3

Instructions for Use

Esteem™

IMPORTANT:
Reference the Operator's Manual for equipment setup/use, implant procedures, and device programming instructions for use. Reference the Surgeon's Manual for details of the implant procedure. Note: Implantation of the Esteem® and the Surgeon's Manual are restricted to surgeons who have successfully completed the Esteem® surgical training.

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Envoy Medical Corporation

CE
0344
Authorized 2006

004382-001 Rev 02

CAUTION:
Federal Law restricts this device to sale by or on the order of a physician.

CAUTION:
The practitioners who may implant this device require specific training. Please contact Envoy Medical Corporation for more information.

Esteem®
The Hearing Implant™

Table of Contents

Esteem® Product Information

Training Requirement:
Implantation of *Esteem*® requires training by Envoy Medical Corporation on the indications, instructions for use and surgical application.

Product Description:
The implanted *Esteem*® uses a patented design based on two piezoelectric transducers and a Sound Processor. The first transducer, the Sensor, is connected to the ossicular chain.

The Sensor is a transducer which detects the motion of the tympanic membrane in response to sound and converts this vibration to an electrical signal. This electrical signal is transmitted to the Sound Processor, where it is modified for the patient's hearing needs. This modified electrical signal is then sent to the second transducer, the Driver, which is attached to the stapes.

The Driver is a transducer that receives the enhanced electrical signal from the Sound Processor and converts it into mechanical vibration to drive the stapes.

The implanted components of the *Esteem* include the Sensor, Driver and Sound Processor.

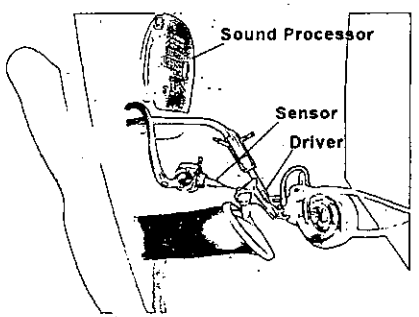

Figure 1: Middle Ear

The *Esteem* uses the natural sound vibrations of the tympanic membrane as a microphone. These sound vibrations generate input signals to the Sensor that are similar to those received by a person with normal hearing.

The *Esteem* is designed to improve the hearing of many adult patients who suffer from moderate to severe hearing loss that is sensorineural in origin.

Indications:
The *Esteem*® is intended to alleviate hearing loss in patients by replicating the ossicular chain and providing additional gain. The *Esteem*® is indicated for patients with hearing loss who meet the following criteria:

- 18 years of age or older
- Stable bilateral sensorineural hearing loss
- Moderate to severe sensorineural hearing loss defined by **Pure Tone Average** (PTA)
- Unaided speech discrimination test score greater than or equal to 40%
- Normally functioning Eustachian tube
- Normal middle ear anatomy
- Normal Tympanic Membrane
- Adequate space for *Esteem*® implant determined via high resolution CT scan
- Minimum 30 days of experience with appropriately fit hearing aids

Contraindications:
Esteem® is contraindicated under the following conditions:

- History of post-adolescent chronic middle ear infections, inner ear disorders or recurring vertigo requiring treatment, disorders such as mastoiditis, Hydrops or Meniere's syndrome or disease
- Known history of fluctuating air conduction and/or bone conduction hearing loss over the past one year period of 15 dB in either direction at 2 or more frequencies (from 500 to 4000 Hz)
- History of otitis externa or eczema for the outer ear canal
- Cholesteatoma or destructive middle ear disease
- Retrocochlear or central auditory disorders
- Disabling tinnitus, defined as tinnitus which requires treatment
- History of keloid formation
- Hypersensitivity to silicone rubber, polyurethane, stainless steel, titanium and/or gold
- A pre-existing medical condition or undergoing a treatment that may affect healing process
- During pregnancy

WARNINGS

Avoiding Head Injury:
After the *Esteem*® is implanted, the recipient should avoid contact sports or other activities that could result in a head injury. Participation in contact sports may result in damage to the patient's hearing or the *Esteem*® implanted components.

Electroconvulsive Therapy
Electroconvulsive Therapy (ECT) must never be used on a patient who has an implanted *Esteem*® because it may damage the patient's hearing or the *Esteem*®.

Electrosurgery
If electrocautery is used, ensure that the *Esteem*® is turned off. Never allow current from an electrosurgical (electrocautery) instrument to be applied directly to an Esteem component, to avoid the risk of damage to the implanted component or to the patient's hearing. Use only a bipolar electrocautery system and never over or near the *Esteem*® implant.

Magnetic Resonance Imaging
Recipients cannot undergo Magnetic Resonance Imaging (MRI) examination or be in close proximity to MRI devices after having had *Esteem*® implanted. Fields produced by the MRI may damage *Esteem*® or cause it to operate improperly.

Avoiding High Pressure
After the *Esteem*® is implanted, the patient should avoid diving to depths more than 10 meters (30 feet) of water as this may result in damage to the *Esteem*®.

Esteem®
The Hearing Implant™

Cell Phone Use/Cell Phone Compatibility

Because there are a wide range of cellular telephones and other wireless devices on the market, it is not possible to ensure *Esteem*®compatibility with all products. In a clinical study that included 70 subjects, seven subjects (10%) reported experiencing noise or feedback when using a cellular or wireless device. In all cases, the noise or feedback only occurred during cellular or wireless device usage and had no long term effects on *Esteem*® or the subject. If unpleasant noise or feedback occurs when using *Esteem*®with a cellular or wireless device, the patient should discontinue use of the cellular or wireless device with the ear that has the *Esteem*®.

PRECAUTIONS

Physical Activities and Sports

Patients should avoid contact sports and physical activities that could result in a hard blow to their head. Patients should avoid diving deeper than 10 m (30 ft) of water, as this may result in damage to *Esteem*®. Questions concerning activities should be directed to a Health Care Professional.

Pushing or Twisting the Implanted Parts of the *Esteem*®

Patients should avoid pushing or twisting the implanted parts of *Esteem*®, such as the Sensor and Driver leads. Either action can cause skin erosion or damage to various parts of the *Esteem*®. Skin erosion or *Esteem*®damage may require surgery to correct.

Travel

Esteem® may set off security devices in airports. If it does, an identification card (provided by Envoy Medical after implantation) should be shown to the security guard. Security systems and metal detectors could temporarily interrupt your hearing. To restore normal hearing, a patient should simply move away from the source of interference. All people while traveling experience pressure changes of the middle ear during flight. *Esteem*® recipients should expect to experience the same subtle changes in hearing and periods of temporary plugged sensation during air travel.

Electrical Devices

Esteem® is designed to be resistant to interference produced by other electrical equipment such as household appliances. Patients may safely operate all common household appliances and office equipment. It is possible that while operating these appliances or equipment the patient may hear noise/interference, however the programming is unaffected. Moving away from the source will, in most cases, mitigate any potential interference.

Clothing and Protective Equipment

Helmets and hats do not present a problem as long as they do not put a significant amount of pressure on the side of the head behind the ear where the Sound Processor is implanted. As customary in loud environments, the use of an earplug is recommended.

ADDITIONAL PRECAUTIONS

If a patient is going to undergo a medical treatment or diagnostic procedure, notify the physician about *Esteem*®. The effects on the *Esteem*® of positron emission tomography (PET) scans, ultrasound, diathermy, radiation, lithotripsy, radio frequency (RF) ablation, transcutaneous electrical nerve stimulation (TENS), and other electronic therapies have not been tested. If a patient requires such treatment, consult with Envoy Medical for current safety information regarding these therapies. During all these types of therapies the *Esteem*® device should always be turned off to avoid interference noises. X-Ray image quality directly around the implant could be compromised. Please avoid electroconvulsive therapy on or near the Sound Processor implant. During emergency use of a defibrillator, the *Esteem*® should be switched off to avoid interference noises. If emergency defibrillation is necessary or elective cardioversion is desired, the *Esteem*® performance and integrity should not change. If Esteem is left on (active) during these procedures, the patient may hear interference and performance could change temporarily, however the long-term performance and integrity should not change whether left on (active) or turned off (standby mode). If the patient believes they have experienced any changes after this procedure, please contact the implanting surgeon or Envoy Medical Corporation.

- If a profession requires vicinity of a high electrical current, consult Envoy Medical before engaging in such activities.
- People who smoke need to be aware that smoking can affect healing after any surgical procedure, including implantation of Esteem®.
- People with diabetes that is not well controlled with medication or diet need to take extra precaution with their surgeon to discuss post-operative healing issues.
- Air-bone gap indicating a conductive or mixed hearing loss has not been studied with *Esteem*®.
- Implanting surgeons should consider psychological, developmental, physical, or emotional disorders before implanting this device.

Explanted Devices:

All explanted components should be returned to Envoy Medical. A bio-safe return mailer kit is available.

To avoid the risk of explosion, never incinerate a Sound Processor. If a patient who has an *Esteem* implanted desires to be cremated upon death, the Sound Processor should be explanted before cremation.

Environmental Hazards:

The *Esteem* is designed to be resistant to electromagnetic interferen (EMI). However, it is possible that radio frequency (RF) sign generated by security systems, microwave equipment, or other devices might introduce static to the *Esteem* system. While such st may result in noise heard by the patient, the system programr is unaffected.

Shelf Life:

Notice the USE BY DATE on the package labels. Do n the part after the USE BY date has passed (example shown 30-SEP-2006).

Esteem® Product Information

2006-09

Mechanical Shock:
The Envoy Medical *Esteem*® is manufactured and packaged in handling containers that are made to withstand reasonable mechanical shock. However, if a unit has been removed from its handling container and is dropped, it may be damaged. If an unpacked unit is dropped, do not implant it. Instead, return it to Envoy Medical.

Sterile Package Handling:
Ensure the package seals and sterile trays are intact and have not been exposed to moisture, opened, punctured, contaminated, or damaged in any way that might compromise sterility.

NOTE: Additional instructions for opening the sterile packaging are described in "Preparing the Esteem Implantable Components" in the Operator's Manual.

Environmental Specifications:
Operating Temperature: 35°C to 40°C (95°F to 104°F)
Storage Temperature: 4°C to 30°C (39°F to 86°F)
The *Esteem* should be brought near to room temperature before implantation. Failure to do so may result in improper system operation.

Risks and Potential Adverse Events

The following information describes potential adverse events that may be possible with the *Esteem*®:

- Erosion of the Sound Processor through the skin or infection to the Sound Processor pocket
- During the surgical implant procedure, the anatomy does not allow enough space for the proper implant of the *Esteem*®. These instances do arise in approximately 3% of the implant procedures. In this case, the *Esteem*® is not implanted and the surgical procedure is terminated.
- Intra-operative injury to the malleus, incus, stapes or cochlea because of physical contact and placement of the Sensor/Driver portion of the device
- Cold, sinus or upper respiratory congestion may result in temporary reduced benefit of Esteem®
- *Esteem*® may offer limited or no benefit, requiring an additional surgery to revise, enhance, replace or remove any or all of the components. During the most recent Clinical trial, a 5% revision surgery and a 2% explant rate were reported.
- *Esteem*® may produce mechanical feedback, requiring an additional surgery to revise, enhance, replace or remove any or all of the components
- Loss of attachment of leads from Sound Processor, and/or transducers from mastoid, and/or ossicular chain bones, requiring surgery to revise, replace or remove any or all of the components
- Loss or worsening of hearing after reconstruction of the ossicular chain in the event of device explant. The amount or degree of loss is dependent upon the method of reconstruction (PORP, TORP or ossicular reconstruction).
- Damage to the stapes or cochlea as a result of removal of the Sensor or Driver connection during surgery, revision or removal of the *Esteem*®
- Dislocation of any of the middle ear bones
- Bleeding and post-operative infection

With any surgical procedure, risks and complications can occur. Below is a list of surgical complications that must be considered. These are potential adverse events that may occur from the surgical procedure used to implant the *Esteem*®. Subsequent surgeries to change the Sound Processor/Battery may induce some of the same potential risks, as many of these complications are associated with any operative intervention. Certain intra- and post-operative complications may occur that are unique to a patient's specific situation.

- Bodily soreness that is associated with intra-operative positioning of the body and a prolonged implant procedure
- Temporary loss of skin sensation in and about the ear may occur following surgery. This numbness may involve the entire outer ear and usually resolves in the months following the procedure.
- Temporary dizziness, light-headedness or vertigo
- During the *Esteem*® implant procedure the chorda tympani may be severed, as done in other middle ear surgeries. Taste disturbance can be a side effect of severing this nerve. Patients reported taste disturbance as mild in intensity and typically temporary in nature.
- Formation of fibrous tissue in the middle ear subsequent to surgical intervention may occur. The likelihood and amount is determined by many surgical and patient variables and can vary greatly amongst patients.
- Infection and/or wound infection may occur following surgery
- Intra-oral discomfort, jaw soreness or stiffness
- Temporary facial paresis/paralysis was reported by up to 7% of the subjects in the clinical trial
- Eardrum perforation and/or drainage from ear canal
- Hematoma/blood-clot
- Neurological complications associated with being under general anesthesia for an extended period of time
- Physical dislocation or fracturing of the malleus, incus, and/or stapes bones
- Partial or total loss of remaining hearing in the implanted ear
- Widening or thickening of the scar behind the ear
- Complications related to anesthesia may occur
- Cerebral spinal fluid leak and meningitis
- The occurrence or changes in existing tinnitus may occur

Below is a table of illustrating adverse events with reported occurrence rate from a recent clinical study.

Adverse Event Category	% of Subject Reported	% Still Ongoing After One Year
Taste Disturbance	42%	14%
Facial Paresis/Paralysis	7%	1%
Tinnitus *Some subjects reported having tinnitus prior to the *Esteem*® Implant	18%	5%

Device Registration:
The U.S. FDA and international regulations require implanted devices to be registered and tracked. These include the Sound Processor, Sensor, Driver, and cements. Please use the universal labels provided with each *Esteem*® implanted product to complete the Envoy Medical Device Registration Form. The serial number for the Sound Processor is laser etched on the front surface of the device.

Electromagnetic Compatibility:
The *Esteem*® meets or exceeds the requirements of EN/IEC 60601-1-2.

Biocompatibility:
The device components in contact with the body are constructed of materials to meet criteria in ISO 10993-1 for equipment that is implanted long-term.

Leakage Current:
The external *Esteem*® components meet the requirements of EN/IEC 60601-1.

Esteem® Clinical Trial Results Summary

A. Study Description

In PMA submission P090018, data is presented from a pivotal trial (IDE G070162) aimed at demonstrating the safety and effectiveness of the *Esteem*® in subjects who have mild to severe hearing loss. This pivotal trial was designed as a prospective, multi-center, nonrandomized, clinical trial. Each of the 57 subjects implanted acted as both the test subject and the control by comparing his/her audiological test results and other measures prior to implant (under both unaided and aided conditions) to results at various time points after implantation. There were three investigational sites.

For the pivotal study, 57 of 60 enrolled subjects were successfully implanted with the study device at three study sites: 22 subjects at Southeastern ENT & Sinus Center in Greensboro, NC; 18 subjects at Shohet Ear Associates Medical Group in Newport Beach, CA; and 17 subjects at Lahey Clinic in Burlington, MA (Table III). Among the 57 implanted subjects, 54 subjects completed the 4-month follow-up (3 subjects had revision surgery due to limited benefit and were excluded from the analysis of the primary and secondary effectiveness outcomes) and 52 subjects completed the 10-month follow-up.

Of the 60 enrolled subjects, three were not implanted. Two patients were enrolled, underwent surgery, but did not receive the implant because the middle ear space was inadequate. A third subject decided to withdraw from the study after signing the consent form.

Of the 57 implanted subjects, three did not make the 4-month follow-up because of revision surgery.

Of the 54 subjects who reached the 4-month follow-up, two subjects did not reach the 10-month follow-up. The first of these subjects was explanted due to an incision breakdown that would not heal (possibly related to a smoking habit). A second subject had not been scheduled for the 10-month follow-up at the time the data base was finalized.

B. Safety and Effectiveness Results

1. Safety Results

The analysis of safety was based on the cohort of 60 subjects. The key safety outcomes for this study are presented below.

Adverse effects that occurred in the PMA clinical study:

Severe Adverse Device Effect (SADE)
The CEC determined that there were 6 SADEs reported in 6 subjects, for an incidence of 10.5% (6/57), as shown below. Among the SADEs, three were due to limited benefit which resulted in revision procedures. One subject had wound infection (resolved with medication) and one subject had incision breakdown (required explantation). The sixth subject experienced severe pain and facial weakness which resolved with medication.

Severe Adverse Device Effects (SADEs)*. Co-Primary Safety Endpoint.

Subject #	Event	Total Number	Intervention	Status
103-24	Severe pain and Facial Weakness	1	Medication	Resolved
109-34	Incision Site Infection	1	Medication	Resolved
103-22 102-22 109-24	Limited Benefit	3	Revision Procedures with replacement of parts of the Device	1 Subject has reached 4 month Endpoint, Remaining 2 Subjects have reached 2 month post-operative period, but not the 4 month Endpoint at the time of this report
105- 37	Incision Breakdown	1	Required Explantation	Reconstructed with Incudoplasty
Total SADE Events		**6**		

For more detail concerning the three patients with "Limited Benefit" and one patient who required explantation, refer to table below.

Device Failure/Revisions/Explants and Reconstruction.

Subject #	Event	Implant Date	Elapsed time to resolution	Revision/ Explant Date	Findings at Surgery	Reimplant / Reconstruction Method
103-22	Limited Benefit shortly after Activation	1/30/08	8.5 months	10/16/08	Fibrous Adhesions fixing sensor to incus and Driver Additional observation: MedCem butted against the short process of incus causing lower than expected Sensor and ISA test performance at implant.	Replaced Sound Processor and Sensor
109-22	Limited Benefit at Activation	5/16/08	12.5 months	5/29/09	Extensive Fibrous adhesions in the facial recess surrounding the Driver and stapes. Additional observation: An unusually small amount of EnvoyCem was present to form the Driver to Stapes connection.	Replaced Sound Processor and Driver
109-24	Limited Benefit	5/30/08	11 months	5/01/09	Extensive Fibrous adhesions noted in the facial recess surrounding the Driver and stapes. Additional findings: Driver tip pulled away from stapes & unusually small amount EnvoyCem	Replaced Sound Processor and Driver
105-37	Repeated Incision breakdown	6/27/08	8 months	2/27/09	Incision had a large opening under the scab	Reconstructed with Incudoplasty

Bone Conduction Threshold - Cochlear Stability

The objective was to demonstrate that the subject's cochlear function remains unchanged with the *Esteem*® as shown by comparison of the subject's pre-implant baseline Bone Conduction Threshold (BCT) vs. the subject's 4-month and 10-month post-activation BCT. Average and individual changes were evaluated per the protocol. Bone conduction was measured with forehead probe placement. Stable results should be within ± 10 dB. A Safety Algorithm (Appendix 2) was adopted to measure cochlear stability for any bone conduction results outside the stability range.

At the group level, changes in bone conduction threshold were used to determine whether the *Esteem*® caused damage to residual cochlear function. The average 3-frequency (500, 1000, 2000 Hz) bone conduction change from baseline for all subjects was 0.1 ± 0.9 dB (mean ± standard error) at 4 months and -0.8 ± 1.1 dB (mean ± standard error) at 10 months. This small change is indicative of no systemic cochlear damage being caused by either the implant or the therapy.

Esteem®
The Hearing Implant™

Average Bone Conduction Threshold Results (reported as mean +/- standard error).

