The Esteem®
Middle-Ear Hearing Implant

Esteem®
The Hearing Implant

Why aren't more people with hearing loss using hearing aids?

Esteem®
The Hearing Implant

Continued low uptake of HAs, in spite of a growing prevalence of hearing loss and significant advances in hearing aid technology

Research has identified 3 major facilitators of help-seeking and successful hearing aid use:

- Positive attitudinal beliefs about hearing aids
- Support of significant others
- Self-efficacy for hearing aids

(Louise Hickson, HEARing Cooperative Research Centre & School of Health and Rehabilitation Sciences, The University of Queensland, Australia)

2

Why aren't more people with hearing loss using hearing aids?

Esteem®
The Hearing Implant

- "Attitudinal beliefs about hearing aids"
  - Positive: belief that hearing aids will help
  - Negative: perceived stigma; association with aging
- "Self-efficacy for hearing aids"
  - Confidence in one's ability to insert, remove, and manipulate hearing aids, replace batteries, etc. on one's own

3

The significance: A place for a totally-implantable hearing system

Esteem® The Hearing Implant

The Esteem Hearing Implant represents another option on the continuum of care for hearing-impaired individuals – an option for those seeking an alternative to traditional hearing aids.

4

Testimonial Clips

Esteem® The Hearing Implant

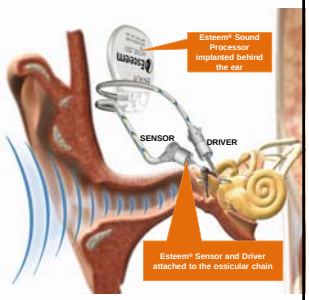
5

Fully Implantable

FDA APPROVED (PMA) MARCH 2010

Esteem® The Hearing Implant

- The only FDA-approved, totally implanted, active middle ear implant
- Moderate to severe sensorineural hearing loss
- Does not interface directly with the outer ear
  - No speaker or artificial microphone
  - No external components
  - Nothing in the ear canal



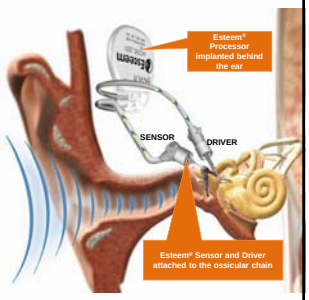
6

Unique Lifestyle Benefits

COMFORT AND CONVENIENCE

Esteem® The Hearing Implant

- Invisible
- 24/7 hearing
- Swim, shower, or exercise without worry of damage or discomfort
  - Waterproof
  - Underwater depth rating of 33 ft
- No daily maintenance



7

Esteem Animation

Esteem® The Hearing Implant

8

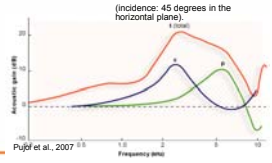
Advantages of using TM as a natural microphone

Esteem® The Hearing Implant

- Less processing of input sound
  - Vibrations generated at TM produce input signals naturally
- Retention of natural resonances of ear
  - Shape of pinna, resonance of ear canal result in spectral shaping of acoustic waves as they approach the TM
  - relative reduction in amplitude of sound < 1000 Hz
  - relative increase in amplitude of spectrum from 1000 - 6000 Hz

Influence of the pinna (p) and of the ear canal (c) on the amplitude of the signal reaching the ear drum

(incidence: 45 degrees in the horizontal plane).



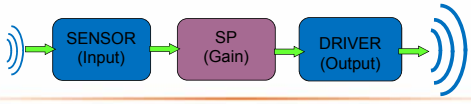
Pujol et al., 2007

9

Esteem System Components

The Esteem is an amplification system, similar in some ways to conventional hearing aids

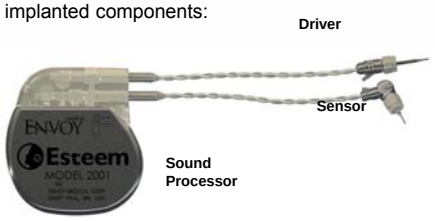
- **Sensor**: senses vibration from incus as input signal; comparable to microphone in conventional HA
- **Driver**: delivers amplified output signal as vibrations to stapes; comparable to receiver (speaker) in conventional HA
- **Sound Processor**: processes and amplifies acoustic signals according to programmed settings and algorithms; comparable to processor in conventional HA



10

Esteem System Components

Three fully implanted components:



These three components work in series to provide amplification of the input signal propagated through the tympanic membrane, malleus, and incus.

