# SSQ3.1.2

**S**[peech] **S**[patial] **Q**[ualities]

**I. Speech hearing rating scale**

**INTERVAL:** **Baseline** ❍ **6 Month** ❍ **12 Month** ❍

**PATIENT ID:** [redacted]_ **BEST LISTENING CONDITION:** _____ **EVALUATION DATE:** _____

| | | | |
|---|---|---|---|
| 1. You are talking with one other person and there is a TV on in the same room. Without turning the TV down, can you follow what the person you're talking to says? | Not at all — Perfectly<br>0 (Min) 1 2 3 4 5 6 7 8 9 10 (Max) | Check if not applicable or wouldn't hear ☐ | Aid not used ☐ |
| 2. You are talking with one other person in a quiet, carpeted lounge-room. Can you follow what the other person says? | Not at all — Perfectly<br>0 (Min) 1 2 3 4 5 6 7 8 9 10 (Max) | Check if not applicable or wouldn't hear ☐ | Aid not used ☐ |
| 3. You are in a group of about five people, sitting round a table. It is an otherwise quiet place. You can see everyone else in the group. Can you follow the conversation? | Not at all — Perfectly<br>0 (Min) 1 2 3 4 5 6 7 8 9 10 (Max) | Check if not applicable or wouldn't hear ☐ | Aid not used ☐ |
| 4. You are in a group of about five people in a busy restaurant. You can see everyone else in the group. Can you follow the conversation? | Not at all — Perfectly<br>0 (Min) 1 2 3 4 5 6 7 8 9 10 (Max) | Check if not applicable or wouldn't hear ☐ | Aid not used ☐ |
| 5. You are talking with one other person. There is continuous background noise, such as a fan or running water. Can you follow what the person says? | Not at all — Perfectly<br>0 (Min) 1 2 3 4 5 6 7 8 9 10 (Max) | Check if not applicable or wouldn't hear ☐ | Aid not used ☐ |
| 6. You are in a group of about five people in a busy restaurant. You cannot see everyone else in the group. Can you follow the conversation? | Not at all — Perfectly<br>0 (Min) 1 2 3 4 5 6 7 8 9 10 (Max) | Check if not applicable or wouldn't hear ☐ | Aid not used ☐ |

# SSQ3.1.2

**S**[peech] **S**[patial] **Q**[ualities]

**I. Speech hearing rating scale**

**INTERVAL:** **Baseline** ❍ **6 Month** ❍ **12 Month** ❍

**PATIENT ID:** _[redacted]

| | | | |
|---|---|---|---|
| 7. You are talking to someone in a place where there are a lot of echoes, such as a church or railway terminus building. Can you follow what the other person says? | Not at all — Perfectly<br>0 (Min) 1 2 3 4 5 6 7 8 9 10 (Max) | Check if not applicable or wouldn't hear ☐ | Aid not used ☐ |
| 8. Can you have a conversation with someone when another person is speaking whose voice is the same pitch as the person you're talking to? | Not at all — Perfectly<br>0 (Min) 1 2 3 4 5 6 7 8 9 10 (Max) | Check if not applicable or wouldn't hear ☐ | Aid not used ☐ |
| 9. Can you have a conversation with someone when another person is speaking whose voice is different in pitch from the person you're talking to? | Not at all — Perfectly<br>0 (Min) 1 2 3 4 5 6 7 8 9 10 (Max) | Check if not applicable or wouldn't hear ☐ | Aid not used ☐ |
| 10. You are listening to someone talking to you, while at the same time trying to follow the news on TV. Can you follow what both people are saying? | Not at all — Perfectly<br>0 (Min) 1 2 3 4 5 6 7 8 9 10 (Max) | Check if not applicable or wouldn't hear ☐ | Aid not used ☐ |
| 11. You are in conversation with one person in a room where there are many other people talking. Can you follow what the person you are talking to is saying? | Not at all — Perfectly<br>0 (Min) 1 2 3 4 5 6 7 8 9 10 (Max) | Check if not applicable or wouldn't hear ☐ | Aid not used ☐ |
| 12. You are with a group and the conversation switches from one person to another. Can you easily follow the conversation without missing the start of what each new speaker is saying? | Not at all — Perfectly<br>0 (Min) 1 2 3 4 5 6 7 8 9 10 (Max) | Check if not applicable or wouldn't hear ☐ | Aid not used ☐ |