	500 Hz mean ± se (CI range)	1000 Hz mean ± se (CI range)	2000 Hz mean ± se (CI range)	4000 Hz mean ± se (CI range)	PTA mean ± se (CI range)
Pre-Implant	45.0±1.9 (41.3, 48.7)	57.5±1.7 (54.1, 60.8)	66.6±1.4 (63.7, 69.4)	63.0±1.7 (61.5, 68.5)	56.3±1.3 (53.7, 58.9)
4-Month	45.4±1.9 (41.7, 49.1)	57.9±1.6 (54.6, 61.1)	67.4±1.3 (64.8, 70.0)	63.6±1.5 (62.6, 68.6)	56.4±1.3 (53.7, 59.0)
Mean Difference	0.0 ± 0.9 (-1.8, 1.8)	0.0 ± 1.0 (-2.0, 2.0)	2.2 ± 1.3 (-0.4, 4.8)	1.2 ± 1.2 (-1.3, 3.7)	0.1 ± 0.9 (-1.7, 2.0)
10-Month	47.6±2.0 (38.7, 46.5)	56.9±1.6 (53.8, 60.1)	68.0±1.4 (65.2, 70.7)	66.3±1.5 (63.4, 69.3)	55.3±1.5 (52.3, 58.3)
Mean Difference	-2.3±1.0 (-4.4, -0.3)	-0.3±1.2 (-2.7, 2.0)	1.3±1.4 (-1.5, 4.1)	2.7±1.3 (-0.5, 4.8)	-0.8±1.1 (-3.1, 1.5)

There was no mean change in bone conduction threshold at 4-months relative to the baseline for frequencies 500 and 1000 Hz (0.0 ± 6.4 dB, 0.0 ± 7.0 dB, respectively; mean ± standard deviation). There were slight increases in the bone conduction threshold for frequencies 2000 and 4000 Hz (2.2 ± 7.8 dB, and 1.2 ± 7.6 dB, respectively; mean ± standard deviation).

At the individual level, all subjects with 4-month and 10-month data in the database as of July 27, 2009, were analyzed according to the change criteria adopted in bone conduction (BC) and safety algorithm (SA) in accordance with the clinical protocol (i.e., 2 out of 4 frequencies change greater than 10 dB or 1 frequency greater than 20 dB; for details, see Appendix 2). For the 54 subjects, no subjects had a BC/SA threshold shift at the 4-month endpoint greater than the protocol criteria. At 10 months, for the 52 subjects, one subject (0204-103-28-TOSTR) had a BC/SA threshold shift of greater than 20 dB at 4000 Hz.

Esteem® Product Information

A summary of clinical safety outcomes is provided below.

Summary of Clinical Safety Data.

Clinical Protocol Objectives	4 Month Results	10 Month Results
Primary Safety Objective: • Serious Adverse Device Effects (SADE) • Incidence of Device Failures and Replacements	SADE • Three (3) subjects for facial weakness / incision issues • Three (3) subjects for revision procedures to date • SADE rate: 10.5% (6 of 57) Failures • Three (3) failures resulting in approved revisions were reported in three unique subjects prior to the 4-month follow-up • Failure rate: 5.3% (3 of 57)	SADE • No additional SADE were reported between the 4- month and 10-month follow-up visits Failures • No additional failures were reported between the 4-month and 10-month follow-up visits
Primary Safety Objective: • Bone conduction (BC) threshold at 4 months post-activation vs. pre-implant • Safety Algorithm (SA) for those that fail BC	Bone Conduction • Average 3 frequency (500, 1K, 2K) bone conduction change of 0.1 dB at 4 months vs. pre-implant. • Individually, no subjects (0) at 4 months had BC/SA change per the protocol criteria from pre-implant.	Bone Conduction • Average 3 frequency (500, 1K, 2K) bone conduction change of -0.8 dB at 10 months vs. pre-implant. • Individually, one subject (1) at 10 months had BC/SA change per the protocol criteria from pre-implant at 4 kHz.

Adverse Event Results

The list of reported adverse events related to the device as determined by the CEC is shown in table below:

- 96 ADEs were reported if they were found during CEC adjudication to be not serious and were found to be caused by the mastoidectomy w/facial recess, device, peri-operative surgery related, or device implant procedure related.
- Majority of these Adverse Effects were classified as mild or moderate.
- 70% of the ADEs have resolved.
- Remaining 30% of the ADEs are ongoing for over a year at the time of this report. Ongoing ADEs include conditions like Taste Disturbance, Facial weakness/paralysis, Tinnitus, Dizziness, Middle Ear Effusion, and Ear Pain.

The list of reported adverse events that are not device related as determined by the CEC is shown in the table below:

- Events were classified as AE's if they were found during CEC adjudication to be caused by underlying or concomitant illness, concomitant medications, or other causes.
- Seventeen events were classified as mild, four as moderate, and one as severe.
- Of the 29 AEs reported, 21 (72%) have recovered.
- 8/29 AEs (28%) were still ongoing at the time of this report.

All events have been grouped into 9 broad categories of Taste, Middle Ear Effusion, Pain, Tinnitus, Imbalance/Dizziness, Facial Paresis, Limited Benefit, Headache, and Miscellaneous. The table below summarizes all 133 adverse events observed during this study and subject status at the time of this PMA submission. A detailed description of the adverse events in each of the 9 categories is also provided. The following observations can be made from these two tables:

- Of the 133 adverse events, 78% have resolved, 21% remain unresolved, and the status of 1 event is unknown.
- The most frequent adverse event was taste disturbance (24 of 57 subjects, 42%). This adverse event has not resolved for 8 subjects (14%).
- Serious adverse events such as facial paresis/palsy were noted in four subjects each and has not resolved in two subjects.
- 52 (91%) of 57 subjects experienced AEs; 36 of 52 Subjects experienced multiple (2-8) AEs, not all events are resolved; 26 Subjects have ongoing AEs.

Categories of Adverse Events and Status.

Adverse Event (AE) Categories	Number of AEs (% of total AEs)	Number of Subjects with AEs (% of 57 implanted subjects)	Number of Resolved AEs (% of category)	Number of Subjects with Resolved AEs (% of 57 implanted subjects)	Number of AEs Ongoing (% of category)	Number of Subjects with Ongoing AEs (% of 57 implanted subjects)	Number of AEs with Resolution Status Unknown (% of category)	Number of Subjects with Resolution Status Unknown (% of 57 implanted subjects)
Taste Disturbance	25 (19%)	24 (42)%	16 (64%)	15 (26%)	8 (32%)	8 (14%)	1 (4%)	1 (2%)
Middle Ear Effusion	18 (14%)	18 (32%)	18 (100%)	18 (32%)	0	0	0	0
Pain	12 (9%)	12 (21%)	8 (67%)	8 (14%)	4 (33%)	4 (7%)	0	0
Imbalance/ Vertigo /Dizziness	11 (8%)	11 (19%)	9 (82%)	9 (16%)	2 (18%)	2 (4%)	0	0
Tinnitus	10 (8%)	10 (18%)	7 (70%)	7 (12%)	3 (30%)	3 (5%)	0	0
Facial Paresis/ Paralysis	4 (3%)	4 (7%)	2 (50%)	2 (4%)	2 (50%)	2 (4%)	0	0
Limited Benefit	4 (3%)	4 (7%)	4 (100%)*	4 (7%)	0	0	0	0
Headaches	3 (2%)	3 (5%)	3 (100%)	3 (5%)	0	0	0	0
Miscellaneous	46 (34%)	30 (52%)	37 (80%)	**	9 (20%)	**	0	0
Total	133 (100%)	52 (91)%	104(78%)	***	28 (21%)	***	1 (.008%)	1 (2%)

***One Subject resolved without intervention, One Subject has reached the 4-month Endpoint; Two Subjects have only reached 2-month post-operative period, but not the 4 month Endpoint at the time of this report.**

**** Twelve of Thirty Subjects (40%) experienced 2-4 AEs in Miscellaneous category, not all events resolved; Twelve Subjects have ongoing AEs**

***** Thirty-six of Fifty-two Subjects experienced 2-8 AEs, not all events resolved; Twenty-six Subjects have ongoing AEs**

Description of Adverse Events with Categories.

Adverse Event Category	Description of Adverse Event	Number of Events
Taste Disturbance		25
	Taste Disturbance	18
	Metallic Taste	3
	Altered Taste	1
	Disturbed Taste	1
	Taste Disturbance	1
	Taste Disturbance (Delayed Onset)	1
Middle Ear Effusion		18
	Middle Ear Fluid	5
	Effusion	3
	Fluid Behind TM	2
	Crackling Sound	1
	Crackling Drainage Sound	1
	Effusion (R)	1
	Fluid AS	1
	Middle Ear Effusion	1
	Middle Ear Fluid	1
	Middle Ear Effusion , Rt. Ear, Implant Ear	1
	Residual Effusion L Middle Ear	1
Pain		12
	Otalgia	2
	Discomfort Above Implant	1
	Discomfort/Pain R Side of Head	1
	Ear Canal Pain	1
	Ear Pain	1
	Ear Pain/Pressure	1
	Intermittent Otalgia	1
	L Ear Pain	1
	Pain Around Incision	1
	Pain in Temporal Region /Cheek	1
	Pain/Incision discomfort	1
Vertigo/ Dizziness/ Imbalance		11
	Vertigo	3
	Dysequilibrium	2
	Imbalance	1
	Mild Dysequilibrium	1
	Unsteadiness	1
	Unsteadiness	1
	Dizziness	2
Tinnitus		10
	Tinnitus Left Ear	2
	Right Ear Roaring	1
	Slight Increase in Tinnitus	1
	Tinnitus Left Ear	1
	Tinnitus	5
Facial Paresis		4
	Facial Palsy	1
	L Facial Paresis	1
	Facial Weakness	1
	R Facial Weakness	1
Limited Benefit		4
	Limited Benefit *	1
	Limited Benefit **	1
	Limited Benefit **	1
	Limited Benefit **	1
Headaches		3
	Headache	1
	Headache	1
	Frontal Headache	1
Miscellaneous		46
	Aural Fullness	2
	Nose Bleed	2
	Sinus Infection	2
	Motor Boat Sound/Shorting Out of Sound	2
	URI	2 (1 each)
	Ankle Trouble/Broken leg	2
	Apnea (pre-existing)	2 (1 each)
	Incision Breakdown (1), Infection(2), and Discomfort (1)	1
	Nasal Drainage/Post Nasal Drip	4
	TM Perforation/TM Blistering	2 (1 each)
	Otitis Externa (1), Debris in Ear Canal (2), and Sore in Ear Canal (1)	2 (1 each)
	Eustachian Tube Dysfunction/Feedback	4
	TIA, Chest Pain, Knee Pain, Pregnancy, MVA	2 (1 each)
	Rapid Heart Beat, Rash, Tooth Pain	5 (1 each)
	Yeast Infection, Discomfort, Light Headedness	3 (1 each)
	Hair Follicle Incision and Blood Fluid (L)	2 (1 each)
	Dry Eye, Eye Irritation, Eye Squint	3 (1 each)
	Numbness, Numbness of left Tongue, Numbness of Tongue	
Grand Total		133

*** One Subject with Limited Benefit improved without intervention**

**** Three Subjects with Limited Benefit underwent revision surgery**

Unanticipated Adverse Device Effect (UADE)
The Clinical Events Committee (CEC) determined that there were no UADEs reported during this trial.

2. Effectiveness Results

Speech Reception Threshold

The protocol criterion is that the 95% Lower Confidence Bound (LBC) for the mean of difference between the SRT at baseline versus four months is greater than or equal to -5 dB.

The mean SRT scores for baseline unaided, baseline aided, 4-months, and 10-months are shown below. As reported, the mean SRT decrease at 4-months from baseline (pre-implant, aided) was 10.6 with a 95% confidence interval ranging from 7.1 to 14.2.

Mean Improvement in SRT Scores at 4 and 10 Months (Unadjusted).

Follow-up Period	SRT (in dB) mean ± se n (min, max)		
	Pre-Implant Aided	4-Month	10-Month
	41.2 ± 1.5 57 (38.3, 44.1)	30.6 ± 1.6 54 (27.4, 33.7)	29.4 ± 1.6 52 (26.1, 32.7)
Mean Improvement (95% CI)	NA	10.6 ± 1.8 (7.1, 14.2)	11.4 ± 1.8 (7.7, 15.2)

However, as shown in table below the heterogeneity in the treatment effect among sites is statistically significant (p-value < 0.01). Overall, the mean SRT improvement with the *Esteem*® compared to the pre-implant hearing aid was 10.6 dB with the site-specific mean improvement between 1.3-16.9 dB.

Mean Speech Reception Threshold (SRT) Decrease at 4-Months Relative to the Baseline (Aided Condition) for the Three Investigational Sites.

Analysis	Site 103 Mean ± SE	Site 105 Mean ± SE	Site 109 Mean ± SE	P-value for Site Differences
Un-adjusted	11.9±2.6	16.9±2.8	1.3±3.0	<0.01

Word Recognition Score

The second objective was to demonstrate that the *Esteem*® at the 4-months post-activation visit is as effective as or better than the hearing aid for improving speech discrimination (intelligibility) as shown by the word recognition score at 50 dB HL.

The endpoint was the comparison of the word recognition score (WRS) using the *Esteem*® at 4-months post-activation compared to the pre-implant baseline aided condition. The objective of WRS was to provide a comparison of the Word Recognition Scores at 50 dB HL associated with the *Esteem*® versus the baseline aided condition. There was no formal hypothesis, and the WRS was analyzed using the method described by Thornton and Raffin (Speech discrimination scores modeled as a binomial variable; J Speech Hear Res 1978; 21:507-18) regarding upper and lower limits for various word lists based upon percentage scores. An analysis showing the % better than, % equal to, and % below the pre-implant baseline aided condition was presented.

The table below displays the WRS results at the 4- and 10-month intervals. At 4-months, 93% of the subjects' WRS was as good as or better than that in the aided baseline condition (HA), and 7% exhibited below. The percentage of subjects having equivalent or better than HA decreased to 88% at 10 months, and those exhibiting below HA increased to 12%.

Word Recognition Scores (WRS) at 50 dB HL.

	All Subjects	
	4 Month N=54	10 Month N=52
% Better HA	30/54 (56%)	32/52 (62%)
% = HA	20/54 (37%)	14/52 (27%)
% Below HA	4/54 (7%)	6/52 (12%)

The mean change in WRS at the 4-month visit was 21.7%, with a 95% confidence interval of 13.3 to 30.1. However, as also observed in the SRT endpoint data, there is statistically significant heterogeneity in WRS among the sites. The mean change in WRS at 4-months varied from 3.6 to 37.1 and at 10-months varied from 0 to 32.4, depending on the site.

Mean Change in WRS at 4-Month Follow-Up.

	Unadjusted
Follow-up	Mean ± SE (95% CI)
4 Months	21.7 ± 4.2 (13.3, 30.1)
10 Months	19.8 ± 4.3 (11.1, 28.4)

Word Recognition Score at 4-Months Compared to Baseline.

	Site 103 N (%)	Site 105 N (%)	Site 109 N (%)
Better HA	11 (52.4)	15 (83.3)	4 (26.7)
= HA	9 (42.9)	3 (16.7)	8 (53.3)
Below HA	1 (4.8)	0 (0.0)	3 (20.0)

Overall, 93% of *Esteem*® recipients scored equal to or better than their pre-implant hearing aid. A summary of the WRS data follows:

- 7% scored less than their pre-implant hearing aid (0%-20% depending upon clinical site),
- 37% scored equal to their pre-implant hearing aid (17%-53% depending upon clinical site), and
- 56% scored better than their pre-implant hearing aid (27%-83% depending upon clinical site).

Secondary Effectiveness Endpoint Analysis

Pure Tone Average (PTA)

The objective was to demonstrate that the *Esteem*® at the 4-month post-activation visit improves the 3-frequency (500, 1000, and 2000 Hz) pure tone average (PTA) when compared to the baseline unaided condition. For each subject, the 4-month, as well as the 10-month, air conduction data were compared to the baseline unaided data at various frequencies (Hz).

The table below details the mean air conduction change and the number of subjects in each functional "benefit" group at each frequency. There were 96% (52/54) of subjects at the 4-month interval and 92% (48/52) at the 10-month interval who had PTA change greater than 10 dB.

Air Conduction Threshold Change at 4 and 10 Months.

	Air Conduction Thresholds 4 Months N=54								
	250	500	1000	2000	3000	4000	6000	8000	PTA
Mean delta from Baseline ± SE (CI range)	12 ± 2 (16, 8)	19 ± 2 (22, 16)	26 ± 2 (30, 23)	35 ± 2 (39, 32)	23 ± 2 (27, 19)	17 ± 2 (21, 12)	8 ± 2 (12, 4)	0 ± 2 (5, -5)	27 ± 1 (30, 24)
% Greater than +10 dB	25/54 (46%)	38/54 (70%)	49/54 (91%)	51/54 (94%)	44/54 (81%)	35/54 (65%)	23/54 (43%)	8/54 (15%)	52/54 (96%)
% Stable (±10 dB)	28/54 (52%)	16/54 (30%)	5/54 (9%)	3/54 (6%)	8/54 (15%)	16/54 (30%)	20/54 (37%)	23/54 (43%)	2/54 (4%)
% Less than -10 dB	1/54 (2%)	0/54 (0%)	0/54 (0%)	0/54 (0%)	1/54 (2%)	2/54 (4%)	6/54 (11%)	7/54 (13%)	0/54 (0%)
% No Response	0/54 (0%)	0/54 (0%)	0/54 (0%)	0/54 (0%)	1/54 (2%)	1/54 (2%)	5/54 (9%)	16/54 (30%)	0/54 (0%)

	Air Conduction Thresholds 10 Months N=52								
	250	500	1000	2000	3000	4000	6000	8000	PTA
Mean delta from Baseline ± SE (CI range)	11 ± 2 (15, 8)	20 ± 1 (23, 17)	27 ± 2 (30, 23)	36 ± 2 (40, 33)	26 ± 2 (30, 22)	18 ± 2 (22, 14)	10 ± 2 (15, 5)	1 ± 3 (6, -5)	27 ± 1 (30, 25)
% Greater than +10 dB	23/52 (44%)	40/52 (77%)	46/52 (88%)	49/52 (94%)	43/52 (83%)	35/52 (67%)	25/52 (48%)	10/52 (19%)	48/52 (92%)
% Stable (±10 dB)	29/52 (56%)	12/52 (23%)	5/52 (10%)	3/52 (6%)	6/52 (12%)	13/52 (25%)	16/52 (31%)	20/52 (38%)	4/52 (8%)
% Less than -10 dB	0/52 (0%)	0/52 (0%)	1/52 (2%)	0/52 (0%)	1/52 (2%)	3/52 (6%)	6/52 (12%)	6/52 (12%)	0/52 (0%)
% No Response	0/52 (0%)	0/52 (0%)	0/52 (0%)	0/52 (0%)	3/52 (4%)	1/52 (2%)	5/52 (10%)	16/52 (31%)	0/52 (0%)

The denominator of 54 includes those who had "No Response." There were 5/54 (9%) and 16/54 (30%) "No Response" for 6000 and 8000 Hz, respectively. "No Response" for 6000 and 8000 Hz would not affect PTA

The mean PTA change at the 4-month from the baseline was 27 dB (SD=11). There were 52 out of 54 subjects who had PTA change greater than 10 dB, two subjects within ± 10 dB, and no subject below 10 dB.

QuickSIN

The objective was to demonstrate that the *Esteem*® at the 4-months post-activation visit is as effective as or better than the hearing aid for improving speech discrimination (intelligibility) as shown by the QuickSIN (speech in noise) test results.

The change with the *Esteem*® from the aided baseline was -1 ± 1 at 4-month and 0 ± 0 at 10-month follow-up. The QuickSIN Test

Manual quantifies the amount of SNR Loss (in dB) in relation to the degree (category) of SNR loss. Based on the cutoff values specified in QuickSIN Test Manual, the distributions of SNR Loss for the baseline aided and unaided conditions as well as for the 4- and 10-month intervals are provided below. The distributions of SNR loss at baseline aided condition and at the 4- and 10-month visits were comparable.