11

Esteem System Features

- Custom integrated circuitry
  - low energy requirements
  - frequency range 200 - 6000 Hz
  - system gain of up to 50 dB (electrical gain).
- Non-magnetic, biocompatible Sound Processor case is 6.4 mm thick; houses the battery and processor
- Lithium iodine battery life of 4.5 - 9 years* (median 5.5 years)

*Battery life may be reduced to 2.8 years if continually exposed to very loud sound levels using the highest gain settings.

12

Sound Processor Features

Esteem® The Hearing Implant

- Broadband filters absorb electromagnetic interference (EMI), preventing most electrical interference.
- Inductive bidirectional telemetry enables noninvasive interrogation and programming of the implanted Sound Processor.
- Programmability allows audiologist to customize parameter combinations to each patient's needs.

13

Analog processing -- why?

Esteem® The Hearing Implant

- The Esteem utilizes digital control of analog signal processing ("hybrid" processing technique)
- The low power requirement of analog signal processing allows the Esteem to achieve multi-year battery life
- Analog processing preserves the natural sound captured at the TM
- Digital control of the analog signal allows for greater programmability of the analog signal processor

14

Piezoelectric transducers

Esteem® The Hearing Implant

- Crystal aggregate material
  - Bending bimorph
  - Layers of materials, such as lead and titanium oxides
- Reversible electromechanical transduction
  - When a force is applied, a voltage is generated
  - When a voltage is applied, motion is generated

15

Esteem Sensor & Driver

PIEZOELECTRIC TRANSDUCERS

Esteem® The Hearing Implant

- **Sensor** – displacement of incus deflects Sensor, which produces electrical signal that is sent to Sound Processor
- **Driver** – electrical signal from Sound Processor causes deflection of Driver, which is transferred to stapes

Key Benefits

- Ultra-low power
- Low distortion, even at max output levels
- Very low noise
- Titanium enclosure is 100% hermetically sealed for safe, reliable, long-term implantation

16

Sound Processor

Esteem® The Hearing Implant

Receives electrical signal from Sensor, processes signal, and sends modified signal to driver

Key Features:

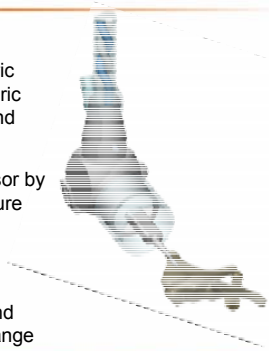
- Dual-channel analog processor
- Easily replaced and backward-compatible
- Three programmable listening profiles
- Output-controlled compression
- 100% hermetically sealed for safety & reliability

17

Sensor

Esteem® The Hearing Implant

- Abuts body of incus bone
- As incus vibrates, piezoelectric element flexes, creating electric signal that travels to the Sound Processor
- Connected to Sound Processor by detachable lead, allowing future Sound Processor battery replacement without Sensor replacement
- Sensitive, energy-efficient, and linear over a wide dynamic range



18

Driver

- Connected to stapes
- Receives electrical signals from Sound Processor, causing piezoelectric element to flex, vibrating stapes. These vibrations are delivered through the stapes to the cochlea
- Hermetic titanium enclosure for reliable long-term implantation
- Connected to Sound Processor by detachable lead, allowing future Sound Processor battery replacement without Driver replacement

19

Esteem Commander

- Software used to evaluate device performance postoperatively and program the Esteem Sound Processor.
- Accessed through dedicated laptop computer provided by Envoy Medical
- Communicates with implanted device via telemetry wand (aka Personal Programmer)

Functions:

- Interrogate the implanted Sound Processor
- Program the implanted Sound Processor
- Perform diagnostic tests to assess device performance

