



Continuum of Care: A Lifetime of Hearing Solutions for your Patients

Presenter, Date

Hear now. And always



Presentation Overview



- Introduction
- Cochlear and Implantable Solutions
- The Cochlear™ Nucleus® & Hybrid™ Systems
- The Cochlear™ Baha® System
- Conclusion - Questions & Answers

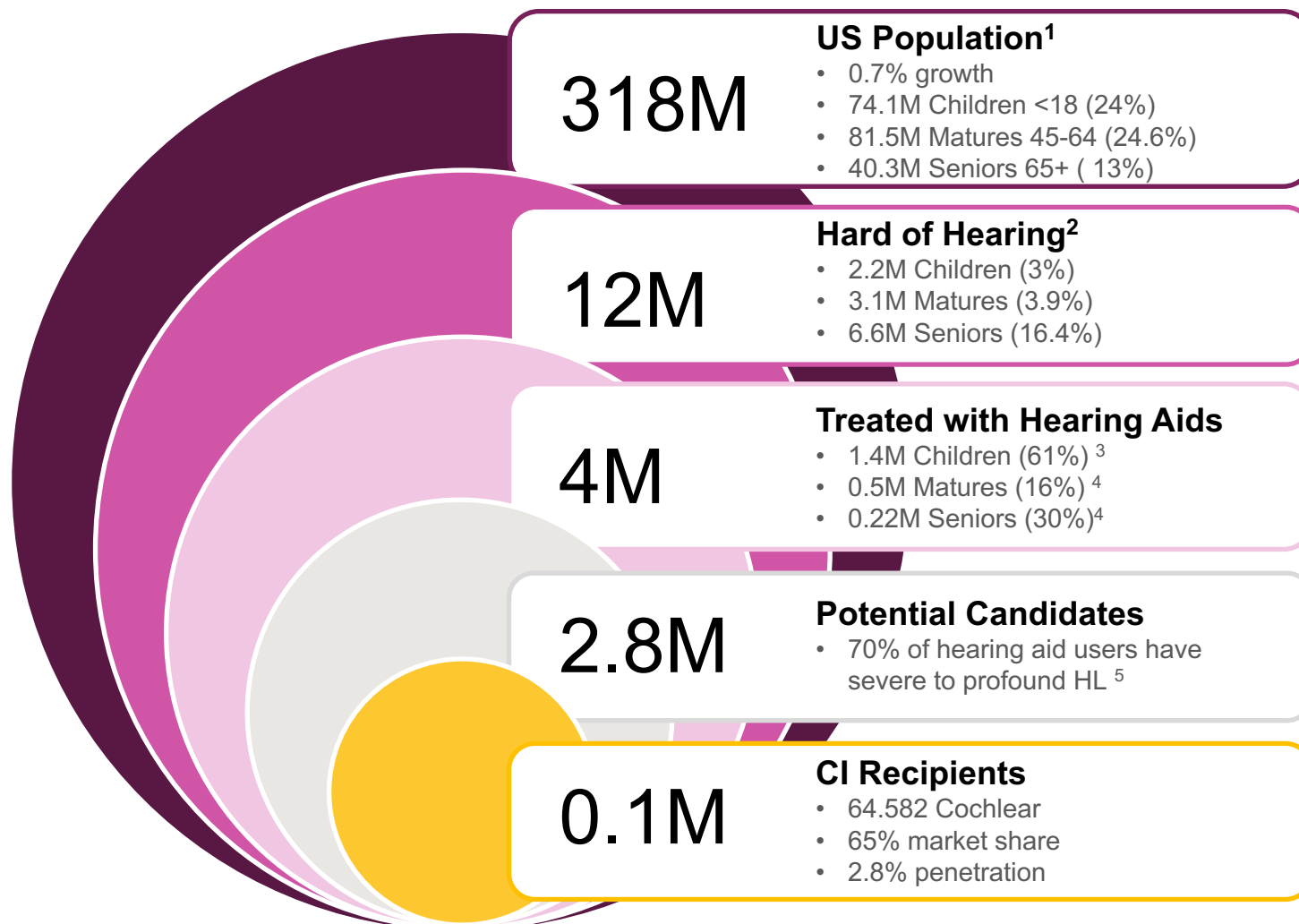
Hearing Loss in the U.S.

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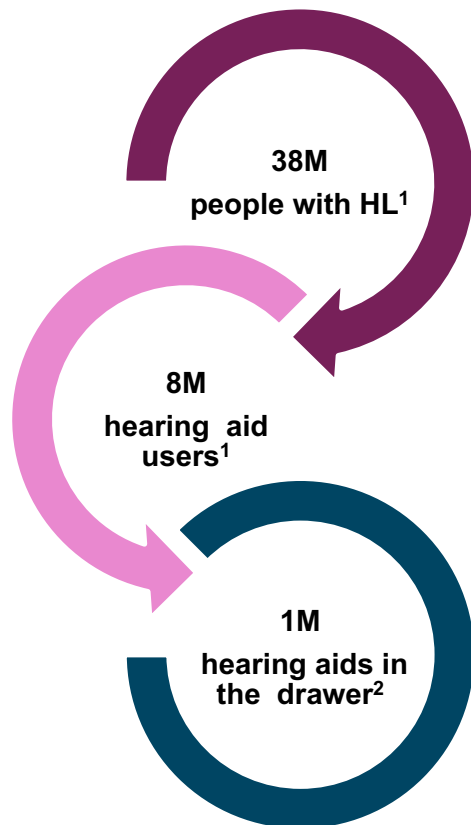
Cochlear®

Finding Candidates



1. US Census 2010
2. US Census SIPP data, 2002, <http://research.gallaudet.edu/Demographics/deaf-US.php>
3. CDC, 2006 <http://asha.org>
4. NIDCD <http://www.nidcd.nih.gov/health/statistics/Pages/quick.aspx>
5. MarketTrak <http://www.betterhearing.org/hearingpedia/hearing-loss-treatment>

Hearing Aid Satisfaction



“I am straining to hear even with the most advanced hearing aids and noisy places are miserable for me...I am not deaf so I am not a CI candidate. I am concerned about my future if I cannot hear”

“My hearing loss is getting worse but I do hear some things at least with my hearing aids. I am concerned to consider a CI if it means I may not hear as well as I do today.”

¹ Kochkin, S. (2009) MarkeTrak VIII: 25-Year Trends in the Hearing Health Market. The Hearing Review, October

² Kochkin, S. (2007) MarkeTrak VII: 25-Year The Hearing Journal, April.

Industry Challenge



Less than 5% of people who could benefit from implantable hearing solutions receive them^{1,2,3,4}

1. US Census 2010
2. US Census SIPP data, 2002, <http://research.gallaudet.edu/Demographics/deaf-US.phpuld>
3. CDC, 2006 <http://asha.org>
4. Cochlear internal estimate, recipients data.

Summary



- > Expanding candidacy criteria means there are more hearing implant candidates than ever before.
- > Market penetration for implants is a fraction of that for Hearing Aids.
- > Implants are covered by a variety of carriers including Medicare & Medicaid, depending on eligibility criteria. Patients should check with their own insurance carriers for confirmation.
- > Majority of CI recipients report they did *not* receive information about implants from their dispensing audiologist or HA provider.¹



Cochlear's Implantable Solutions

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Cochlear Implantable Solutions



Cochlear Nucleus® System

A system that helps individuals* with severe to profound sensorineural hearing loss who only receive limited benefit from amplification



Cochlear Nucleus Hybrid System

Hybrid Hearing delivers maximum long-term performance outcomes for patients with severe to profound high frequency hearing loss**



Cochlear Baha® System

An osseointegrated auditory implant system for individuals† with unilateral profound hearing loss (single-sided deafness), mixed or conductive hearing loss



* Children 2-17: severe-to-profound SNHL, children 1-2 years: profound SNHL, adults: moderate-to-profound SNHL ** Hybrid L24 approved for recipients 18 and older. The Cochlear Nucleus Hybrid acoustic component is not compatible with the Kanso Sounds Processor. The Kanso Sound Processor is not intended to be used by Hybrid L24 Cochlear Implant recipients who receive benefit from the acoustic component. †Implant appropriate for aged >5 years old. Younger children may use the Baha Softband system

The Cochlear™ Nucleus® & Hybrid Systems

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Cochlear Implant Basics



There are two main parts of the
Nucleus Implant System:

An External Sound Processor

&

An Internal Implant

Cochlear Implant – How it works



https://youtu.be/LcigkxUL__4

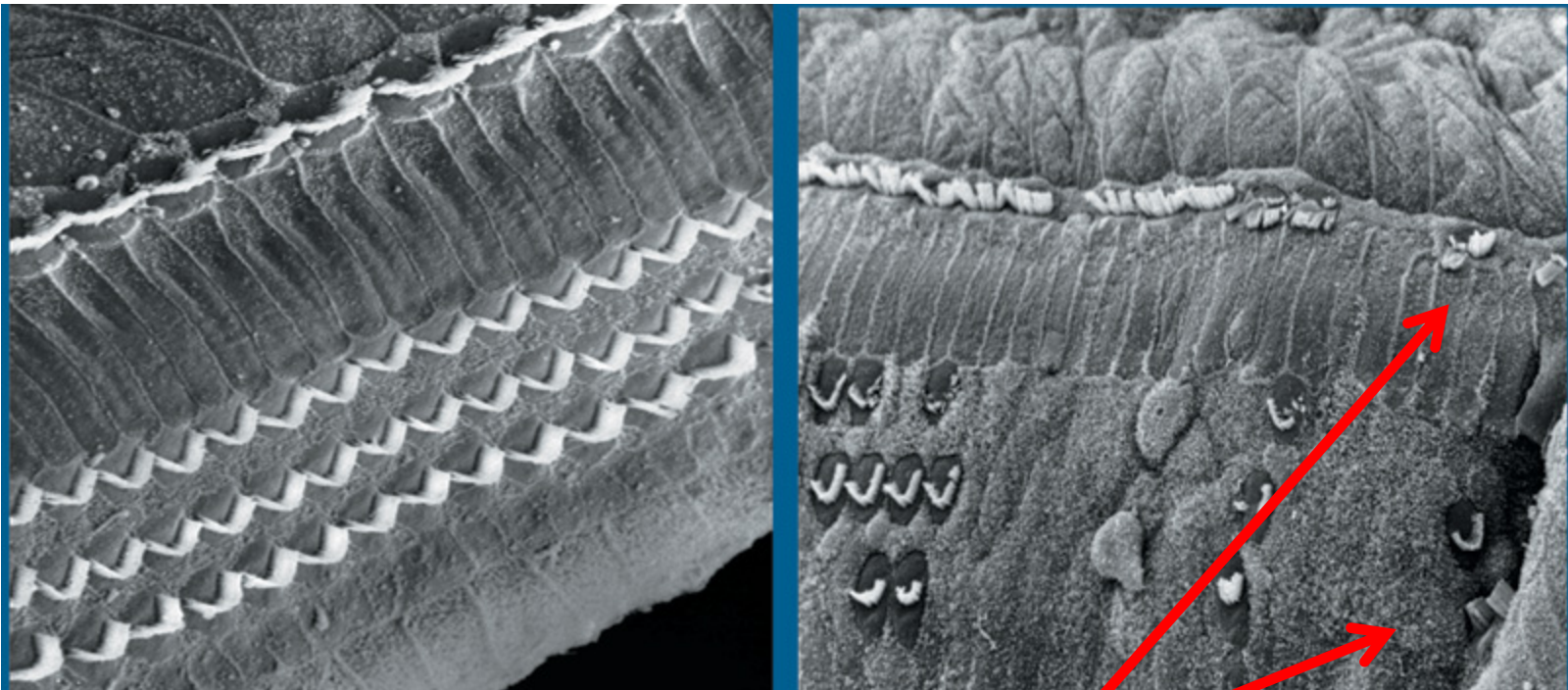
Hybrid Hearing – How it works



https://youtu.be/8hvdPZgKH_M

Physiological Limitations : Cochlear Dead Regions

Cochlear dead regions are prevalent when thresholds ≥ 70 dB HL (~60%) Vinay & Moore (2007)



Severe to profound hearing loss
associated with hair cell damage

Terminology



Receiving input from both ears:

Bilateral = input to 2 ears

Bimodal = a different mode
in each ear (CI+HA)

Hybrid Hearing = acoustic
and electric in the same ear
CI+HA

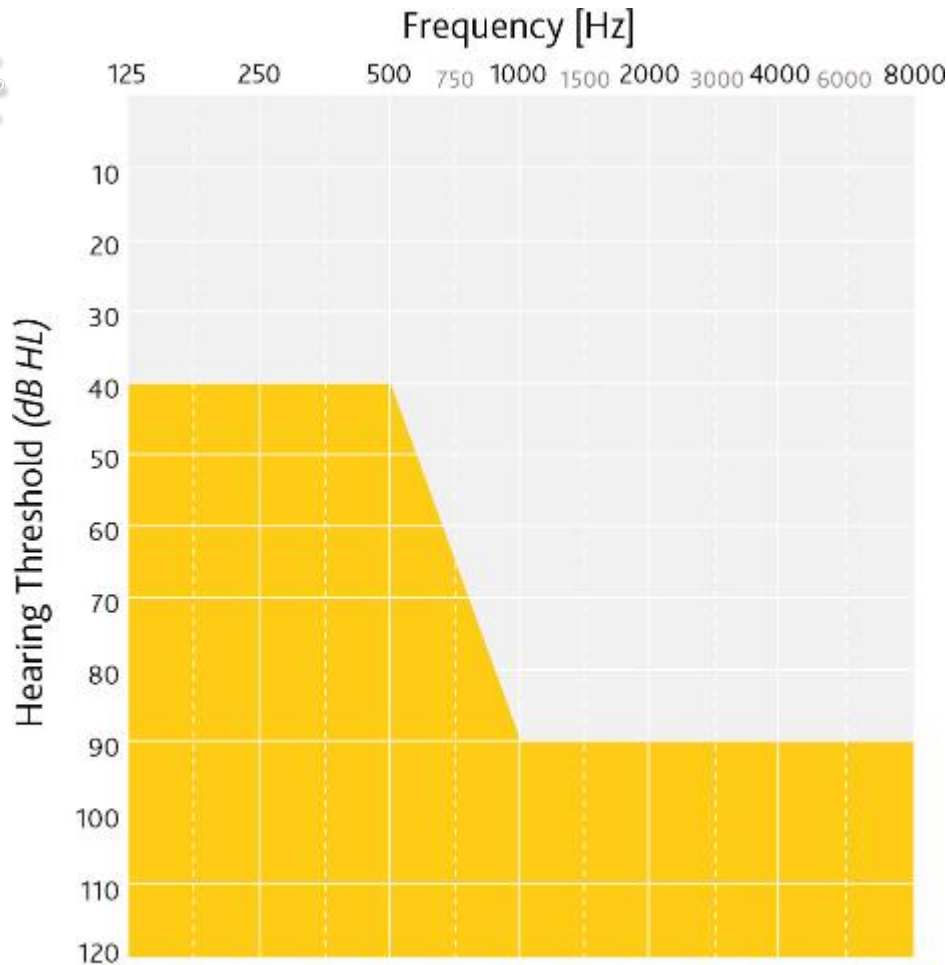


Indications for Nucleus Hearing Implants

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Nucleus[®] Cochlear Implant Indications for Adults



 Cochlear Implant Electrode Candidate

Cochlear Implant:

Sentence Score no better than 50% in the ear to be implanted and no better than 60% in the best aided condition

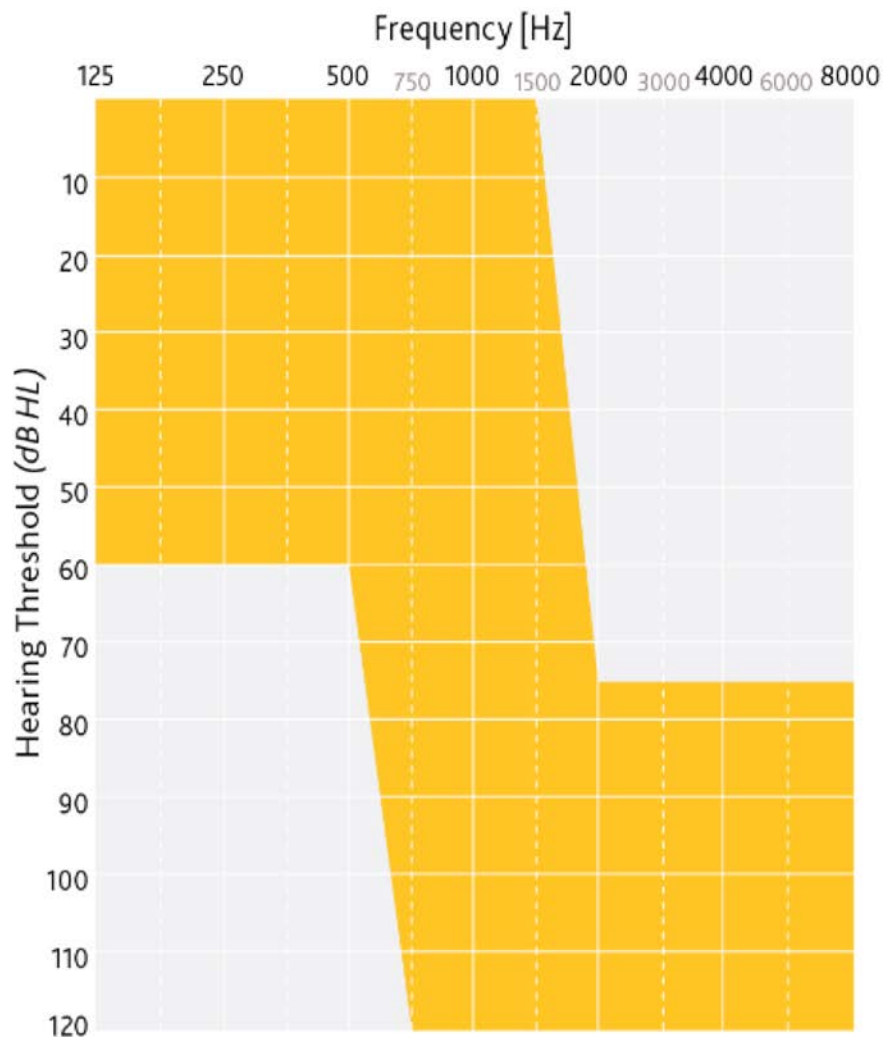
Medicare National Coverage Determination:

Sentence Score no better than 40% (best aided) unless enrolled in a clinical trial

Current opportunity: Evaluation of Revised Indications for Cochlear Implant Candidacy for the Adult CMS Population

<https://clinicaltrials.gov/ct2/show/NC T02075229>

Hybrid™ L24: An Expanded Indication



Ear to be Implanted

- Aided CNC word score between 10% and 60% correct, inclusively
- Normal to moderate SNHL in the low frequencies; PTA of 2k, 3k, 4k ≥ 75 dB HL

Contralateral Ear

- Aided CNC word score better than ear to be implanted but less than 80% correct
- PTA of 2k, 3k, 4k, ≥ 60 dB

Adults

- aged 18 years and older
- unilateral implantation of poorer ear

*The Acoustic Component should only be used when behavioral audiometric thresholds can be obtained and the recipient can provide feedback regarding sound quality
Hybrid L24 implant is approved for use in adults ages 18 and older

Summary of Cochlear™ Nucleus® Indications



For Hybrid L24*: BEST AIDED

Word (*CNC*) score $\geq 10\%$ and $\leq 60\%$ in the poorer ear (ear to be implanted)
PTA of 2k, 3k, 4k ≥ 75 dB HL

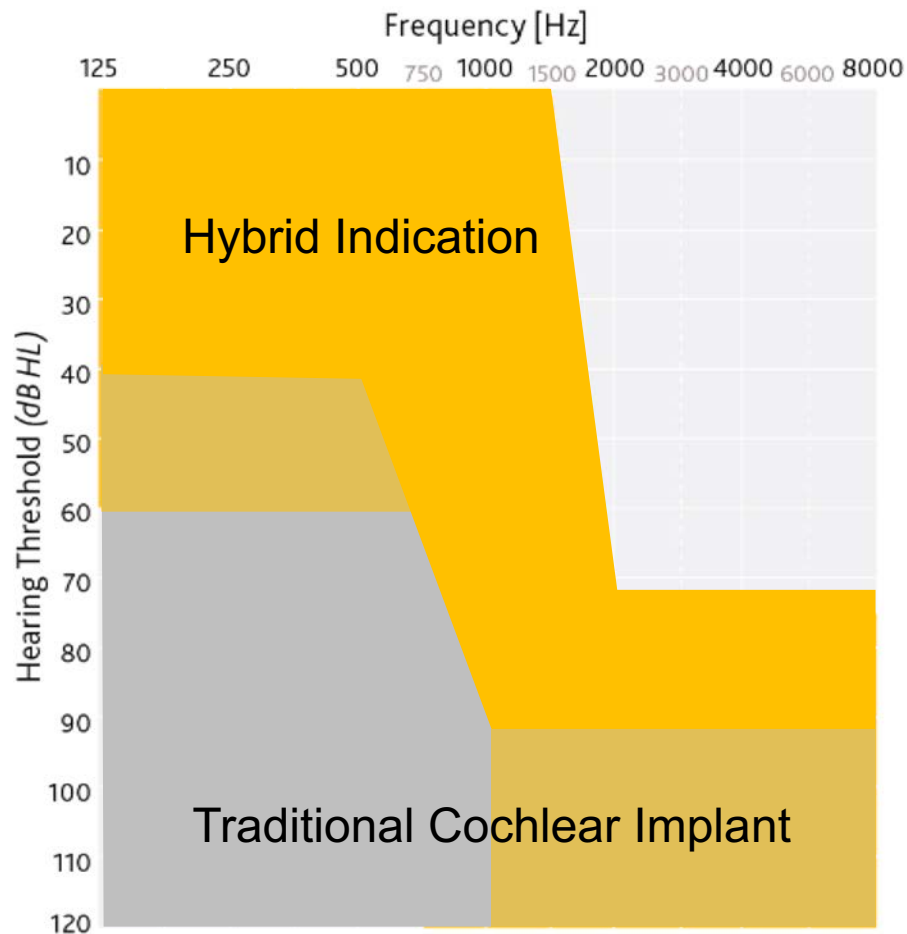
Word (*CNC*) score $\leq 80\%$ in the opposite ear (better ear)
PTA @ 2k,3k, 4k ≥ 60 dBHL

For Traditional CI: BEST AIDED

Sentence score $\leq 50\%$ in the poorer ear

Sentence score $\leq 60\%$ in the best listening condition

Medicare: Sentence Score no better than 40% (best aided) unless enrolled in a clinical trial



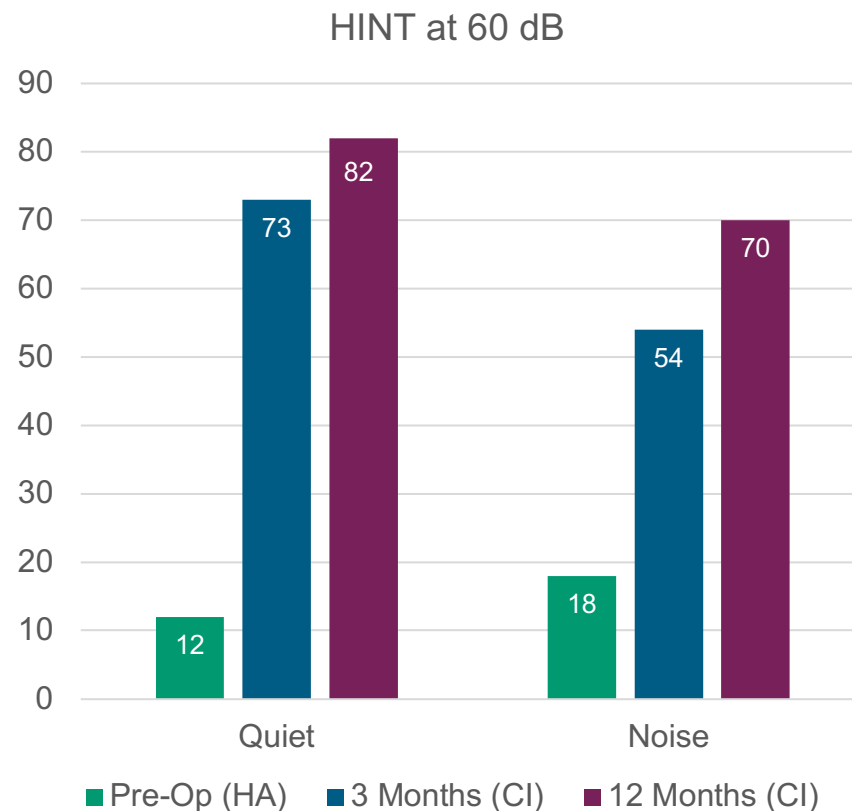
*The Hybrid L24 Implant is approved in the US for adults ages 18 years and older for unilateral use only

Nucleus Cochlear Implant



- > Implant performance as compared to best aided pre-operative condition according to a post-market surveillance study of Nucleus CI24RE recipients¹

If you see a patient with hearing aids not performing as well as most cochlear implant users, it may be time to consider an evaluation for implantation



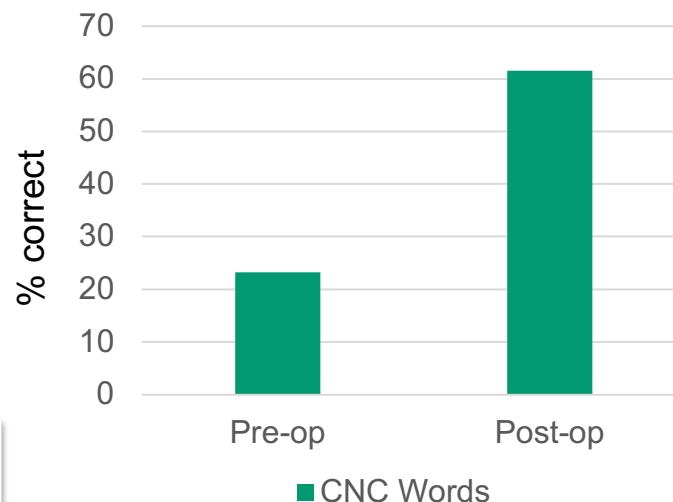
Factors that influence Performance



Holden, et al (2013)

- 201 Adults, mean age 57.4 years
- Average duration of severe to profound hearing loss was 13 years
- Pre-CI 4-frequency Pure Tone Average (.5, 1, 2 & 4 kHz) = 99.6 dB
- Reached peak performance at about 6 months post-op
- Factors identified that influence performance:
 - > Age
 - > Duration of hearing loss
 - > Hearing aid use
 - > Location of the electrode array
 - > Perimodiolar position
 - > Cognition (may be related to age)

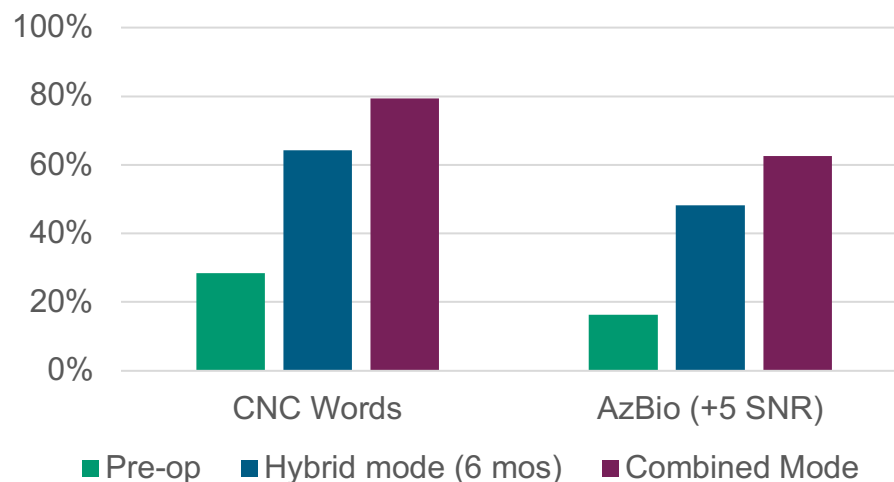
These factors will be considered by the implanting center and used to plan care, but they are usually not barriers to treatment



Performance: Hybrid Clinical Trial

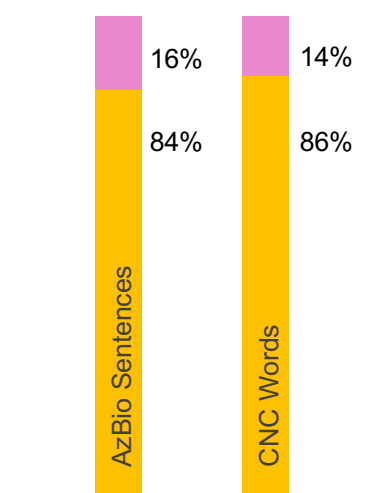


Hybrid Clinical Trial (2013)²



100% score the same or better when using two ears

■ Better
■ Same
■ Poorer



Individual Results¹

- Hybrid Clinical Trial
- 50 Adult Subjects
- Average age of implantation was 64 years
- Average duration of hearing loss was 28 years

34% of the clinical trial patients were unable to use the acoustic component post-operatively due to a loss of residual hearing. These recipients performed as well as typical CI recipients and performed better as a group than their pre-operative performance².

1 – The Cochlear Nucleus Hybrid System: FDA Clinical Trial Results: 2013 November (N=50)

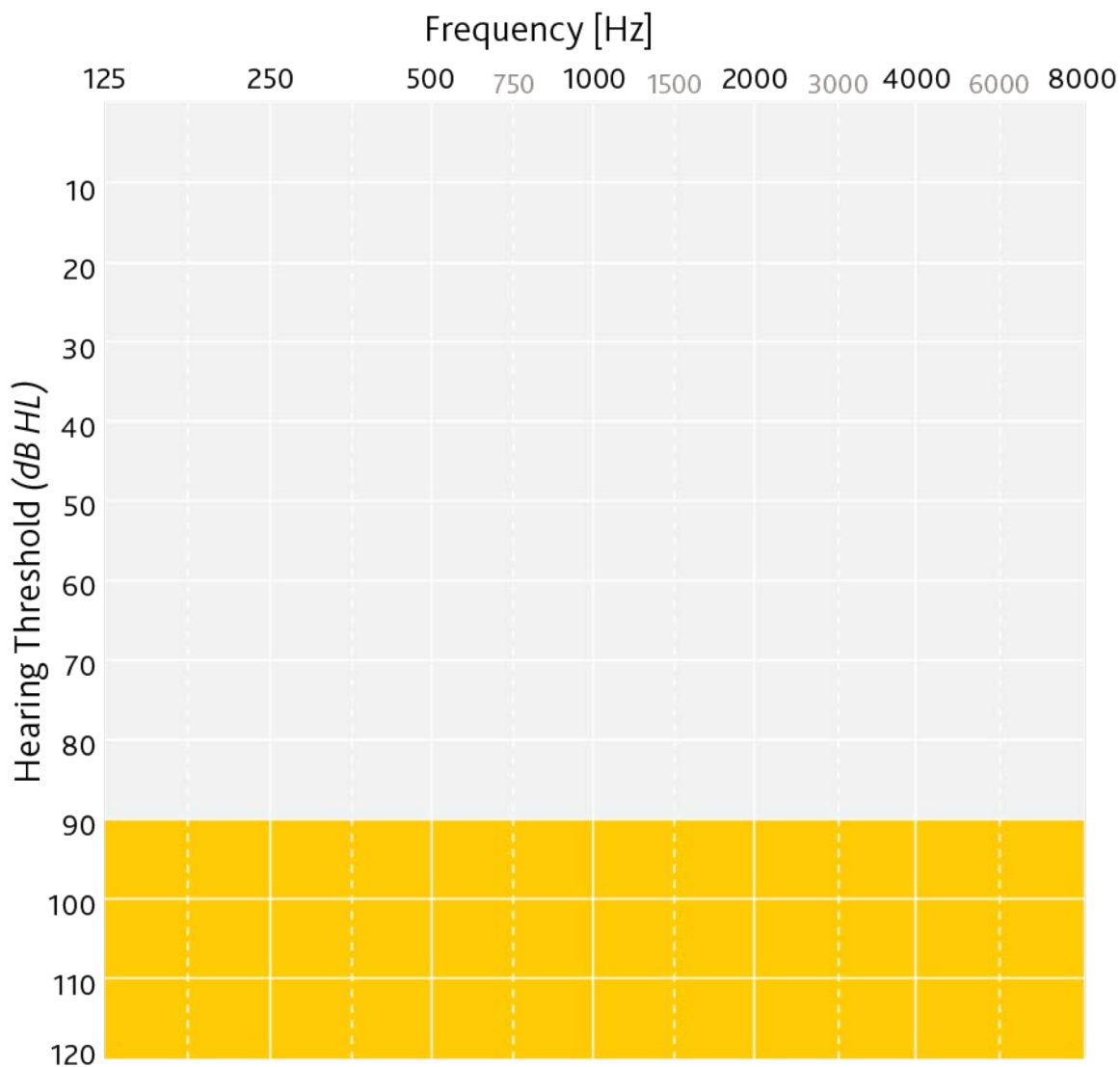
2 – Roland et al (2016) United States multicenter clinical trial of the Cochlear Nucleus Hybrid implant system. *Laryngoscope*, 126:175-181.

