*Clinical White Paper*

# Clinical Recommendations for Effective Electric-acoustic Stimulation Treatment for Patients with Severe High-frequency Hearing Loss

In collaboration with Bruce Gantz, MD; Camille Dunn, PhD; René Gifford, PhD; Thomas Roland, MD; Kristen Lewis, AuD; and participants of the Cochlear Sponsored EAS Thought Leader Workshop

## Introduction

While cochlear implants (CIs) were initially intended for the profoundly deaf, indications have expanded to incorporate a broader range of hearing losses (e.g., Buchman et al., 2020). In 1999 Cochlear launched the first clinical trial of the Hybrid S or "short-electrode" designed to preserve hearing and combine acoustic and electric inputs in the implanted ear (Gantz & Turner, 2004). Combined electric-acoustic stimulation (EAS) or "hybrid hearing" is viable when postoperative low-frequency thresholds through 500 Hz remain functionally aidable (<80 dB HL) Adunka et al., 2018. In 2013, the FDA approved the Nucleus Hybrid L24 CI system as the first commercially available EAS fitting solution for patients with normal to moderate low-frequency hearing loss and severe to profound mid- and high-frequency sensorineural hearing loss. Long-term clinical trial results with the Hybrid L24 indicated that 72% of recipients were still utilizing EAS up to 5 years post-implantation making EAS a long-term hearing solution (Roland et al., 2018). More recently, recipients with full-length perimodiolar and lateral wall electrodes have demonstrated preserved hearing and have been able to receive EAS (e.g., Kay-Rivest et al., 2022; Sharma et al., 2022).

The benefits of EAS are often underestimated because they are not fully revealed by common clinical assessments involving speech in quiet or speech with collocated noise (e.g., Gifford et al., 2014a). Low-frequency acoustic input to the implanted ear can provide acoustic access to valuable interaural time difference (ITD) cues that benefit a range of auditory percepts (e.g., Tejani & Brown, 2020). EAS users demonstrate improved sound localization—beyond that afforded by a bimodal hearing configuration— when acoustic input is provided from the implant ear(s) resulting in a combined electric and binaural acoustic hearing (Dunn et al., 2010; Gifford et al., 2014b; Plant & Babic, 2016). Indeed, electric and binaural acoustic stimulation yields significant benefit on tasks of horizontal-plane localization of approximately 20 degrees of error as compared to bimodal hearing with contralateral (i.e., monaural) acoustic hearing. In addition to localization benefits, EAS listeners also demonstrate more robust neural encoding of speech in noise (Shim et al., 2022) and improved speech perception in complex listening scenarios involving spatially separated speech and noise and/or semi-diffuse noise translating to a 10 to 20 percentage point improvement (Gifford et al., 2013, 2017, 2022; Plant & Babic, 2016; Gifford & Stecker, 2020) or 2- to 5-dB improvement in the signal-to-noise ratio (SNR; Dunn et al., 2010, Gifford et al., 2010, 2013, 2017, 2022).

In addition to the significant improvements in localization and speech perception, EAS listeners with binaural acoustic hearing also report reduced listening effort as compared to the bimodal hearing condition (Gifford et al., 2017, 2022). These benefits

are often present immediately or acutely following fitting of the acoustic component in the implant ear(s) with the potential for additional benefits over time as the brain adapts (Gifford et al., 2017, 2022). The magnitude of EAS benefit has been shown to be significantly correlated with underlying ITD sensitivity (Gifford et al., 2013, 2014b, 2017; Gifford & Stecker, 2020) and is not significantly correlated with the unaided audiogram (e.g., Gifford et al., 2013; Gifford & Stecker, 2020). Therefore, EAS should be a consideration for any patient with sufficient functionally aidable postoperative hearing, further defined in this guidance document.

Acoustic input to the implant ear(s) additionally provides acoustic access to low-frequency temporal fine structure cues that support more naturalistic hearing than electric input alone. This leads to significantly higher ratings of communication, sound quality, and spatial hearing (Plant & Babic, 2016), as well as enhanced music perception and recognition with EAS (Gfeller et al., 2006, 2007; Parkinson et al., 2019; Plant & Babic, 2016). The benefits of EAS for music perception have been observed between groups of CI + bilateral acoustic users and bimodal users (Gfeller et al., 2006, 2007; Parkinson et al., 2019), as well as intraindividually when implanted recipients are programmed both with and without acoustic stimulation to the implant ear (Plant & Babic, 2016). Given the opportunity to try bimodal and CI + bilateral acoustic configurations, most patients with sufficient low-frequency hearing prefer EAS in the implant ear (Jang et al., 2022; Plant & Babic, 2016).