20

Esteem Commander

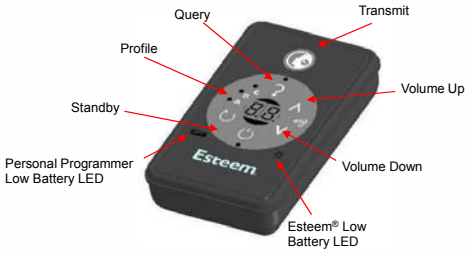
- Device Diagnostic tests performed by the Commander:
  - **EnvoyGram:** assesses Driver performance
  - **Sensor Test:** evaluates Sensor performance
  - **Feedback Test:** determines if mechanical feedback levels are outside accepted limits for the Esteem
  - **Max Gain:** using an automated algorithm, determines the maximum amount of gain that the Esteem can provide at fixed parameter settings without causing feedback

21

Personal Programmer

Esteem® The Hearing Implant

Remote control used by the patient to adjust the volume and select one of three profiles in the Sound Processor.



22

Fitting the Esteem

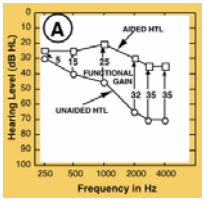
Esteem® The Hearing Implant

- Prescriptive gain targets provide guidance in fitting amplification
- With hearing aids, can determine desired amount of gain as a function of frequency, then verify by measuring output (insertion gain) to see if target values met
- With Esteem, we cannot measure insertion gain (or actual output at stapes footplate) – can only use behavioral measures

23

Esteem® The Hearing Implant

- Final frequency response of Esteem will be somewhat dependent on anatomy and transducer placement, in addition to transfer function of system
- Verification is limited to behavioral threshold measures (functional gain)

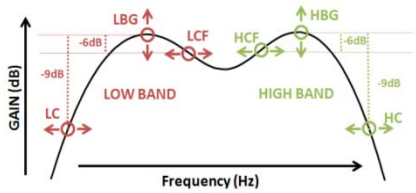


24

Fitting Parameters for the Esteem

Esteem® The Hearing Implant

Three primary fitting parameters may be adjusted for each band: cuts, crossovers, and gains. The combination of all six parameters will define the Esteem transfer function.



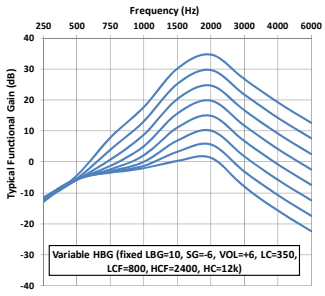
25

High Band Gain Parameter (HBG)

Esteem® The Hearing Implant

- Primarily affects gain above 1 kHz
- HBG is programmable in 5 dB increments from 5 dB to 40 dB

Displayed functional gain for fixed parameters: LBG=10, SG=-6, VOL=+6, LC=350, LCF=800, UCF=2400, HC=12k. Displayed functional gain is typical. Individual results may vary.



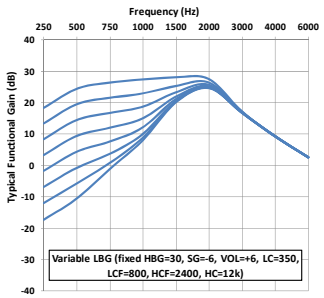
26

Low Band Gain Parameter (LBG)

Esteem® The Hearing Implant

- Primarily affects gain below 1 kHz
- LBG is programmable in 5 dB increments from 5 dB to 40 dB

Displayed functional gain for fixed parameters: HBG=30, SG=-6, VOL=+6, LC=350, LCF=800, UCF=2400, HC=12k. Displayed functional gain is typical. Individual results may vary.

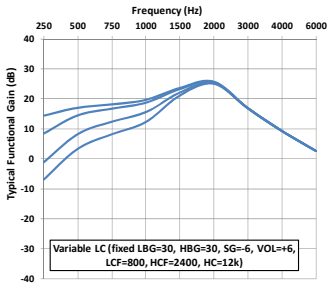


27

Low Cut Parameter (LC)

- Programmable to 4 different levels.
- Recommended default is 350 Hz.

Displayed functional gain for fixed parameters: LBG=30, HBG=30, SG=-6, VOL=+6, LCF=800, UCF=2400, HC=12k. Displayed functional gain is typical. Individual results may vary.