QuickSIN SNR Loss Distributions.

SNR Loss	Degree of SNR Loss	Baseline Unaided (N=57)	Baseline Aided (N=57)	4 Month (N=54)	10 Month (N=52)
0-3 dB	Normal/ near normal	2 (4%)	1 (2%)	1 (2%)	1 (2%)
>3-7 dB	Mild	12 (21%)	10 (18%)	8 (15%)	10 (19%)
>7-15 dB	Moderate	19 (33%)	29 (51%)	24 (44%)	29 (56%)
>15 dB	Severe	24 (42%)	17 (30%)	20 (37%)	12 (23%)

APHAB Quality of Life (QOL)

The objective was to show that the *Esteem*® improves Quality-of-Life when compared to the baseline aided condition as shown by APHAB scores. The mean benefit scores over the unaided condition were collected for the pre-implant baseline aided condition and at the 4- and 10-month intervals as shown below. The APHAB score is broken down into sub-categories of Easy Communication Situations (EC), Background Noise Situations (BN), Reverberate Environments (RV) and Aversiveness (AV).

There was a mean increase of 10.9 (standard deviation = 17.9) in benefit score (APHAB) at 4-month comparing to the baseline (pre-implant aided condition). The mean change in the four subscales ranged from 8.4 to 13.5, with the Easy Communication Situations (EC) subscale having the largest increase and the Reverberate Environment (RV) subscale having the smallest increase.

APHAB Mean Benefit Score (mean +/- standard error).

	Global Score mean ± se n (95% CI)	EC Scale mean ± se n (95% CI)	BN Scale mean ± se n (95% CI)	RV Scale mean ± se n (95% CI)	AV Scale mean ± se n (95% CI)
Baseline Aided	18.7±1.7 59 (15.4, 22.0)	38.9±2.9 59 (33.1, 44.7)	29.8±2.2 59 (25.4, 34.3)	34.7±2.6 59 (29.6, 39.9)	-28.9±2.9 59 (-34.8, -23.0)
Esteem 4-Month	28.3±2.5 53 (23.3, 33.3)	50.5±3.1 53 (44.3, 56.7)	39.5±3.3 53 (32.8, 46.2)	42.0±3.5 53 (35.0, 49.0)	-19.0±3.8 53 (-26.6, -11.4)
Mean Difference in Benefit Score	10.9±2.5 53 (5.9, 15.8)	13.5±3.2 53 (7.1, 20.0)	10.2±3.1 53 (4.1, 16.3)	8.4±3.1 53 (2.1, 14.6)	11.4±4.0 53 (3.3, 19.5)
Esteem 10-Month	26.3±2.8 51 (20.7, 31.8)	48.1±3.4 51 (41.2, 55.0)	36.0±3.6 51 (28.7, 43.3)	38.5±3.9 51 (30.6, 46.4)	-17.9±3.9 51 (-25.7, -10.2)
Mean Difference in Benefit Score	8.9±2.6 51 (3.8, 14.1)	11.4±3.4 51 (4.5, 18.3)	7.1±3.2 51 (0.7, 13.4)	5.0±3.1 51 (-1.3, 11.3)	12.2±4.0 51 (4.1, 20.2)

The table below provides the individual subject APHAB scores in percentage steps for Esteem at 4-months and 10-months follow-up compared to pre-implant baseline aided condition. The number and percent of subjects meeting each comparison step are provided for each APHAB score.

APHAB Comparison by Subject.

	4 Month APHAB Comparison Results N=53				
	Total	EC	BN	RV	AV
% Better HA > +22%	13/53 (25%)	15/53 (28%)	18/53 (34%)	14/53 (26%)	17/53 (32%)
% Better HA +10 to 21%	14/53 (26%)	12/53 (23%)	10/53 (19%)	9/53 (17%)	11/53 (21%)
% Better HA +5 to 9%	5/53 (9%)	10/53 (19%)	4/53 (8%)	5/53 (9%)	4/53 (8%)
% Equal HA (±4%)	11/53 (21%)	6/53 (11%)	7/53 (13%)	9/53 (17%)	9/53 (17%)
% Below HA -5 to -9%	3/53 (6%)	1/53 (2%)	7/53 (13%)	6/53 (11%)	1/53 (2%)
% Below HA -10 to -21%	4/53 (8%)	6/53 (11%)	4/53 (8%)	8/53 (15%)	4/53 (8%)
% Below HA < -22%	3/53 (6%)	3/53 (6%)	3/53 (6%)	2/53 (4%)	7/53 (13%)

	10 Month APHAB Comparison Results N=51				
	Total	EC	BN	RV	AV
% Better HA > +22%	9/51 (18%)	13/51 (25%)	13/51 (25%)	11/51 (22%)	16/51 (31%)
% Better HA +10 to 21%	16/51 (31%)	16/51 (31%)	10/51 (20%)	13/51 (25%)	11/51 (22%)
% Better HA +5 to 9%	7/51 (14%)	6/51 (12%)	3/51 (6%)	1/51 (2%)	3/51 (6%)
% Equal HA (±4%)	8/51 (16%)	8/51 (16%)	10/51 (20%)	8/51 (16%)	7/51 (14%)
% Below HA -5 to -9%	6/51 (12%)	3/51 (6%)	5/51 (10%)	5/51 (10%)	5/51 (10%)
% Below HA -10 to -21%	2/51 (4%)	3/51 (6%)	6/51 (12%)	9/51 (18%)	7/51 (14%)
% Below HA < -22%	3/51 (6%)	2/51 (4%)	4/51 (8%)	4/51 (8%)	2/51 (4%)

As for the individual benefit comparison, according to the *Instructions for Manual Scoring of the APHAB*, a significant benefit has occurred if a difference of ≥ 22% is obtained for the EC, RV or BN score. If all three scores improve by ≥ 10%, there is a 96% probability that a true benefit has occurred. If all three scores improve by ≥ 5%, there is an 89% probability that a true benefit has occurred. Scoring of the benefit scores for the baseline aided condition and the Esteem at 4 and 10-month follow-up was calculated versus baseline unaided condition. In addition, the *Esteem*® at the 4 and 10-month evaluation was compared to the baseline aided condition for each subject according to these same criteria. The number of subjects meeting each of the above scoring criteria is presented in the table below.

There were 25 subjects (47%) at 4-month follow-up and 21 subjects (41%) at 10-month follow-up who had a greater than 22% change in EC, RV or BN. However, less than one in three showed 96% probability of a significant benefit according to the APHAB scoring guideline.

APHAB – Benefit Categories.

Benefit Categories	Esteem vs Hearing Aid n/N (%) 4-Month	Esteem vs Hearing Aid n/N (%) 10-Month
Significant Benefit Subjects with a ≥ 22% improvement in EC, RV, or BN	25/53 (47.2%)	21/51 (41.2%)
96% Probability of a Significant Benefit Subjects with a ≥ 10% improvement in EC, RV, and BN	16/53 (30.2%)	13/51 (25.5%)
89% Probability of a Significant Benefit Subjects with a ≥ 5% improvement in EC, RV, and BN	23/53 (43.4%)	19/51 (37.3%)

Esteem®
The Hearing Implant™

Esteem® Product Information

Esteem® Questionnaire Quality of Life (QOL)

The objective was to gather subject's feedback and comments on the use of the *Esteem*® relative to the baseline aided condition as shown by the *Esteem*® Questionnaire (time period not specified in the protocol). At the 4- and 10-month follow-up, subjects completed a questionnaire rating various subjective attributes concerning their experience with the *Esteem*® as compared to the baseline aided condition. Ratings were on a scale of 1 to 5, where 1 is much worse, 2 is somewhat worse, 3 is about the same, 4 is somewhat better, and 5 is much better.

The questions and responses are provided below. Subject ratings are summarized below:

- Clarity of Sound: 78% somewhat or much better, 7% equal, 15% somewhat or much worse
- Ability to Understand Speech in Background Noise: 69% somewhat or much better, 13% equal, and 18% somewhat or much worse
- Natural Sounding Voices: 76% somewhat or much better, 11% equal, 13% somewhat or much worse
- Understanding Conversation: 72% somewhat or much better, 17% equal, 11% somewhat or much worse
- Activity Level: 85% somewhat or much better, 11% equal, 4% somewhat or much worse
- Feeling of Confidence: 84% somewhat or much better, 8% equal, 8% somewhat or much worse
- Benefit of Invisibility: 66% somewhat or much better, 17% equal, 17% somewhat or much worse

***Esteem*® Questionnaire (Quality of Life).**

Question	4 Month Response				
	1	2	3	4	5
How do you rate the clarity of the sound you hear with the *Esteem* compared to your hearing aid?	3/54 (6%)	5/54 (9%)	4/54 (7%)	13/54 (24%)	29/54 (54%)
How do you rate your ability to understand speech in background noise or street noise with the *Esteem* as compared to your hearing aid?	3/54 (6%)	7/54 (13%)	7/54 (13%)	17/54 (31%)	20/54 (37%)
How natural sounding are voices and other sounds compared to your hearing aid?	1/54 (2%)	6/54 (11%)	6/54 (11%)	13/54 (24%)	28/54 (52%)
How do you rate the benefit of the entire system being invisible to the onlooker compared to your hearing aid?	9/54 (17%)	0/54 (0%)	9/54 (17%)	12/54 (22%)	24/54 (44%)
How well do you understand conversation with your *Esteem* even when several people are talking compared to your hearing aid?	3/54 (6%)	3/54 (6%)	9/54 (17%)	18/54 (33%)	21/54 (39%)
How confident do you feel with the *Esteem* compared to your hearing aid?	2/53 (4%)	2/53 (4%)	4/53 (8%)	13/53 (25%)	32/53 (60%)
Does the Esteem allow you to live a more active lifestyle?	1/54 (2%)	1/54 (2%)	6/54 (11%)	13/54 (24%)	33/54 (61%)

Question	10 Month Response				
	1	2	3	4	5
How do you rate the clarity of the sound you hear with the *Esteem* compared to your hearing aid?	3/52 (6%)	5/52 (10%)	3/52 (6%)	7/52 (13%)	34/52 (65%)
How do you rate your ability to understand speech in background noise or street noise with the *Esteem* as compared to your hearing aid?	5/52 (10%)	3/52 (6%)	7/52 (13%)	14/52 (27%)	23/52 (44%)
How natural sounding are voices and other sounds compared to your hearing aid?	3/52 (6%)	5/52 (10%)	4/52 (8%)	14/52 (27%)	26/52 (50%)
How do you rate the benefit of the entire system being invisible to the onlooker compared to your hearing aid?	5/52 (10%)	0/52 (0%)	11/52 (21%)	15/52 (29%)	21/52 (40%)
How well do you understand conversation with your *Esteem* even when several people are talking compared to your hearing aid?	3/52 (6%)	4/52 (8%)	10/52 (19%)	12/52 (23%)	23/52 (44%)
How confident do you feel with the *Esteem* compared to your hearing aid?	4/52 (8%)	3/52 (6%)	3/52 (6%)	12/52 (23%)	30/52 (58%)
Does the Esteem allow you to live a more active lifestyle?	1/52 (2%)	3/52 (6%)	3/52 (6%)	10/52 (19%)	35/52 (67%)

Overall, the *Esteem*® met all safety and effectiveness objectives in this clinical trial.

Esteem®
The Hearing Implant™

Esteem® Sensor Model 7002

Sensor Description:
The Sensor Model 7002 is positioned within the mastoid cavity and held in place with MedCem. The transducer tip is attached to the ossicular chain with EnvoyCem and detects the sound vibrations of the tympanic membrane. The Sensor converts the sound vibration to an electrical signal. The electrical signal is transmitted to the Sound Processor by a short, flexible lead. The lead is terminated with an IS-1 connector that inserts into the lower connector port on the Sound Processor.

Sensor Component Descriptions:
The components of the Sensor include: the Lead, Legs, Housing, Stabilizer Socket, MedCem Shield, Transducer, and Tip.

- *Lead:* Flexible wires insulated with silicone that transmit the electronic signals to the Sound Processor.
- *Legs:* Malleable extensions used to anchor the Sensor.
- *Housing:* Supports the legs, stabilizer socket, lead assembly and encloses the transducer, while providing hermeticity.
- *Stabilizer Socket:* Holds the Glasscock Stabilizer pin to the Sensor.
- *MedCem Shield:* Shield to prevent MedCem from interfering with transducer output.
- *Transducer:* The transducer converts sound pressure movements of the ossicular chain to an electrical signal received by the Sound Processor.
- *Tip:* The contact point of the Sensor to the ossicular chain.

The Sensor detail is shown in Figure 2.

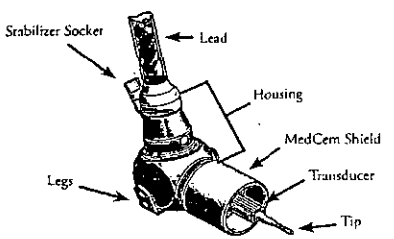

Figure 2: Sensor Components

Glasscock Stabilizer Description and Use:
Model 1730, the Glasscock Stabilizer, is a temporary retainer used to position and stabilize the Sensor during implantation.

The Glasscock Stabilizer is shown connected to a Sensor in Figure 3.

Physical Specifications - Sensor:

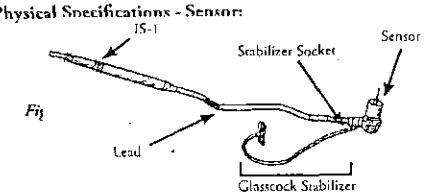

Figure 3: Sensor and Glasscock Stabilizer

- *Transducer Housing:* Hermetic titanium assembly
- *Lead:* 1.8 mm diameter, 6 cm long silicone insulated lead with IS-1 connector
- *Size (without legs):* 13.3 mm L, 5.5 mm H, 4.1 mm D
- Mass: 1.7 g
- *Volume (without lead):* 0.19 cc
- *Insertion Force (IS-1):* 3.3 lbs. maximum
- *Withdrawal Force (IS-1):* 1.1 lbs. minimum

Glasscock Stabilizer Materials:
Platinum-iridium, tin, stainless steel and silicone tubing.

Esteem® Driver Model 7502

Driver Description:
The Driver Model 7502 is positioned within the mastoid cavity and held in place with MedCem. The transducer tip is positioned directly over the stapes and connected to the stapes with EnvoyCem. The electrical signal from the Sound Processor is transmitted to the Driver through a lead. It is terminated with an IS-1 connector that inserts into the upper connector port of the Sound Processor.

Driver Component Descriptions:
The components of the Driver include: Lead, Legs, Housing, Stabilizer Socket, MedCem Shield, Transducer and Tip.

- *Lead:* Flexible wires insulated with silicone that transmit the electronic signals from the Sound Processor.
- *Legs:* Malleable extensions used to anchor the Driver.
- *Housing:* Holds the legs, stabilizer socket, lead assembly together and encloses the PZT, while providing hermeticity.
- *Stabilizer Socket:* Connects the Glasscock Stabilizer pin to the Driver.
- *MedCem Shield:* Shield to prevent MedCem from interfering with transducer output.
- *Transducer:* The active PZT driving component when connected to the Sound Processor.
- *Tip:* The contact point of the Driver to the stapes.

The Driver detail is shown in Figure 4.

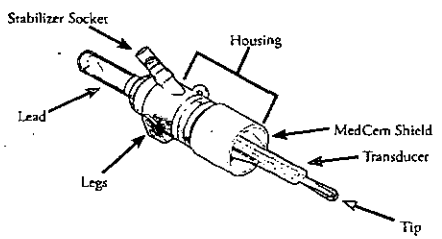

Figure 4: Driver Components

Glasscock Stabilizer Description and Use:
Model 1730, the Glasscock Stabilizer, is a temporary retainer used to position and stabilize the Driver during implantation.

The Glasscock Stabilizer is shown connected to a Driver in Figure 5.

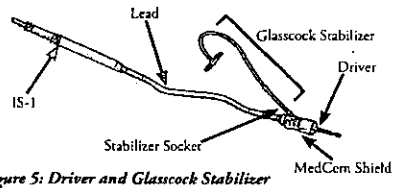

Figure 5: Driver and Glasscock Stabilizer

Physical Specifications - Driver:

- *Transducer Housing:* Hermetic titanium assembly
- *Lead:* 1.8 mm diameter, 6 cm long silicone insulated lead with IS-1 connector
- *Size (without legs):* 21.1 mm L, 6.0 mm H, 4.2 mm D
- *Mass:* 1.5 g
- *Volume (without lead):* 0.14 cc
- *Insertion Force (IS-1):* 3.3 lbs. maximum
- *Withdrawal Force (IS-1):* 1.1 lbs. minimum

Glasscock Stabilizer Materials:
Platinum-iridium, tin, stainless steel and silicone tubing.

Esteem® Sound Processor Model 2001

Sound Processor Description:
The *Esteem* Model 2001, the Sound Processor, is placed in a surgically created bed in the temporal bone, and connected to the Sensor and Driver by their leads. The Sound Processor filters and increases the signals received by the Sensor and outputs these signals to the Driver. The Sound Processor parameters can be adjusted using the Esteem Programmer or the Personal Programmer.

Sound Processor Battery Description:
The Sound Processor contains a lithium iodine battery to power the circuits and bidirectional telemetry functions. The Sound Processor uses microelectronic circuit technology, enabling small device size and long battery life. Figure 6 shows the Model 2001 Sound Processor.

Sound Processor Connectors:
The polyurethane header of the Sound Processor contains IS-1 connector ports for the Sensor and Driver leads. The lead pin of the Driver must be inserted in the upper connector port; the lower connector port is for the Sensor lead pin. Venting strips (not shown in Figure 6) are removed after lead insertion.

Sound Processor Function:
The electrical signal from the Sensor is conducted to the Sound Processor via the Sensor lead. The signal is increased and filtered to meet the patient's particular hearing needs. The electrical output signal is conducted from the Sound Processor to the Driver via the Driver lead.

The Sound Processor detail is shown in Figure 6.

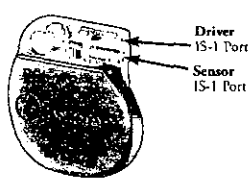

Figure 6: Sound Processor

SOUND PROCESSOR BATTERY

Elective Replacement Indication (ERI):
The Sound Processor monitors its battery voltage and triggers an ERI low battery warning when the battery begins to deplete. The ERI is indicated to the patient by a change in the Personal Programmer Confirmation Tone from a single tone to a dual tone. Note that only the patient hears this tone. Also, the Sound Processor sends a message to the Personal Programmer to visually display *Esteem* ERI.

Battery End of Life (EOL):
EOL occurs approximately 2 weeks after the ERI is first indicated. This assumes that the patient uses the Personal Programmer during this timeframe, and can therefore notice the first time that ERI is indicated.

The patient should be instructed to immediately inform their health care professional when a two-tone confirmation is heard or when their Personal Programmer displays *Esteem* ERI. This will allow sufficient time to schedule replacement of the Sound Processor prior to loss of Sound Processor functionality that will occur after the battery voltage falls below EOL.

Battery (Sound Processor) Replacement:
When the battery needs to be replaced it may be done under local anesthetic. The previous incision is reopened, the Sensor lead and the Driver lead are removed from the connector ports of the Sound Processor and the Sound Processor is removed. The integrity of the Sensor and Driver are confirmed. Then the Sensor lead and the Driver lead are inserted into the connector ports of a new Sound Processor, and the new Sound Processor is placed in the already existing, surgically created bed in the temporal bone. The incision is closed.

