Vibrant Soundbridge ®
Implantable Hearing System

Kristin M. Avitabile, MS, CCC-A
Clinical Manager, Southeastern U.S.
MED-EL Corporation
Hearing Technology

- **Hearing Aids**
  - Mild to severe HL
  - Problems with feedback and cosmetics

- **Middle Ear Implants**
  - Moderate to severe HL
  - For people who are unable to achieve adequate benefit or medically unable to tolerate HAs

- **Cochlear Implants**
  - Severe to profound HL
Hearing Loss Prevalence

Hearing loss is one of the most prevalent chronic conditions in the United States, affecting more than nine million Americans over the age of 65 and 10 million Americans age 45 to 64.

But about three out of five older Americans with hearing loss and six out of seven middle-aged Americans with hearing loss do not use hearing aids.

Only 1 in 5 use amplification
Vibrant Soundbridge Middle Ear Implant

- First FDA-approved MEI for moderate to severe SNHL
- Utilizes direct drive technology, offering a clearer, more natural sound quality without occluding the ear canal
Vibrant Soundbridge

A prosthetic device designed for people who:

- Are unsuccessful or unable to achieve adequate benefit with hearing aids
- Cannot tolerate hearing aids
- Medically unable to use conventional amplification
Conditions That May Preclude Conventional Amplification

- Chronic otitis externa
- Exostosis
- Eczema or psoriasis
- Allergies
- Stenotic canal

- Absence of the pinna
- Mandibular fractures
- Excessive wax production
- Excessive perspiration
History

- Developed in 1996 by Symphonix
- Designer Geoff Ball is a bilateral user
- FDA approved in 2000
  - First ME prosthesis to obtain FDA approval
- Assets purchased by MED-EL in 2003
- Thousands of implants worldwide
History

- After MED-EL purchase, manufacturing moved to Austria
- FDA re-approval of the new manufacturing facility in 2007
- US re-launch in 2007
- Planned clinical trials for expanded use
Amplification vs. Direct Drive

• Amplification issues:
  – Occlusion, insertion loss, feedback

• Direct drive solutions:
  – Mechanical energy delivered directly to the ossicles
  – Enhances natural vibratory motion
  – Eliminates many of the acoustic issues inherent in traditional amplification
Amplification vs. Direct Drive
Soundbridge Components

- Audio Processor receiver
- Vibrating Ossicular Prosthesis (VORP) implant
- Conductor Link
- Floating Mass Transducer

Detail of Floating Mass Transducer
Advantages of Direct Drive

• Open ear canal for comfort
• No occlusion
  – Low frequencies enter the ear naturally
  – Better hearing in background noise
• Better cosmetics
• Reduction of feedback
• Clearer, more natural sound
VORP - Vibrating Ossicular Prosthesis
FMT - Floating Mass Transducer
Surgery

- Similar procedure to cochlear implants
- Minimal shaving, small incision
- Outpatient procedure 1.5 - 2 hours
- AP fit after 8 weeks
The Audio Processor (AP)

- Microphone & digital signal processor
- 1 x 675 zinc air battery for one week’s use
- 2.5 cm diameter
- Adjustable magnet
- Available in 3 colors
Audio Processor

- No occlusion of the ear canal
- Easily hidden under the hair
- Held in place by magnetic attraction
- No interference with glasses
Candidacy

- Adults (18+) with bilateral moderate to severe SNHL
  - 55dB loss maximum at 500 Hz
- Word recognition of 50% or better
  - With hearing aids at 65dB SPL
  - Under headphones at MCL
- Normal middle ear anatomy
- Realistic expectations
Candidacy
Who is Not a Candidate?

