



**Earlens Candidacy**  
Key criteria for consideration & long term success




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**Overview**

- The Earlens Contact Hearing Solution utilizes a unique method of direct drive of the auditory system which does not require surgery, and which can be easily removed if required
- Direct drive overcomes the limitations of conventional technologies, providing unprecedented audible bandwidth and more natural, high-quality sound with an open fitting
- This session will describe patient candidacy guidelines and considerations for clinicians




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**Your speaker...**

- Drew Dundas, PhD, FAAA
- Vice President, Audiology & Product Strategy
- Earlens Corporation, Menlo Park, CA

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### Patient Candidacy Evaluation



#### Hearing Profile

Mild to severe sensorineural hearing loss  
Audibility is primary limitation  
Wears hearing aids daily



#### Anatomy

Good visibility of the TM  
Fairly open canal for Lens placement  
Normal ear canal anatomy



#### Patient Factors

Tolerates ear cleaning  
Follows directions  
Accepting of new technology




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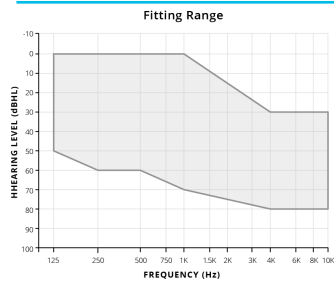
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### Fitting Range & Indications for Use



18+ years of age

Mild-to-Severe sensorineural hearing loss

Can benefit from amplification – high WRS indicate audibility is the primary limitation to performance




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### Rules of thumb

- No more than two primary audiometric frequencies outside the Earlens fitting range
- Unaided word recognition scores  $\geq 50\%$  at MCL
- Type A tympanogram – No significant conductive component to HL
- Able to be compliant and learn new technology
- Don't pick your most problematic or hard to please patient to start!




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## Contraindications



### Hearing loss

- Rapidly Progressive Hearing Loss
- Fluctuating Hearing Loss

### Outer Ear

- Restrictive ear canal anatomy
- Compromised immune system affecting tissue of pinna or ear canal

### Middle ear

- >10 dB conductive component
- Abnormal tympanic membrane
- Perforated tympanic membrane
- Abnormal middle ear
- History of middle ear surgery
- Chronic and/or recurrent ear infections



Detailed information can be found in the Hearing Professional Instructions for Use, available at [Earlens.com/ifu](http://Earlens.com/ifu)

## Is Earlens a Good Fit For My Patient?

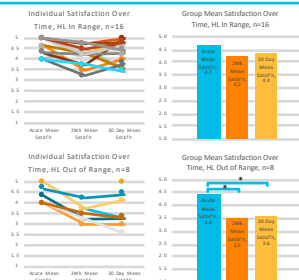
In addition to assessing hearing profile, anatomy and patient factors:

- Consider Power Requirements
  - Earlens is not a power system
  - Maximum output is limited to 132dB
- Instead, consider whether the patient's needs are met with current hearing instruments in terms of:
  - Sound quality?
  - Audible bandwidth?
  - Insufficient gain before feedback?



## Satisfaction Over Time – by Hearing Loss

- Q: Does severity of hearing impairment impact satisfaction?
- Initial Satisfaction is comparable between hearing loss groups
- At 2 weeks and 30 days, satisfaction is significantly lower in the 'out of range' group
- Avoid out-of-range temptation even if highly motivated – satisfaction may decrease over time






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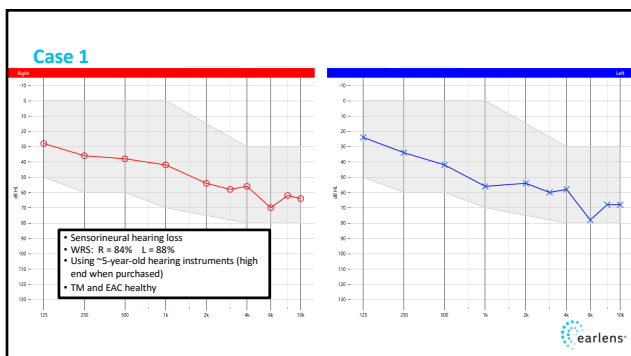
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Case 1 – Earlen's candidate?