Battery Longevity:
The battery life is estimated to be about 4½ years if the *Esteem* is left active at all times—that is, if the patient never programs *Esteem* to the low power standby mode. The battery life is estimated to be 6 ½ years if the *Esteem* is left active for two thirds of the time—that is, if the low power standby mode is enabled by the patient one-third of the time, or eight hours a day (usually during sleep).

Estimated Battery Longevity:

On 24 hours each day - 4 years and 6 months to ERI

On 16 hours each day - 6 years and 6 months to ERI

On 8 hours each day - 9 years and 0 months to ERI

External Communication with the Esteem Programmer:
The health care professional and patient communicate with the *Esteem* Sound Processor using RF telemetry by holding the Telemetry Wand or Personal Programmer directly over (within 1.5 inches [3.8 cm.]) the implanted Sound Processor.

Using the *Esteem* Programmer (Model 6001), the health care professional can program the *Esteem* Sound Processor with the patient's prescription, and interrogate the Sound Processor to read its programmed parameters and serial number.

Using the Personal Programmer (Model 8001), the patient can select volume and environment settings from those pre-programmed by the health care professional.

Programmable Parameters:
When using the *Esteem* Programmer to program the Sound Processor, the Programmer displays the communication status. Successful communication is confirmed by an indicator on the *Esteem* Programmer screen.

Esteem® Sound Processor Model 2001

Parameter Descriptions and Values:

- *Sound Processor ON/OFF:* Enables the Sound Processor to be activated or disabled. -- ON, OFF (standby)
- *Confirmation Tone Frequency, Amplitude, and Duration:* A single tone (double tone @ERI) emitted by the Sound Processor when a parameter value is changed using the Personal Programmer. The available frequencies are 0.5, 1.0, 1.5, and 2.0 kHz. The available amplitudes are 76, 88, 100, and 112 dB. The available durations are 0.1, 0.2, 0.3, and 0.4 seconds.
- *Volume and Volume Limits:* The Volume may be set between –21 dB and +24 dB in steps of 3 dB. The maximum and minimum available Volume settings (limits) may be set to any of these levels.
- *Upper and Lower Band Gain:* The *Esteem* has two frequency bands in which the gain is independently programmable to levels between 5 dB and 40 dB in steps of 5 dB.
- *Primary Compression Thresholds and Ratios:* The *Esteem* has two frequency bands in which the primary compression settings are independently programmable. In each band, the primary compression threshold is programmable to levels 12, 18, 24, and 30 dB below maximum output. In each band, the primary compression ratio is programmable to 1.3, 1.5, 2.0, and 3.0.
- *Secondary Compression Threshold:* Secondary compression in *Esteem* provides a programmable parameter to limit the maximum output level of the system. The secondary compression thresholds are programmable to levels of 117, 114, 111, and 105 dB (note that these levels are relative to typical middle ear displacement).
- *Filter Crossover Frequencies:* The crossover frequencies for both the upper and lower band are each independently programmable to eight (8) different values. The crossover frequencies define the transition region between the two bands. The available crossover frequency settings for the upper band are:

  0.35; 0.45, 0.60, 0.85, 1.20, 1.80, 2.4 and 3.40 kHz

  The available crossover frequency settings for the lower band are:

  0.60, 0.80, 1.20, 1.60, 2.20, 3.20, 4.40 and 6.00 kHz
- *High Cut and Low Cut:* The upper and lower frequency processing limits are programmable through the High Cut and Low Cut frequencies. The Low Cut frequency defines the lower frequency limit of the lower band and is programmable to 175, 350, 700, and 1000 Hz. The High Cut frequency defines the upper frequency limit of the upper band and is programmable to 3.0, 4.0, 6.0, and 12.0 kHz.
- *Input Sensor Gain:* The input sensor gain is also programmable to levels of +6, 0, -3, and –6 dB.
- *Band Enable:* Each of the two bands may be deactivated to conserve battery current if the desired fitting prescription can be achieved with a single band. Deactivating one of the bands results in a 15% reduction in the quiescent current of the Sound Processor.

Personal Programmer Settings:

The patient, using the Personal Programmer, can adjust the following pre-programmed parameters in the implanted Sound Processor. Patient instructions for changing settings are contained in the Patient Manual.

- *Volume:* 16 increments of 3 dB
- *Programmed Modes:* Three modes: 1, 2, and 3.
- *Standby:* OFF

Shelf Life:

Notice the USE BY DATE on the package labels. Do not use the Sound Processor after the USE BY date has passed (example shown below, 15-SEP-2009).

2009-09-15

Physical Specifications:

Materials: Hermetically sealed titanium assembly with two IS-1 connector ports in a sealed polyurethane header. Meets IS-1 dimensional specifications.

- *Size:* 41.2 mm L, 44.1 mm H, 6.4 mm D
- *Mass:* 20.7 g
- *Volume:* 9.5 cc
- *Insertion Force (IS-1):* 3.3 lbs. maximum
- *Withdrawal Force (IS-1):* 1.1 lbs. minimum

X-ray Identifier:

The Sound Processor contains a radiopaque identification tag that, when x-rayed, displays the manufacturer name (EMC) and identifier unique to the model, as shown here.

Esteem® The Hearing Implant™ MedCem® Hydroxyapatite Cement Model 1610

Cement Description:
MedCem is made from a craniofacial calcium phosphate ceramic bone filler (hydroxyapatite) cement for craniofacial reconstruction. Envoy Medical identifies MedCem as Model 1610. MedCem is a two-component system consisting of a calcium phosphate powder and a sterile setting solution in a liquid form.

Directions for Use:
MedCem is indicated solely for the cementing of the *Esteem* Sensor and Driver to the mastoid floor.

MedCem is for single patient use and should never be reused. MedCem is provided in single use bottles containing materials to produce 5 g of cement for use. Mixing of these two components, using the included tray and mixing stick, forms a liquid paste that can be deposited using a sterile syringe (Model 1710) with a sterile tapered tip (Model 1725) and which will harden in situ if the directions and precaurions provided in this sheet are followed.

1. Use the MedCem in a dry surgical field and aseptically according to the following instructions for use.
2. Control of active bleeding should be achieved prior to implantation of the MedCem. The surgical field should be thoroughly dried.
3. Pour the powder component into the mixing bowl provided. Pour the liquid component onto the powder component.
4. Use the mixing stick provided to mix the powder and liquid components together for 30 seconds until moistened and it is a homogenous liquid paste.
5. Mix paste in a shearing fashion for an additional 30 seconds.
6. Place the mixture into a syringe with a tapered tip and dispense around the Sensor and Driver.
7. Once the liquid paste begins to harden, it should be left undisturbed for a minimum of 10 minutes.

Indications:
MedCem is indicated solely for the cementing of the *Esteem* Sensor and Driver to the mastoid floor.

Contraindications:
MedCem MUST NOT be used:

- if there is an existing acute or chronic infection in the mastoid.
- in a stress bearing application.
- if the surrounding bone is nonviable or is incapable of supporting or anchoring the implant.
- if the patient conditions include: a) metabolic bone disease, b) acute traumatic injuries with open wounds close to the use site which are likely to become infected, c) immunologic abnormalities, d) systemic disorders which result in poor wound healing or will result in tissue deterioration over the implant site, e) inflammatory bone disease, f) severe vascular or neurological disease.
- Impaired kidney function, altered calcium metabolism

Precautions:
DO NOT mix with other materials (e.g., fibrin glue).

Control fluid accumulation of the surgical site when applying MedCem.

Drug Interactions:
No interactions with drugs or other medical devices have been identified for MedCem.

Warnings:

1. The surgeon is to be familiar with the material properties, handling characteristics, the method of application, and the surgical procedure prior to performing the surgery.
2. Noncompliance with surgical site preparation, cement mixing and curing instructions could lead to failure of the MedCem which could require additional surgery and material removal.
3. If bone wax or gel foam is used, it should be removed from the bone interface prior to the administration of the MedCem.
4. The safety and effectiveness of adding any substance to the MedCem is not known. Additional substances may effect the setting time, strength, and reaction rate.
5. The safety and effectiveness of the MedCem when used adjacent to non-viable bone is not known.
6. Placement over inadequate or non-vascularized tissues or allograft material is not recommended.
7. As with any surgical procedure, care should be exercised in treating individuals with pre-existing conditions that may affect the success of the procedure. This includes individuals with bleeding disorders of any etiology, long term steroidal therapy, immunosuppression therapy, or high dosage radiation therapy.

Notes:

- If the liquid paste has not set after 10 minutes, the MedCem should be removed and replaced with new MedCem from a new package.
- Discard any unused MedCem.
- Depending on the size of the implant, several applications of the MedCem can be applied successively.

Environmental Specifications:
MedCem may be cooled prior to use if necessary to extend working time. Do not cool below 4°C (39°F).

Storage Temperature:
Store dry and in the original package. Do not freeze. Optimal storage temperature from 4°C to 23°C (39°F to 74°F). Do not exceed 35°C (95°F) for extended periods, e.g. shelf life is reduced to about 3 months at 50°C.

Sterilization:
The cement is gamma radiation (25 kGy min) sterilized before shipping, and must not be re-sterilized. Ensure the package seals are intact and have not been exposed to moisture, contaminated, punctured, opened, or damaged in any way that might compromise sterility. Components whose sterility is compromised must be replaced. Do not use MedCem after the use by date or for another patient.

Biocompatibility:
MedCem meets the criteria in ISO 10993-1:1997 for long term implantation.

Esteem®
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EnvoyCem® Ionomeric Cement Model 1640

Cement Description:
The EnvoyCem Cement is used during the implantation of the *Esteem* and is indicated solely for the coupling of the *Esteem* Sensor and Driver to the ossicles of the middle ear. Model 1640, EnvoyCem is a two-component system consisting of a glass powder (aluminum-calcium-fluorosilicate glass) and a poly-alkenoic acid which is monomer free and is in a liquid form.

Directions for Use:
EnvoyCem is provided in single use capsules containing materials to produce 0.5 g of cement for use. Depending on the size of the implant, several capsules can be applied successively.

Mixing of these two components, using the Rotary Mixer (Model 1635) which is provided separately, forms a moldable cement which can be applied as required and which will harden in situ if the directions and precautions provided in this sheet are followed. EnvoyCem does not produce heat greater than body temperature during curing.

Important: Please Follow the Directions for Use Precisely
A sufficient contact area between bone, cement, and any affixed implant is required. EnvoyCem is suitable for the following types of fixations:

- Physical and chemical bonding of metal, ceramic, and/or bone

Activate the cement by inserting the capsule into the Activator (Model 1633) and squeezing the EnvoyCem capsule for 2 seconds. Then insert the activated EnvoyCem capsule into the Rotary-Mixer (Model 1635). The recommended mixing time in the mixer is 10 seconds.

Then insert the activated/mixed EnvoyCem capsule into the Extruder/Applicator (Model 1634) to dispense/apply the EnvoyCem to a cold flat surface.

Delays between activation, mixing, and application must be avoided, because the setting of the cement in the capsule progresses continuously and complicates or impedes dispensing.

In the laboratory, the following data was obtained at a temperature of 23°C and a mixing time of 10 seconds:

- Working time 30 seconds to 2 minutes.
- Setting time hardened after 10.5 minutes (including mixing time).

The exact working time depends on the environmental temperature. Do not cool below 4°C.

The EnvoyCem should be applied between and around the Sensor tip and the ossicle. Figure 7 illustrates application.

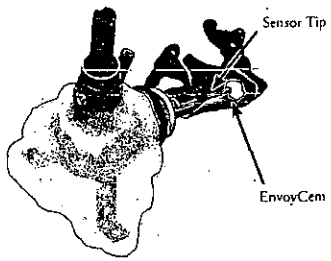

Figure 7: EnvoyCem Application on the Sensor

The EnvoyCem should be applied between and around the Driver tip and the stapes capitulum. Figure 8 illustrates application.

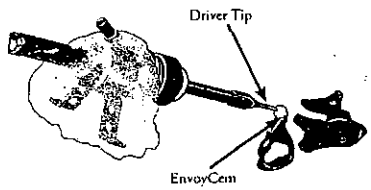

Figure 8: EnvoyCem Application on the Driver

Indications:
EnvoyCem is indicated **solely for the coupling of the *Esteem*** Sensor and Driver to the ossicles of the middle ear.

Contraindications:

EnvoyCem **is contraindicated for CNS surgeries**

EnvoyCem MUST NOT be used:

- in contact with cerebral or nerve tissue, CSF, or inner ear fluid;
- directly on the dura matter;
- for treatment and closure of soft tissue and cartilage defects;
- in cases in which a postoperative radiotherapy of the implantation site or the adjacent area cannot be excluded;
- with known hypersensitive reactions against one or more components of polymaleinate ionomer and/or fluoride;
- in cases of severe systemic diseases (especially with renal insufficiencies).

Model 1633 Activator:
The EnvoyCem Activator is the CE marked Maxicap Activator.

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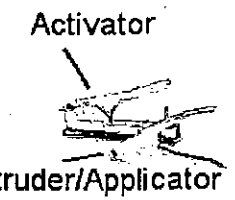
EnvoyCem® Ionomeric Cement Model 1640

Model 1634 Extruder/Applicator:
The EnvoyCem Extruder is the CE marked Maxicap Extruder/ Applicator.



Model 1635 Rotary-Mixer:
The EnvoyCem Rotary-Mixer is the CE marked ROTO-MIX.

Physical Chemical Properties and Precautions:

> During curing, EnvoyCem is sensitive to water and moisture. Excessive moisture contamination inhibits complete hardening. *Only* in such cases, EnvoyCem forms a soft, ion releasing toxic gel and loses its adhesive properties. Therefore, contact with moisture sources (i.e., blood, other body fluids, physiological rinsing solutions, etc.) must be avoided to assure a proper setting of the cement.

After curing, EnvoyCem should not be allowed to desiccate as this may produce superficial cracks and reduction of mechanical strength. Once set, EnvoyCem provides a biocompatible, hydrophilic surface.

Side Effects/Warnings:
No experience or animal studies for use in women who are pregnant or lactating exist for EnvoyCem. The safety of EnvoyCem for such women or their nursing infants is not known.

> Use of **EnvoyCem** in Central Nervous System (CNS) surgeries has *been associated with risk of mortality.*

The following side effects / events have been observed:
- in a few cases, reversible seroma
- occasional rejection

Drug Interactions:
No interactions with drugs or other medical devices have been investigated for EnvoyCem

Additional Precautions:
DO NOT mix with other materials (i.e., fibrin glue, etc.)

Use a fresh capsule(s) for each use of EnvoyCem. Uniformity and reproducibility of performance are guaranteed only for cement in intact capsules prior to its use.

The use-site / implantation-site must be as dry as possible during application and hardening of EnvoyCem. Accordingly:
- Careful, complete hemostasis is necessary
- Bone surfaces must be cleaned and kept dry
- Prevent diluted EnvoyCem from coming in contact with facial nerves, round and oval window membranes

Hardened EnvoyCem bonds to metal instruments and should therefore be rinsed off with cold water before setting is completed.

Environmental Specifications:
EnvoyCem may be cooled prior to use if necessary to extend working time. Do not cool below 4°C.

Storage Temperature:
Store dry and in the original package. Do not freeze. Optimal storage temperature from 15°C to 25°C (40°F to 77°F).

Sterilization:
System components are gamma radiation sterilized before shipping, and must not be re-sterilized. Ensure the package seals are intact and have not been exposed to moisture, contaminated, punctured, opened, or damaged in any way that might compromise sterility. Components whose sterility is compromised must be replaced. Do not use EnvoyCem after the use by date or for another patient.

Biocompatibility:
Cured EnvoyCem meets the criteria in ISO 10993-1:1997 for long term implantation.

Esteem®
The Hearing Implant™

Glasscock Stabilizer Model 1730

Product Description:
The Model 1730, Glasscock Stabilizer is a temporary retainer used to position and stabilize the Sensor and Driver during positioning.

Description and Use:
The Glasscock Stabilizer is a temporary device used to assist in the positioning and stabilizing of the Sensor and Driver during the Esteem implantation. Figure 9 illustrates the Stabilizer. A stabilizer is used to place both the Sensor and Driver simultaneously during surgery.

- *Base:* The base is used to temporarily connect the Glasscock Stabilizer to the cortex of the temporal bone using bone screws.
- *Positioning Wire:* Used to position and stabilize the Sensor and Driver during surgery.
- *Stabilizer Pin:* Connects the Glasscock Stabilizer into the Sensor and Driver Stabilizer socket and also provides anti rotational stability.

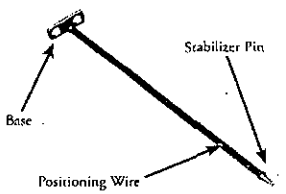


Figure 9: Glasscock Stabilizer

Glasscock Stabilizer Sterilization:
The Glasscock Stabilizer is Ethylene Oxide sterilized before shipping, and must not be re-sterilized. Components whose sterility is compromised must be replaced.

NOTE: Additional information pertaining to the Glasscock Stabilizer is noted in the Operator's Manual.

Mechanical Shock:
The Glasscock Stabilizer is manufactured and packaged in handling containers made to withstand reasonable mechanical shock. However, if a unit has been removed from its handling container and is dropped, it may be damaged. If an unpacked unit is dropped, do not implant it. Instead, return it to Envoy Medical Corporation.

PRECAUTIONS

Contraindications:
There are no known contraindications for the Glasscock Stabilizer.

Biocompatibility:
The component that comes in contact with the body is constructed of materials to meet criteria in ISO 10993-1 for equipment that is implanted long-term.

Sterile Package Handling:
Ensure the package seals and sterile trays are intact and have not been exposed to moisture, opened, punctured, contaminated, or damaged in any way that might compromise sterility. Components whose sterility is compromised must be replaced. Components must not be re-sterilized.

Sterility:
Components whose sterility is compromised must be replaced. Use a new sterile Glasscock Stabilizer for each patient. To minimize the risk of infection, never re-use any *Esteem* component or accessory. Do not attempt to resterilize any *Esteem* component or accessory. Do not use an *Esteem* component or accessory that has been exposed to an unsterile field. To minimize the risk of infection, use a new, sterile component, and send the contaminated component back to Envoy Medical Corporation.

Storage Temperature:
For best results the Glasscock Stabilizer should be stored in an environment in which the temperature remains between 0°C (32°F) and 50°C (122°F) unless otherwise indicated on the package label. The Glasscock Stabilizer should be brought to room temperature before implant if it has been stored in a warm or cold environment.

Esteem®
The Hearing Implant™

Ear Insert Assembly

Product Description:
The Ear Insert Assembly is used to introduce a stimulus into the ear canal while performing Sensor and system testing.

Description and Use:
The Ear Insert Assembly is used as an accessory item during the implant of the *Esteem*. The Ear Insert Assembly is placed in the ear canal of the ear in which the *Esteem* is being implanted. The ER-2 Speaker and Microphone are connected to the Ear Insert Assembly. The ISA records appropriate signals when sound stimulates the tympanic membrane.

PRECAUTIONS

Contraindications:
There are no known contraindications for the Ear Insert Assembly.

Biocompatibility:
The component that comes in contact with the body is constructed of materials to meet criteria in ISO 10993-1.

Sterilization:
The Ear Insert Assembly is Ethylene Oxide sterilized before shipping, and must not be re-sterilized. Components whose sterility is compromised must be replaced.

Sterile Package Handling:
Ensure the package seals and sterile trays are intact and have not been exposed to moisture, opened, punctured, contaminated, or damaged in any way that might compromise sterility. Components whose sterility is compromised must be replaced. Components must not be re-sterilized.

Sterility:
Components whose sterility is compromised must be replaced. Use a new sterile Ear Insert Assembly for each patient. To minimize the risk of infection, never re-use any *Esteem* component or accessory. Do not attempt to resterilize any *Esteem* component or accessory. Do not use an *Esteem* component or accessory that has been exposed to an unsterile field. To minimize the risk of infection, use a new, sterile component, and send the contaminated component back to Envoy Medical Corporation.