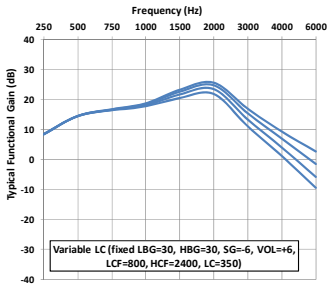


28

High Cut Parameter (HC)

- Programmable to 4 different levels.
- Recommended default is 12k.

Displayed functional gain for fixed parameters: LBG=30, HBG=30, SG=-6, VOL=+6, LCF=800, UCF=2400, LC=350. Displayed functional gain is typical. Individual results may vary.

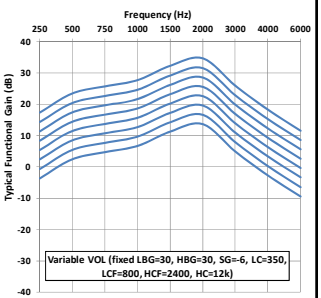


29

Volume (VOL)

- Applies gain approximately equally across entire frequency range
- Programmable to 16 different levels, in 3 dB steps.
- System performance is optimal at -6 dB to +9 dB

Displayed functional gain for fixed parameters: LBG=30, HBG=30, SG=-6, LCF=800, UCF=2400, LC=350, HC=12k. Displayed functional gain is typical. Individual results may vary.



30

Output-limiting Compression

Esteem® The Hearing Implant

- Programmable
  - MPO = 100, 97, 94, or 88 dB SPL
  - Attack and release times: 6ms and 5ms, respectively
- WDRC not available in current SP model, but will be available in next

Clinical Outcomes

Esteem® The Hearing Implant

IDE Pivotal US Clinical Trial

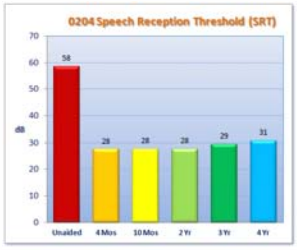
Esteem® The Hearing Implant

- Investigational Device Exemption pivotal US clinical trial (IDE clinical trial) started January 2008
- Three surgical sites; 57 patients.
- Primary objective measures included:
  - SRT
  - WRS measured at 50 dB HL
  - Incidence rate for Serious Adverse Device Events (SADEs)
  - Residual cochlear function, measured by bone conduction and EnvoyGram (a device-specific test)
- Secondary endpoints included:
  - APHAB
  - Quality of Life Questionnaire

IDE Clinical Trial Results: SRT

Esteem® The Hearing Implant

- Preoperative baseline unaided SRTs were compared to Esteem-aided SRTs at 1 month, 4 months, 10 months, 2 years, 3 years, and 4 years.

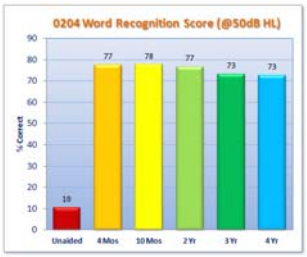


34

IDE Clinical Trial Results: WRS at 50 dB HL

Esteem® The Hearing Implant

- Mean baseline unaided WRSs were compared to mean Esteem-aided WRSs at 4 and 10 months, then annually
- At a 50 dB HL, the Esteem improved WRS by 63% over unaided baseline

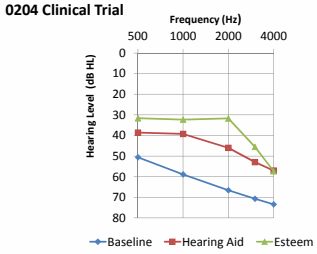


35

IDE Clinical Trial Results: Audiogram

Esteem® The Hearing Implant

- Mean audiometric results at 10 months for all patients

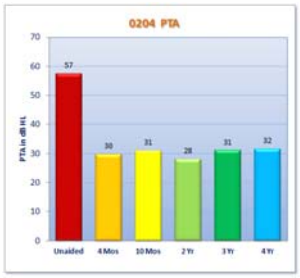


36

PTA Over Time

Esteem® The Hearing Implant

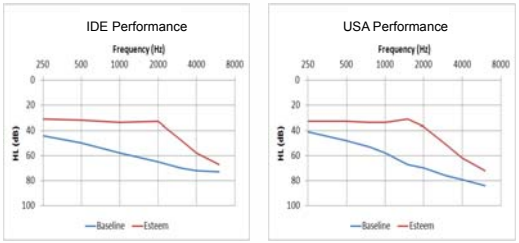
- Average PTA (across all clinical trial subjects) has remained stable over four years