- Conductive/mixed hearing losses
- Progressive or sudden hearing loss
- Active middle ear infection
- Tympanic membrane perforation associated with recurrent middle ear infection
- Retrocochlear or central auditory disorder
- Skin condition that precludes use of the AP
- Unrealistic expectations
Benefits

• High frequency gain without feedback
• No insertion loss
• Elimination of the occlusion effect
• Improved comfort and ease of use
• Distortion-free signal
  – No electronic receiver in the ear canal, which is a major source of distortion with hearing aids
Benefits

• More natural sound quality
• Addresses many medical issues
• Takes advantage of any low frequency residual hearing
  – Low frequencies are still transmitted through the ear canal
• FMT is designed to be linear
  – Mimics the natural vibratory pattern of the ossicular chain through 8000 Hz
Outcomes

• US clinical trial on 53 adult subjects
• Subjects had moderate-severe SNHL with air/bone gap no greater than 10 dB
• All subjects had at least 3 months of hearing aid experience prior to the study
  – Typical Soundbridge candidates tend to be experienced hearing aid users who have never been happy with their aids
Hearing Device Satisfaction Scale

- Overall Sound Quality: 89% (18% Hearing Aid, 83% Vibrant Soundbridge)
- Cl earness of Sound Tone: 86% (31% Hearing Aid, 86% Vibrant Soundbridge)
- Naturalness of Speech: 86% (27% Hearing Aid, 86% Vibrant Soundbridge)
- Sound Quality of Own Speech: 83% (24% Hearing Aid, 83% Vibrant Soundbridge)
Hearing Device Satisfaction Scale

Overall Fit & Comfort: 98%
Speechreading Aid: 56%
Vibrant Soundbridge: 98%
Hearing Aid: 67%

Cleaning and Maintenance: 98%
Speechreading Aid: 54%
Vibrant Soundbridge: 98%
Hearing Aid: 8%

Background Noise: 67%
Speechreading Aid: 8%
Vibrant Soundbridge: 98%
Hearing Aid: 54%
Satisfaction in Specific Listening Environments

- **Enjoyment of Music**: 80% Vibrant Soundbridge, 20% Hearing Aid
- **Movies**: 86% Vibrant Soundbridge, 27% Hearing Aid
- **Theater**: 82% Vibrant Soundbridge, 13% Hearing Aid
- **Television**: 78% Vibrant Soundbridge, 29% Hearing Aid
Summary of Benefits

- Better sound quality
- Improved comfort
- No feedback
- Better hearing in background noise
- No clinically significant impact on residual hearing
Device Warranty

- New, increased warranty coverage
  - 3 years for AP (previously 2)
  - 5 years for VORP
- Loss and damage
  - 1x Loss and Damage for AP during original manufacturer’s warranty (newly implanted patients)
  - ESCO Limited Theft/Loss ($250/yr)
- Repairs
  - $150 flat rate with 6 mo warranty on AP
  - ESCO Repair Coverage (additional $75)
Reimbursement

MED-EL Reimbursement Mission:
Secure third party coverage for VBS with payment levels commensurate with device pricing

• Re-introduction of VSB as a Middle Ear Prosthesis

• Expanded FDA indications to individuals who
  – Receive no adequate benefit from HA
  – Cannot medically tolerate HA
Reimbursement

- Reclassification as a prosthetic device (2006)
  - Middle ear prosthetics should be covered if
    - Medically necessary
    - Documented in patient’s medical record with diagnostic codes
  - Coding recommendations
    - “L” code for prosthetic implants
MED-EL Reimbursement Manual for the Vibrant Soundbridge

- Free guidance document designed to assist clinicians and billing staff with obtaining reimbursement for the VSB
- Step-by-step instructions and templates
Reimbursement

MED-EL reimbursement department services:

- Provider education and follow-up
  - Clinic visits, training to hospital billing staff, claims tracking
- Reimbursement services
  - Personalized assistance for pre-authorization, appeals, etc.
- Collect reimbursement data to support application for better CPT codes
  - Track charge, payment and utilization history across the country
  - Customer support is invaluable in this effort!
Summary

• Proven long term experience
  – FDA approved since 2000
• Safe and effective
• Excellent proven clinical results
• High level of patient satisfaction
• No impact on residual hearing
Summary

- Appropriate for patients seeking alternatives to traditional amplification due to
  - Sound quality issues
  - Occlusion issues
  - Feedback issues
  - Medical contraindications to hearing aid use