Pediatric Indication



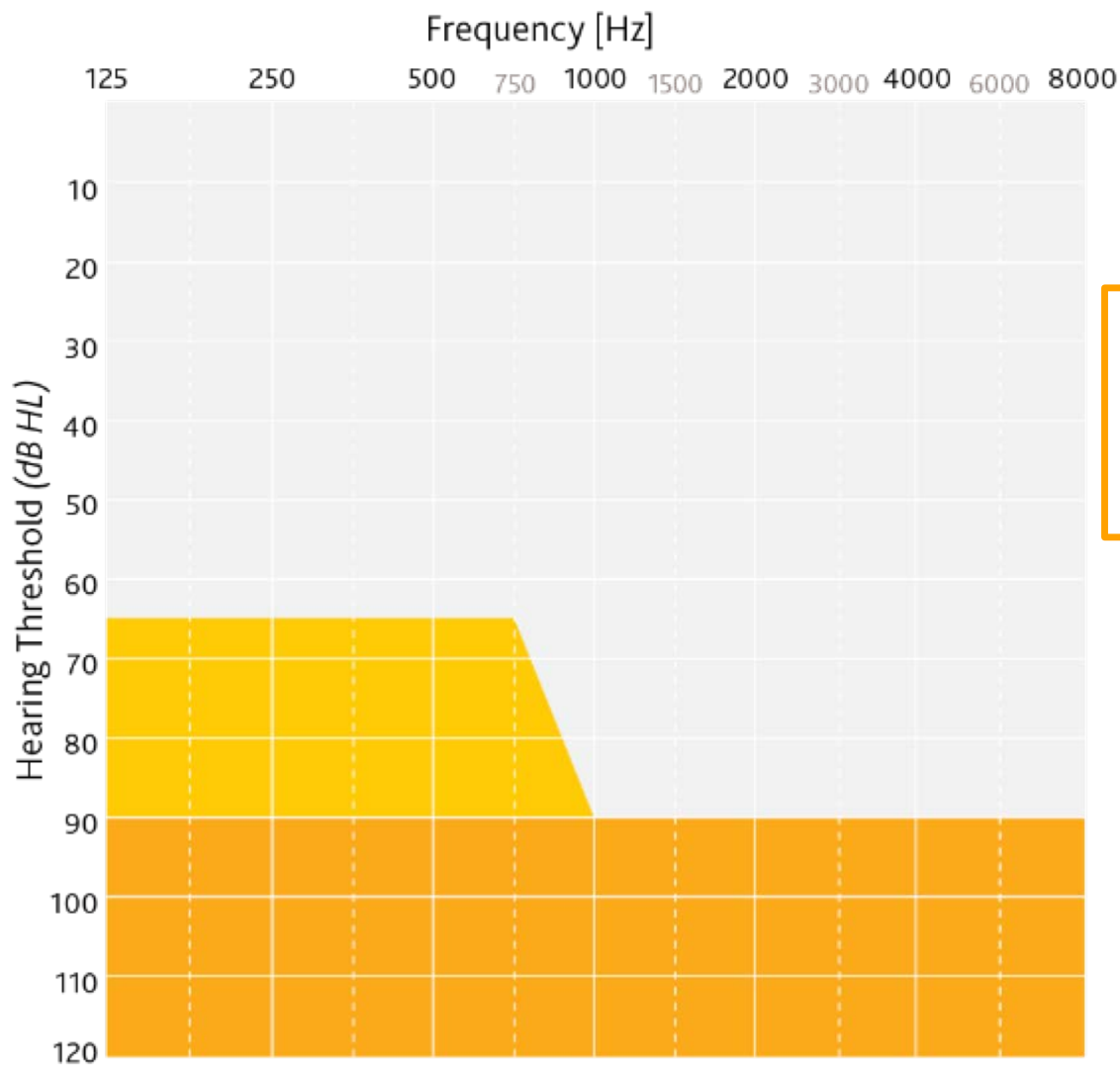
- Children 12 to 24 months of age who have bilateral profound sensorineural deafness and demonstrate limited benefit from appropriate binaural hearing aids.
 - lack of progress in the development of simple auditory skills in conjunction with appropriate amplification and participation in intensive aural habilitation over a three to six month period.
 - quantified on a measure such as the Meaningful Auditory Integration Scale or the Early Speech Perception test
- Children two years of age or older may demonstrate severe to profound hearing loss bilaterally.
 - $\leq 30\%$ correct on the open set Multisyllabic Lexical Neighborhood Test (MLNT) or Lexical Neighborhood Test (LNT), depending upon the child's cognitive and linguistic skills. A three to six month hearing aid trial is recommended for children without previous aided experience.

Nucleus Cochlear Implant Indication



Pediatric: 12 – 24 months Cochlear Implant

Nucleus Cochlear Implant Indication



Pediatric: 2 – 17 years
<30% MLNT or LNT in
best aided condition

Common Candidate Questions



- Wouldn't a stronger hearing aid be a better choice?
- Am I too old for a cochlear implant?
- My hearing aids are at least doing something for me – why would I give that up for a cochlear implant?
- I don't think surgery is necessary – isn't it better to just wait?
- What would a cochlear implant do for me?
- What if I lose my hearing?



They Have Questions; We Have Time



Concierge Team

- Includes individuals who are audiologists, recipients, parents and native Spanish speakers
- They will answer all questions – from easy to difficult – and will support your patient regardless of what they decide
- They have supported thousands of candidates on their journey

concierge@cochlear.com

1-800-216-0228





Current Nucleus Technology

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Cochlear™ Nucleus® Implant Portfolio



Uniquely Designed for Preservation, Performance and Preference



Slim Modiolar Electrode – The Thinnest and Flexible PERIMODIOLAR electrode ¹



Contour Advance® Electrode – Profile™ CI512 is the stylet based Perimodiolar Electrode



Slim Straight Electrode – Profile™ CI522 is the THINNEST full length electrode ¹



Hybrid™ L24 Electrode – The industry's ONLY FDA-approved hearing PRESERVATION electrode



Full-Band Straight Electrode – Ideal for various types of abnormal cochlea

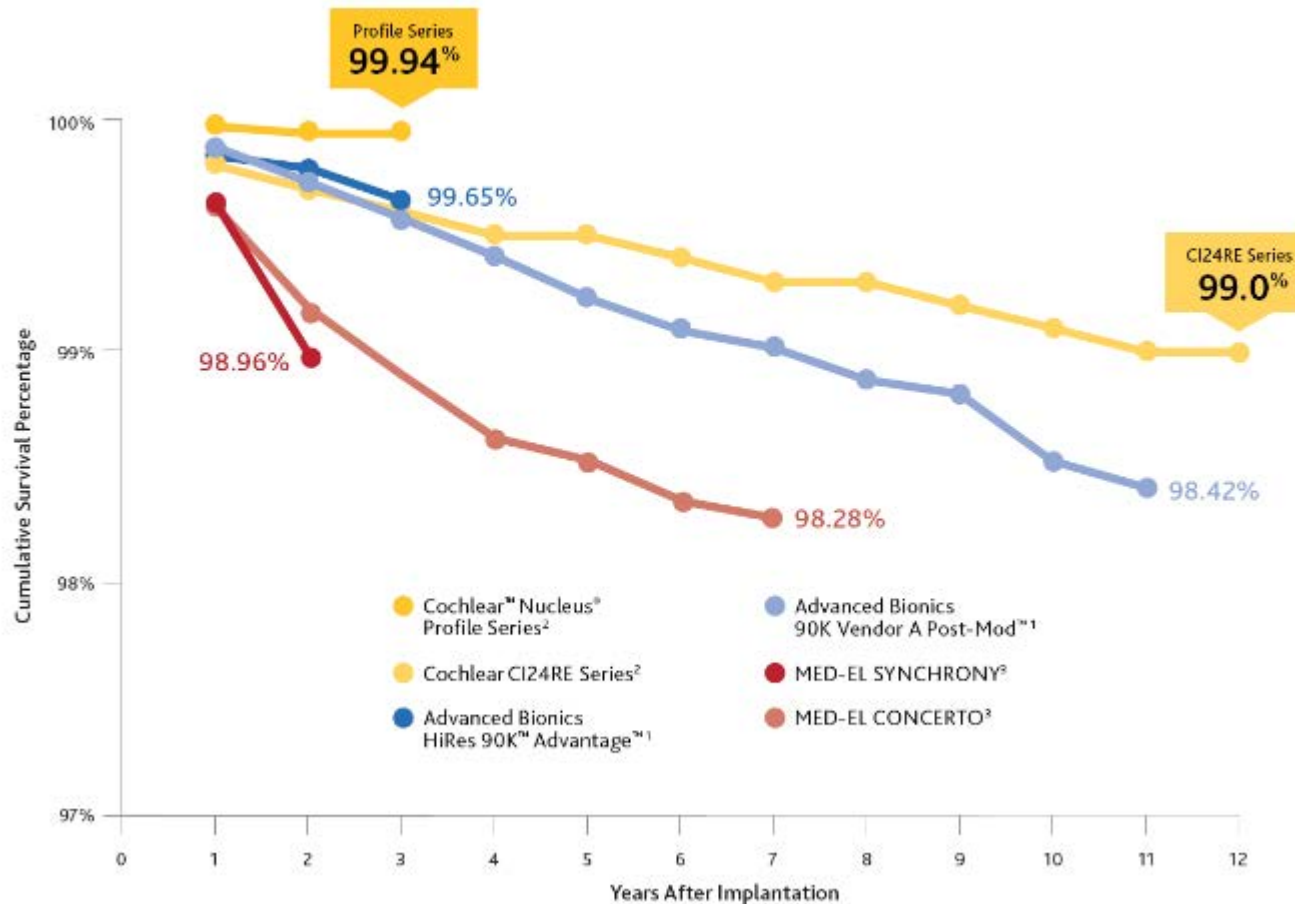


Auditory Brainstem Implant – The ONLY FDA-approved ABI electrode

Cochlear is #1 in Reliability¹⁻⁴



Industry Implant Reliability



1 – 2017 Cochlear Nucleus Implant Reliability Report, Volume 15, January 107

2 – 2016 Cochlear Implant Reliability Report [internet]. 028-M797-02 RevB ©2016 Advanced Bionics AG and affiliates. All rights reserved. [cited 30 March 2017]; Available from: http://www.advancedbionics.com/content/dam/ab/Global/en_ce/documents/candidate/2016-cochlearimplantreliability-report.pdf

3 – Reliability You Can Count On [Internet]. MED-EL. January 2017 [cited 30 March 2017]. Available from: <http://medel.com/reliability-reporting/>

4 – Dowell, R. Evidence about the effectiveness of cochlear implants for adults. Evidence based practice in audiology: evaluating interventions for children and adults with hearing impairment. Plural Publishing. 141-166. 2012.

Nucleus Sound Processors



HearYourWay™



The Nucleus 7 Sound Processor



Nucleus 7 is the **smallest** and only **Made for iPhone** cochlear implant processor which delivers proven **hearing performance**¹.



HearYourWay[™]

SmartSound iQ with SCAN

A range of technologies working together to meet user needs in every hearing situation



Automatically adjusts to the hearing situation

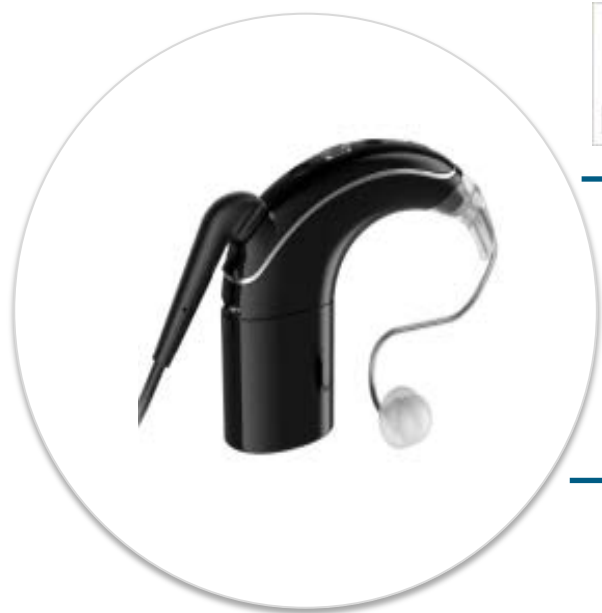
Industry first scene classifier (SCAN)*

Background noise reduction (SNR-NR)*

Wind noise reduction (WNR)*

*SNR-NR and WNR are approved for use with any recipient ages 6 years and older, who is able to 1) complete objective speech perception testing in quiet and in noise in order to determine and document performance 2) report a preference for different program settings. SCAN is FDA approved for use with any recipient age 6 years old and older, to be used at the discretion of the recipient/parent/caregiver.

Nucleus 7 Hybrid Mode



3 Receiver Sizes



Domes - instant fit, covering all recipient needs



Clinics can order custom earmolds when desired

*The Acoustic Component should only be used when behavioral audiometric thresholds can be obtained and the recipient can provide feedback regarding sound quality.

Nucleus 7 Battery Options



Rechargeable
(Compact & Standard)
Disposable
(2 zinc air)




Nucleus 7 Aqua+



- IP68 Ingress Protection for Water and Dust
- Rotating collar to prevent twisting of the coil plug
- Blue strain relief to differentiate coil from standard coil
- Sound processor earhook stays in place





Nucleus 7 is the first
and only **Made for
iPhone** cochlear implant
processor¹

Bluetooth® LE and MFi for
Hearing Device technology
from Apple® lets patients
connect directly to Apple iOS
devices and stream music,
phone calls and more.

Nucleus Smart App



Advanced control of the sound processor and wireless accessories, personalization and support – directly from your iOS device*



*devices running iOS 10 and later



The World's Only Smart Bimodal Solution that's Made for iPhone®



Nucleus® 7



LiNX 3D



True Wireless Accessories



KANSO®

Kanso®: Smart, simple, discreet



SMART

The benefits of Nucleus 7 hearing technology in an off-the-ear solution

SIMPLE

Easy-to-use single unit, cable free, one button set and forget

DISCREET

Smallest and lightest off-the-ear sound processor^{1,2}

1. Cochlear Limited. CP950 Kanso Sound Processor User Guide. Data on file, July 2016.

2. MED-EL. Rondo. The World's First CI Single-Unit Processor. [PDFInternet] [as of August 2016]. Available from: http://s3.medel.com/pdf/US/flbr/23710_21RONDO+US+Factsheet.pdf.

Kanso is Smart



Dual microphones



Uncompromised
Hearing
Performance

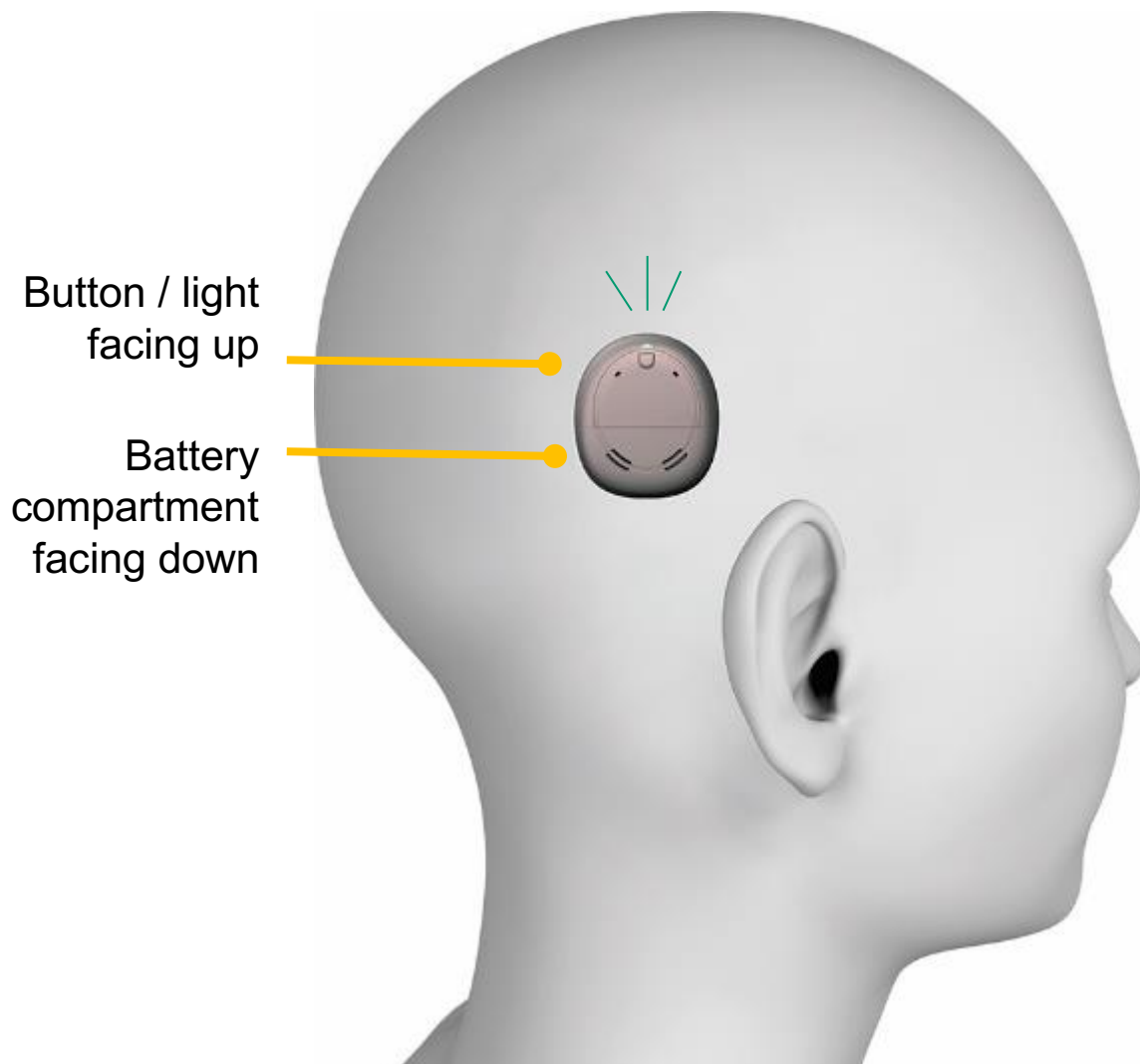
The world's first off-the-ear processor with **SmartSound® iQ with SCAN and dual microphones**.