With continuing advances in electrode design, minimally traumatic surgical techniques, and expansion of audiometric indications, EAS candidacy is an increasingly growing patient population with opportunity for incorporation into routine clinical practice.

Clinical care for EAS patients however differs from that of traditional CI recipients due to the additional considerations regarding postoperative audiometric thresholds and EAS programming. In recognition of this growing patient population and current gaps in clinical practices, Cochlear hosted an EAS Thought Leader Workshop on October 22, 2022. This event brought together 27 expert EAS CI professionals (including 14 surgeons and 13 audiologists [**Table 1**]) to define EAS terminology and develop guidance on incorporating EAS into routine clinical care, including recommendations for candidacy, surgical technique, device programming, and clinical management for EAS patients.

**Table 1: EAS Thought Leader Workshop Participants. *Moderator**

| Surgeons | Affiliation | Audiologists | Affiliation |
|---|---|---|---|
| **Bruce Gantz, MD*** | University of Iowa<br>Iowa City, IA | **Camille Dunn, PhD*** | University of Iowa<br>Iowa City, IA |
| **Oliver Adunka, MD** | Ohio State University<br>Columbus, OH | **René Gifford, PhD*** | Vanderbilt University<br>Nashville, TN |
| **Maura Cosetti, MD** | Mount Sinai<br>New York, NY | **Allison Biever, AuD** | Rocky Mountain Ear Center<br>Denver, CO |
| **Robert Cullen, MD** | Midwest Ear Institute<br>Kansas City, MO | **Lisa Goldin, PhD** | Mount Sinai<br>New York, NY |
| **David Friedmann, MD** | New York University<br>New York, NY | **Meredith Holcomb, AuD** | University of Miami Health System<br>Miami, FL |
| **Jacques Herzog, MD** | Washington University<br>Saint Louis, MO | **Kristen Lewis, AuD** | Midwest Ear Institute<br>Kansas City, MO |
| **Michael Hoa, MD** | Georgetown University<br>Washington, DC | **Susan Rathgeb, MS** | Washington University<br>Saint Louis, MO |
| **David Kelsall, MD** | Rocky Mountain Ear Center<br>Denver, CO | **Aniket Saoji, PhD** | Mayo Clinic<br>Rochester, MN |
| **Thomas Lenarz, MD, PhD** | Hannover University<br>Hanover, Germany | **William Shapiro, AuD** | New York University<br>New York, NY |
| **Eric Lupo, MD** | Washington University<br>Saint Louis, MO | **Emily Spitzer, AuD** | New York University<br>New York, NY |
| **Aaron Remenschneider, MD, MPH** | UMass Memorial Health<br>Worcester, MA | **Sarah Sydlowski, AuD, PhD, MBA** | Cleveland Clinic<br>Cleveland, OH |
| **Thomas Roland, MD** | New York University<br>New York, NY | **Viral Tejani, AuD, PhD** | University Hospitals<br>Cleveland, OH |
| **Amit Walia, MD** | Washington University<br>Saint Louis, MO | **Jace Wolfe, PhD** | Hearts for Hearing<br>Oklahoma City, OK |
| **Erika Woodson, MD** | Kaiser Permanente<br>San Diego, CA | | |

# Terminology and Definitions

## Device configurations:

Unilateral: These configurations may refer to single-ear testing, such as in a research or clinical testing protocol.

- **Cochlear implant (CI):** electric hearing ipsilaterally.

- **Electric-acoustic stimulation (EAS):** combined electric and acoustic hearing ipsilaterally. It is rare that EAS would be a patient's "everyday listening condition", as most patients able to utilize acoustic input in an implanted ear would likely have some hearing available in the contralateral ear.