# SSQ3.1.2

**S**[peech] **S**[patial] **Q**[ualities]

**I. Speech hearing rating scale**

INTERVAL: **Baseline** ❍
**6 Month** ❍
**12 Month** ❍

**PATIENT ID:** [redacted]

| | | | |
|---|---|---|---|
| 13. Can you easily have a conversation on the telephone? | Not at all — Perfectly<br>0 1 2 3 4 5 6 7 8 9 10<br>Min — Max | Check if not applicable or wouldn't hear ☐ | Aid not used ☐ |
| 14. You are listening to someone on the telephone and someone next to you starts talking. Can you follow what's being said by both speakers? | Not at all — Perfectly<br>0 1 2 3 4 5 6 7 8 9 10<br>Min — Max | Check if not applicable or wouldn't hear ☐ | Aid not used ☐ |

# SSQ3.1.2

## S[peech] S[patial] Q[ualities]

### II. Spatial Rating Scale

**INTERVAL:** **Baseline** ❍ **6 Month** ❍ **12 Month** ❍

**PATIENT ID:** [redacted]

| | | | |
|---|---|---|---|
| 1. You are outdoors in an unfamiliar place. You hear someone using a lawnmower. You can't see where they are. Can you tell right away where the sound is coming from? | Not at all — Perfectly<br>0 (Min) 1 2 3 4 5 6 7 8 9 10 (Max) | Check if not applicable or wouldn't hear ☐ | Aid not used ☐ |
| 2. You are sitting around a table or at a meeting with several people. You can't see everyone. Can you tell where any person is as soon as they start speaking? | Not at all — Perfectly<br>0 (Min) 1 2 3 4 5 6 7 8 9 10 (Max) | Check if not applicable or wouldn't hear ☐ | Aid not used ☐ |
| 3. You are sitting in between two people. One of them starts to speak. Can you tell right away whether it is the person on your left or your right, without having to look? | Not at all — Perfectly<br>0 (Min) 1 2 3 4 5 6 7 8 9 10 (Max) | Check if not applicable or wouldn't hear ☐ | Aid not used ☐ |
| 4. You are in an unfamiliar house. It is quiet. You hear a door slam. Can you tell right away where that sound came from? | Not at all — Perfectly<br>0 (Min) 1 2 3 4 5 6 7 8 9 10 (Max) | Check if not applicable or wouldn't hear ☐ | Aid not used ☐ |
| 5. You are in the stairwell of a building with floors above and below you. You can hear sounds from another floor. Can you readily tell where the sound is coming from? | Not at all — Perfectly<br>0 (Min) 1 2 3 4 5 6 7 8 9 10 (Max) | Check if not applicable or wouldn't hear ☐ | Aid not used ☐ |
| 6. You are outside. A dog barks loudly. Can you tell immediately where it is, without having to look? | Not at all — Perfectly<br>0 (Min) 1 2 3 4 5 6 7 8 9 10 (Max) | Check if not applicable or wouldn't hear ☐ | Aid not used ☐ |

# SSQ3.1.2

## S[peech] S[patial] Q[ualities]

### II. Spatial Rating Scale

**INTERVAL:** **Baseline** ❍ **6 Month** ❍ **12 Month** ❍

**PATIENT ID:** [redacted]

| | | | |
|---|---|---|---|
| 7. You are standing on the footpath of a busy street. Can you hear right away which direction a bus or truck is coming from before you see it? | Not at all — Perfectly<br>0 1 2 3 4 5 6 7 8 9 10<br>Min — Max | Check if not applicable or wouldn't hear ☐ | Aid not used ☐ |
| 8. In the street, can you tell how far away someone is, from the sound of their voice or footsteps? | Not at all — Perfectly<br>0 1 2 3 4 5 6 7 8 9 10<br>Min — Max | Check if not applicable or wouldn't hear ☐ | Aid not used ☐ |
| 9. Can you tell from the sound how far away a bus or a truck is? | Not at all — Perfectly<br>0 1 2 3 4 5 6 7 8 9 10<br>Min — Max | Check if not applicable or wouldn't hear ☐ | Aid not used ☐ |
| 10. Can you tell from the sound which direction a bus or truck is moving, for example, from your left to your right or right to left? | Not at all — Perfectly<br>0 1 2 3 4 5 6 7 8 9 10<br>Min — Max | Check if not applicable or wouldn't hear ☐ | Aid not used ☐ |
| 11. Can you tell from the sound of their voice or footsteps which direction a person is moving, for example, from your left to your right or right to left? | Not at all — Perfectly<br>0 1 2 3 4 5 6 7 8 9 10<br>Min — Max | Check if not applicable or wouldn't hear ☐ | Aid not used ☐ |
| 12. Can you tell from their voice or footsteps whether the person is coming towards you or going away? | Not at all — Perfectly<br>0 1 2 3 4 5 6 7 8 9 10<br>Min — Max | Check if not applicable or wouldn't hear ☐ | Aid not used ☐ |