Dual microphones enhance a recipient's ability to hear in noisy environments by up to 30%.¹⁻³

SNR-NR and WNR are approved for use with any recipient ages 6 years and older, who is able to 1) complete objective speech perception testing in quiet and in noise in order to determine and document performance 2) report a preference for different program settings. SCAN is FDA approved for use with any recipient age 6 years old and older, to be used at the discretion of the recipient/parent/caregiver

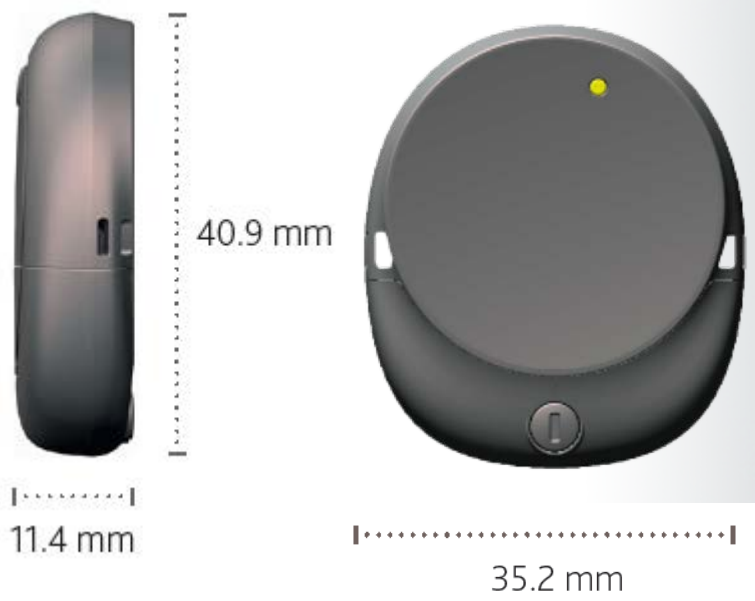
1. Amlani AM. Efficacy of directional microphone hearing aids: a meta-analytic perspective. *J Am Acad Audiol* 2001;12(4):202-14.
2. Bentler RA. Effectiveness of directional microphones and noise reduction schemes in hearing aids: a systematic review of the evidence. *J Am Acad Audiol*. 2005 Jul-Aug;16(7):473-84.
3. Cochlear Limited, A clinical comparison of the Cochlear™ Nucleus®5 noise management options, Cochlear White Paper; 2010, N34545F JUN10 ISS1.

Kanso is Simple



- Kanso is a cable free, single unit with one button to set and forget
- No need to change programs with SmartSound iQ with SCAN
- Indicator light can be set as desired

Kanso is discreet and comfortable



Kanso is the smallest^{1,2} off-the-ear sound processor in the industry

1 Cochlear Limited. CP950 Kanso Sound Processor User Guide. Data on file, July 2016
2 MED-EL Medical Electronics. RONDO User Manual. Last accessed July 2016. Available at: <http://www.mede.com/int/rondo>.

Aqua+ for Kanso

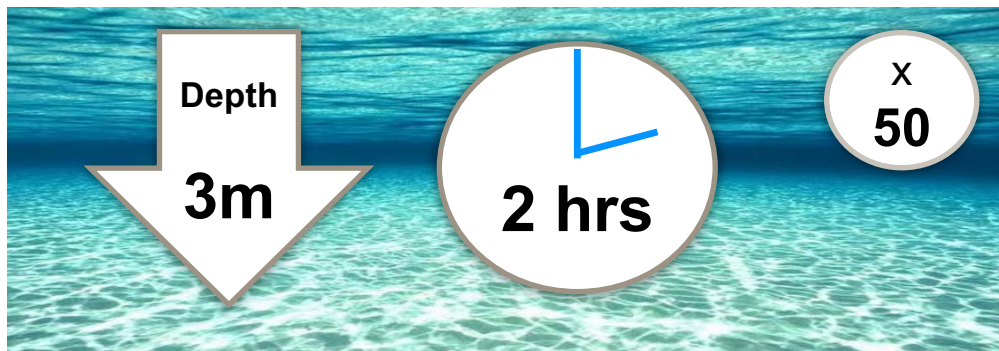


Introducing the Aqua+ for Kanso

Designed especially for Kanso: it is a re-usable sealable cover that keeps Kanso Sound Processor dry during use in or around any kind of water.

Usage:

- Can be used up to **3 meters (almost 10 feet for up to 2 hours)** (IP68)
- Can be **re-used up to 50 times** with appropriate care
- It is intended to be used with **specific disposable batteries**
- Users should be able to **self-report** discomfort



True Wireless devices

- Cochlear is the only hearing implant company delivering True Wireless freedom – no cords, no wires, no bulky neck-worn components.
- Remotes allow recipients to manage their hearing discreetly.



Nucleus 7 and Kanso



	Nucleus 7 (CP1000)	Nucleus Kanso® (CP950)
Off-the-Ear Sound Processor		●
Compatible with Cochlear True Wireless™	●	●
SmartSound® iQ with SCAN	●	●
Dual Microphones	●	●
Supports Hybrid Hearing	●	
Made for iPhone compatibility	●	
FM Connectivity	●	●
Ear-level FM availability	●	
Remote Control	●	●
Remote Assistant		●
Compatible with Monitor Earphones	●	
Zinc Air Battery Options	●	●
Rechargeable Battery Options	●	
8 Blending Color Options		●

Hear now. And always



83

WSP

89

MSP

94

Spectra

97

Sprint™

98

ESprit™

02

Esprit 3G

05

Freedom®

09

Nucleus® 5

13

Nucleus® 6

16

Kanso®

17

Nucleus® 7

Surgical Procedure

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Cochlear®

Cochlear Implantation Surgery is...



- A routine procedure in the hands of an experienced neurotologist/otologic surgeon
- Outpatient surgery
- About 2 hours surgical time
- Relatively low post-op pain
- Minimal post-op medical care required
- Major complications very rare



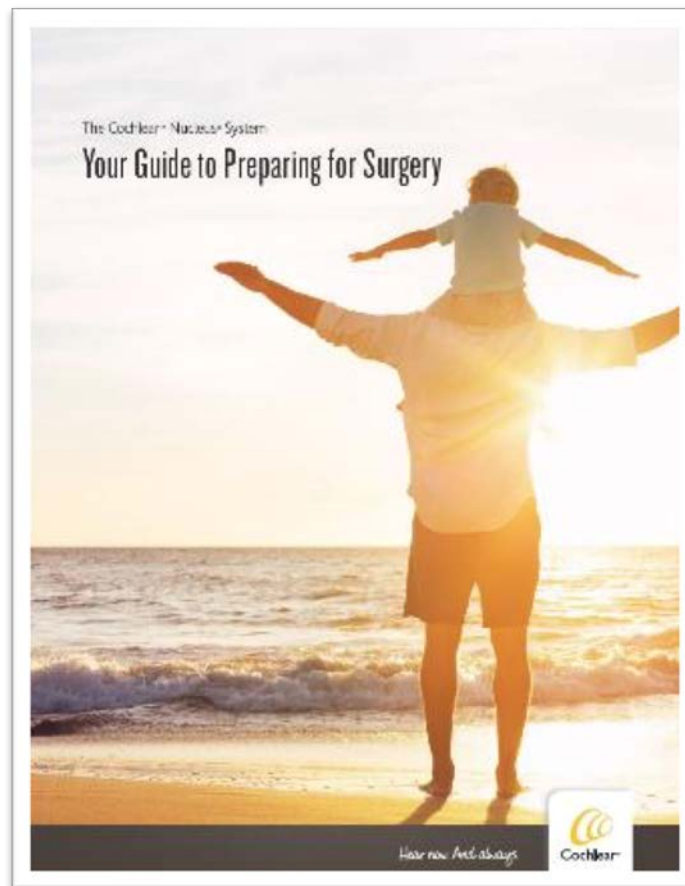
Insertion of the Slim Modiolar Electrode



Typical Post-Operative Care



- Outpatient or 23 hours stay
- Typically remove mastoid dressing the next day
 - Per surgeon recommendation
- Post-op check in 7-14 days
- Follow up visits as needed (at least yearly) by surgeon



Guide to Preparing for Surgery (FUN2590)

Case Studies and Next Steps

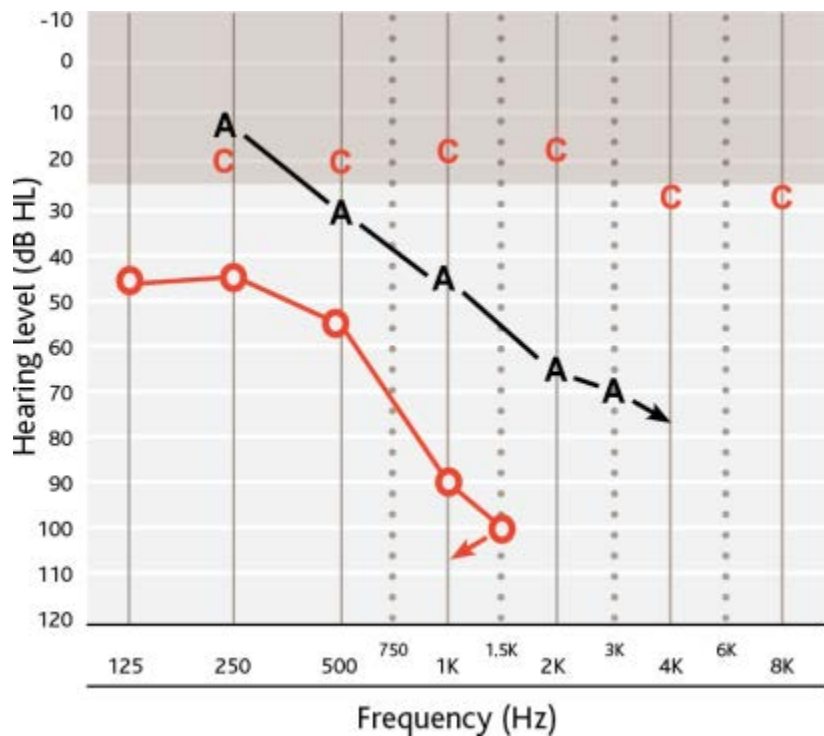
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Case Study One



52 year old female: progressive SNHL, CI-R*



A – Aided SF C - CI right ear

Note: Left side is dead ear

Pre-op best aided	Aided scores
Az Bio	12%
CUNY	19%
CNC	0%

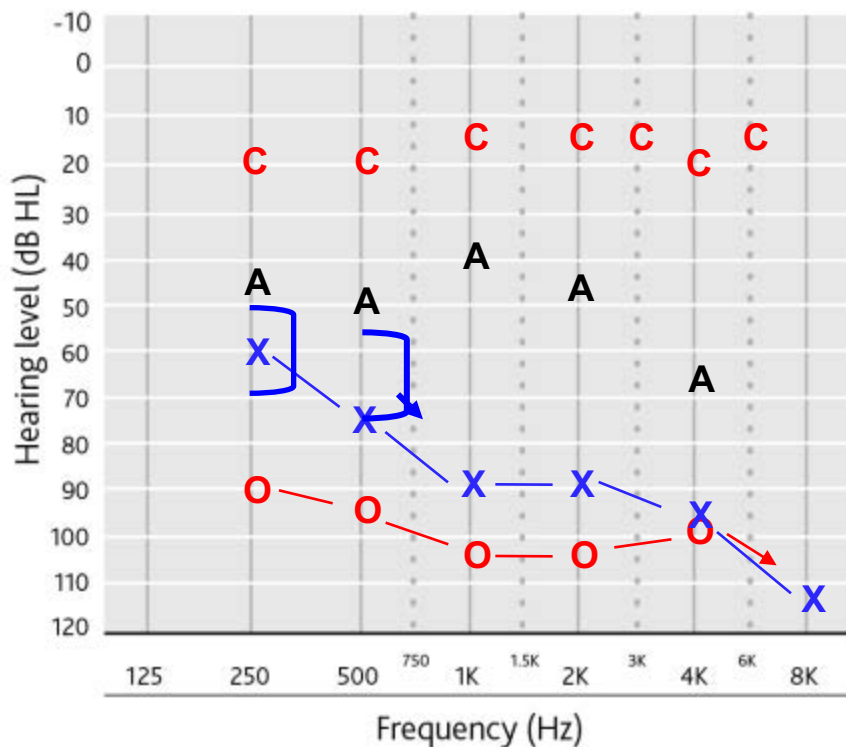
Post-op CI	Aided scores
Az Bio - Q	87%
CUNY	92%
CNC	78%

* For illustration purposes only

Case Study Two



63 year old male: noise exposure + progressive SNHL, right CI*



A – AU Aided SF C - CI right ear

Bone AD = NR

Pre-op best aided	
WRS %	AU
HINT- Q†%	12
HINT- Q†%	20
Post-op (6 mos)	
WRS %	AU
HINT- Q†%	80
HINT- N**	100
HINT- N**	82

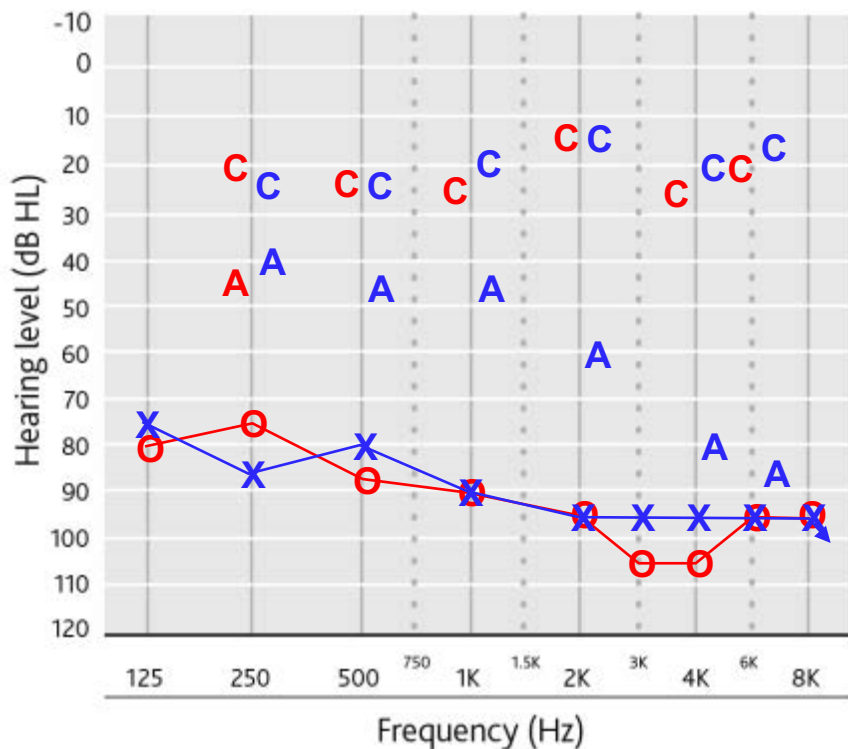
† 60dB SPL ** +10/SNR

* For illustration purposes only

Case Study Three



29 year old female: Rapid SNHL, Bilateral CI*



Pre-op best aided	R	L	AU
HINT- Q†%	31	28	31

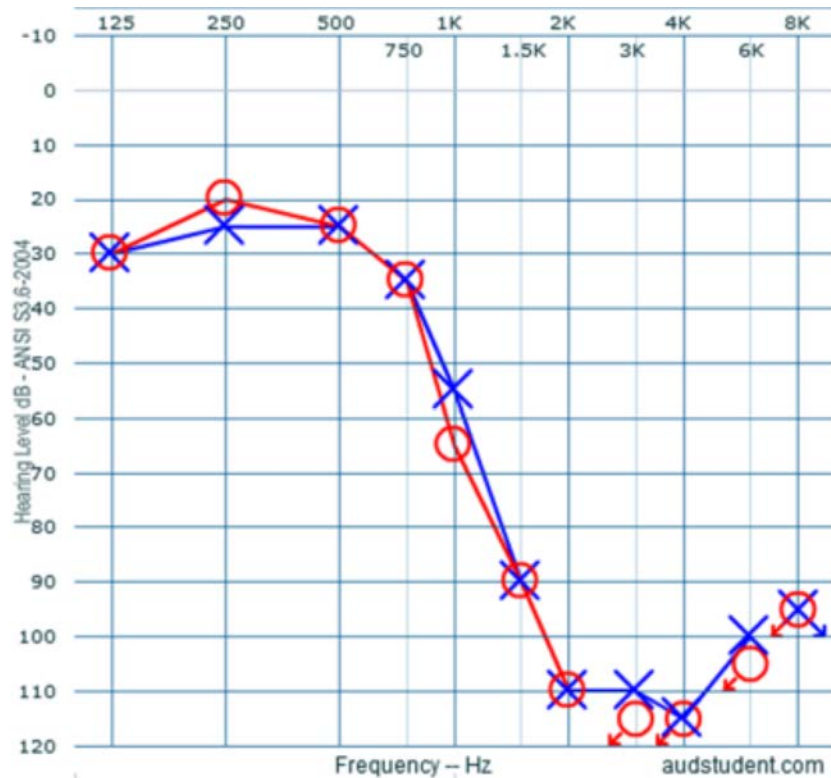
Post-op (6 mos)	R (CI)	L (CI)	AU
HINT- Q†%	98	99	
HINT- N**			89

†60dB SPL **+10/SNR

A – right aided A – left aided Bone conduction = NR
 C - CI right ear C - CI left ear

* For illustration purposes only

Case Study Four – pre-operative



Ear	CNC	AzBio
Right	54%	91%
Left	52%	91%

- 50 year old female (“Annie”) diagnosed with hearing loss in 1991
- Fit with bilateral amplification
- Licensed Social Worker
 - > Difficulties listening at work
 - > Using the telephone
 - > Watching movies and live theater

Case Study four - Initial Activation



“I continue to be in a bit of amazement.

Shortly after the activation last Tuesday, I went to a small park and when walking over a footbridge, HEARD the water flowing over the rocks in a small stream! I was totally blown away, I had forgotten that I no longer heard that sound and just imagined it. Totally a shock! I am hearing much better at work and in social conversations, yeehaa!!”