37

Audiometric Results: Clinical Trial vs. Post-Approval Commercial Patients

Esteem® The Hearing Implant

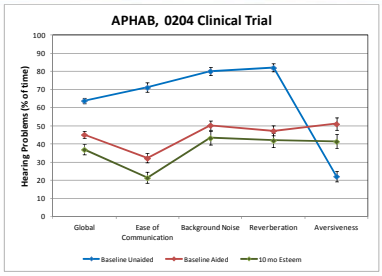


(Data averaged across all patients)

38

APHAB

Esteem® The Hearing Implant



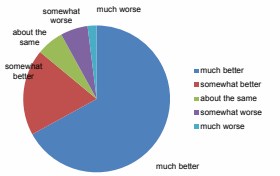
Mean responses across all subjects are shown. Error bars indicate 1 SE.

39

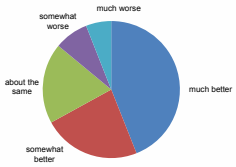
Quality of Life Questionnaire

Esteem® The Hearing Implant

- seven questions to subjectively rate the patient's experience with the Esteem as compared to their experiences with their pre-implant hearing aid.



*86% reported that their **activity level** was somewhat or much better with the Esteem.*



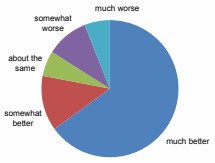
*67% reported **understanding conversation when several people are talking** as somewhat or much better with the Esteem.*

Individual results may vary.

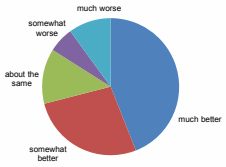
40

Quality of Life (Continued)

Esteem® The Hearing Implant



*78% of respondents rated **clarity of sound** as somewhat or much better with the Esteem.*



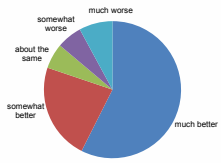
*71% of respondents rated the **ability to understand speech in background noise** as somewhat or much better with the Esteem.*

Individual results may vary.

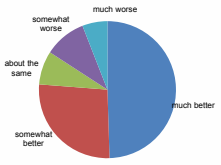
41

Quality of Life (Continued)

Esteem® The Hearing Implant



*81% said their **feeling of confidence** was somewhat or much better with the Esteem.*



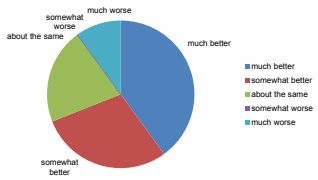
*77% reported **voices sounding natural** as somewhat or much better with the Esteem.*

Individual results may vary.

42

Quality of Life (Continued)

Esteem® The Hearing Implant



*69% rated the benefit of the entire system being **invisible** to the onlooker as somewhat or much better with the Esteem®.*

Individual results may vary.

43

Surgical Overview

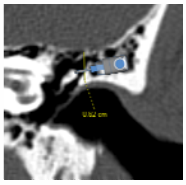
Esteem® The Hearing Implant™

44

Anatomical Considerations

Esteem® The Hearing Implant

CT scans are obtained to ensure that the patient's anatomy is compatible with the Esteem



45

Basic Surgical Steps

Esteem® The Hearing Implant

1. Create the Sound Processor bed
2. Perform mastoidectomy and atticotomy; create facial recess
3. Conduct intact chain displacement measurements.
4. Resect the incus long process and prepare the stapes
5. Position the Sensor and Driver transducers
6. Cement the transducers into place
7. Conduct intra-operative testing of the components and system

46

Esteem Intra-Operative Testing

Esteem® The Hearing Implant

- Prior to closing, testing is performed on each device component using the Intra-Operative System Analyzer (ISA)
  - Sensor Test
  - Driver Test
  - Feedback Test
  - System Test

47

Sound Processor/Battery Change

Esteem® The Hearing Implant

- Usually performed under local anesthesia; can be an in-office procedure.
  - Takes approximately 60 minutes
- Sound Processor is set to factory specifications; connected to patient's implanted Sensor/Driver leads.
- Patient confirms that confirmation tones from the Personal Programmer are audible.
- Incision is closed.
- Patient is sent to audiologist for device programming.