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Tapered Syringe Tip Model 1725

Tapered Syringe Tip Description and Use:
The Model 1725, Tapered Syringe Tip is a luer lock tip placed on a standard syringe (Model 1710) and is used to dispense MedCem cement around the Sensor and Driver in the mastoid. The Model 1725 syringe tip is essential in that it controls the flow, volume, and location of MedCem as it is placed around the transducers. Figure 10 is a drawing of a Tapered Syringe Tip coupled with a standard syringe.

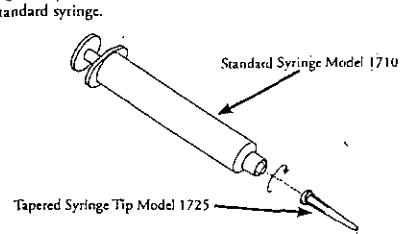

Figure 10: Tapered Syringe Tip

MedCem Product Description:
MedCem is made from a craniofacial calcium phosphate ceramic bone filler (hydroxyapatite) cement for craniofacial reconstruction. Envoy Medical identifies MedCem as Model 1610. MedCem is a two-component system consisting of a calcium phosphate powder and a sterile setting solution in a liquid form. MedCem is indicated solely for the cementing of the Esteem Sensor and Driver to the mastoid floor.

MedCem is for single patient use and should never be reused. MedCem is provided in single use bottles containing materials to produce 5 g of cement for use. Mixing of these two components, using the included tray and mixing stick, forms a liquid paste that can be deposited using a sterile syringe with a sterile tapered tip (Model 1725) and which will harden in situ if the directions and precautions provided are followed.

PRECAUTIONS

Contraindications:
There are no known contraindications for the Tapered Syringe Tip.

Sterilization:
The Tapered Tips are Ethylene Oxide sterilized before shipping, and must not be re-sterilized. Components whose sterility is compromised must be replaced.

Storage Temperature:
For best results the Tapered Syringe Tip should be stored in an environment in which the temperature remains between 0°C (32°F) and 50°C (122°F) unless otherwise indicated on the package label.

The Tapered Syringe Tip should be brought to room temperature before use if it has been stored in a warm or cold environment.

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Laser Reflector Model 1250

Product Description:
Model 1250, Laser Reflector is cut to size and temporarily placed in the middle ear during the implant procedure. It is used to reflect a low power laser signal from a Laser Doppler Vibrometer (LDV) in order to measure displacement of the ossicular chain or transducer displacement.

Laser Reflector Directions for Use:
Model 1250, Laser Reflector is cut to a size not larger than ½ mm x ½ mm and is temporarily placed on the ossicular chain for the appropriate measurements.

The reflectors are used to reflect a low power laser signal from a Laser Doppler Vibrometer (LDV) in order to measure ossicular chain displacement through a frequency spectrum.

PRECAUTIONS

Contraindications:
There are no known contraindications for the Laser Reflector.

Storage Temperature:
For best results the Laser Reflector should be stored in an environment in which the temperature remains between 0°C (32°F) and 50°C (122°F) unless otherwise indicated on the package label.

Esteem®
The Hearing Implant™

Replica Sound Processor Model 1500

Product Description:
The Model 1500, Replica Sound Processor is used to determine the best position and placement for the implanted Sound Processor. It is a non-functional model of the implanted Sound Processor and serves as a template for surgical preparation.

Product Directions for Use:
The Replica Sound Processor is the approximate size of the *Esteem* Sound Processor. The Replica Sound Processor can be used non-sterile to determine the position of the Sound Processor and surgical incision. The Replica Sound Processor can also be sterilized to use in the sterile filed for placement of the Sound Processor bed.

The Replica Sound Processor is made from stainless steel and has a satin finish.

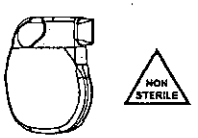

Figure 11: Replica Sound Processor

Sound Processor Description:
The *Esteem* Model 2001, the Sound Processor, is placed in a surgically created bed in the temporal bone and connected to the Sensor and Driver by their leads. The Sound Processor filters and increases the signals received by the Sensor and outputs these signals to the Driver. The Sound Processor parameters can be adjusted using the *Esteem* Programmer or Personal Programmer.

STERILIZATION:
The Replica Sound Processor is shipped non-sterile. Prior to use, this device must be thoroughly cleaned and autoclave sterilized as follows:

Cleaning Instructions:
It is the responsibility of the user facility to make sure that appropriate cleaning methods are used where Envoy Medical Corporation's recommendations are not followed.

New Replica Sound Processor must be carefully cleaned before initial sterilization. Trained personnel must perform cleaning along with maintenance and mechanical inspection prior to initial sterilization. Contaminated Replica must not be placed into a sterilization module.

Replica should be cleaned in accordance with the following automatic cleaning specifications:

Preparation of Washing And Rinsing Agents:
The washing machine cleaning process must permit the Replica Sound Processor to remain still when they are cleaned. It is recommended that Replica be cleaned in sterilization module. Washing machines should not be over loaded.

In accordance with the manufacturers instructions, add the necessary amount of washing and rinsing agent into the washing machine. Envoy Medical Corporation recommends only the use of neutral pH cleaning agents.

Esteem®
The Hearing Implant™

Replica Sound Processor Model 1500

1) CLEANING PROCESS

In accordance with EN ISO 15883, the following phases should be adhered to:

- Washing phase: increase temperature to 93–98 °C (200–208 °F), allowing the washing agent to eliminate, disperse, and suspend any excess debris from the Replica Sound Processor.
- Thermal disinfection phase: Hold temperature at 93–98 °C (200–203 °F), for 10 minutes. Do not add any additional agents.
- Rinsing Phase: Rinse Replica Sound Processor successively with de-mineralized water to remove any excess cleaning agents.

2) DRYING PROCESS

- Remove the Replica Sound Processor upon completion of the cleaning process.
- If the cleaning process does not include a drying cycle, thoroughly dry the Replica Sound Processor in an oven at a temperature below 110 °C (230 °F).

3) STERILIZATION PROCESS

- If not expressly specified as sterile, the product is supplied non sterile.
- Exact compliance is required with the manufacturers' user instructions for sterilizers.
- It is the responsibility of the user facility to make sure that appropriate sterilization methods are used where Envoy Medical Corporation recommendations are not followed to account for potential differences in sterilization chambers, wrapping methods and load configurations.
- All non-sterile products are sterilized by steam sterilization (autoclaving). For initial sterilization and resterilization, the following parameters can be used.

Shelf Life:
The *Esteem* Sound Processor Replica has no shelf life restrictions.

Storage Temperature:
The *Esteem* Sound Processor Replica has no storage temperature limitations.

Precautions and Contraindications:
There are no known contraindications for the Replica Sound Processor.

Biocompatibility:
The component that comes in contact with the body is constructed of Stainless Steel (316L SST) to meet criteria in ISO 10993-1 for equipment that is biocompatible.

	3.5 min Hi Vac	18 min Hi Vac	273 °F Gravity Flash	273 °F Gravity
Sterilizer Type	Pre-vacuumed sterilizer	Pre-vacuumed sterilizer	Gravity displacement sterilizer	Gravity displacement sterilizer
Exposure Time	3.5 min	18 min	10 min	35 min
Temperature	274–279 °F (134–137 °C)	274–279 °F (134–137 °C)	273 °F (134 °C)	273 °F (134 °C)
Drying Time	60 min	60 min	60 min	60 min
Wrapping	Wrapped in a Universal System Sterilization Container	Wrapped in a Universal System Sterilization Container	Unwrapped in a Universal System Sterilization Container	Wrapped in a Universal System Sterilization Container

Container is wrapped using the AAMI (Association for the Advancement of Medical Instrumentation) CSR double wrapping technique. Use only single sterilization system in the chamber and using the middle shelf.

Esteem® The Hearing Implant™ Intraoperative System Analyzer and Accessories

System Description:
The Model 3001 Intraoperative System Analyzer™ (ISA) performs intraoperative testing of the Sensor, Driver, Driver-to-Sensor feedback and system-level performance of the implanted *Esteem®*.

Description and Use:
The ISA system consists of a Medical Panel computer, Patient Interface Device (PID), Etymotic Research™ ER-2 Stimulator, Microphone, LCR Meter and LCR Meter Adapter. The ISA provides patient isolation for the Sensor and Driver connections. The ISA is configured so all equipment can be set up prior to the start of the surgical procedure.

The ISA provides two Auxiliary inputs for connection to the external Laser Doppler Vibrometer (LDV), and to the ear canal Microphone.

ISA Accessory Equipment/Cables:
The following accessories are used with the Intraoperative System Analyzer (ISA).

Accessory Items
Patient Interface Device (PID)
USB Cable
PID to Driver Cable*
PID to Sensor Cable*
Patient Cable
PID to Earphone Cable
ER-2 Insert Earphone Assembly
PID to Microphone Cable
PID to LDV Cable
ISA Cable Kit
LCR Meter
Adaptor, LCR Meter
** Separate Sterile Package*

Equipment Component Descriptions and Use:
Envoy Commander:
The Medical Panel Computer runs the ISA application software.

Patient Interface Device:
The Patient Interface Device (PID) shown in Fig. 12 provides the connections between the patient, the Medical Panel Computer and other test devices.

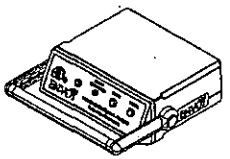

Figure 12: Patient Interface Device

USB Cable:
A 0.91 meter Universal Serial Bus (USB) cable to connect the PID to the Medical Panel Computer.

PID to Driver Cable: [STERILE]
A 4.88 meter signal cable with a black marker at each end to connect the PID to the Driver. The cable is Ethylene Oxide sterilized and intended for single use.

PID to Sensor Cable: [STERILE]
A 4.88 meter signal cable with a yellow marker at each end to connect the PID to the Sensor. The cable is Ethylene Oxide sterilized and intended for single use.

Patient Cable:
A 4.88 meter patient cable (green) to connect Subdural Needle Electrode to electrical ground during testing with the ISA.

PID to Earphone Cable:
A 3.05 meter sound stimulator cable to connect the PID to ER-2 Stimulator.

Esteem® The Hearing Implant™

Intraoperative System Analyzer and Accessories

ER-2 Insert Earphone Assembly:
The ER-2 Assembly (Figure 13), includes an Etymotic Research ER-2 sound stimulator which includes an earphone/speaker assembly.

Figure 13: ER-2 Earphone/Stimulator

Earphone Features
- Flat frequency response at the eardrum
- 70+ dB isolation between ears: reduces the need for masking
- 30+ dB external noise exclusion

Assembly Includes
- Earphones
- Dual-mono 7 ft. cable assembly
- 50 foam eartips (regular, 13 mm)
- 50 foam eartips (baby, 10 mm)
- 2 immittance probe tip adapters with tubing
- 4 front tube replacements
- Velcro clips

PID to Microphone Cable:
A 4.5m shielded USB cable to connect the PID to Microphone assembly.

Microphone Assembly:

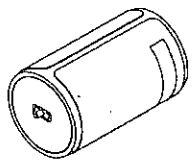

Figure 15: Microphone Assembly

Microphone Features
- 1mm OD probe microphone for real ear measurement
- Equalized to flat frequency response beyond 10 kHz

PID to LDV Cable:
A 3.05 meter BNC to BNC cable to connect the PID to a Laser Doppler Vibrometer (LDV).

ISA Cable Kit:
A collection of all non-sterile reusable ISA System Cables and LCR meter adaptor needed for intraoperative system analysis.

Isolation Transformer:
The 110/220 volt isolation transformer must be used with the ISA.

Esteem® The Hearing Implant™ Intraoperative System Analyzer and Accessories

LCR Meter:
The Model 3104, is a B&K Precision 878A™ LCR Meter used to measure Sensor and Driver capacitance during implant. A 3-Pin (Transducer cable, 2 active pins + 1 ground) to Banana plug (Meter) adaptor is required to connect the LCR Meter with the transducer cables.

Figure 16: LCR Meter

Features
- Selectable test frequencies 120Hz, 1KHz
- Simultaneously displays measured component value and Q or Dissipation Factor (D)
- Display hold
- Relative mode
- Tolerance mode
- RS 232 Interface (cable and software required)

Adaptor, LCR Meter:
An electrical adaptor to connect the 3-pin transducer cables (Sensor or Driver) to the LCR Meter for measuring capacitance.

ISA System Precautions & Contraindications:
There are no known contraindications for the ISA system or any of its components.

Cleaning Instructions
Clean the ISA with a soft cloth dampened with water.

Electrosurgery:
Never allow current from an electrosurgical (electrocautery) instrument to be applied directly to any ISA cable.

Storage Temperature:
All ISA cables have no storage temperature limitations.

Sterility:
The PID to Driver and PID to Sensor Cables are ethylene-oxide sterilized before shipping. Components whose sterility is compromised must be replaced. Use new, sterile products for each patient. To minimize the risk of infection, never re-use any *Esteem* component. Do not attempt to re-sterilize any *Esteem* component.

Do not use an *Esteem* component that has been exposed to an unsterile field. To minimize the risk of infection, use a new, sterile component, and send the contaminated component back to Envoy Medical Corporation.

Sterile Package Handling:
Ensure the Sensor and Driver cable sterile packages are intact and have not been exposed to moisture, opened, punctured, contaminated, or damaged in any way that might compromise sterility of the Sensor and Driver cables. Components whose sterility is compromised must be replaced. Components must not be re-sterilized.

Non-Sterile:
All other instruments not listed above are shipped non-sterile and are reusable components of the ISA System.

Mechanical Shock:
The ISA and components are manufactured and packaged to withstand reasonable mechanical shock. However, if a unit has been removed from its packaging and is dropped, it may be damaged. Inspect prior to use for any visible damage. If damaged, return to Envoy Medical Corporation.

Storage Temperature:
The ISA equipment and components should be stored in an environment in which the temperature remains between 0°C (32°F) and 50°C (122°F). Allow the components to adjust to room temperature before use, if they have been stored in a warm or cold environment. Failure to do so may result in improper system operation. The Medical Panel Computer is designed to operate under normal room temperatures.

Electromagnetic Compatibility:
The ISA equipment is designed to be resistant to electromagnetic interference (EMI). However, it is possible that extrinsic radio frequency (RF) signals generated by cellular telephones, microwave equipment, security systems, or other RF devices might introduce noise in the measured signals. If this happens, eliminate the source of interference.

Biocompatibility:
The device components that may come in contact with the body are constructed of materials that meet the criteria in ISO 10993-1.

Safety Testing:
The ISA System components meet the requirements of EN/IEC 60601-1.

Cable Interconnections:
Ensure that the cable interconnections do not contact any fluid during the procedure; contact with fluid will result in erroneous test data. The ISA cables have either unique connector configurations or have color coded connectors. Refer to the ISA manual for complete information on cable connections and operation instructions.

Esteem®
The Hearing Implant™

Durable Surgical Supplies

Disclaimer:
The following surgical supplies, tools, and accessories are provided to support *Esteem* implants. These products are commonly available for direct purchase by the hospital or implant center. Each item is packed either in a protective bag or the original shipping carton. Each item is labeled by the original manufacturer in accordance with their CE Mark and regulatory requirements. Envoy Medical Corporation does not manufacture these products and does not modify the original labeling or packaging. These products are provided for your convenience.

Accessory Items	REF	CE Mark
Screwdriver Handle	1210	CE 0125
Screwdriver Blade	1211	CE 0125
Bone Screw Dispenser	1215	CE 0125
Sterilization Tray, Surgical Tools	1216	CE
Curved Rosen Pick	1220	CE 0123
Activator Tool, EnvoyCem	1633	CE 0123
Extruder/Applicator Tool	1634	CE 0123
Mixer, Rotary, EnvoyCem	1635	CE 0123

Component Descriptions and Use:

Screwdriver Handle:
The Model **1210** is a standard reusable surgical tool in which the 1211 Screwdriver Blade fits. The 1210/1211 tool assembly is used to install Model 1790 Bone Screws which fasten Model 1730 Glasscock Stabilizers to the temporal bone during transducer positioning and may be used to fasten the Model 2000 Sound Processor in the Sound Processor bed.

Screwdriver Blade:
The Model **1211** is a standard reusable surgical tool that fits in the 1210 Handle. The blade size conforms to Model 1790 Bone Screws.

Bone Screw Dispenser:
The Model **1215** is a reusable bone screw holder and dispenser for sterilization.

Sterilization Tray, Surgical Tools:
The Model **1216** is a reusable surgical tool container and sterilizing tray.

Curved Rosen Pick/Wullstein Needle:
The Model **1220** is a standard reusable surgical tool primarily used to apply EnvoyCem. It may be used for other purposes during the implant procedure.

Activator Tool, EnvoyCem:
The Model **1633** is a reusable 3M ESPE* tool for activating Model 1640 EnvoyCem (glass ionomer cement) in its capsule.

Extruder/Applicator Tool, EnvoyCem:
The Model **1634** is a reusable 3M ESPE* tool for extruding and applying a capsule of EnvoyCem.

Mixer, Rotary, EnvoyCem:
The Model **1635** is a reusable 3M ESPE* rotary mixer for mixing EnvoyCem prior to use.

Precautions & Contraindications:
Read the product labeling and instructions for use provided by the original manufacturer.

Cleaning and Sterilization Instructions
Clean and sterilize per instructions for use provided by the original manufacturer.

Storage Temperature:
All components have no storage temperature limitations. Envoy Medical recommends storage between 4°C (39°F) and 50°C (122°F) and allowing products to reach room temperature prior to use.

Mechanical Shock:
The supplies are packaged in a shipping carton to withstand reasonable mechanical shock. However, if a unit has been removed from its packaging and is dropped, it may be damaged. If any component is damaged do not use.

medical
ENVOY

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Envoy Medical Corporation
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Saint Paul, MN 55110 USA
Worldwide Telephone: 651-361-8000
Fax: 651-361-8099
Toll Free (USA) 866-950-4327

www.envoymedical.com

Esteem®
The Hearing Implant™

Disposable Surgical Supplies

...mer:
...owing surgical supplies, tools, and accessories are provided to ...t *Esteem* implant procedures. These products are commonly ...le for direct purchase by the hospital or implant center. Each ... is packed either in a protective bag or the original shipping ...n. Each item is labeled by the original manufacturer in ...rdance with their CE Mark and regulatory requirements. Envoy ...lical Corporation does not manufacture these products and does ...modify the original labeling or packaging. These products are ...vided for your convenience.

Accessory Items	REF	CE Mark
Wand Sleve, Sterile Drape	701300-002	CE 0044
Syringes, MedCem [4]	1710	CE 0050
Subdural Needle Electrode	1740	CE 0336
Bone Screw, Self Drilling [5]*	1790	CE 0125

* *NON-STERILE (REF 1790): See Manufacturer's instructions for cleaning and sterilization prior to use. See Manufacturer's inserts for specific cautions and instructions for use.*

Component Descriptions and Use:

Wand Sleeve, Sterile Drape:
The Model 901300-100 is a disposable sterile Wand Sleeve (EZ-SERT® Video Camera Drape) clear plastic cover or sheath that allows the non-sterile telemetry Wand of the Envoy Commander to be brought into a sterile surgical field. The length of the sleeve assures coverage of the Wand cable.

Syringes, 10cc, MedCem Applicators [4]:
The Model 1710 are disposable sterile 10cc syringes used with Model 1725 Tapered Tips to apply Model 1610 MedCem (hydroxyapatite cement).

Subdural Needle Electrodes:
The Model 1740 is a disposable sterile EEG needle electrode, 13x0.40 mm, 1 m length, with DIN 42802 connector.