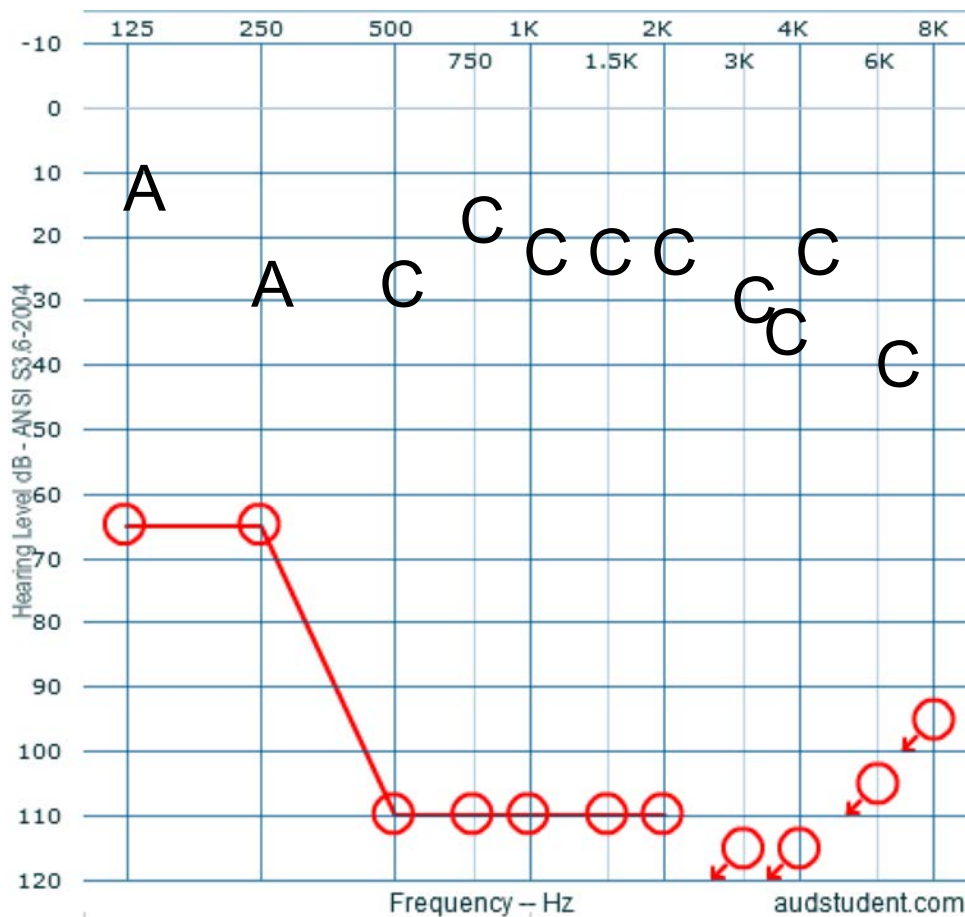
~”Annie”

Case Study Four - Three Months



I'm sure that I'm hearing better since the last check. I am consistently amazed as the positive changes continue just when I'm thinking I've probably gotten as much as possible. Guess I'll revise my thinking!"

	CNC	AzBio +10
Pre	54%	DNT
Post-Hybrid	64%	67%
Post-Combined	70%	73%



Insurance Coverage



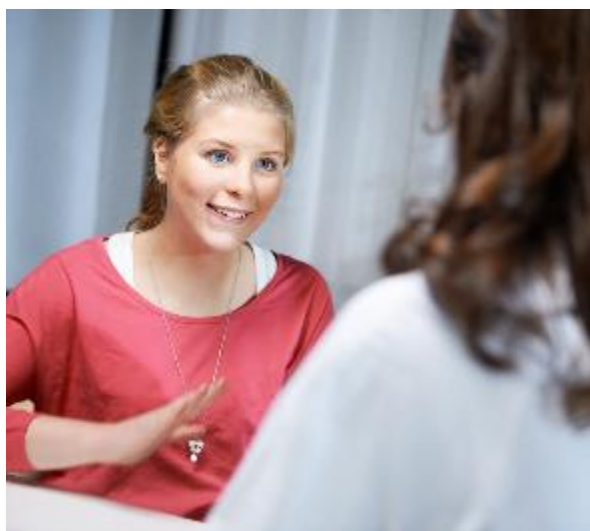
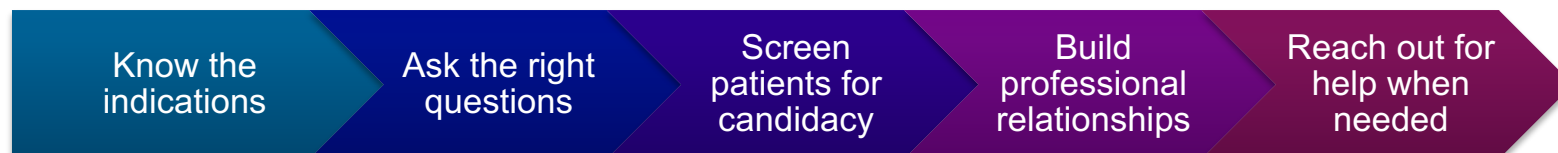
- Unlike hearing aids, hearing implants may be covered by your patients' insurance plan, including Medicare and Medicaid.*†
- Our Insurance Support Team will help patients obtain insurance coverage or help you navigate through the appeals process if you have been denied.
- Visit [Cochlear.com/US/Insurance](https://www.cochlear.com/US/Insurance) for more information.



*Many insurance companies cover the Cochlear Nucleus Hybrid Implant System for patients who qualify. Contact your insurance company or local Hearing Implant Specialist to determine eligibility for coverage. Coverage for adult Medicaid recipients varies according to state-specific guidelines

†May be covered for patients that meet Medicare's current coverage criteria

What can you do?



Cochlear is here to help!

Learn which clinics work with implants in your community. Most are happy to see patients for evaluation even if you are unsure about candidacy.

Test patients in the soundfield with hearing aids at normal conversational levels (ie, 50 dB SPL). How do they compare to Hybrid or CI candidacy indications?

Can your patient hear on the phone? Can they hear in background noise? Are they pulling back from social situations?

Compare your patient's audio to the candidacy criteria – does it match?

The Cochlear™ Baha® System

Hear now. And always



A Lifetime of Innovation...



1970's

Researchers at the University of Gothenburg discover osseointegration and create the Baha® System

2010

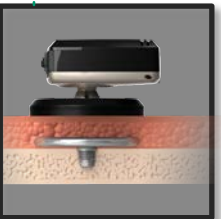
Baha® 3 Systems set new standards for implant stability

2013

Cochlear introduces the Baha® Attract

2015

Baha® 5 is introduced – incredibly small, unbelievably smart



1995

FDA approves the Baha® System for use in the US (approved for SSD in 2002)

2012

Cochlear's DermaLock™ abutment is designed to further improve patient outcomes and surgical procedure

2014

True wireless is introduced to Baha recipients with the innovative Baha® 4

TODAY

Baha 5 Systems expanded to offer more power and more choices

Why Consider the Baha[®] System?



Direct Bone Conduction:

- Works independently of ear canal and middle ear
- Direct transmission gives the power needed to hear what's missing
 - Pre-operative testing is possible
 - High wearing comfort
- Typically a routine outpatient procedure
 - Predictable outcome



How the Baha[®] Connect System works



<https://youtu.be/L0nYthMMnQU>

How the Baha[®] Attract System works



<https://youtu.be/1IdcXI5gBvM>

Surgical options



Processor

*Baha 5 suite of processors
attach for incredibly smart,
unbelievably powerful hearing*

Connection

*BIM400 Implant Magnet or
BA400 Abutment connect
recipients for a lifetime of
hearing*

Implant

*BI300 Implant provides a strong
foundation*

One Implant. Two Systems.



Baha Attract

*Cosmetically appealing
Less risk of soft tissue reaction
MRI safe (up to 1.5 Tesla)*



Baha Connect

*Maximizing hearing performance
No soft tissue reduction
MRI safe*

Non-surgical option



The new Baha Softband takes inspiration from the success of the Baha Attract System to provide children with a new level of comfort and performance.



Addition of the ¹ SoftWear Pad provides **3 dB** better sound transmission, while reducing the average pressure against the skin by **50%**¹

1. Flynn MC, Fyrlund H. Design concept and technological considerations for the new Baha Softband. Cochlear Bone Anchored Solutions AB, 631194, 2015.

Candidacy for Baha[®] Systems

Hear now. And always

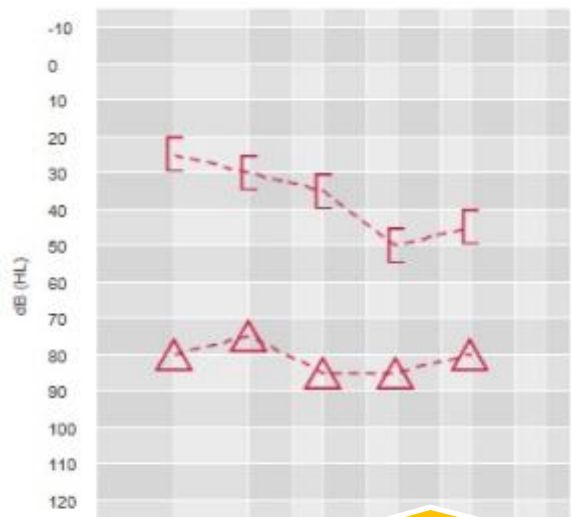


Cochlear[®]

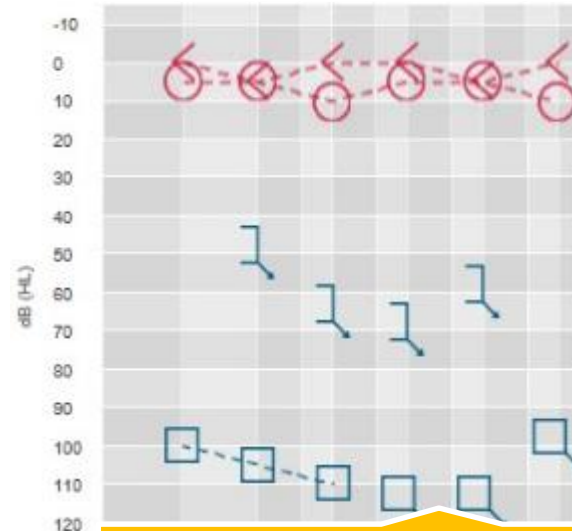
Baha System Candidacy



Conductive
Hearing Loss



Mixed Hearing
Loss



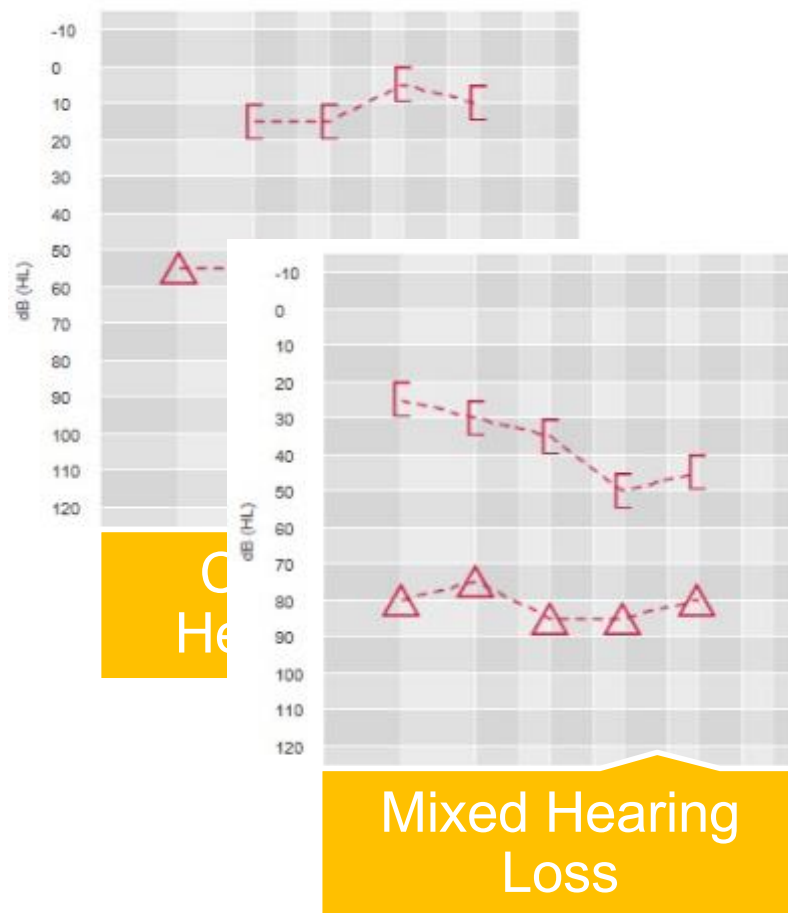
Single-Sided
Deafness (SSD)

FDA Indication for Implantation



Mixed & Conductive Hearing Loss

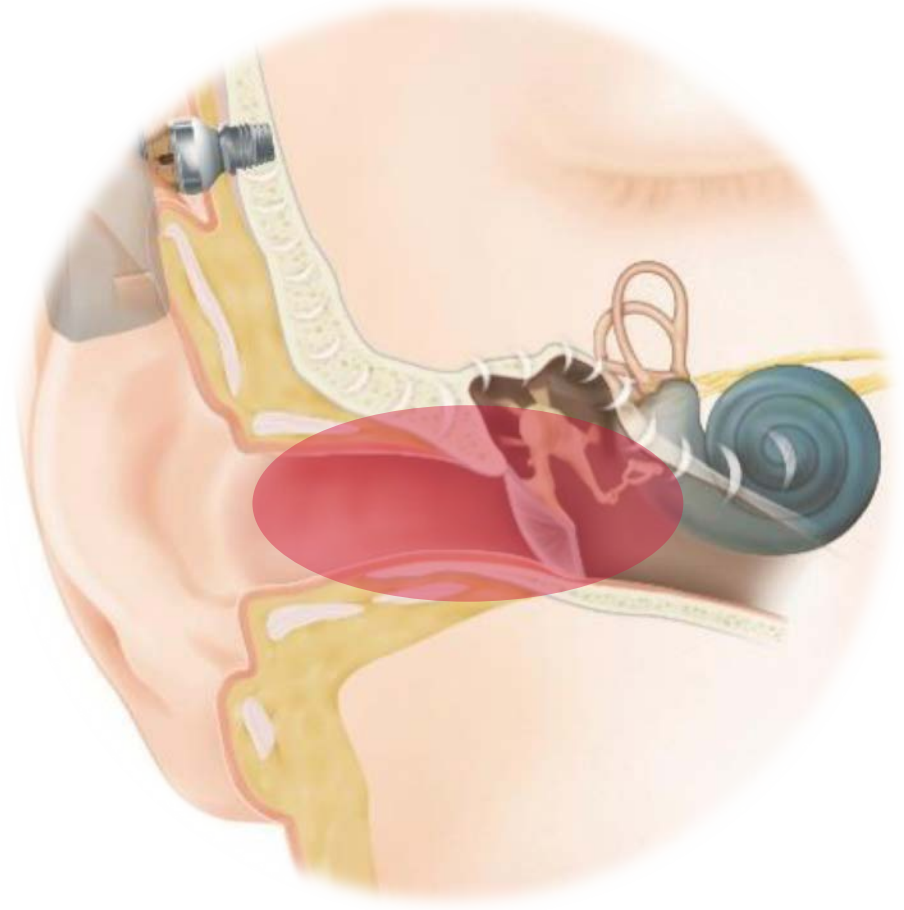
- ≥ 5 years of age
- ≤ 65 dB HL Bone Conduction PTA
> PTA of 0.5, 1, 2 & 3 kHz
- For bilateral fitting, symmetric bone conduction thresholds are defined as less than 10 dB difference on average (0.5, 1, 2 & 3 kHz) or less than 15 dB at individual frequencies



Baha Solutions: Conductive & Mixed Hearing Loss



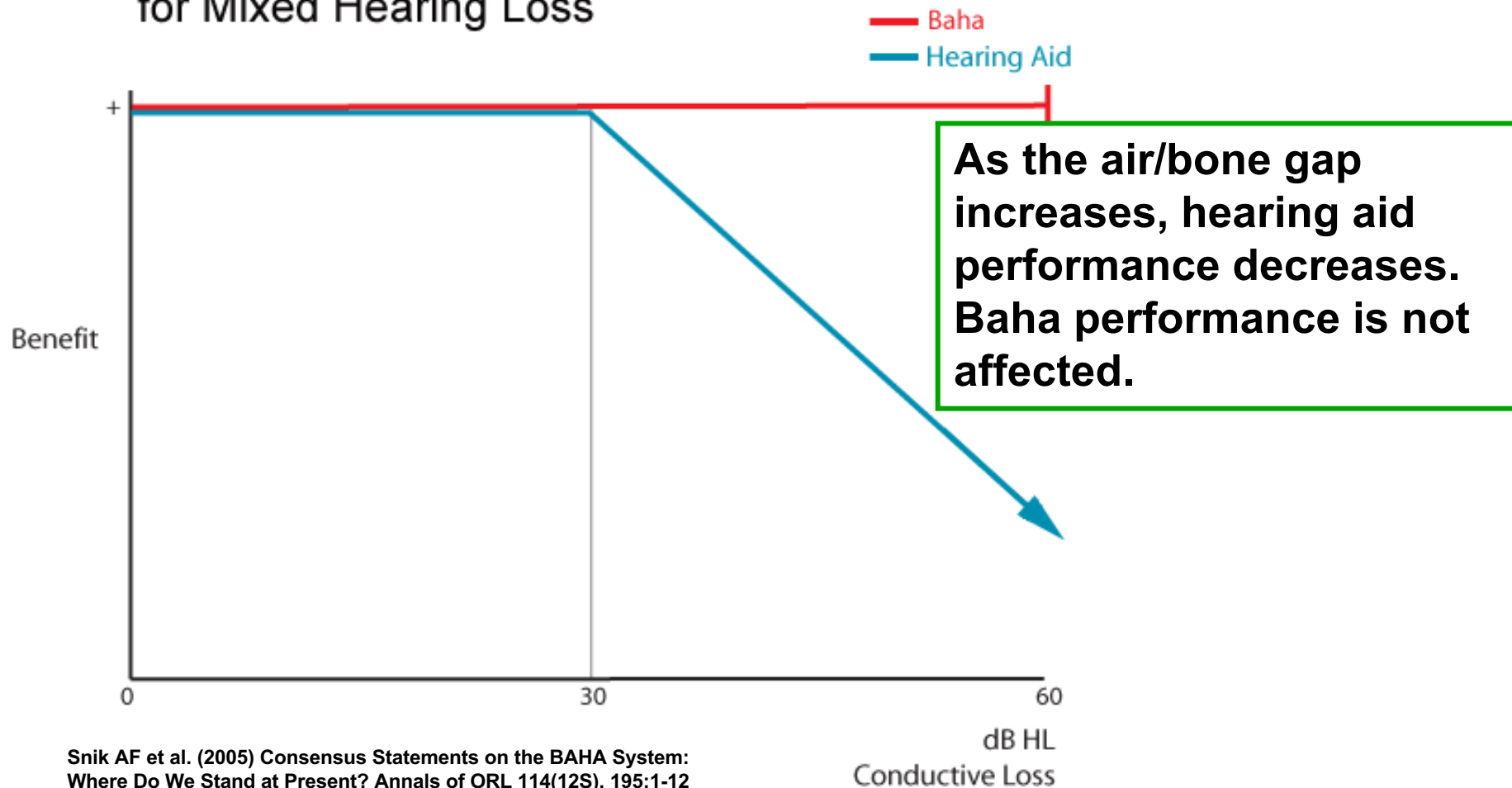
- Direct bone conduction bypasses the outer and middle ear
- Baha solutions treat conductive & mixed hearing loss
 - Atresia
 - Chronic middle ear disease
 - Cholesteatoma
 - Congenital abnormalities
- Baha devices do not have to overcome conductive component, only amplify for any sensorineural component



Baha Device or Hearing Aids?