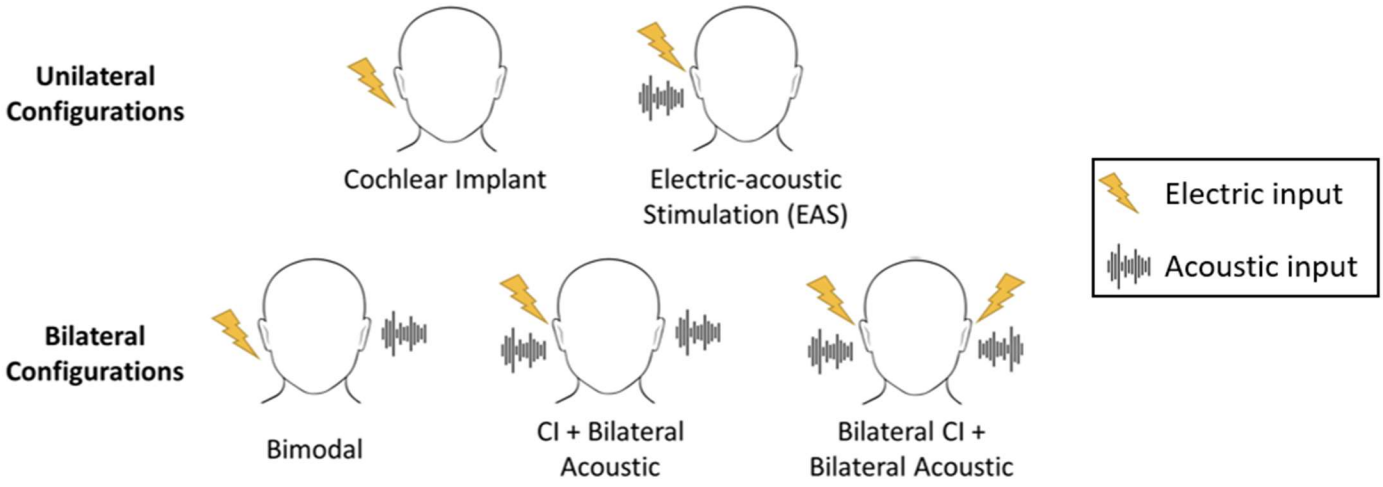
Bilateral: These configurations may refer to testing, such as in a research or clinical testing protocol, or when describing an individual's "everyday listening condition."

- **Bimodal:** electric hearing via a cochlear implant ipsilaterally and acoustic hearing via amplification contralaterally. Contralateral acoustic input may be provided via amplification or through natural, unaided hearing, such as in the case of single-sided deafness.

- **CI + bilateral acoustic:** combined electric and acoustic hearing ipsilaterally and acoustic hearing via amplification contralaterally.

- **Bilateral CI + bilateral acoustic:** combined electric and acoustic hearing bilaterally via cochlear implants each with an acoustic component.

**Figure 1: Schematic of various unilateral and bilateral configurations of electric and/or acoustic hearing and their recommended terminology.**



### Hearing levels:

- **Functionally aidable hearing:** postoperative low-frequency pure-tone average (LFPTA) from 125 to 500 Hz that is <80 dB HL. This criterion represents the upper limit at which amplification will reliably meet targets for prescriptive fitting formulae (e.g., NAL-R, DSL v5.0, etc.), as well as the ability of the underlying auditory system to benefit from acoustic amplification. (Adunka et al., 2018).

- **Measurable hearing:** measured audiometric thresholds ≥80 dB HL, that are not beyond audiometric limits or vibrotactile only. CI recipients with measurable hearing may obtain some acoustic audibility in the implanted ear(s) but are less likely to be able to be utilized as acoustic amplification for the conveyance of more meaningful information beyond sound awareness (e.g., cues to facilitate speech understanding, localization, and music perception).

## EAS Clinical Care Recommendations

This section provides the professional with a suggested protocol for the pre/postoperative identification, surgical technique, fitting, and follow-up of EAS patients, based on guidance from the Thought Leaders Workshop participants.

### Preoperative EAS Candidacy

On average, cochlear implant surgery causes an approximately 20-25 dB shift in low-frequency thresholds within the first year post implant (e.g., Bourn et al., 2020; Hey et al., 2020; Nassiri et al., 2020; Sharma et al., 2022; Skarzynski et al., 2012); however, individuals vary widely and can experience anything from no post implantation audiometric change to total loss. An ideal EAS candidate is one with the maximum likelihood of maintaining functionally aidable hearing postoperatively. Factors that may influence this likelihood are:

- **Preoperative Hearing:** ideal preoperative EAS candidates are considered those that have preoperative low-frequency thresholds through 500 Hz and/or a LFPTA (125-500 Hz or 250 and 500 Hz) ≤60 dB HL. This 60 dB HL criterion accounts for any immediate postoperative loss along with the likelihood of some continued postoperative shift over time, while remaining functionally aidable. It is recommended that 125 Hz be measured preoperatively to provide a more holistic depiction of low-frequency hearing ability that can be factored into the EAS candidacy consideration.

- **Age:** younger individuals (<70 years) are likely to have less postoperative audiometric change and better speech recognition outcomes compared to older individuals.