# SSQ3.1.2

**S**[peech] **S**[patial] **Q**[ualities]

## II. Spatial Rating Scale

**INTERVAL:** **Baseline** ❍ **6 Month** ❍ **12 Month** ❍

**PATIENT** [redacted]

| | | | |
|---|---|---|---|
| 13. Can you tell from the sound whether a bus or truck is coming towards you or going away? | Not at all — Perfectly<br>0 (Min) 1 2 3 4 5 6 7 8 9 10 (Max) | Check if not applicable or wouldn't hear ☐ | Aid not used ☐ |
| 14. Do the sounds of things you are able to hear seem to be inside your head rather than out there in the world? | Inside My Head — Out There<br>0 (Min) 1 2 3 4 5 6 7 8 9 10 (Max) | Check if not applicable or wouldn't hear ☐ | Aid not used ☐ |
| 15. Do the sounds of people or things you hear, but cannot see at first, turn out to be closer than expected when you do see them? | Much Closer — Not Closer<br>0 (Min) 1 2 3 4 5 6 7 8 9 10 (Max) | Check if not applicable or wouldn't hear ☐ | Aid not used ☐ |
| 16. Do the sounds of people or things you hear, but cannot see at first, turn out to be further away than expected when you do see them? | Much Further — Not Further<br>0 (Min) 1 2 3 4 5 6 7 8 9 10 (Max) | Check if not applicable or wouldn't hear ☐ | Aid not used ☐ |
| 17. Do you have the impression of sounds being exactly where you would expect them to be? | Not at all — Perfectly<br>0 (Min) 1 2 3 4 5 6 7 8 9 10 (Max) | Check if not applicable or wouldn't hear ☐ | Aid not used ☐ |

# SSQ3.1.2

## S[peech] S[patial] Q[ualities]

## III. Sound Qualities Rating Scale

**INTERVAL:** **Baseline** ❍ **6 Month** ❍ **12 Month** ❍

**PATIENT ID:** [redacted]

| | | | |
|---|---|---|---|
| 1. Think of when you hear two things at once, for example, water running into a basin[a power-tool being used][a plane flying past] and, at the same time, a radio playing[the sound of hammering][a truck driving past]. Do you have the impression of these as sounding separate from each other? | Not at all — Perfectly<br>0 (Min) 1 2 3 4 5 6 7 8 9 10 (Max) | Check if not applicable or wouldn't hear ☐ | Aid not used ☐ |
| 2. When you hear more than one sound at a time, do you have the impression that it seems like a single jumbled sound? *<br>***If you have this experience, can you give examples of the sounds in question?** | Jumbled — Not Jumbled<br>0 (Min) 1 2 3 4 5 6 7 8 9 10 (Max) | Check if not applicable or wouldn't hear ☐ | Aid not used ☐ |
| 3. You are in a room and there is music on the radio. Someone else in the room is talking. Can you hear the voice as something separate from the music? | Not at all — Perfectly<br>0 (Min) 1 2 3 4 5 6 7 8 9 10 (Max) | Check if not applicable or wouldn't hear ☐ | Aid not used ☐ |
| 4. Do you find it easy to recognize different people you know by the sound of each one's voice? | Not at all — Perfectly<br>0 (Min) 1 2 3 4 5 6 7 8 9 10 (Max) | Check if not applicable or wouldn't hear ☐ | Aid not used ☐ |
| 5. Do you find it easy to distinguish different pieces of music that you are familiar with? | Not at all — Perfectly<br>0 (Min) 1 2 3 4 5 6 7 8 9 10 (Max) | Check if not applicable or wouldn't hear ☐ | Aid not used ☐ |