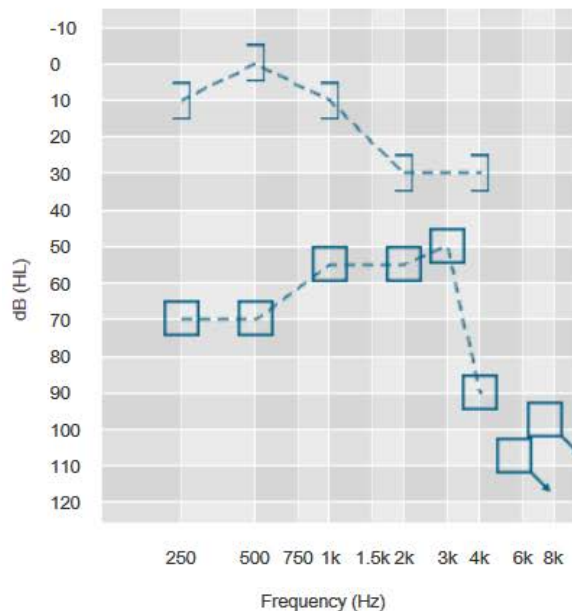
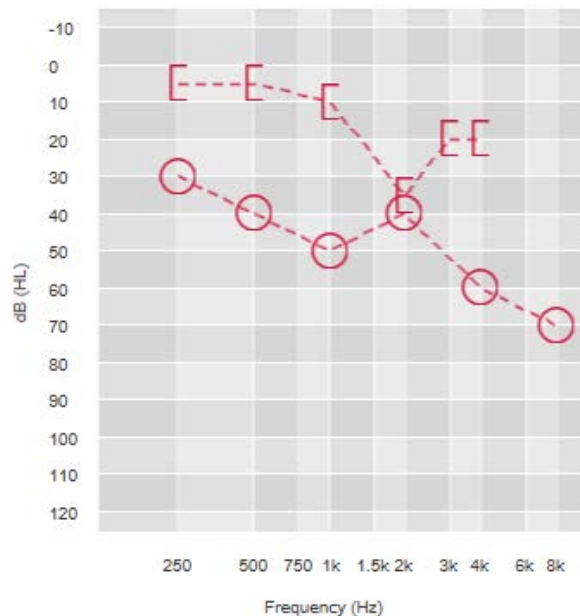


Comparative Benefits of Baha vs Hearing Aids for Mixed Hearing Loss



Snik AF et al. (2005) Consensus Statements on the BAHA System: Where Do We Stand at Present? Annals of ORL 114(12S), 195:1-12

Juan



Audiogram thresholds:

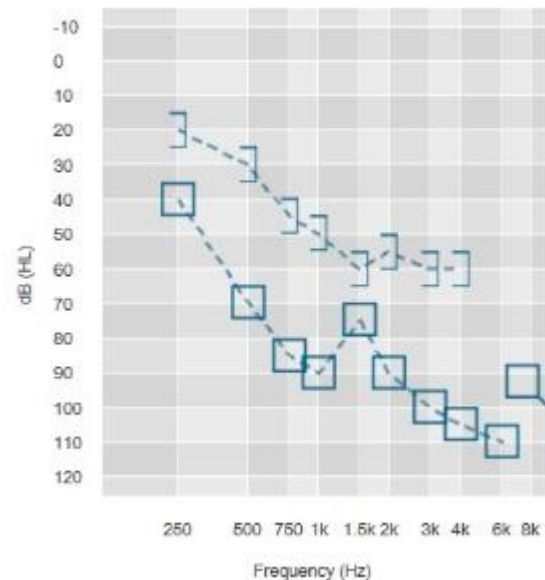
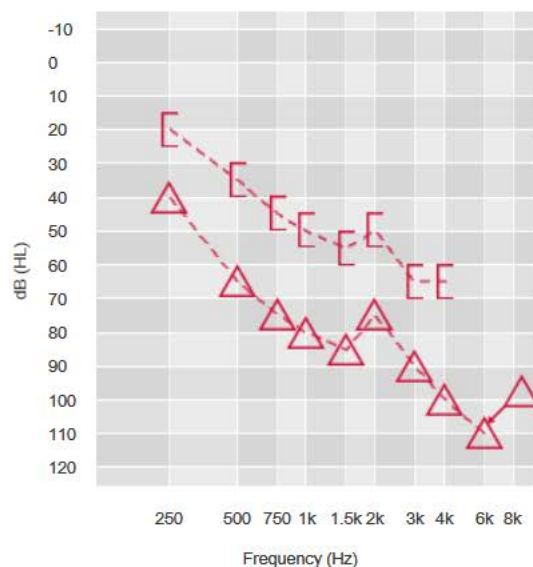
L	250	500	750	1000	1500	2000	3000	4000	6000	8000
BC	10	0		10		30		30		
AC	70	70		55		55	60	90	NR	NR

R	250	500	750	1000	1500	2000	3000	4000	6000	8000
BC	5	5		10		35	20	20		
AC	30	40		50		40		60		70

- 47 year old male with conductive hearing loss due to otosclerosis
- Previously had 2 surgeries on the right and 3 on the left to try to close air bone gap but hearing loss persists
- Has a hearing aid in the left but does not use regularly (especially at work)
- Owns a small construction company



Lucy



Audiogram thresholds:

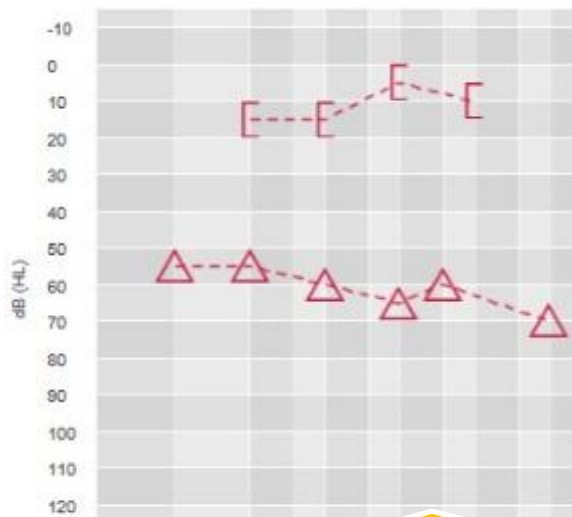
L	250	500	750	1000	1500	2000	3000	4000	6000	8000
BC		30	45	50	60	55	60	60		
AC	40	70	85	90	75	90	100	105	110	

R	250	500	750	1000	1500	2000	3000	4000	6000	8000
BC	20	35	45	50	55	50	65	65		
AC	40	65	75	80	85	75	90	100	110	

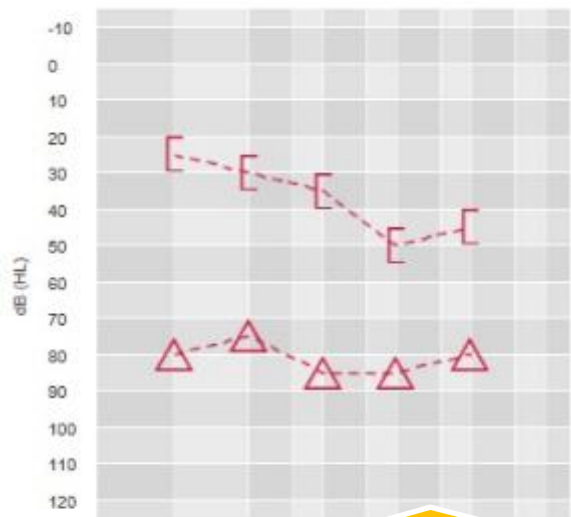
- Female hairdresser, age 55 years
- Chronic Suppurative Otitis Media and long duration bilateral Mixed Hearing Loss.
- Very unsuccessful with hearing aids; currently using 10 year old power BTE's but often has to go without in one or both ears due to drainage
- Feels she can hear in quiet, but isn't able to keep up with conversations in the new salon.



Baha System Candidacy



Conductive Hearing Loss



Mixed Hearing Loss



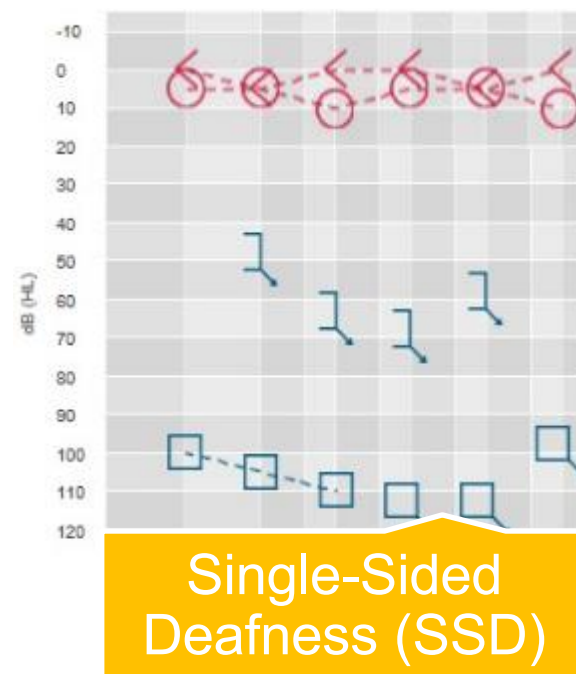
Single-Sided Deafness (SSD)

FDA Indication for Implantation



Single-sided Deafness

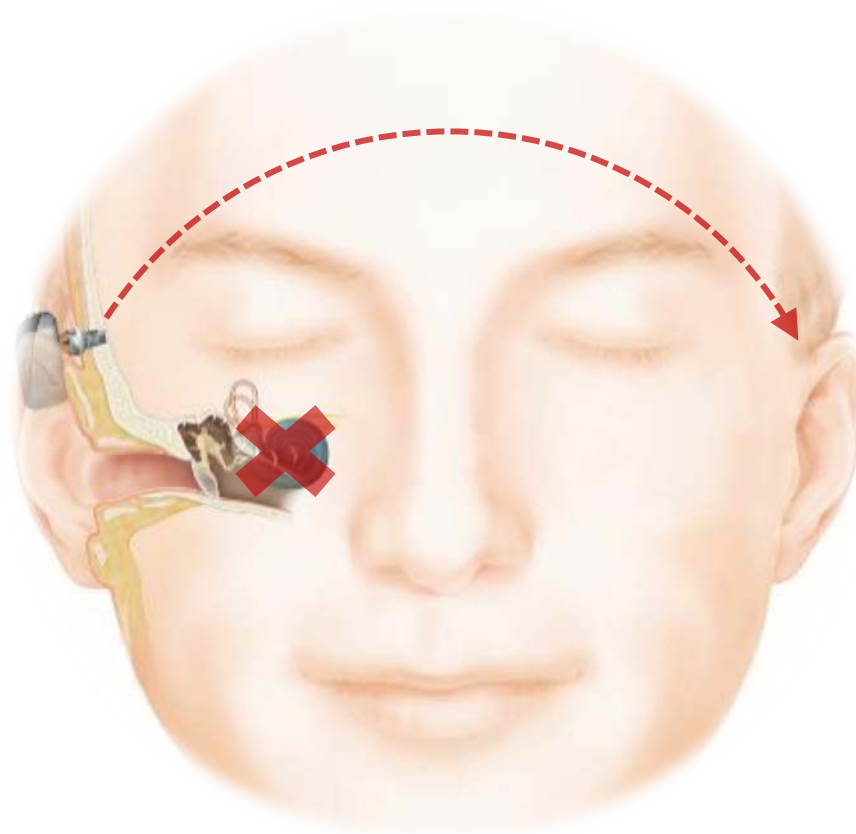
- ≥ 5 years of age
- Normal Hearing in the contralateral ear
 - > Defined as PTA Air Conduction thresholds equal to or better than 20 dB at 0.5, 1, 2 & 3 kHz
- Functions by transcranial routing of the signal



Baha Solutions: Single-Sided Deafness



- Sound travels via direct bone conduction to stimulate the better hearing cochlea
- Baha technology can bypass the deaf ear and bring sound from the bad side to the good side
- Reduces the head shadow effect
- Direct stimulation of cochlea and no device in the better hearing ear



Impact of Single-Sided Deafness



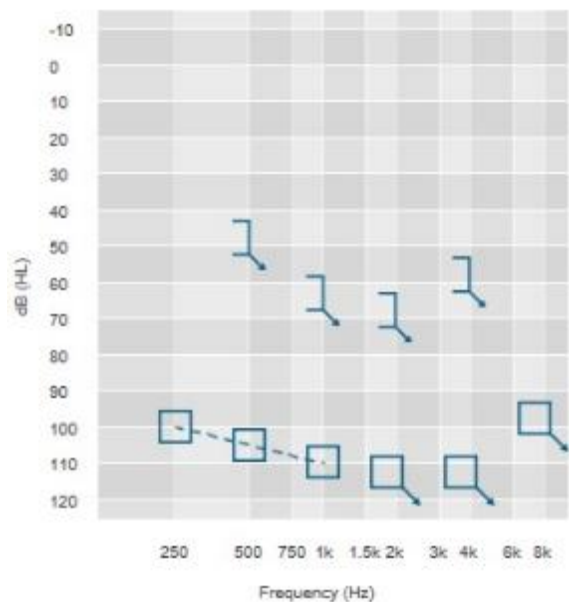
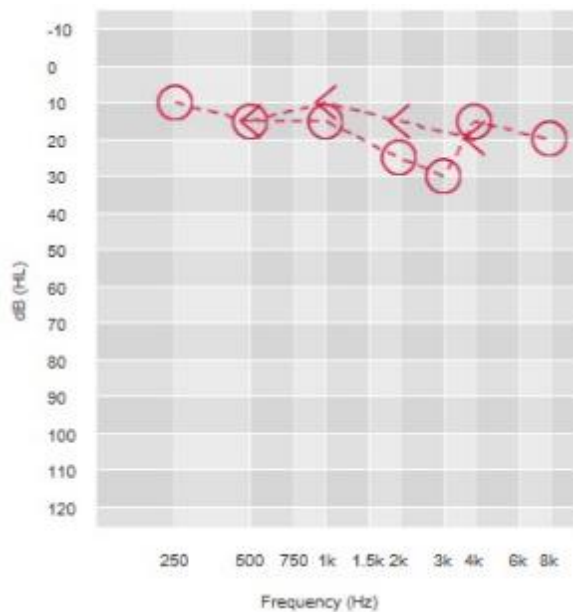
- Difficulty hearing in background noise, problems with localization and difficulty hearing someone who is seated on the “bad” side¹
- Problems can occur when communicating in a crowd, in a restaurant, at work, in a car or walking on busy streets¹
- For children with single-sided deafness, they can experience behavior problems at home and at school, difficulty in noisy environments and poor localization²



1. American Academy of Audiology Clinical Practice Guidelines: Evidence-Based Best Practice Guideline for Adult Patients with Severe-Profound Unilateral Sensorineural Hearing Loss. 5/6/2015.

2. Bess, Tharpe (1986) Identification, assessment and management of children with unilateral sensorineural hearing loss. Ear Hear, 7(1):43-51.