- **Etiology:** certain hearing loss etiologies, such as Ménière's disease and noise-induced hearing loss, have greater threshold shift post cochlear implantation; therefore, patients with these etiologies may be less ideal than those with other etiologies, such as congenital or genetic hearing loss.

- **Duration of High Frequency Hearing Loss:** profound hearing loss in the high frequency region of the cochlea that has not been aidable for >20 years might not be ideal for EAS stimulation.

- **Comorbidities:** perioperative steroid use may reduce cochlear inflammation and improve hearing outcomes. Some comorbidities, such as diabetes, may be a contraindication for the use of steroids; therefore, an ideal EAS candidate is one without comorbidities precluding a steroid regimen.

Patients should be counselled with realistic expectations regarding their potential postoperative hearing with messaging tailored

based on the relevant patient factors above. Not all patients who meet the above preoperative criteria for potential EAS candidacy will maintain functionally aidable hearing postoperatively. Therefore, counselling should be balanced so that patients do not defer or delay cochlear implantation due to the possibility of not maintaining functionally aidable levels. Regardless of whether functionally aidable acoustic hearing is maintained, recipients are likely to perform significantly better with a cochlear implant in the bimodal or CI + bilateral acoustic hearing configurations than they were with bilateral hearing aids (Buchman et al., 2020).

## Surgical Recommendations

Minimally invasive surgical techniques have evolved over the years, decreasing possible trauma within the cochlea, and increasing the opportunity to preserve functionally aidable hearing. The surgical approach to access the cochlea, whether round window, extended round window, or cochleostomy, should align to an atraumatic insertion into the scala tympani with a slow and steady advancement of the array to minimize disruption of the cochlea environment and excessive force to the basilar membrane. Despite utilizing minimally traumatic surgical techniques, the cochlea will react to the array with some type of foreign body response. It is recommended to conduct a regimen of perioperative steroids to minimize this natural reaction and inflammation. (Causon et al.; 2015). Example regimens include intravenous dexamethasone or topical application to coat the electrode array and/or at the facial recess.

## Fitting of EAS

All patients who present preoperatively as an EAS candidate (thresholds through 500 Hz and/or LFPTA ≤60 dB HL) should receive a postoperative audiogram—including air and bone condition testing—at initial activation prior to programming of the cochlear implant. Air-bone gaps are common post-surgery; therefore, the initial activation and postoperative audiometric assessment should be scheduled 3 to 4 weeks post-surgery to allow time for any conductive component to stabilize. While not all patients who previously met the preoperative EAS criterion will maintain functionally aidable hearing, the inverse is also true. Some patients with thresholds exceeding the preoperative recommendation may postoperatively present with functionally aidable hearing postoperatively due to experiencing little to no audiometric change. Therefore, an audiogram should still be considered for these patients prior to activation to check their postoperative status.

Ideal postoperative EAS candidates are those with postoperative low-frequency thresholds through 500 Hz and/or a LFPTA ≤ 70 dB HL; any patient meeting this criterion should be fit with EAS via an acoustic component. It is our stance that even patients with functionally aidable hearing only at 250 Hz should be considered for fitting with EAS in their daily listening environments to determine levels of benefit, as studies have shown that even EAS users with functionally aidable hearing only at 250 Hz derive significant benefit in complex listening scenarios (e.g., Gifford et al., 2013, 2017, 2022). Table 2 summarizes these preoperative and postoperative EAS candidacy recommendations.

**Table 2: Summary of EAS fitting and candidacy recommendations based on preoperative and postoperative audiometric profiles.**

| Audiometric Profile | EAS Recommendation |
|---|---|
| Preoperative low-frequency thresholds through 500 Hz and/or a LFPTA (125-500 Hz or 250 and 500 Hz) ≤60 dB HL | This is an ideal preoperative EAS candidate and should receive a postoperative audiogram at initial activation to confirm hearing thresholds |
| Postoperative low-frequency thresholds through 500 Hz and/or a LFPTA (125-500 Hz or 250 and 500 Hz) ≤70 dB HL | This is an ideal postoperative EAS candidate and should be fit with EAS at initial activation |
| Postoperative LFPTA (125-500 Hz or 250 and 500 Hz) and/or any low-frequency thresholds through 500 Hz <80 dB HL | This patient may benefit from EAS due to having one or more functionally aidable low-frequency thresholds |