Bone Screws, Self-Drilling, 1.5x4mm [5]:
The Model 1790 are non-sterile bone screws used to fasten the Model 1730 Glasscock Stabilizers during implant and may be used to fasten the Model 2001 Sound Processor in the Sound Processor bed. Use Model 1210 Screwdriver and 1211 Blade to install screws. **The Bone Screws must be sterilized prior to use.**

Cleaning and Sterilization Instructions (for items not provided sterile)
Clean and sterilize per instructions for use provided by the original manufacturer.

Precautions & Contraindications:
Read the product labeling and instructions for use provided by the original manufacturer.

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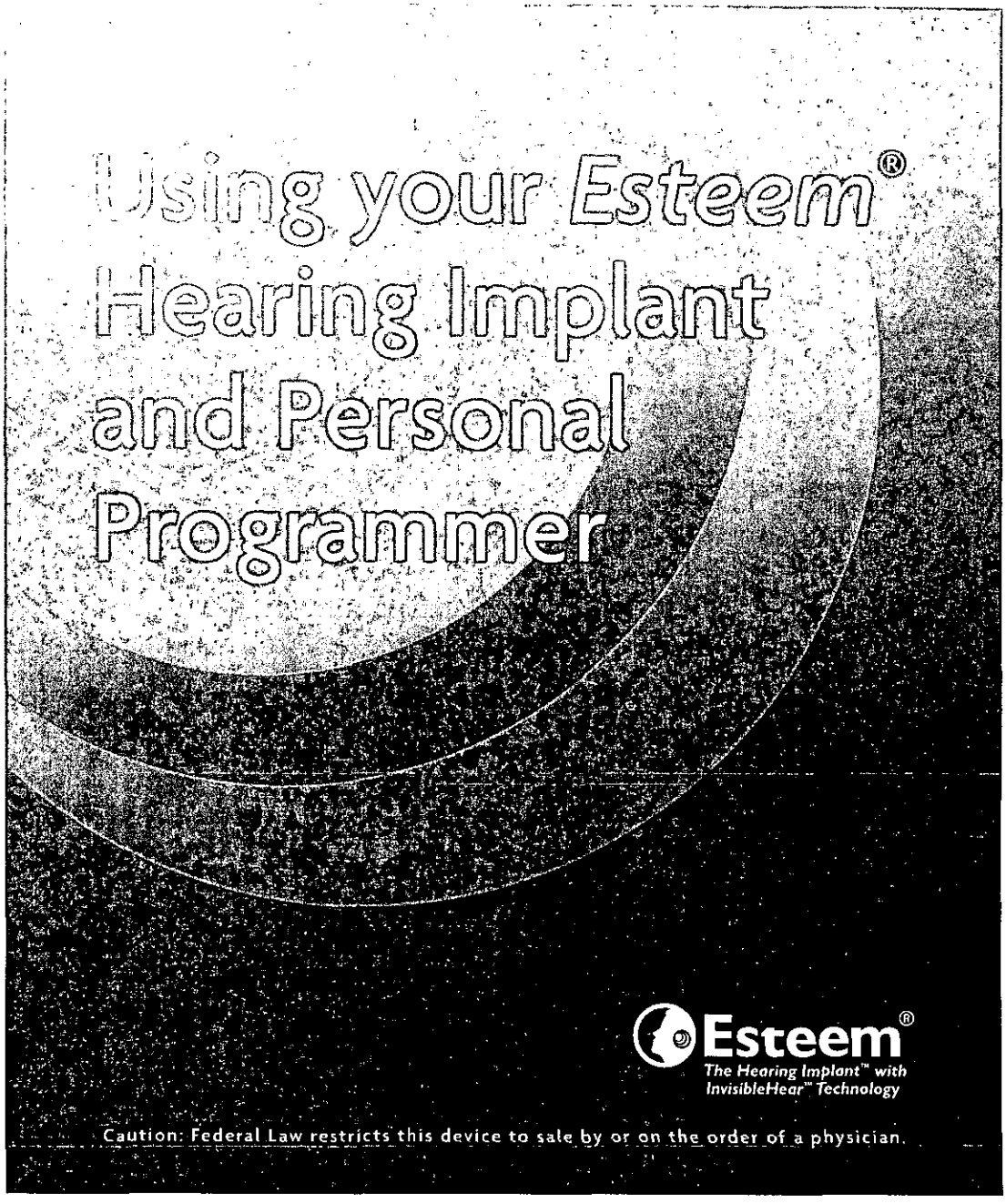

Using your Esteem®
Hearing Implant
and Personal
Programmer
Esteem®
The Hearing Implant™ with
InvisibleHear™ Technology
Caution: Federal Law restricts this device to sale by or on the order of a physician.

Patient Notes

Name of Your Physician: _____

Address: _____

Telephone: _____

Name of Your Hospital: _____

Address: _____

Telephone: _____

Your *Esteem*® Sound Processor

Model Number: _____

Serial Number: _____

Date of Implant: _____

Your *Esteem*® Sensor

Model Number: _____

Serial Number: _____

Date of Implant: _____

Your *Esteem*® Driver

Model Number: _____

Serial Number: _____

Date of Implant: _____

Special Instructions:

_____

_____

_____

_____

Table of Contents

Table of Contents *(continued)*

Glossary

Adverse event — Any undesirable clinical event occurring to a patient.

Air-bone gap — A difference in decibels between hearing thresholds for air-versus bone-conduction stimulation. A sign of conductive hearing loss.

Amplifies — To increase the strength or amount of. To make louder.

Anesthesia — A process to control pain during medical procedures. It includes using medicines to keep you comfortable, and may also be used to help control breathing, blood pressure, blood flow, and heart rate and rhythm, when needed. The two most common types of anesthesia are general and local.

Anxiety — An abnormal and overwhelming sense of apprehension and fear often marked by physiological signs (as sweating, tension, and increased pulse).

Auditory nerve — Either of the eighth cranial nerves connecting the inner ear with the brain, transmitting impulses concerned with hearing and balance, and composed of the cochlear nerve and the vestibular nerve.

Bilateral — Affecting both the right and left sides of the body.

Cholesteatoma — A skin growth located in the middle ear behind the eardrum.

Chorda tympani — One of three nerves that are involved in taste, it is a branch of the facial nerve (the seventh cranial nerve) that serves the taste buds in the front of the tongue. The nerve passes through the middle ear.

Chronic — A disease or ailment that is long-lasting or recurrent.

Cochlea — The main portion of the inner part of the ear, it is a bony labyrinth coiled into the form of a snail shell. It picks up mechanical signals from the middle ear and converts them into nerve impulses, which can be interpreted by the brain as sound.

Conductive hearing loss — A type of hearing loss due to the interruption of normal sound transmission through the outer and/or middle ear. Causes can be anything from earwax build up to the absence or malformation of a part of the ear's anatomy.

Contraindication — Something, such as a symptom or condition, that makes a particular treatment or procedure inadvisable.

CT Scan — A sectional view of the body constructed by computed tomography.

Depression — A psychoneurotic or psychotic disorder marked especially by sadness, inactivity, difficulty in thinking and concentration.

Diathermy — The generation of heat in tissue by electric currents for medical or surgical purposes.

Disarticulate — The separation of bone at a joint. To reduce feedback the incus cut and separated from the stapes during implantation of the *Esteem*®.

Driver — An implanted component of the *Esteem*®. Attached with bone cement to the stapes, it mechanically vibrates the stapes in order to stimulate the cochlea.

Eardrum — A thin membrane separating the ear canal from the middle ear that vibrates in response to sound energy and transmits the resulting mechanical vibrations to the structures of the middle ear.

Eardrum perforation — A rupture of the eardrum or tympanic membrane.

Eczema — An inflammatory condition of the skin characterized by redness, itching, and oozing vesicular lesions which become scaly, crusted, or hardened.

Electrical current — A flow of electric charge.

Enhance — To increase or improve in value, quality, desirability, or attractiveness.

Eustachian tube — Small passageway from nasopharynx to the middle ear space for equalizing air pressure on both sides of the tympanic membrane.

External defibrillation — An electric shock to restore the rhythm of a fibrillating heart.

Facial paresis — A light or partial paralysis of the face.

Feedback — Sound created when a transducer such as a microphone picks up sound from a speaker connected to an amplifier and regenerates it back through the amplifier.

Fibrotic tissue — Tissue characterized by a fibrous (versus bony) composition. Fibrotic tissue is often encountered in the middle ear as result of surgical intervention or infection.

Filters — Electronic circuits which perform signal processing functions, specifically to remove unwanted frequency components from a signal and to enhance wanted ones.

Fracture — The breaking of hard tissue, such as bone.

Frequency — The number of occurrences of a repeating event per unit of time.

General anesthesia — General anesthesia, commonly produced by intravenous drugs or inhaled gasses, is a treatment that puts you to sleep during a medical procedure, so that you don't feel or remember anything that happens during the medical procedure.

Glossary *(continued)*

Genetic — A trait that is inherited through an individual's genes.

Hematoma — A mass of usually clotted blood that forms in a tissue, organ, or body space as a result of a broken blood vessel.

HFPTA — High Frequency Pure Tone Average: an audiological test done to determine an individual's level of hearing loss across several frequencies.

Hydrops — The abnormal accumulation of fluid beneath the skin or in one or more cavities of the body.

Hypersensitivity — Excessively or abnormally sensitive.

Illuminated — The action of supplying or brightening with light or the resulting state.

Implantation — Medical treatment by the insertion of an implant.

Incus — The second of the three ossicles connecting the tympanic membrane to the cochlea (inner ear). The body of the incus is attached to the head of the malleus, and the rounded projection at the lower end of the incus (lenticular process) is attached to the head of the stapes.

Indication — A symptom or particular circumstance that indicates the advisability or necessity of a specific medical treatment or procedure.

Inner ear — Also called the "cochlea." A coiled, snail-like structure located within the temporal bone, containing the sensory organ for hearing. All acoustic stimulation must activate the inner ear to be perceived as sound.

Interference — Anything which alters, modifies, or disrupts a message as it travels along a channel between a source and a receiver.

Keloid — A thick scar resulting from excessive growth of fibrous tissue and occurring especially after burns or radiation injury.

Lithotripsy — The breaking of a concentration of minerals in the body into pieces small enough to be voided or washed out.

Local anesthesia — Local anesthesia, commonly produced by giving a shot directly into the surgical area, numbs a small part of the body. It is used only for minor procedures.

Malleus — The first and largest of the three ossicles connecting the tympanic membrane to the inner ear. The malleus is the outermost of the three auditory ossicles that are located in the middle ear. Its shape resembles a club. The handle of the malleus (manubrium) is attached to the tympanic membrane, and the head of the malleus is attached to the body of the incus.

Mastoid — A particular portion of the skull located behind the ear.

Mastoiditis — Inflammation of the mastoid.

Mechanical feedback — Sound created when a transducer picks up movement from another transducer and regenerates it back through the original transducer.

Meniere's disease — Pathology affecting the cochlea and resulting in sensory (sensorineural) hearing impairment. Characteristic signs and symptoms are tinnitus, vertigo, sensation of ear fullness, and a fluctuating, low-frequency sensorineural hearing impairment.

Microphone — An electronic device for converting acoustic signal (a sound wave) into an electrical signal.

Middle ear — A small membrane-lined cavity that contains the three ossicles ,which pick up sound vibrations from the eardrum, amplify them, and transfer their energy to the inner ear (cochlea).

Mild hearing loss — Hearing loss between 25 and 40 dB.

Mixed hearing loss — Hearing loss with both conductive and sensory components. The audiogram shows a bone-conduction hearing deficit plus an air-bone gap.

Moderate hearing loss — Hearing loss between 40 and 70 dB.

MRI — Magnetic resonance imaging, is primarily a medical imaging technique most commonly used in radiology to visualize detailed internal structure and limited function of the body.

Neurological — Of or relating to the scientific study of the nervous system especially in respect to its structure, functions, and abnormalities.

Ossicles — The three small bones of the middle ear - the malleus, incus, and stapes - extending from the tympanic membrane through the tympanic cavity to the oval window.

Ossicular chain — The three small bones of the middle ear - the malleus, incus, and stapes.

Otitis externa — Inflammation of the external auditory canal.

Outer ear — The outer visible portion of the ear that collects and directs sound waves toward the eardrum by way of the ear canal.

Oval window — One of two openings into the inner ear (cochlea) from the middle ear space. Sound vibrations carried along the ossicles are transmitted to the cochlea through the stapes footplate, which is connected to the oval window.

Glossary *(continued)*

Paranoia — A mental condition characterized by delusions of persecution or grandeur.

Personal Programmer — A remote control device is used by the patient to adjust the volume and select pre-programmed settings in the sound processor.

PET Scan — A sectional view of the body constructed by positron-emission tomography.

Pinna — The outer, most obvious portion of the ear consisting of a cartilage framework. Parts of the pinna are the helix, the lobe, and the concha.

Polyurethane — A type of polymer that is used in flexible and rigid foams, elastomers, and resins.

Profound hearing loss — Hearing loss 90 dB or greater.

PORP — Partial Ossicular Replacement Prosthesis

PTA — Pure Tone Average (3-frequency average for 500, 1000, 2000 Hz) is the key hearing test used to identify hearing threshold levels of an individual, enabling determination of the degree, type and configuration of a hearing loss.

Radio frequency (RF) ablation — A medical procedure using high frequency alternating current to treat a medical disorder.

Reconstruction — Repair of an organ or body part by reconstructive surgery.

Resonating tube — A hollow tube with dimensions chosen to permit internal resonant oscillation of acoustical waves of specific frequencies.

Respiratory infection — An infection of or relating to an individual's respiratory system.

Retrocochlear disorder — The portion of the auditory system that is behind the cochlea – the Eighth nerve, or central auditory nervous system. Retro-cochlear auditory dysfunction often refers only to dysfunction involving the Eighth (auditory) nerve.

Sensor — Implanted component of the *Esteem*® that is used to pick up sound vibration from the incus.

Sensorineural hearing loss — Hearing loss due to cochlear (sensory) or VIIIth nerve (neural) auditory dysfunction. Also sometimes referred to as neurosensory.

Severe hearing loss — A severity of hearing loss between 71 and 90 dB.

Sound Processor — Implanted device in the *Esteem*® system used to filter and increase the electrical signals and send them to the Driver.

Sound wave — Longitudinal pressure waves especially when transmitting audible sound.

Speaker — A device that changes electrical signals into sounds loud enough to be heard at a distance.

Speech discrimination score — The percentage of one-syllable words a person can identify (without visual cues), when the words are heard at a loudness level that is comfortable.

Stapes — The innermost and smallest of the three auditory ossicles that are located in the middle ear. Its shape resembles a stirrup. The head of the stapes is attached to the lenticular process of the incus, and the footplate nearly fills the oval window and is attached there by the annular ligament.

Taste disturbance — A condition characterized by mild alterations of the sense of taste.

Tinnitus — The perception of a noise in the ear (e.g., ringing, cricket sound, roaring) when the internally perceived sound is absent externally.

TORP — Total ossicular replacement prosthesis

Transcutaneous electrical nerve stimulation — The application of electrical current through the skin for pain control.

Tympanic membrane — Also referred to as the eardrum, it is a thin membrane separating the ear canal from the middle ear that vibrates in response to sound energy and transmits the resulting mechanical vibrations to the structures of the middle ear.

Ultrasound — The diagnostic or therapeutic use of ultrasound and especially a noninvasive technique involving the formation of a two-dimensional image used for the examination and measurement of internal body structures and the detection of bodily abnormalities.

Vertigo — A vestibular symptom; the patient has a spinning sensation or senses that the environment is spinning around; may have many causes; faintness, lightheadedness, or dizziness.

Vibrate — To oscillate with a continuing periodic change relative to a fixed reference point.

How *Esteem*® Improves Hearing

Thank you for purchasing the *Esteem*® Hearing Implant. As you're aware, *Esteem*® is designed to help improve the hearing of many adults with moderate to severe sensorineural hearing loss. *Esteem*® is implanted in the middle ear. The technology consists of the Sound Processor, implanted behind the outer ear, and two transducers (called the Sensor and Driver) that are implanted in the middle ear.

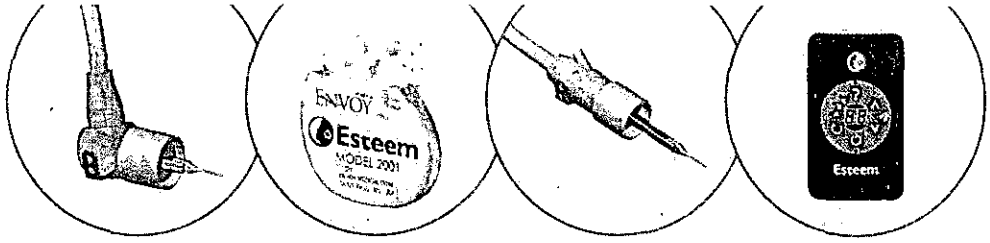
Because all the parts of *Esteem*® are implanted, *Esteem*® is invisible to you and others. The materials used to make *Esteem*® have been proven safe and reliable in millions of pacemakers and other implanted medical devices. *Esteem*® uses your own eardrum as a natural microphone, picking up sounds through the ear canal, thereby using the body's natural anatomy to reduce the background noise, distortion, and acoustic feedback that people experience with conventional hearing aids.

The Sensor, previously described, is attached to the ossicular chain. It picks up vibrations from the eardrum, malleus and incus bones and converts the vibrations into electrical signals. These signals are sent to the Sound Processor. The Sound Processor filters and increases the electrical signals and sends them to the Driver.

The Sound Processor is programmed by your Health Care Professional to customize *Esteem*® settings for your particular hearing needs. The Sound Processor case also contains the battery.

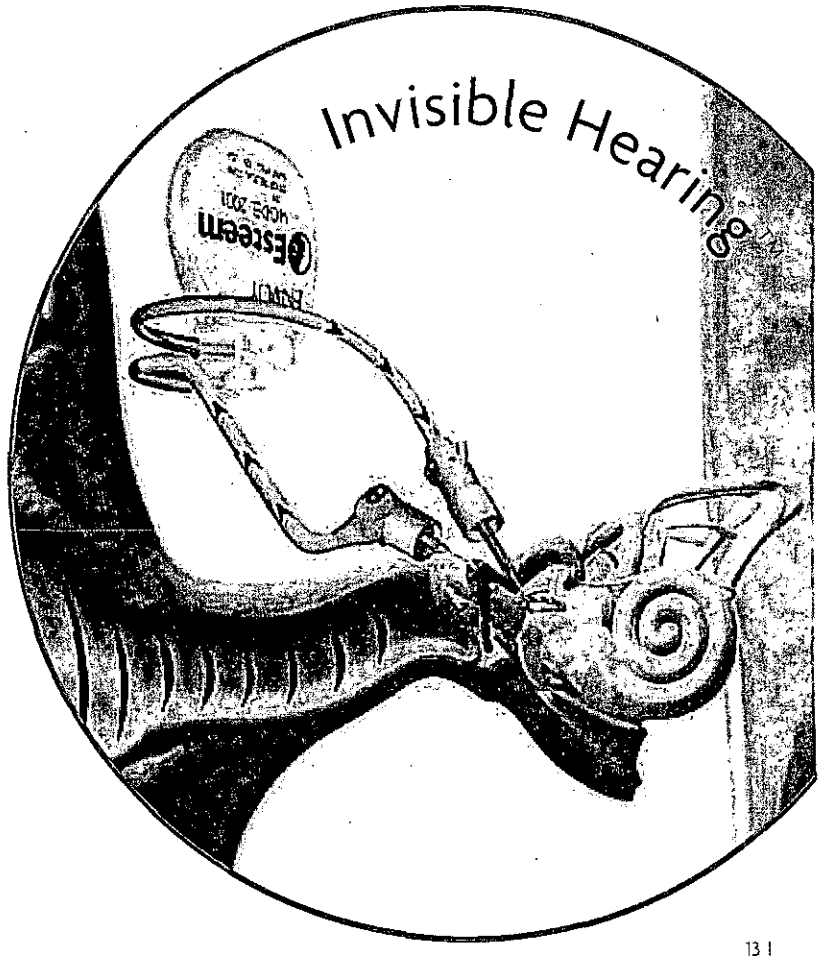
The Driver is attached to the stapes in the middle ear. The Driver converts the electrical signals that it has received from the Sound Processor back into mechanical vibrations and transmits these signals to the stapes and the cochlea.