- Audiograms and speech understanding performance are ideal
- Age of existing hearing aids suggest potential for a substantial 'wow factor' with Earlen's

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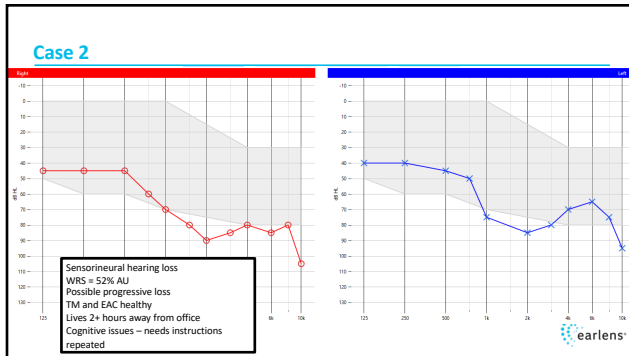
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### Case 2: Earlens candidate?

- While right ear is technically within our rule of thumb, the loss violates the spirit of the fitting range
- May not be able to provide adequate audibility for speech
- May struggle with compliance and learning new technology

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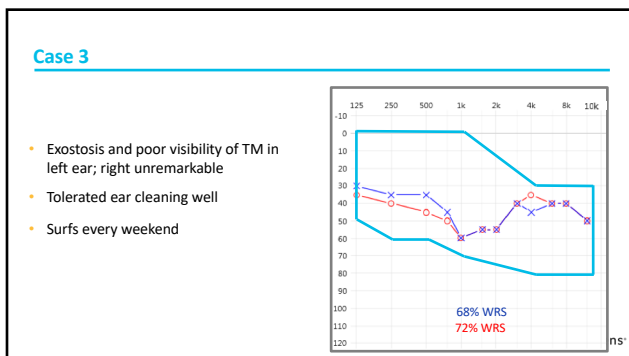
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### Case 3: Earlens candidate?



- Anatomical criteria are not met
- Patient's lifestyle may pose challenges for the Lens-based technology platform




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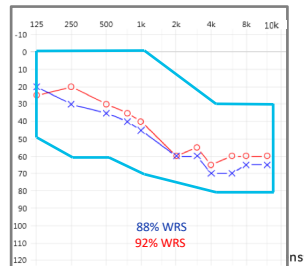
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### Case 4

- Anatomy unremarkable
- Excellent visibility of TM
- Desire for better music sound quality



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### Case 4 – Earlens candidate?

- Audiograms and speech understanding performance are ideal to receive full benefit
- Listening goals suggest potential to have "wow factor" from extended bandwidth




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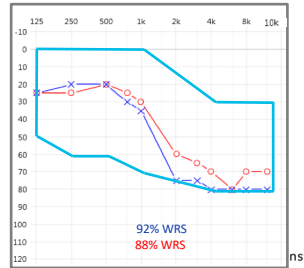
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### Case 5

- Exostoses bilaterally with fairly good visibility of TM
- Tolerated ear cleaning well



### Case 3 – Earlens candidate?

- Audiograms and speech understanding performance are ideal
- It is often more difficult to place the Lens in the ears with exostoses and the Ear Tip may require more modifications
- An acceptable candidate but not a good initial patient



### From our experience

- Motivation and hearing goals are important.
- But when the patient is not an audiometric or speech understanding candidate, try not to be overly swayed by their *or* your enthusiasm.
- To increase the likelihood of success, do not start with your most challenging or difficult-to-please patients first.
- Selecting the right candidates to start benefits all involved – a “wow” experience for patient and providers!



Instructions for Use available at: [Earlens.com/ifu](http://Earlens.com/ifu)



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