## Programming Recommendations

EAS should be fit at initial activation following confirmation of aidable unaided audiometric thresholds. A 100-dB-gain receiver is recommended for all EAS patients. An 85-dB-gain receiver can be used for patients with smaller ear canals that cannot accommodate the larger receiver size of the 100-dB receiver as compared to the 85-dB receiver. Custom earmolds are strongly recommended for all EAS patients to ensure appropriate amplification of the low frequencies. To avoid purchasing an earmold for patients who do not end up being eligible for EAS postoperatively, earmold impressions can be taken at initial activation, or even preoperatively, and earmolds ordered only after the postoperative audiogram confirms aidable thresholds at initial activation. To still provide EAS at initial activation, patients can be fit with a non-custom, occluding dome as a temporary solution until an earmold can be fit at the earliest opportunity—typically at 1-month postactivation. If a patient is unwilling or unable to use an earmold this should not preclude them from EAS. While it may not be possible to completely meet low-frequency targets with a dome, patients may still achieve partial audibility that could provide additional benefit over electric stimulation alone. Simulation frequencies should be adjusted accordingly.

When first fitting an EAS patient, it is recommended to provide two programs at initial activation to take home:

1. **EAS MAP**: It is suggested the EAS MAP have a low-frequency electric cutoff ≤438 Hz to provide robust electrical encoding of the first speech formant. Furthermore, research has shown that a 438-Hz cutoff yielded significant benefit and was typically the electric cutoff affording the best speech recognition performance and perceived reduced listening difficulty (Gifford et al., 2017, 2022). However, an even lower or higher electric cutoff may be appropriate depending on the 500 Hz pure-tone threshold. For the acoustic programming, it is recommended to never exceed a high-frequency electrical cutoff of 1000 Hz as that is close to the upper limit at which ITD cues are conveyed (e.g., Hartmann & Macauley, 2014). An appropriate fitting formula (e.g., NAL-R, DSL v5.0, etc.) should be used so that appropriate amplification can be verified via real-ear measures, consistent with audiological best practices.

2. **Electric-only MAP**: Due to the possibility of delayed hearing loss and continued audiometric changes, a fully electric program acts as back-up in the event the patient loses acoustic hearing or if the acoustic component malfunctions between clinic visits.

Patients should be counselled on the use of the different programs and encouraged to explore preference and self-perceived benefit in their daily listening environments.

## Evaluation Protocol

The postoperative follow-up schedule for EAS patients differs from that of traditional CI patients due to the possibility of delayed audiometric changes. However, the suggested evaluation protocol adheres to the same framework of Activate, Optimize, and Maintain. Patients should be counseled to do weekly listening checks of the acoustic component by leaving the receiver in the ear and disconnecting the magnet to check if they can perceive any acoustic output. If they cannot, the patient should switch to the Electric-only MAP and return to their clinic for device malfunction inspection and examination of changes in acoustic thresholds or other ontological issues.

- **Activate:** Initial activation is the first opportunity for the patient to experience EAS and should be programmed as described above. During this phase, the upper limits of electric and acoustic stimulation should be set to maximize the available dynamic range while avoiding loudness discomfort that might deter full time device usage (i.e., 10+ hours per day).

Table 3 summarizes a minimum clinical, non-research evaluation protocol to provide EAS clinical care and maximize clinic efficiency. Research protocols should involve additional speech testing, including bimodal, CI + bilateral acoustic, and EAS configurations, to better capture the separate benefits of providing acoustic input to the implant ear(s) and contralateral ear.

**Table 3: Minimum evaluation protocol for EAS patient care. *The audibility assessment as initial activation may be formal (e.g., soundfield audiogram) or informal (e.g., patient report). **Device reprogramming with real-ear measure (REM) verification should be completed as needed postoperatively based on audiometric changes. AC: air conduction; BC: bone conduction; CI: cochlear implant; CNC: Consonant-Nucleus-Consonant; HAs: hearing aids; SSQ: Speech, Spatial and Qualities of Hearing Scale; SNR: signal-to-noise ratio.**