The Personal Programmer is your personal "remote control" that can be used to turn your *Esteem*® On or Off (standby), select the volume and select one of three unique program settings. You will be able to adjust your *Esteem*® to your own comfort level no matter where you are — at home, using the telephone, in a crowded restaurant, or on a noisy street.



Sensor | Sound Processor | Driver | Personal Programmer

1 Sound Processor
2 Sensor
3 Driver



What makes *Esteem*® Absolutely Unique

Completely implanted – Completely invisible

Nobody notices when you have the *Esteem*® and when you look in the mirror in the morning you're not reminded of your hearing aid. You can still switch it on and off and regulate the volume with a convenient Personal Programmer.

No microphone or speaker – No noise interference

Esteem® uses the eardrum as a natural microphone in the form of a smart bridge in the anatomical auditory canal. In this way the ear filters out background noise naturally. There is no acoustic feedback.

No charging – No maintenance

Esteem®'s maintenance-free battery lasts 4.5 to 9 years, depending on use. Once it is depleted, the battery is replaced in a minor outpatient surgical operation. Changing batteries every two weeks and laborious charging are things of the past.

Warnings

Avoiding Head Injury

After the *Esteem*® is implanted, you should avoid contact sports or other activities that could result in a head injury. Participation in contact sports may result in damage to your hearing or the *Esteem*® implanted components.

Electroconvulsive Therapy

Electroconvulsive Therapy (ECT) must never be used on a patient who has an implanted *Esteem*® because it may damage your hearing or the *Esteem*®.

Electrosurgery

If electrocautery is used, ensure that the *Esteem*® is turned off.

Never allow current from an electrosurgical (electrocautery) instrument to be applied directly to an *Esteem*® component, to avoid the risk of damage to the implanted component or to your hearing. Use only a bipolar electrocautery system and never over or near the *Esteem*® implant.

Magnetic Resonance Imaging

You cannot undergo Magnetic Resonance Imaging (MRI) examination or be in close proximity to MRI devices after you have had *Esteem*® implanted. Fields produced by the MRI may damage your *Esteem*® or cause it to operate improperly.

Avoiding High Pressure

After the *Esteem*® is implanted, you should avoid diving to depths more than 10 meters (30 feet) of water as this may result in damage to the *Esteem*®.

Cell Phone Use/Cell Phone Compatibility

Because there are a wide range of cellular telephones and other wireless devices on the market, it is not possible to ensure *Esteem*® compatibility with all products. In a clinical study that included 70 subjects, seven subjects (10%) reported experiencing noise or feedback when using a cellular or wireless device. In all cases, the noise or feedback only occurred during cellular or wireless device usage and had no long term effects on *Esteem*® or the subject. If unpleasant noise or feedback occurs when using your *Esteem*® with a cellular or wireless device, you should discontinue use of the cellular or wireless device with the ear that has the *Esteem*®.

Precautions

Physical Activities and Sports

When your Health Care Professional says it is okay, you can return to most of the activities you enjoyed before receiving your *Esteem*®. Avoid contact sports and physical activities that could result in a hard blow to your head. Avoid diving deeper than 10 m (30 ft) of water, as this may result in damage to your *Esteem*®. If you have any questions concerning your activities, check with your Health Care Professional.

Pushing or Twisting the Implanted Parts of Your *Esteem*®

Avoid pushing or twisting the implanted parts of your *Esteem*®, such as the Sensor and Driver leads. Either action can cause skin erosion or damage to various parts of the *Esteem*®. Skin erosion or *Esteem*® damage may require surgery to correct.

Travel

Esteem® may set off security devices in airports. If it does, show your identification card (provided by Envoy Medical after implantation) to the security guard. The identification card is described in detail in later pages of this brochure. Security systems and metal detectors could temporarily interrupt your hearing. To restore normal hearing, simply move away from the source of interference. All people while traveling experience pressure changes of the middle ear during flight. *Esteem*® recipients should expect to experience the same subtle changes in hearing and periods of temporary plugged sensation during air travel.

Electrical Devices

Your *Esteem*® is designed to be resistant to interference produced by other electrical equipment such as household appliances. You may safely operate all common household appliances and office equipment. It is possible that while operating these appliances or equipment you may hear noise/interference, however the programming is unaffected. Moving away from the source will, in most cases, mitigate any potential interference.

Clothing and Protective Equipment

Helmets and hats do not present a problem as long as they do not put a significant amount of pressure on the side of the head behind the ear where the Sound Processor is implanted. As customary in loud environments, the use of an earplug is recommended.

Additional Precautions

If you are going to undergo a medical treatment or diagnostic procedure, you must notify your physician that you have *Esteem*®.

The effects on the *Esteem*® of positron emission tomography (PET) scans, ultrasound, diathermy, radiation, lithotripsy, radio frequency (RF) ablation, transcutaneous electrical nerve stimulation (TENS), and other electronic therapies have not been tested. If you require such treatment, you should let your physician know to consult with Envoy Medical for current safety information regarding these therapies. During all these types of therapies the *Esteem*® device should always be turned off to avoid interference noises. X-Ray image quality directly around the implant could be compromised. Please avoid electroconvulsive therapy on or near the Sound Processor implant. During emergency use of a defibrillator, the *Esteem*® should be switched off to avoid interference noises. If emergency defibrillation is necessary or elective cardioversion is desired, the *Esteem*® performance and integrity should not change. If *Esteem*® is left on (active) during these procedures, you may hear interference and performance could change temporarily, however the long-term performance and integrity should not change whether left on (active) or turned off (standby mode). If you believe you have experienced any changes after this procedure, please contact your implanting surgeon or Envoy Medical Corporation.

- If your profession requires you to be in the vicinity of a high electrical current, consult your physician before engaging in such activities.
- People who smoke need to be aware that smoking can affect healing after any surgical procedure, including implantation of *Esteem*®.
- People with diabetes that is not well controlled with medication or diet need to take extra precaution with their surgeon to discuss post-operative healing issues.
- The *Esteem*® Implant has an approximate revision/enhancement rate of 5%, requiring patients to have an additional surgical procedure to increase benefit. During the most recent trial a 2% explant rate was reported.
- Air-bone gap indicating a conductive or mixed hearing loss has not been studied with *Esteem*®.
- Implanting surgeons should consider psychological, developmental, physical, or emotional disorders before implanting this device.

Esteem® Battery Longevity

The battery life of the *Esteem*® will vary depending on the number of hours the device is left on and the average noise level the *Esteem*® is exposed to during the day. The *Esteem*® will remain on as long as you do not turn the implant off by using the Personal Programmer to switch to the Standby Mode. Unlike hearing aids and partially implantable devices, you have the realistic option of leaving the device on 24 hours each and every day. The fully implantable *Esteem*® does not have to be turned off during a shower, swimming, physical activity or while you sleep.

The following battery life estimates assume the patient is exposed to a typical amount of noise while his or her *Esteem*® is on and active. The estimates were determined by laboratory testing and mathematical extrapolation. Results, which may not be typical, from some clinical trial patients indicate that these estimates may be conservative and that battery life may be longer under "real life" conditions.

- 4.5 years – 24 hours/day, 7 days/week
- 6.5 years – 16 hours/day, 7 days/week
- 9 years – 8 hours/day, 7 days/week

**Please note, if an Esteem® recipient is continuously exposed to excessively loud sound levels (90 dB SPL, 24 hours per day) and is using the highest gain settings, battery life can be reduced. Testing under these worst case scenario conditions demonstrated that battery life could be as short as 2.8 years.*

Esteem® Battery Replacement Indicator (ERI)
The *Esteem*® triggers a battery elective replacement indicator (ERI) when the battery begins to deplete.

The ERI is indicated by the Personal Programmer confirmation tone changing

from a single tone to a dual tone. Also, the "*Esteem*® Low Battery LED" will illuminate on your Personal Programmer. Your Personal Programmer must be activated to detect low battery life.

Esteem® Battery End of Life (EOL)
EOL occurs approximately 2 weeks after the ERI is first indicated. This assumes that you use the Personal Programmer during this time frame, and can therefore notice the first time that ERI is indicated.

Contact your Health Care Professional immediately when a two-tone Personal Programmer confirmation tone is heard or when the Personal Programmer shows an illuminated "*Esteem*® Low Battery LED". This will enable sufficient time to schedule replacement of the *Esteem*® battery.

Esteem® Battery (Sound Processor) Replacement
The Sound Processor Battery is changed in a surgical procedure. This Sound Processor/ Battery change is done by your surgeon using a local anesthesia. Local anesthesia, commonly produced by giving a shot directly into the surgical area, numbs a small part of the body for minor procedures. This surgery takes approximately one hour. After this outpatient surgery, your *Esteem*® is turned on the same day.

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Risks and Potential Adverse Events

The following information describes potential adverse events that may be possible with the *Esteem*®:

- Erosion of the Sound Processor through the skin or infection to the Sound Processor pocket
- During the surgical implant procedure, your surgeon may determine that your anatomy does not allow enough space for the proper implant of the *Esteem*®. These instances do arise in approximately 3% of the implant procedures. In this case, the *Esteem*® will not be implanted and the surgical procedure will be terminated.
- Intra-operative injury to the malleus, incus, stapes or cochlea because of physical contact and placement of the Sensor/ Driver portion of the device
- Cold, sinus or upper respiratory congestion may result in temporary reduced benefit of *Esteem*®
- *Esteem*® may offer limited or no benefit, requiring an additional surgery to revise, enhance, replace or remove any or all of the components. During the most recent Clinical trial, a 5% revision enhancement surgery and a 2% explant rate were reported.
- *Esteem*® may produce mechanical feedback, requiring an additional surgery to revise, enhance, replace or remove any or all of the components.
- Loss of attachment of leads from Sound Processor, and/or transducers from mastoid, and/or ossicular chain bones, requiring surgery to revise, replace or remove any or all of the components
- Loss or worsening of hearing after reconstruction of the ossicular chain in the event of device explant. The amount or degree of loss is dependent upon the method of reconstruction (PORP, TORP or ossicular reconstruction). Please consult your physician regarding the options. A PORP or TORP is an ossicular replacement prosthesis.
- Damage to the stapes or cochlea as a result of removal of the Sensor or Driver connection during surgery, revision or removal of the *Esteem*®

- Dislocation of any of the middle ear bones
- Bleeding and post-operative infection

With any surgical procedure, risks and complications can occur. Below is a list of surgical complications that must be considered in your decision. These are potential adverse events that may occur from the surgical procedure used to implant the *Esteem*®. Subsequent surgeries to change the Sound Processor/Battery may induce some of the same potential risks, as many of these complications are associated with any operative intervention. Please consult your surgeon before electing this procedure to appreciate the risks associated with the *Esteem*® implant procedure. Certain intra- and post-operative complications may occur that are unique to your specific situation that have not been mentioned in this brochure.

- Bodily soreness that is associated with intra-operative positioning of the body and a prolonged implant procedure
- Temporary loss of skin sensation in and about the ear may occur following surgery. This numbness may involve the entire outer ear and usually resolves in the months following the procedure.
- Temporary dizziness, light-headedness or vertigo
- During the *Esteem*® implant procedure one of the three nerves involved in taste (the chorda tympani) may be severed, as done in other middle ear surgeries. Taste disturbance can be a side effect of severing this nerve. Patients reported taste disturbance as mild in intensity and typically temporary in nature.
- Formation of fibrous tissue in the middle ear subsequent to surgical intervention may occur. The likelihood and amount is determined by many surgical and patient variables and can vary greatly amongst patients.
- Infection and/or wound infection may occur following surgery
- Intra-oral discomfort, jaw soreness or stiffness
- Temporary facial paresis/paralysis was reported by up to 7% of the subjects in the clinical trial

Risks and Potential Adverse Events *(continued)*

- Eardrum perforation and/or drainage from ear canal
- Hematoma/blood clot
- Neurological complications associated with being under general anesthesia for an extended period of time
- Physical dislocation or fracturing of the malleus, incus, and/or stapes bones
- Partial or total loss of remaining hearing in the implanted ear
- Widening or thickening of the scar behind the ear
- Complications related to anesthesia may occur
- Cerebral spinal fluid leak and meningitis
- The occurrence or changes in existing tinnitus (perception of ringing of sound) may occur

Please consult your physician before engaging in this procedure to assess the potential occurrence of any of these complications.

Below is a table of illustrating adverse events with reported occurrence rate from a recent clinical study.

Adverse Event Category	% of Subject Reported	% Still Ongoing After One Year
Taste Disturbance	42%	14%
Facial Paresis/Paralysis	7%	1%
Tinnitus (Some subjects reported having tinnitus prior to the *Esteem*® Implant)	18%	5%

Benefits Provided by *Esteem*®

During a recent U.S. Clinical trial held in multiple locations throughout the U.S., the *Esteem*® Hearing Implant showed marked improvement for a majority of recipients implanted. Below are definitions of the tests conducted with corresponding results.

All implanted recipients in this trial were current hearing aid users. The average time of hearing aid use was over 13 years. Of the subjects implanted, 86% used hearing aids in both ears.

Description of Tests Used to Evaluate *Esteem*®

Speech Reception Threshold (SRT)
These tests try to determine the faintest level at which a person can hear and correctly repeat two-syllable (spondaic) words. When the individual hears a word, he or she repeats the word (or points to pictures) as the audiologist´s voice gets softer and softer. The faintest level, in decibels, at which 50% of the two-syllable words are correctly identified, is recorded as the Speech Reception Threshold (SRT). A separate SRT is determined for each ear.

Word Recognition (WRS)
These tests attempt to evaluate how well a person can distinguish words at a comfortable loudness level. It relates to how clearly one can hear single-syllable (monosyllabic) words when speech is comfortably loud. In this test, the audiologist´s voice (or a recording) stays at the same loudness level throughout. The individual being tested repeats words (or points to pictures). The percentage of words correctly repeated is recorded for each ear. Thus, a score of 100% would indicate that every word was repeated correctly. A score of 0% would suggest no understanding. Word recognition is typically measured in quiet.

The APHAB (Abbreviated Profile of Hearing Aid Benefit)
This test is a 24-item self-assessment inventory in which patients report the amount of trouble they are having with communication or noises in various everyday situations. Benefit is calculated by comparing the patient´s reported difficulty in the unaided condition with

their amount of difficulty when using amplification. The APHAB produces scores for 4 categories: Ease of Communication (EC), Reverberation (RV), Background Noise (BN), and Aversiveness to Loud Sounds (AV).

Quality of Life (QOL) Measurement
After ten months of using the *Esteem*® Hearing Implant™, patients were asked to complete a questionnaire subjectively rating their experience with their *Esteem*® as compared to their experiences with their pre-implant hearing aid (aided condition).

Results of Tests

Results of Speech Reception Threshold (SRT)
Overall, the mean SRT improvement with the *Esteem*® Hearing Implant™ compared to the pre-implant hearing aid was 10.6 dB with the range of mean improvement between 1.3-16.9 dB. SRT Improvement varied due to clinical site variability.

Results of Word Recognition (WRS)
Overall, 93% of *Esteem*® Hearing Implant™ recipients scored equal to or better than their pre-implant hearing aid.

- 7% Scored less than their pre-implant hearing aid (0%-20% depending upon clinical site)
- 37% Scored equal to their pre-implant hearing aid (17%-53% depending upon clinical site)
- 56% Scored better than their pre-implant hearing aid (27%-83% depending upon clinical site)

Results of APHAB (Abbreviated Profile of Hearing Aid Benefit)
Overall, 80% of *Esteem*® Hearing Implant™ recipients rated *Esteem*® better than or equal to their pre-implant hearing aid in the APHAB questionnaire.

- 19% Rated *Esteem*® below the hearing aid (7%-33%, depending upon clinical site)
- 21% Rated *Esteem*® equal to the hearing aid (11%-29%, depending upon clinical site)
- 60% Rated *Esteem*® better than the hearing aid (56%-64%, depending upon clinical site)

Results of Quality of Life (QOL) Measurement

The results of the questionnaire indicate that a strong majority of patients consider the *Esteem*® somewhat or much better than their hearing aid.

Activity Level:
85% somewhat-much better;
11% equal
4% somewhat-much worse

Feeling of Confidence:
84% somewhat-much better
8% equal
8% somewhat-much worse

Clarity of Sound:
78% somewhat-much better
7% equal
15% somewhat-much worse

Natural Sounding Voices:
76% somewhat-much better
11% equal
13% somewhat-much worse

Understanding Conversation:
72% somewhat-much better
17% equal
11% somewhat-much worse

Ability to Understand Speech in Noise:
69% somewhat-much better
13% equal
18% somewhat-much worse

Benefit of Invisibility:
66% somewhat-much better
17% equal
17% somewhat-much worse

Individual results may vary.

What to expect the first 6 months

A) Implant Procedure

Esteem® is implanted during a surgery that takes approximately 3-4 hours. During the procedure the device is tested to help ensure accurate placement of the Sensor and Driver to obtain optimal gain for the patient. After the surgery, you will not be able to hear with the implanted ear until the device is turned on, which typically occurs within 6-8 weeks. After any middle ear surgery, it is normal for the middle ear space to fill with fluid to promote healing. The area around the implanted Sound Processor may be tender as your incision heals.

B) Device On

After 6-8 weeks, depending upon your surgeon's recommendation, your *Esteem*® Hearing Implant is turned on. At this initial Turn-On visit, it is typical that your device is set with minimal gain. This will allow you to become accustomed to having the device. *Esteem*® recipients state that it takes time to become familiar with sounds and also to identify what they are hearing. Your brain learns to identify sounds again with *Esteem*®.

C) Activation

Approximately one month after the device is turned on, we would like to see patients back for a programming adjustment.

At this Activation visit, your *Esteem*® Hearing Implant will be programmed for your unique hearing loss needs. We will customize three different programs that you can switch between with your own Personal Programmer. Many patients (as many as 50%) do not routinely use their Personal Programmer. They have *Esteem*® set to their liking and they use this setting in all hearing situations. These recipients keep their Personal Programmer in a safe location, rarely needing it. They do not require changes and would rather not make adjustments. Other patients choose to carry the Personal Programmer with them for periodic minor adjustments.

Patients find that it takes time to become familiar with certain sounds. For the first several months after implantation, many recipients claim sounds seem quite loud to them. It is normal to report after your device Turn-On that your own voice seems loud

with your *Esteem*® implant. Because hearing aids can cause an occlusion effect of the ear canal, patients are often not accustomed to hearing their own voices. It is also normal to hear bodily noises, for example, hearing yourself swallow or noises when you chew. People with normal hearing are accustomed to these routine sounds.

Patients also claim that sounds seem more natural. Patients find that they are receiving a lot more information with an *Esteem*® implant and therefore it takes time for them to acclimate. Results with *Esteem*® show a steady and constant improvement in speech recognition over several months. Patients have said that in the beginning, they do not realize they are hearing every single word in a sentence. This heightened level of hearing can be overwhelming; therefore *Esteem*® patients need to be aware and understand that the first several months will be an acclimation period.