Steve



Audiogram thresholds:

L	250	500	750	1000	1500	2000	3000	4000	6000	8000
BC		NR		NR		NR		NR		
AC	100	105		110		NR		NR		NR

R	250	500	750	1000	1500	2000	3000	4000	6000	8000
BC		15		10		15		20		
AC	10	15		15		25	30	15		20

- Steve is a 38 year old man with sudden SSD of unknown etiology 3 years ago
- He sings in a 1940's tribute band and wears suits and horn-rimmed glasses everyday.
- He has been “making do” with his hearing loss but he notices a hard time following his bandmates and conversing with fans in noisy bars



Baha[®] 5 Portfolio

Hear now. And always



Cochlear[®]

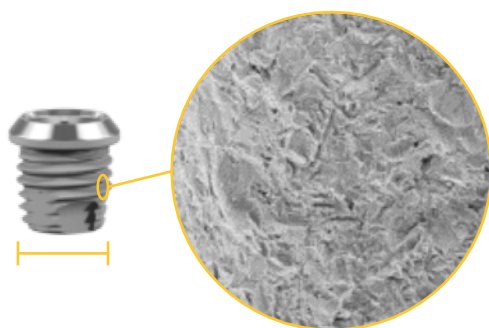


BI300 Implant

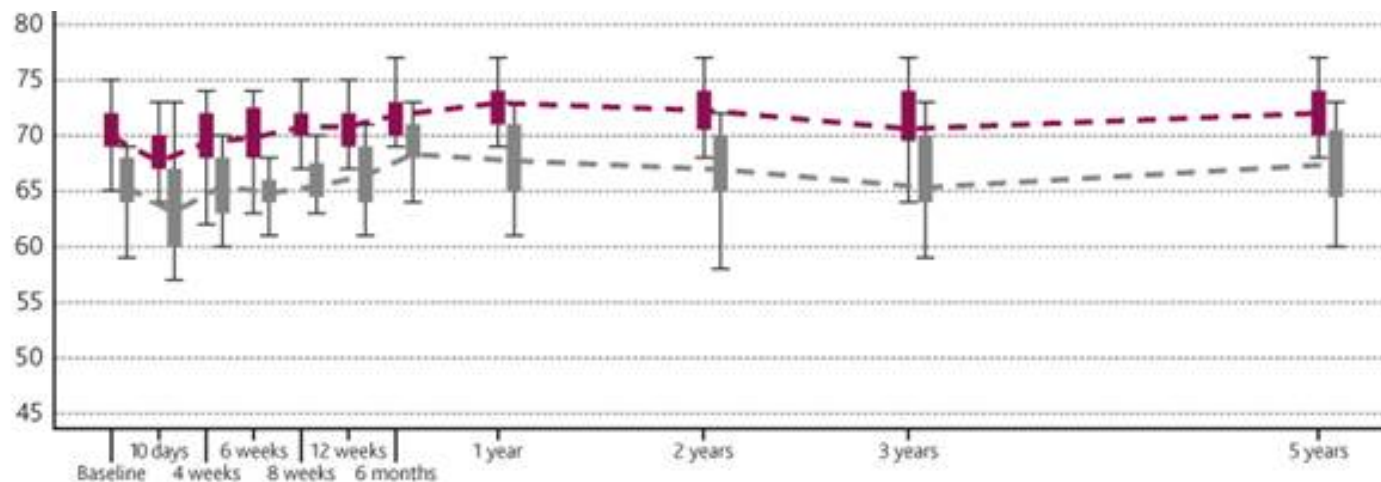
Proven Stability: 5 Years of Clinical Study



The Baha® BI300 Implant provides early access to sound as the stable foundation for the Baha Connect and Attract Systems



The long-term clinical performance of the BI300 is proven through 5 years¹ of continuous clinical study. The wider 4.5 mm diameter and TiOblast™ surface enhances primary and long-term stability.



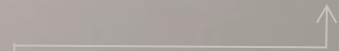
1. 1. Cochlear Bone Anchored Solutions AB, Mölnlycke, Sweden. Long term stability, survival and tolerability of a (novel) Baha® implant system. In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). [Cited 2016 Jan 6]. Available from: <https://clinicaltrials.gov/ct2/show/NCT02092610>. NLM Identifier:NCT02092610.



DermaLock™ Abutments



BI300 Implant



The Gold Standard in Bone Conduction



Since its introduction in 2012, the Baha Connect System with DermaLock™ technology demonstrates good clinical and patient-reported outcomes with fast surgery time.¹

MORE THAN

25,000*

DERMALOCK PATIENTS!

*Data on File, Cochlear internal Data (Jul 2016)

1 – Wilkie MD, Chakravarthy KM, Mamais C, Temple RH. Osseointegrated hearing implant surgery using a novel hydroxyapatite-coated concave abutment design. Otolaryngol Head Neck Surg. 2014;151(6):1014-1019

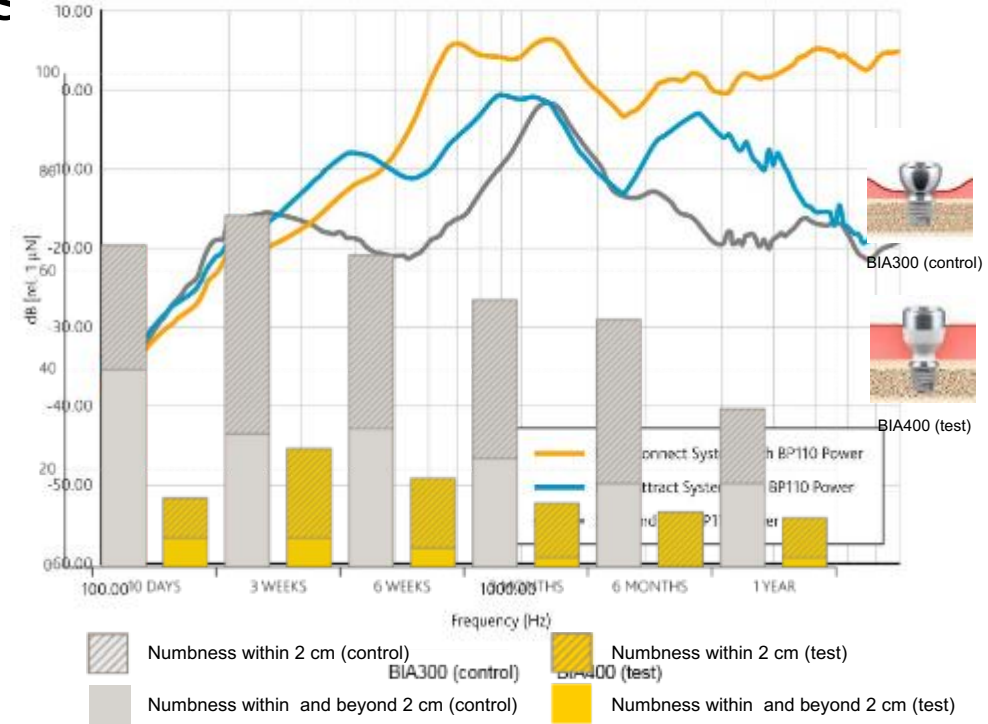
Advantages of the Baha® Connect System



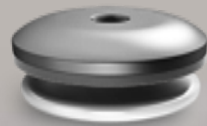
No soft tissue reduction is needed so surgery takes less time¹

Direct connection with the implant provides the maximum possible gain compared to a transcutaneous system with less numbness over previous generation technology¹

Significantly shorter surgery time
 Comparison of sound transmission through the Baha Connect System, Baha Attract System and Baha Softband.
25 mins
Significantly less numbness



1. Clinicaltrials.gov ID NCT01796236. Clinical and Health Economic Evaluation With a New Baha® Abutment Combined With a Minimally Invasive Surgical Technique.



SP & Implant Magnets



DermaLock™ Abutments



BI300 Implant



The Most Implanted Magnetic System



Since its introduction in August 2013, the Baha Attract System is the most widely used magnetic bone conduction system in the industry.

MORE THAN
10,000⁺*

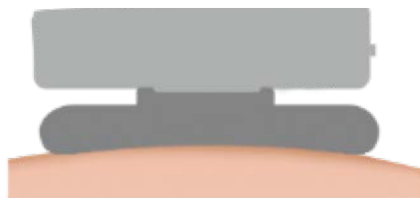
PATIENTS WORLDWIDE!

* Data on file

More Comfortable than Other Magnet Systems



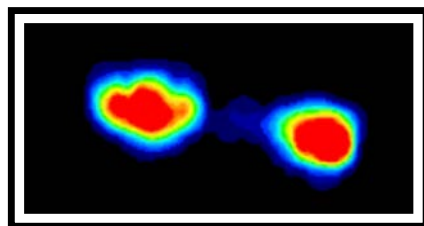
Technical tests show that the unique Baha SoftWear™ Pad reduces pressure by up to 59% and peak pressure by up to 70% compared to other magnet systems.¹



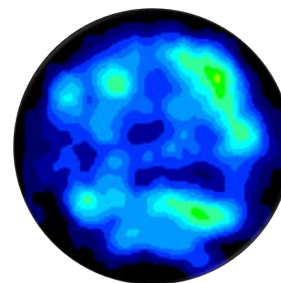
Other magnet plate



Baha SP Magnet
with Baha SoftWear™ Pad



Force: **1N**
Average pressure: **0.58 N/cm²**
Peak pressure: **1.65 N/cm²**



Force: **1N**
Average pressure: **0.23 N/cm²**
Peak pressure: **0.49 N/cm²**

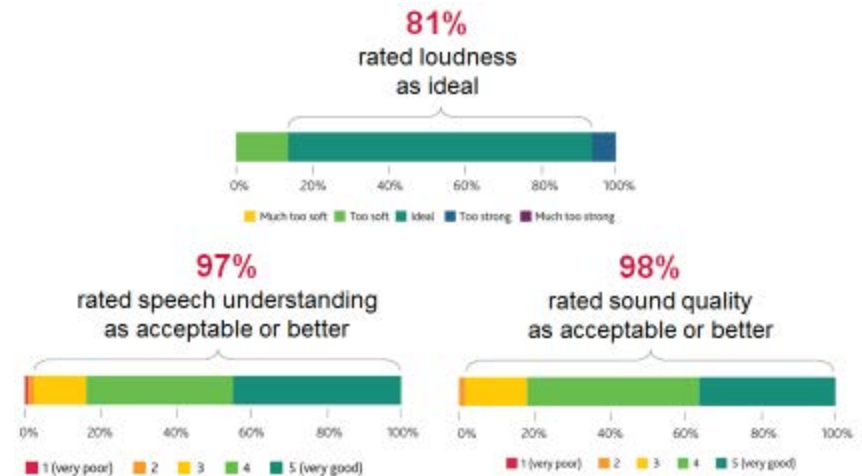
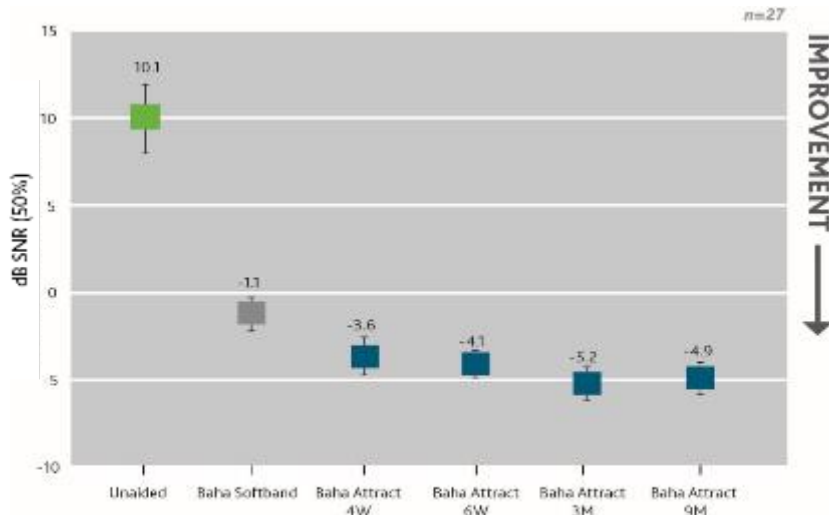
1. Fyrlund, H., Pressure with Baha Attract w/wo Baha SoftWear Pad relative Sophono, Cochlear Bone Anchored Solutions, Technical report no 633480, May 2015.

Clinically Proven Hearing Performance



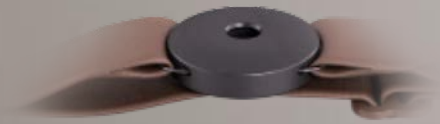
Significantly improved speech recognition in noise compared to the unaided situation and compared to the sound processor on a Baha® Softband.^{1,2}

In the post-market follow-up, patients (N=163) rated loudness, sound quality and speech understanding at fitting.¹

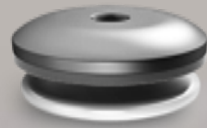


1. Briggs R, Van Hasselt A, Luntz M, Goycoolea M, Wigren S, Weber P, Smeds H, Flynn M, Cowan R. Clinical performance of a new magnetic bone conduction hearing implant system: results from a prospective, multicenter, clinical investigation. *Otol Neurotol*. 2015;36(5):834-41.
 2. Flynn M.C. Cochlear Baha Attract System - Summary of clinical results and benefits. Cochlear Bone Anchored Solutions AB. E83112, 2014.





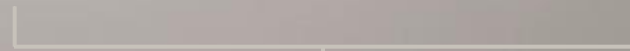
Baha Softband



SP & Implant Magnets



DermaLock™ Abutments



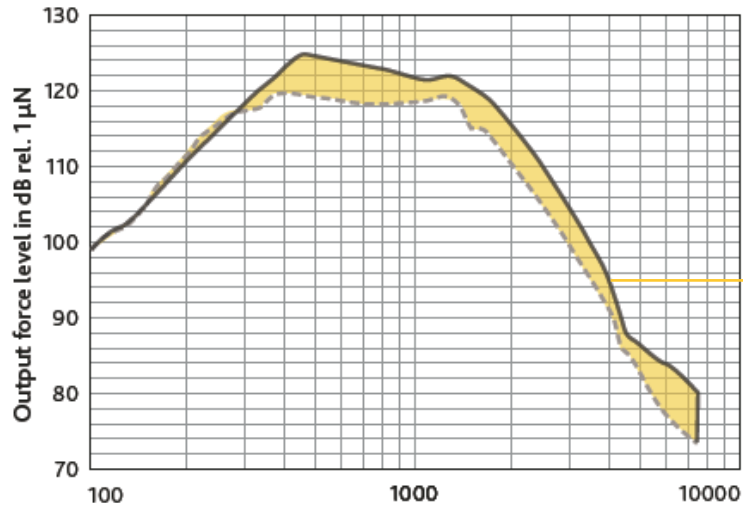
BI300 Implant

The Gentle First Step Kids Deserve

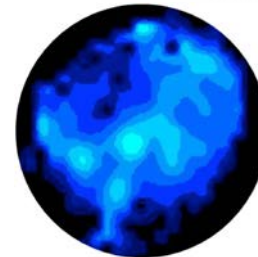


The Baha® Softband takes inspiration from the success of the Baha Attract System to provide children with a new level of comfort and performance.

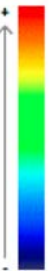
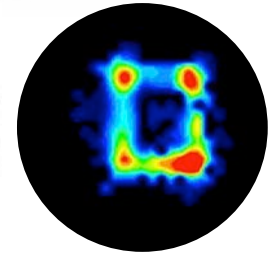
3.8 dB BETTER SOUND TRANSMISSION¹



Baha Softband with Baha SoftWear™ Pad



Other soft band



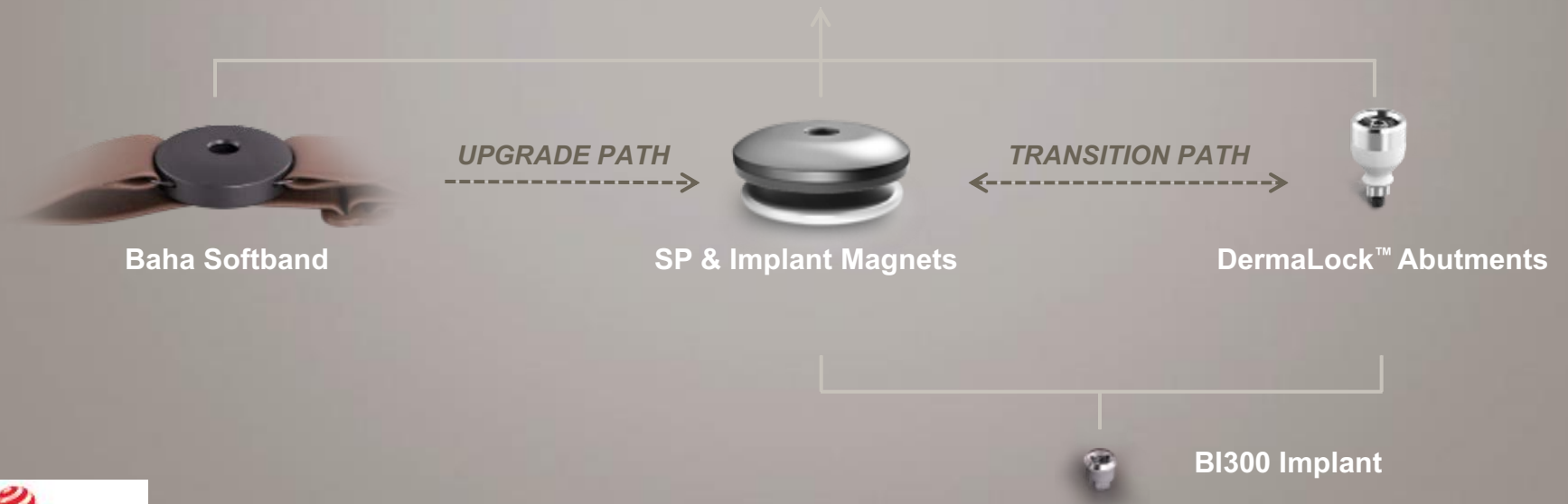
50% LESS

PRESSURE COMPARED TO OTHER SOFTBANDS¹

1. Flynn MC, Fyrlund H. Design concept and technological considerations for the new Baha Softband. Cochlear Bone Anchored Solutions AB, 631194, 2015.



Baha 5 Sound processors



Baha Softband

UPGRADE PATH

SP & Implant Magnets

TRANSITION PATH

DermaLock™ Abutments

BI300 Implant

Small. Smart. Powerful.



Baha® 5 Sound Processors share the same unique technology building blocks to deliver a smart and seamless hearing experience to all patients.