| | | Activate | Optimize | | Maintain |
|---|---|---|---|---|---|
| | **Candidacy** | **Initial Activation** | **1 month** | **3 month** | **12 month and as needed** |
| **Audiometric Evaluations** | Unaided AC/BC both ears<br><br>Tympanometry | Unaided AC/BC CI ear<br><br>Audibility assessment* | Unaided AC/BC CI ear<br><br>Soundfield audiogram CI ear | Unaided AC/BC CI ear<br><br>Soundfield audiogram CI ear | Unaided AC/BC both ears<br><br>Soundfield audiogram CI ear |
| **Outcome Measures** | Aided CNC @ 60 dBA implant ear and contralateral ear<br><br>Aided AzBio 65 dBA @+5 dB SNR implant ear and bilateral HAs<br><br>SSQ-12 and/or CIQOL-10 | | | Aided CNC @ 60 dBA CI ear<br><br>Aided AzBio 65 dBA @+5 dB SNR CI + bilateral acoustic | Aided CNC @ 60 dBA CI ear<br><br>Aided AzBio 65 dBA @+5 dB SNR CI + bilateral acoustic<br><br>SSQ-12 and/or CIQOL-10 |
| **Other Procedures** | Case History<br><br>Hearing aid check w/REM | Datalogging<br><br>Programming w/REM<br><br>Earmold impression | Datalogging<br><br>Reprogramming w/earmold and REM | Datalogging<br><br>Reprogramming w/REM** | Datalogging<br><br>Reprogramming w/REM** |

- **Optimize:** After activation, EAS programming is optimized over the 1- and 3-month visits by fitting the acoustic component with the earmold and reprogramming in response to audiometric changes, as needed. During this period, datalogging should be monitored to ensure patients are using their devices for at least 10 hours a day and reprogramming performed to ensure this wear time target is met.
- **Maintain:** At the 12-month visit, acoustic and electric devices are reprogrammed as needed to maintain hearing performance. By this point audiometric thresholds in the implant ear should be stable and where changes occur, progress at a similar rate as the contralateral ear (Roland et al., 2018). From this point forward, patients need only return as required to address patient concerns.

### Results Reporting

Consistent reporting of EAS results is important both for scientific publication and for consistency in clinic reports and notes. For research reporting specific to EAS the following guidelines are provided:

- **Reporting group**: Postoperative outcomes should always be reported as a minimum on patients who met the preoperative EAS candidate criterion (preoperative low-frequency thresholds through 500 Hz and/or a low-frequency pure-tone average LFPTA (125-500 Hz or 250 and 500 Hz) that is ≤60 dB HL). Patients who lose hearing should not be excluded from analyses but may be grouped separately.
  - **Timeline**: Due to the potential for delayed hearing loss, long-term audiometric outcomes should be reported preferably at 1-year post-surgery to determine preserved functionally aidable hearing.

  - **Outcomes**: Results should be reported using a variety of measures that reflect both group-level and individual outcomes:

    - The proportion of patients who maintained functionally aidable hearing (<80 dB HL) both at individual frequencies and LFPTA, in accordance with American Academy of Otolaryngology reporting standards (Adunka et al., 2018).

    - The proportion of recipients who are utilizing EAS.

    - A pre- to postoperative change in hearing thresholds (i.e., delta score) expressed as a LFPTA and for individual frequencies with individual results categorized as 0-15 dB, 15-30 dB, >30 dB, or No Measurable Hearing (total loss).

    - Audiometric results should always be accompanied by hearing performance measures (i.e., speech perception and/or patient-reported outcomes) in their daily listening configurations to provide a holistic view of patient outcomes.

## Conclusion

Patients presenting preoperatively with low-frequency thresholds through 500 Hz and/or a LFPTA (125-500 Hz or 250 and 500 Hz) that is ≤60 dB HL should be considered potential EAS candidates and receive an unaided audiogram at activation to confirm postoperative thresholds. Patients with postoperative thresholds through 500 Hz and/or a LFPTA (125-500 Hz or 250 and 500 Hz) that is ≤70 dB HL should be fit with EAS at activation. They can subsequently expect to receive a range of benefits from combined stimulation over electric-only hearing, including improved sound localization, better speech understanding in noise, and reduced listening effort. Additional recommendations for minimally traumatic surgical techniques, device programming, and follow-up care for EAS patients are given to provide surgeons and audiologists with the resources to integrate and optimize EAS clinical care in routine practice. The EAS patient population is growing with exciting opportunities for ongoing real-world evidence research and clinical growth.

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This material is intended for health professionals. If you are a consumer, please seek advice from your health professional about treatments for hearing loss. Outcomes may vary, and your health professional will advise you about the factors which could affect your outcome. Always read the instructions for use. Not all products are available in all countries. Please contact your local Cochlear representative for product information.

The results from the field evaluation reported here are influenced by the survey design, clinics, clinicians', and recipients involved. Application and suitability of the Nucleus 8 Sound Processor with ForwardFocus in the broader cochlear implant population may vary according to local clinical protocols and individual recipient characteristics.




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