D) Follow-Up Appointments

Some patients like to have follow-up appointments after two, four and/or six months. Envoy offers these appointments as options to recipients of *Esteem*®. The purpose of these visits is to make any changes to the programming in order to provide additional gain, address any concerns you may have, and monitor your progress.

E) Battery (Sound Processor) Replacement

The battery life of the *Esteem*® varies depending on the number of hours it is left on and the average noise level it is exposed to. The Sound Processor triggers an ERI (Elective Replacement Indication) sound through the Personal Programmer when the battery needs to be replaced. After approximately 4.5 to 9 years (depending upon your use of the *Esteem*® Hearing Implant), you will need to use your Personal Programmer on occasion to monitor whether the Personal Programmer

What to Expect *(continued)*

confirmation has changed from one tone to two tones, indicating the battery is low. When you change a program or switch the *Esteem*• on or off, you automatically interrogate your Sound Processor. Typically you will hear a single tone to confirm that the change has been captured by the Sound Processor. When your Sound Processor battery is depleted you will hear a dual tone. The dual tone indicates that you need to contact your Health Care Professional for an appointment to have your Sound Processor/Battery changed. This Sound Processor/Battery change is done with a surgical procedure by your surgeon using a local anesthesia and takes approximately one hour. After this minor surgery, your *Esteem*• is turned on the same day.

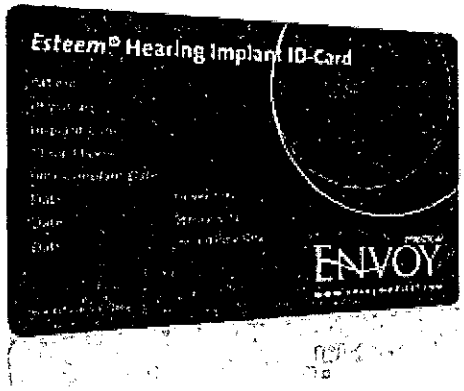
Having an *Esteem*® Implant

Your Patient Identification Card

As soon as you receive your *Esteem*®, you will receive a temporary Identification Card. This will be replaced by a permanent Identification Card that will be sent to you.

The Identification Card serves the following purposes:

- Identifies you as a patient with an implanted hearing device
- Supplies basic information about your *Esteem*®
- Provides your health care professional's name and telephone number
- The Identification Card should be carried with you at all times.



When to Call Your Physician

Please call your Health Care Professional if you experience any of the following:

- You get dizzy or existing dizziness gets worse
- You have drainage from your ear
- The discomfort from your surgery doesn't lessen with time
- You develop an elevated temperature or fever
- Your incision is hot to the touch or very tender
- You experience any of the adverse events explained in the brochures provided
- Your face gets weak or your eyelid will not close
- You are involved in a bodily injury that could affect the *Esteem*® performance
- You hear a dual Personal Programmer confirmation tone
- The performance of the *Esteem*® changes significantly
- You experience any other unexplained symptoms

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Using the Personal Programmer Remote

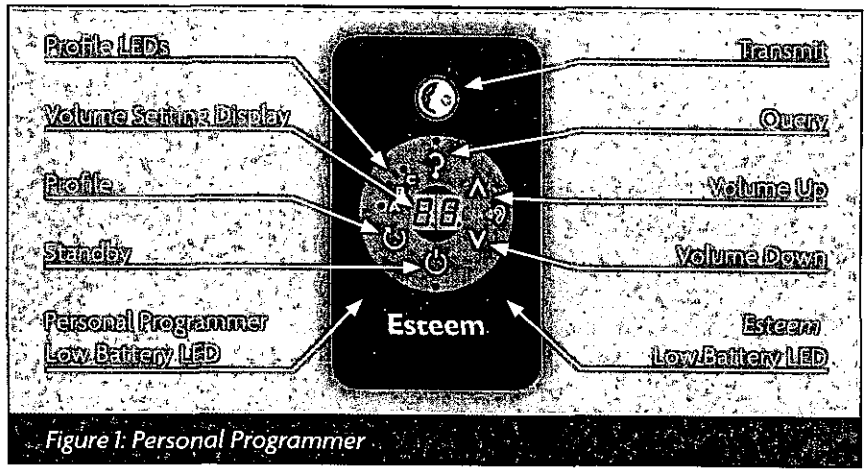

Figure 1: Personal Programmer

How to Adjust your *Esteem*®

After your *Esteem*® is implanted and programmed, you can use your Personal Programmer to activate the *Esteem*®, change the environment setting, adjust the volume, and query the current settings of your *Esteem*®. You can also put the system in standby mode, at any time. Using standby mode prolongs battery life of the implanted *Esteem*®.

How to Put Your *Esteem*® in the Active Mode and Selecting a Profile

1. Turn on the Personal Programmer by pressing and holding the "Standby" button for a few moments; lights will illuminate.


Standby

2. Select the desired profile by pressing the "Profile" button.


Profile

3. Locate the "Transmit" button.


Transmit

4. Hold the Personal Programmer directly over the implanted *Esteem*® (see Fig. 2).

Figure2: Personal Programmer Placement

5. Press the "Transmit" button.

6. Listen for the confirmation tone, and check profile LED on the Personal Programmer. If the LED next to the selected profile is steady, the *Esteem*® is currently in Active Mode in the selected Profile. If the LED is blinking, communication was not successful, repeat steps 2-6. If communication is still unsuccessful, see the Personal Programmer Troubleshooting section.

Profile

How to Query Your Current *Esteem*® Settings

1. Turn on the Personal Programmer by pressing and holding the "Standby" button for a few moments; lights will illuminate.


Standby

2. Press the "Query" button.


Query

3. Locate the "Transmit" button


Transmit

4. Hold the Personal Programmer directly over the implanted *Esteem*® (see Fig. 2).

5. Press the "Transmit" button.


Transmit

6. Check Profile LED and Volume Setting Display on the Personal Programmer. If the Profile LED and Volume Setting are steady, the *Esteem*® Query was successful.

Profile

If the Query LED is blinking, communication was not successful, repeat steps 2-5. If communication is still unsuccessful, see the Personal Programmer Troubleshooting section.


Query

How to Make Sounds Louder or Quieter

1. Turn on Personal Programmer by pressing and holding the "Standby" button for a few moments; lights will illuminate.


Standby

2. Locate the "Volume Up" or "Volume Down" arrows on your Personal Programmer (see Fig. 1). The "Volume Up" arrow increases the "Volume Setting Display" (see Fig. 1) and makes sounds louder, and the "Volume Down" arrow decrease the "Volume Setting Display" and makes sounds quieter.


Volume


Volume Display

3. Press the "Volume Up" or "Volume Down arrows to increment the "Volume Setting Display" to the desired volume setting.


Volume

4. Locate the "Transmit" button.


Transmit

5. Hold the Personal Programmer directly over the implanted *Esteem*® (see Figure 2).

6. Press the "Transmit" button.


Transmit

7. Listen for the confirmation tone, and check the "Volume Setting Display" on the Personal Programmer. If the "Volume Setting Display" is steady, the *Esteem*® is currently in Active Mode with the selected Volume setting. If the LED is blinking, communication was not successful, repeat steps 2-7. If communication is still unsuccessful, see the Personal Programmer Troubleshooting section.


Volume Display

How to Turn Off Your Personal Programmer

1. The Personal Programmer has a built-in time-out and after 15 seconds of inactivity will turn itself off.

2. To manually turn the Personal Programmer off, press and hold the "Standby" button for three seconds. After one second, the volume display will count down from 2 to 0. When the display reaches 0, it will go into Standby.


Standby

Troubleshooting

Personal Programmer Will Not Turn On

If your Personal Programmer does not turn on, try the following steps in order:

1. The batteries may be depleted. Change the batteries as shown on page as described in the replacing your Personal Programmer battery section. If replacing the batteries does not correct the issue, proceed to the next step.
2. The batteries may not be oriented correctly. Remove the batteries and reinsert them into the battery compartment taking special care to ensure they are in the correct orientation (Note: the two batteries should be in opposite directions relative to each other). If your Personal Programmer will not turn on after re-inserting the batteries in the battery compartment, proceed to the next step.
3. There may be debris or corrosion at the battery contact points. Open the battery compartment, remove the batteries, and check for any debris or corrosion on the battery terminals or the contact points. If there is loose debris, remove it. If there is corrosion on either of the batteries, replace them with new batteries. If you see corrosion or damage to the battery contact points in the Personal Programmer battery compartment, please contact Envoy Medical Customer Service for a replacement.
4. If after trying steps 1 – 3 above, your Personal Programmer will still not turn on, please contact Envoy Medical Customer Service for help or replacement.

Uplink from the Sound Processor is not Received

If you hear the confirmation tones, but the lights on your Personal Programmer are blinking after communication, try the following:

1. The confirmation tone you heard means the implant was successfully changed. The blinking lights on your Personal Programmer means it did not hear the confirmation uplink from your implant. Press the "Query" button on your Personal Programmer so it lights, and then press the "Transmit" button while holding it over your implanted *Esteem®*.


Query


Transmit

Troubleshooting *(continued)*

Verify the correct profile and volume settings.

2. If you continue to see the lights blinking on your Personal Programmer even after hearing confirmation tones, proceed to the next step.

3. Your Personal Programmer may need to be in a different position over the implanted *Esteem*®. Make sure the label on the back of your Personal Programmer is directly over the implant when programming. The anatomy of your head is unique, so you may find that slightly different positions give more or less consistent communications. The optimal position may change as the batteries in your Personal Programmer go from new to depleted. If you are still getting a blinking light on your Personal Programmer after programming, proceed to the next step.

4. Your Personal Programmer may need to be a different distance over the implant. The anatomy of your head is unique, so you may find that slightly different distances give more or less consistent communications. Initially, make sure the label on the back of your Personal Programmer is directly against your implanted *Esteem*® when programming. You may find that keeping the Programmer slightly away from the implant (about the thickness of your fingers) may provide more consistent communications. The optimal distance may change as the batteries in your Personal Programmer go from new to depleted. If you are still getting a blinking light on your Personal Programmer after programming, proceed to the next step.

5. Change the batteries on your Personal Programmer. Press the "Query" button on your Personal Programmer so it lights, and then press the "Transmit" button while holding it over your implanted *Esteem*®.


Query


Transmit

6. If after trying steps 1 – 5 above, you are still hearing the confirmation tone but seeing blinking lights on your Personal Programmer, please contact Envoy Medical Customer Service for help or replacement.

Downlink is Not Communicating

If you don't hear the confirmation tones and the lights on your Personal Programmer are blinking after communication, try the following:

1. Press the "Query" button on your Personal Programmer so it lights, and then press the "Transmit" button while holding it over your implanted *Esteem*®. Verify the profile and volume status of your implant. If you are unable to successfully Query the implant, proceed to the next step.


Query


Transmit

2. Your Personal Programmer may need to be in a different position over the implanted *Esteem*®. Make sure the label on the back of your Personal Programmer is directly over the implant when attempting to Query. The anatomy of your head is unique, so you may find that slightly different positions give more or less consistent communications. The optimal position may change as the batteries in your Personal Programmer go from new to depleted. If you are unable to successfully Query the implanted *Esteem*® with different Personal Programmer positions over the implant, proceed to the next step.

3. Your Personal Programmer may need to be a different distance over the implant. The anatomy of your head is unique, so you may find that slightly different distances give more or less consistent communications. Initially, make sure the label on the back of your Personal Programmer is directly against your implanted *Esteem*® when programming. You may find that keeping the Programmer slightly away from the implanted *Esteem*® (about the thickness of your fingers) may provide more consistent communications. The optimal distance may change as the batteries in your Personal Programmer go from new to depleted. If you are unable to successfully Query the implanted *Esteem*® with different Personal Programmer distances over the implant, proceed to the next step.

4. Change the batteries on your Personal Programmer. Press the "Query" button on your Personal Programmer so it lights, and then press the "Transmit" button while holding it over your implanted *Esteem*®.


Query


Transmit

5. When you are able to find the optimal position and distance for your Personal

Troubleshooting *(continued)*

Programmer over your implanted *Esteem*®, attempt to adjust the Volume or Profile to the desired settings.

6. If after trying steps 1 – 5 above, you are still unable to successfully Query or program your implanted *Esteem*®, please contact Envoy Medical Customer Service for help or replacement.

Concurrent Changes on Remote

If you are attempting to change both profile and volume but the changes don't seem to be getting to the implant even though you hear the confirmation tone:

1. Press the "Query" button on your Personal Programmer so it lights, and then press the "Transmit" button while holding it over your implanted *Esteem*®. Verify the profile and volume status of your implant.


Query


Transmit

2. You are only able to change the Profile or the Volume each time you press the "Transmit" button. Using the Volume Up or Volume Down buttons, set the Volume to the desired level.


Volume

While holding your Personal Programmer over the implanted *Esteem*®, press the "Transmit" button.


Transmit

3. Press the "Query" button on your Personal Programmer so it lights, and then press the "Transmit" button while holding it over your implanted *Esteem*®. Verify the correct Volume setting.


Query


Transmit

4. Using the "Profile" button, set the desired Profile. While holding your Personal Programmer over the implanted *Esteem*®, press the "Transmit" button.

Profile


Transmit

5. Press the "Query" button on your Personal Programmer so it lights, and then press the "Transmit" button while holding it over your implanted *Esteem*®. Verify the correct Profile setting.


Query


Transmit

Esteem® Implant/Sound Processor Seems to be in Off Mode

If you are unable to turn on your implanted *Esteem*®:

1. If the lights on your Personal Programmer are blinking after attempting to turn the implant on, follow the steps above for "Downlink is Not Communicating".

2. If the lights on your Personal Programmer are not blinking after attempting to turn on the implant, select the desired Profile using the "Profile" button. While holding your Personal Programmer over the implanted *Esteem*®, press the "Transmit" button. To turn on the implant, you activate either the A, B, or C Profile. Query the implanted *Esteem*® to verify status.

Profile


Transmit

3. If you still believe the implant is off, increase the Volume setting. Query the implanted *Esteem*® to verify status.

4. If after trying steps 1 – 3 above, you are still unable to successfully turn on your implanted *Esteem*®, please contact Envoy Medical Customer Service for help or replacement.

Esteem® Implant/Sound Processor Seems to be in On Mode

If you are unable to turn off your implanted *Esteem*®:

1. If the lights on your Personal Programmer are blinking after attempting to turn the implant off, follow the steps above for "Downlink is Not Communicating".

2. If the lights on your Personal Programmer are not blinking after attempting to turn off the implant, quickly press the Standby button on your Personal Programmer so it lights up. While holding your Personal Programmer over the implanted *Esteem*®, press the "Transmit" button. To turn off the implant, you select and "Transmit" the standby. Query the implanted *Esteem*® to verify status.


Standby


Transmit

3. If you still believe the implant is on, Query the implanted *Esteem*® to verify status.

Troubleshooting *(continued)*

4. If after trying steps 1 – 3 above, you are still unable to successfully turn off your implanted *Esteem*®, please contact Envoy Medical Customer Service for help or replacement.

Multiple Tones When Programming

If you hear multiple confirmation tones when programming your implanted *Esteem*®:

1. If you hear multiple confirmation tones, but the *Esteem*® Low Battery LED is not lit after programming then it is likely that the uplinks are not consistently being heard by your Personal Programmer. Go to the "Uplink from the Sound Processor is not Received" section above.

Esteem® Low Battery

2. If you hear multiple confirmation tones and there are blinking lights on your Personal Programmer after programming then it is likely that the uplinks are not consistently being heard by your Personal Programmer. Go to the "Uplink to the Sound Processor is not Received" section above..

3. If you hear multiple confirmation tones, AND the *Esteem*® Low Battery LED is lit after programming, AND there are no blinking lights on your Personal Programmer please contact Envoy Medical Customer Service to determine if it is time for a battery replacement.

Esteem® Low Battery

If all troubleshooting attempts fail, please contact Envoy Medical Customer Service (1-866-950-HEAR (4327)) for help or replacement of your Personal Programmer remote control.

Use and Care of the Personal Programmer

Handle the Personal Programmer like other electronic equipment in your home.

Don't put the Personal Programmer near hot appliances such as stoves or irons.

Do not submerge the Personal Programmer in water or liquid. Water or liquids should not enter the Personal Programmer. Water will result in a malfunction of the Personal Programmer and potentially void the Personal Programmer warranty.

If the Personal Programmer gets wet due to spill, immediately remove batteries and let sit to dry completely. After an appropriate drying period insert the AAA batteries, if the Personal Programmer malfunctions, contact Envoy Medical Customer Service for replacement.

Cleaning the Personal Programmer
To clean the Personal Programmer, use a soft water-only dampened cloth to wipe the outside of the Programmer.

Preventive Inspection and Maintenance
Inspect the Personal Programmer before each use. Do not use a Personal Programmer that shows signs of obvious damage. The Personal Programmer does not require preventive maintenance other than battery replacement upon receiving a low battery indication.

Personal Programmer Batteries
The Personal Programmer uses two AAA alkaline batteries. When the batteries are good, the Personal Programmer shows a green light when you activate a button to change a setting. Replace the batteries if the indicator shows a yellow light.

Personal Programmer Battery Replacement
Insert the new batteries properly (positive--positive, negative-negative). Remove the backside battery compartment cover by sliding it off. Remove existing batteries and properly discard. Orient the new AAA alkaline batteries as shown on the inside of the battery compartment. Place one end of the battery in first as shown in this picture, then push the other end down into the battery compartment. Slide the cover back into position until it locks into place.

Use and Care of the Personal Programmer *(continued)*

The Personal Programmer is powered by two AAA alkaline batteries. Do not dispose of the batteries along with household waste. Contact your local city office, your household waste disposal service, or where you purchased the batteries for the address of the nearest battery deposit center.

NOTE: If the Personal Programmer will not be in use for an extended period, remove the alkaline batteries from the Personal Programmer to prevent damage to the device due to battery leakage.

Lost or Damaged Personal Programmer

If you lose or damage your *Esteem*® Personal Programmer, please contact Envoy Medical Customer Service for warranty information and replacements.

Warranty Information

Esteem® Hearing Implant
(Sound Processor Model 2001, Sensor Model 7002, Driver Model 7502)

The following warranty applies to the implantable components of the *Esteem*® Hearing Implant. Envoy warrants that the *Esteem*® System will be free from defects which cause the System to fail to perform as intended within its normal tolerances for a period of three (3) years from the date of implantation of the System (the "Warranty Period"). Note that the ability of the System to function within normal tolerances will be affected by the patient's post implant healing and could take several months. This Warranty does not apply to normal battery depletion/replacement; or defects arising from any of the following: fair wear and tear; misuse, abuse, neglect or accident, use of the *Esteem*® otherwise than in accordance with the product documentation which is supplied to the surgeon by Envoy Medical Corporation or any alterations or repairs which are carried out without the prior written authorization from Envoy Medical.

Warranty Information *(continued)*

Esteem® Personal Programmer
(Model 8001)

The following warranty applies to the external Personal Programmer remote control that is utilized to change settings on the implanted *Esteem*®. Envoy warrants that the Personal Programmer will be free from defects which cause the device to fail performance as intended within its normal tolerances for a period of one (1) year from the date of implantation of the *Esteem*® Hearing Implant (the "Warranty Period").

This Personal Programmer Warranty does not apply to normal battery depletion or need for battery replacement or defects arising from any of the following: fair wear and tear, misuse, abuse, neglect or accident and use of the Device otherwise than in accordance with the product documentation which is supplied by Envoy Medical Corporation. In addition, no alterations or repairs should be carried out by third party organization without prior written authorization from Envoy Medical.

Full warranty information for all components is supplied after implantation and packaged with your Personal Programmer. If this information is misplaced, please contact Envoy Medical Customer Service to obtain additional copies (Toll Free 1-866-950-HEAR 4327 or 1-651-361-8000).