PERCEIVED AIDED BENEFIT IN VARIOUS LISTENING SITUATIONS

The Abbreviated Profile of Hearing Aid Benefit (APHAB) is a questionnaire used to assess the subject’s perceived performance benefit in three areas: Ease of Communication (EC), Reverberation (RV), and Background Noise (BN). These were reported at pre-implant using the subject’s acoustic hearing aid and at 20 weeks using the MAXUM System. On average, the hearing aid condition provided a score of 34.7 points of aided benefit and the MAXUM 20 week condition provided a score of 42.2 points of aided benefit for the three subscales. While individual results varied, the average improvement across the three subscales is 7.2 ±19.9 points of improvement of aided benefit which is statistically significant.
Out of 94 subjects responding, 84 of those subjects (89%) preferred the MAXUM in terms of overall satisfaction. Satisfaction was measured by a four point scale with four being very satisfied and one being not at all satisfied. Using this scoring method, satisfaction with the MAXUM increased by an average of 30.8% (median = 16.7%) from the subject’s acoustic hearing aid (p-value < 0.0001, Paired t-test).

- Sixty-three of 94 subjects (67%) reported having feedback with their acoustic hearing aid. At 20 weeks, only 8 (9%) subjects reported feedback using the MAXUM System (p-value < 0.0001, McNemar’s Test). Out of 94 subjects responding, 93 subjects (99%) preferred the MAXUM as having the least amount of feedback.

- Subject Perceived Quality of Speech was rated by a 7-point scale. The mean percentage increase relative to the subject’s optimally fit hearing aid equaled 27.8% (median =19.2%) for the MAXUM (p-value< 0.0001, Paired t-test).

- Out of 94 subjects responding, 84 of those subjects (89%) responded that they preferred the MAXUM over their acoustic hearing aids in the area of sound quality.

- Fifty of 92 subjects (54%) reported occlusion with their acoustic hearing aids. 21 of 92 subjects (23%) reported occlusion with the MAXUM using the MAXUM System (p-value < 0.0001, McNemar’s Test). (Two of 94 subjects did not respond to the question concerning occlusion).

- Twenty-one of 41 (51%) subjects reporting tinnitus pre-implant reported that their hearing aid decreased their perception of tinnitus. Twenty of 30 (67%) subjects reporting tinnitus post-implant reported that the MAXUM System decreased their perception of tinnitus.
STORAGE, HANDLING AND STERILIZATION

See TECHNICAL SPECIFICATIONS section for information about storage conditions.

An expiration date is printed on the implant device packaging. Do not use expired product. The Surgeon’s Set components are not subject to aging.

Handle the MAXUM System package with care. Damage to the outer storage package may rupture the inner sterile tray. The MAXUM Systems’ implant is supplied sterile. Before opening, inspect the sterile package for integrity and to ensure the seal is not broken. If the package or seal is damaged return the device to Ototronix.

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

For storage, handling and sterilization information for other components of the MAXUM System, see Clinician’s Guide.

INFORMATION FOR USE AND RECOMMENDED TRAINING

Surgeons should be experienced in middle ear surgery including stapedectomy. It is recommended that surgeons receive specific training regarding the deep ear impression procedure and implantation technique of the MAXUM System. It is strongly recommended that a surgeon work closely with a clinician when selecting candidates to be implanted and during the post operative management of patients. Surgeons should refer to the Ototronix MAXUM System Surgeon’s Manual for specific instruction for use.
SAFETY

This manual contains information and warnings, which must be followed to ensure safe performance of the MAXUM System. Local government rules and regulations, if applicable, should also be followed at all times.

Glossary of Symbols

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<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Non-ionizing radiation</td>
</tr>
<tr>
<td></td>
<td>Store at temperatures between -10°C and +55°C (14°F and 131°F)</td>
</tr>
<tr>
<td></td>
<td>Caution: Federal Law restricts this device to sale by or on the order of a physician</td>
</tr>
<tr>
<td></td>
<td>Single Use Only</td>
</tr>
<tr>
<td></td>
<td>Sterilized using Ethylene Oxide</td>
</tr>
<tr>
<td></td>
<td>Date of Manufacture</td>
</tr>
<tr>
<td></td>
<td>Use By (Expiration Date)</td>
</tr>
<tr>
<td></td>
<td>Keep Dry</td>
</tr>
<tr>
<td></td>
<td>Store at Relative Air Humidity of 95% or Less</td>
</tr>
</tbody>
</table>
TECHNICAL SPECIFICATIONS

Component List

MAXUM Implant Assembly:
- MAXUM Implant Assembly, Full Coil, Left Ear (M210L); MAXUM Implant Assembly, Full Coil, Right Ear (M210R)
- MAXUM Implant Assembly, Split Coil Left Ear (M220L); MAXUM Implant Assembly, Split Coil, Right Ear (M220R)
- Surgeon’s Manual (403-0004-001)

MAXUM Surgeon’s Set (M7000):
- See page 32 for full component list

Operating Environment

Temperature: -10°C to +55°C (14°F to 131°F)
Rel. Humidity: <95%, non-condensing
Air Pressure: 500 hPa to 1060 hPa

Storing and Handling

Temperature: -10°C to +55°C (14°F to 131°F)
Rel. Humidity: <95%, non-condensing
Clinical Support:
(877) 410-4327 or (281) 203-0250
support@ototronix.com

Ototronix, LLC
26620 I-45 North
Houston, Texas 77386 USA
www.ototronix.com

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