48

Explant and Ossicular Reconstruction

Esteem® The Hearing Implant

Common Methods of Reconstruction:

- K-Helix
- Envoycem bridge
- PORP/TORP

K-Helix

http://www.obex.co.nz/Product/Index/1190

49

Audiometric Candidacy

Esteem® The Hearing Implant™

50

Patient Selection: Indications for Use

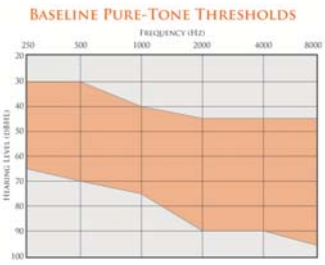
Esteem® The Hearing Implant

- 18 years of age or older
- Stable, bilateral, moderate to severe sensorineural hearing loss (PTA = 40-90 dB HL)
- Unaided word recognition test score ≥ 40%
- Normally functioning Eustachian tube
- Normal TM and middle ear anatomy
- Adequate space for Esteem implant, determined via high-resolution CT scan
- Minimum 30 days' experience with appropriately fit hearing aids

51

Ideal Fitting Range for Esteem

Esteem® The Hearing Implant



Orange shaded region: range of audiometric thresholds that are most likely to achieve prescriptive gain targets, with sufficient dynamic range to enable good speech recognition

52

Patient Selection: Contraindications for Use

Esteem® The Hearing Implant

- History of post-adolescent **chronic middle ear infections**, inner ear disorders or recurring vertigo requiring treatment; disorders such as mastoiditis, endolympatic hydrops, or Meniere's disease
- Known history of **fluctuating conductive and/or sensorineural hearing loss over the past one-year period** of 15 dB in either direction at two or more frequencies (from 500 to 4000 Hz)
- **Air-bone gap** indicating a conductive or mixed hearing loss
- History of **otitis externa** or eczema of the outer ear canal
- **Cholesteatoma** or destructive middle ear disease
- Retrocochlear or central auditory disorders

53

Patient Selection: Contraindications for Use

Esteem® The Hearing Implant

- Disabling tinnitus, defined as tinnitus that requires treatment
- History of keloid formation
- Hypersensitivity to silicone rubber, polyurethane, stainless steel, titanium, and/or gold
- Pre-existing medical condition or current treatment that may affect healing process
- During pregnancy

54

Audiological Candidacy Assessment

Esteem® The Hearing Implant

Unaided – Right and Left Ears

- Air Conduction
- Bone Conduction
- Tympanometry
- WRS (recorded materials)
- SRT

Aided – Right and Left Ears

- Sound-field Aided Thresholds
- Word recognition test at 50 dB HL and MCL (recorded lists)
- SRT

55

Guiding Patients' Expectations

Esteem® The Hearing Implant

- Audiologists should guide patients toward appropriate expectations. **The Esteem will not restore normal hearing.**
  - In some cases, Esteem may provide more benefit than the patient's current hearing aid (as seen in the IDE clinical trial).
  - However, Esteem cannot always match the performance of a well-fit hearing aid.
    - Average maximum Esteem functional gain: 40-45 dB
    - Average PTAGain: approximately 26 dB*
    - Maximum Power Output: 100 dB SPL

* based on data from 0204 pivotal trial

56

Esteem SoundFit®

Esteem® The Hearing Implant

- Web-based tool developed by Envoy, based on analysis of 540 clinical case histories
- Uses a patient's baseline (unaided) pure-tone thresholds to calculate recommended settings for best fit to NAL-RP prescriptive targets and to estimate projected Esteem-aided thresholds
- Supports evaluation of device capabilities and limitations, relative to a given audiometric configuration
- Useful in evaluation of patient candidacy for the Esteem; may be used to directly support patient counseling prior to referral for surgical consultation

57

Esteem SoundFit

Esteem® The Hearing Implant

- App Elements:
  - Baseline hearing thresholds (entered by User)
  - Recommended implant settings to NAL prescriptive target
  - Sandbox (entered by User)
  - Audiogram (projected -- individual results may vary)

58

Questions?

Esteem® The Hearing Implant™

59