- The industry's smallest sound processor.¹
- The only smart processors with direct-to-device wireless streaming and control.
- Two power sound processors including the industry's most powerful solution.²



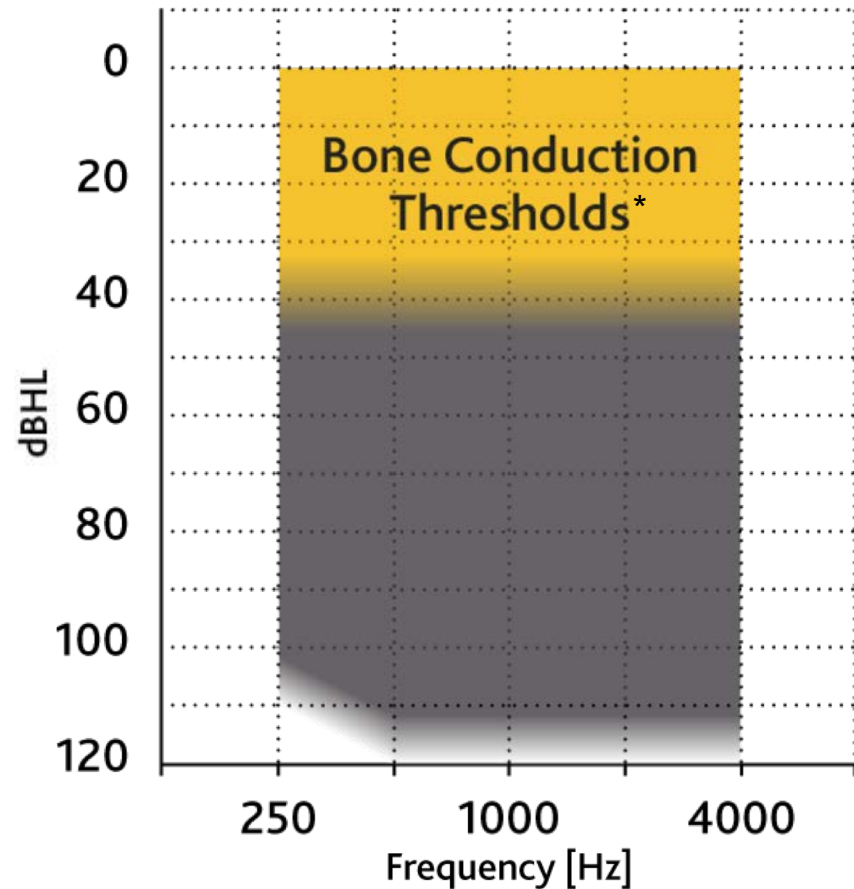
1. Flynn MC. Smart and Small – innovative technologies behind the Cochlear Baha 5 Sound Processor. Cochlear Bone Anchored Solutions AB, 629761, 2015.
2. Norman, J, Review of fitting ranges. Cochlear Bone Anchored Solutions AB, D773528, 2015.



The Widest and Most Powerful Portfolio¹



Up to **45 dB** SNHL



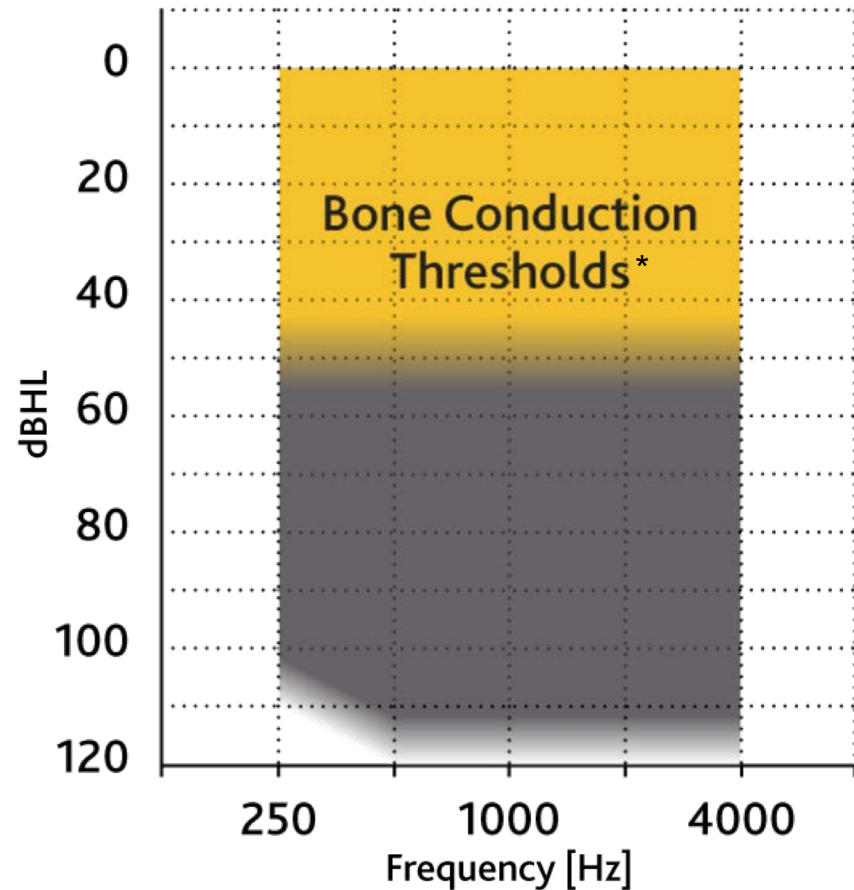
* Fitting ranges shown are for patients with Mixed/Conductive hearing loss

1. Normman, J, Review of fitting ranges. Cochlear Bone Anchored Solutions AB, D773528, 2015.

The Widest and Most Powerful Portfolio¹



Up to **55 dB** SNHL

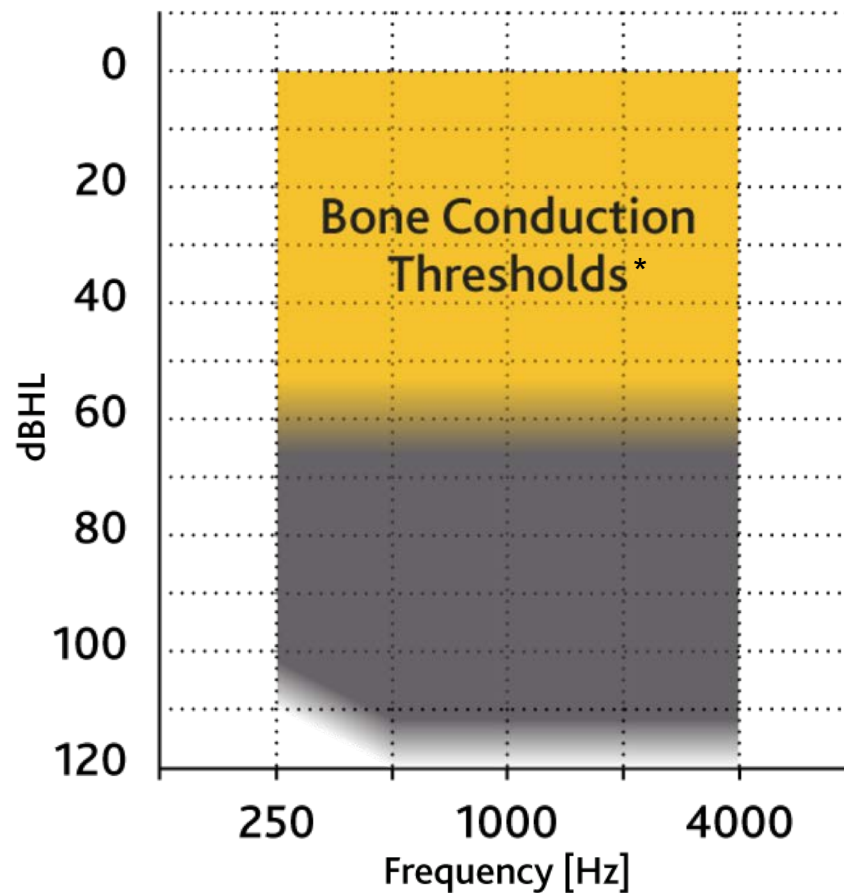


* Fitting ranges shown are for patients with Mixed/Conductive hearing loss

The Widest and Most Powerful Portfolio¹



Up to **65 dB** SNHL



* Fitting ranges shown are for patients with Mixed/Conductive hearing loss

1. Norman, J, Review of fitting ranges. Cochlear Bone Anchored Solutions AB, D773528, 2015.

SmartSound® iQ Signal Processing



The Scene Classifier II in SmartSound® iQ measures the input sound level and signal-to-noise ratio to define and categorize the patient's acoustic environment.

It selects the best signal processing strategy utilizing:



Active Gain



Active Balanced Directionality



Noise Manager II

Smart Connectivity for Direct-to-Device Communication



With new Bluetooth® technology designed by Apple, Baha 5 sound processors are the hearing implant industry's only Made for iPhone Hearing Devices.



Live Listen
and device control



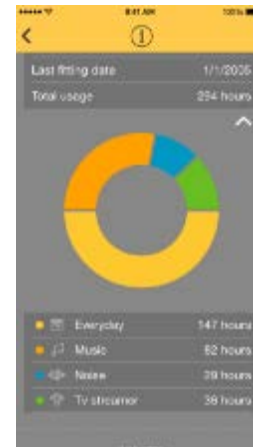
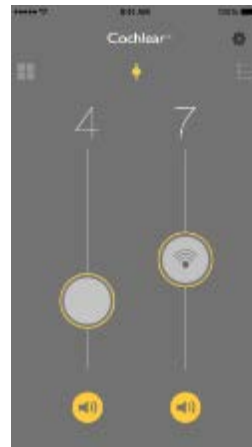
Streamed phone calls, music
and turn-by-turn navigation



The First Smart App for Bone Conduction



Advanced control of sound processor and wireless accessories, personalization and support – directly from iPhone®, iPad®, iPod touch® and **now also Android™ smartphones.**



True Wireless™ Accessories



●● NEW

**Cochlear™ Wireless
Mini Microphone 2+**

**Cochlear™ Wireless
Mini Microphone 2**



**Cochlear™ Wireless
TV Streamer**

**Cochlear™
Wireless
Phone Clip**



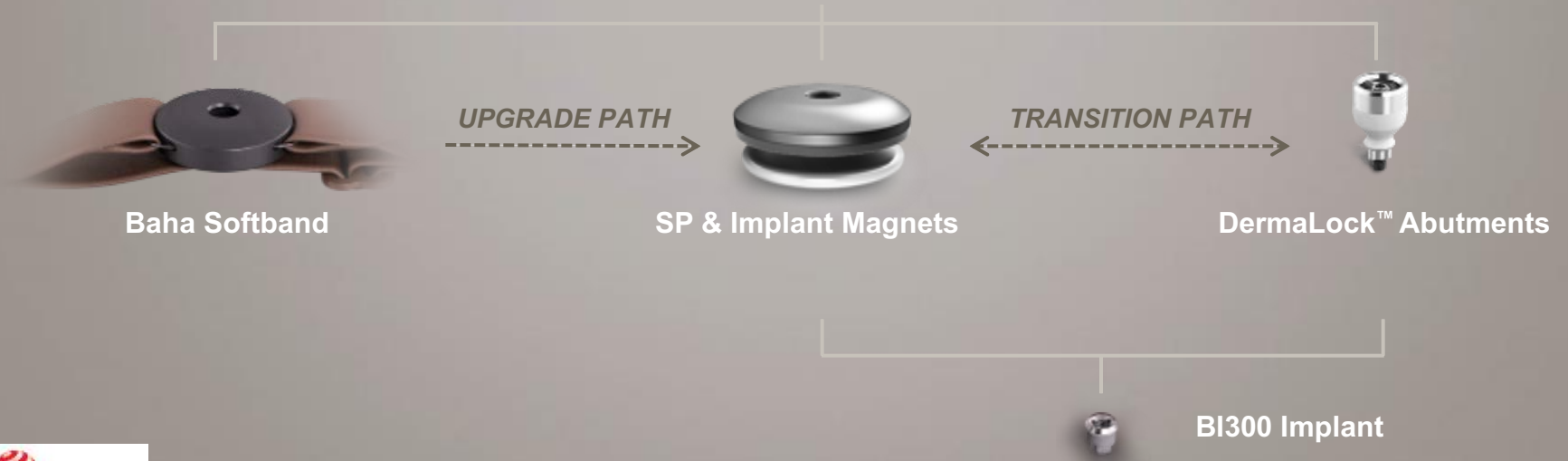
Wireless & Apps



Baha 5 Sound processors



Fitting Software



Baha Softband

UPGRADE PATH

SP & Implant Magnets

TRANSITION PATH

DermaLock™ Abutments

BI300 Implant



Baha Surgery, Aftercare, Fitting



Surgical Details



- Surgical procedure is straight-forward, usually lasting less than an hour
- Designed and FDA-cleared for preservation of soft tissue
- One or two stage surgery depending on age and bone integrity
- Outpatient procedure
- Adult surgeries can be done under local anesthesia
- Sound processor is fit after osseointegration

Cochlear™ Baha® Connect System

Straightforward surgical procedure



Mark site



Make the incision



Drill and place implant



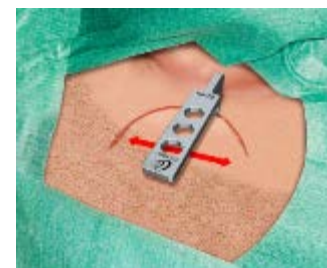
Cochlear™ Baha® Attract System Straightforward surgical procedure



Based on the same principles as Baha Connect System surgery.

Mean surgery time of 45 mins¹.

Fitting in four weeks¹.



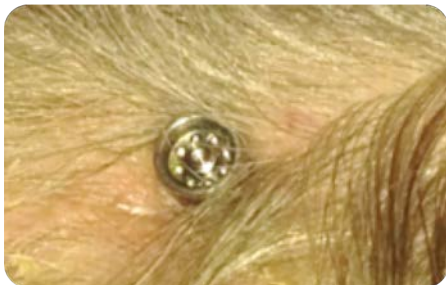
1. Briggs R, Van Hasselt A, Luntz M, Goycoolea M, Wigren S, Weber P, Smeds H, Flynn M, Cowan R. Clinical performance of a new magnetic bone conduction hearing implant system: Results from a prospective, multicenter, clinical investigation. Otol. Neurotol. 2015 Jan 28.

Aftercare Schedule



Baha Connect

- 10-14 days: Dressing and healing cap removed
- Patient is instructed to keep abutment site clean
- Processor Fitting:
 - Adults: processor fitting at 12 weeks
 - Children or individuals with compromised bone integrity: processor fitting at 6 mos



12 weeks post-op

Baha Attract

- 5-7 days: Dressing removed
- 10-14 days: Sutures removed
- Processor Fitting at 4-6 weeks



5 weeks post-op

Andria's Story



- <https://youtu.be/i8j85R0-ko0>

Summary

Hear now. And always



Take Aways



- > CI and Baha Systems are covered by Medicare[†], most insurance plans, and may be covered by Medicaid (for patients meeting payer-specific criteria)*
- > People in your practice could likely benefit
- > Satisfied patients are good ambassadors for your practice

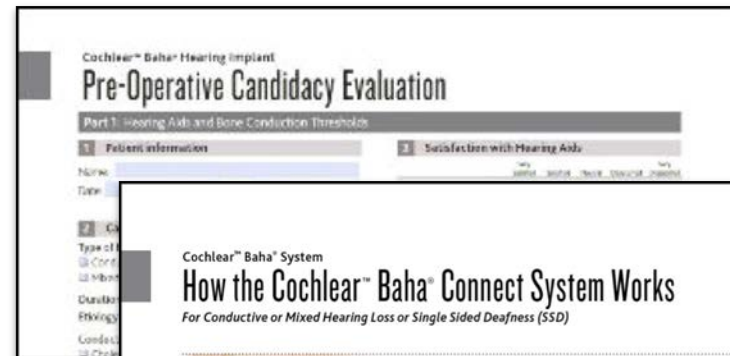
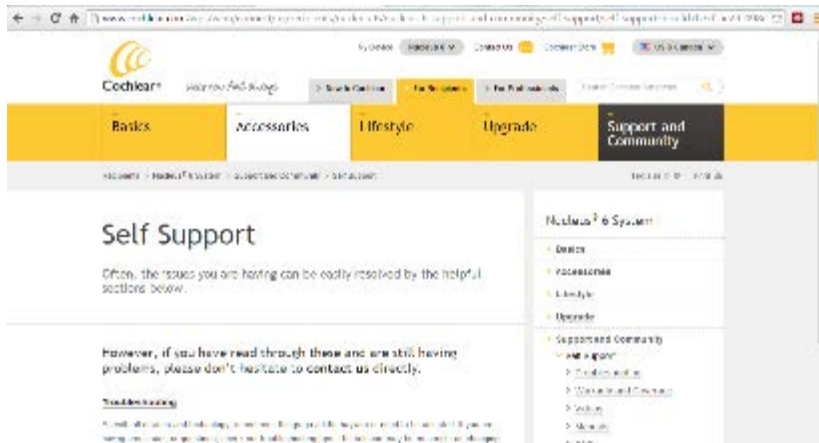
†May be covered for patients that meet Medicare's current coverage criteria

*Contact your insurance company or local Hearing Implant Specialist to determine your eligibility for coverage. Many insurance companies cover the Cochlear Nucleus Hybrid Implant. Coverage for adult Medicaid recipients varies according to state specific guidelines.

Online Clinical Resources



- Cochlear's website: www.cochlear.com/us
- myCochlear Clinic: www.mycochlear.com
- Sign up for Cochlear's professional newsletters and follow us on social media for the latest updates





Hear now. And always

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