# SSQ3.1.2

## S[peech] S[patial] Q[ualities]

## III. Sound Qualities Rating Scale

**INTERVAL:** **Baseline** ❍ **6 Month** ❍ **12 Month** ❍

**PATIENT ID:** [redacted]

| | | | |
|---|---|---|---|
| 6. Can you tell the difference between different sounds, for example, a car versus a bus; water boiling in a pot versus food cooking in a frying pan? | Not at all — Perfectly<br>0 (Min) 1 2 3 4 5 6 7 8 9 10 (Max) | Check if not applicable or wouldn't hear ☐ | Aid not used ☐ |
| 7. When you listen to music, can you make out which instruments are playing? | Not at all — Perfectly<br>0 (Min) 1 2 3 4 5 6 7 8 9 10 (Max) | Check if not applicable or wouldn't hear ☐ | Aid not used ☐ |
| 8. When you listen to music, does it sound clear and natural? | Not at all — Perfectly<br>0 (Min) 1 2 3 4 5 6 7 8 9 10 (Max) | Check if not applicable or wouldn't hear ☐ | Aid not used ☐ |
| 9. Do everyday sounds that you can hear easily seem clear to you (not blurred)? | Not at all — Perfectly<br>0 (Min) 1 2 3 4 5 6 7 8 9 10 (Max) | Check if not applicable or wouldn't hear ☐ | Aid not used ☐ |
| 10. Do other people's voices sound clear and natural? | Not at all — Perfectly<br>0 (Min) 1 2 3 4 5 6 7 8 9 10 (Max) | Check if not applicable or wouldn't hear ☐ | Aid not used ☐ |
| 11. Do everyday sounds that you hear seem to have an artificial or unnatural quality? | Unnatural — Natural<br>0 (Min) 1 2 3 4 5 6 7 8 9 10 (Max) | Check if not applicable or wouldn't hear ☐ | Aid not used ☐ |

# SSQ3.1.2

## S[peech] S[patial] Q[ualities]

## III. Sound Qualities Rating Scale

**INTERVAL:** **Baseline** ❍ **6 Month** ❍ **12 Month** ❍

**PATIENT ID:** [redacted]

| | | | |
|---|---|---|---|
| 12. Does your own voice sound natural to you? | Not at all — Perfectly<br>0 (Min) 1 2 3 4 5 6 7 8 9 10 (Max) | Check if not applicable or wouldn't hear ☐ | Aid not used ☐ |
| 13. Can you easily judge another person's mood from the sound of their voice? | Not at all — Perfectly<br>0 1 2 3 4 5 6 7 8 9 10 | Check if not applicable or wouldn't hear ☐ | Aid not used ☐ |
| 14. Do you have to concentrate very much when listening to someone or something? | Concentrate Hard — No Need to Concentrate<br>0 (Min) 1 2 3 4 5 6 7 8 9 10 (Max) | Check if not applicable or wouldn't hear ☐ | Aid not used ☐ |
| 15. When you are the driver in a car, can you easily hear what someone is saying who is sitting alongside you? | Not at all — Perfectly<br>0 (Min) 1 2 3 4 5 6 7 8 9 10 (Max) | Check if not applicable or wouldn't hear ☐ | Aid not used ☐ |
| 16. When you are a passenger in a car, can you easily hear what the driver is saying who is sitting alongside you? | Not at all — Perfectly<br>0 (Min) 1 2 3 4 5 6 7 8 9 10 (Max) | Check if not applicable or wouldn't hear ☐ | Aid not used ☐ |
| 17. Do you have to put in a lot of effort to hear what is being said in conversation with others? | Lot of Effort — No Effort<br>0 (Min) 1 2 3 4 5 6 7 8 9 10 (Max) | Check if not applicable or wouldn't hear ☐ | Aid not used ☐ |

# SSQ3.1.2

**S**[peech] **S**[patial] **Q**[ualities]

**III. Sound Qualities Rating Scale**

**INTERVAL:** **Baseline** ❍ **6 Month** ❍ **12 Month** ❍

**PATIENT ID:** [redacted]

| | | | |
|---|---|---|---|
| 18. Can you easily ignore other sounds when trying to listen to something? | Not Easily Ignored — Easily Ignored<br>0 (Min) 1 2 3 4 5 6 7 8 9 10 (Max) | Check if not applicable or wouldn't hear ☐ | Aid not used ☐ |

# Preoperative Device Use Questionnaire



Evaluation Date (MM/DD/YYYY): ☐☐ / ☐☐ / ☐☐☐☐

Patient ID: [redacted]

**Hearts for Hearing**
Clinic Name

Audiologist

**1. Which of the following statements best describes your <u>overall</u> <u>preferred</u> way of listening most of the time?**
***(Mark only one response)***

○ a. I use both hearing aids together

○ b. I use my left hearing aid

○ c. I use my right hearing aid

○ d. I don't use any hearing aids

**If you chose "a", "b" or "c", skip to question #8**
**If you chose "d" in question #1, please answer questions #2 - #7, then skip to question #11**

**In Question #1, you indicated that you do not use hearing aids. Please indicate if the following situations apply or do not apply to the cause of not using hearing aids:**

| | Apply | Does Not Apply | |
|---|---|---|---|
| **2.** | ○ | ○ | Sound from the hearing aid(s) do not blend. |
| **3.** | ○ | ○ | My performance is clearly best when using alternative systems (e.g., FM System). |
| **4.** | ○ | ○ | It is too inconvenient wearing a hearing aid(s). |
| **5.** | ○ | ○ | I receive no additional benefit when wearing hearing aid(s). |
| **6.** | ○ | ○ | Other* |

**7.** If Other, please specify: _____

**Skip to Question #11**

# Preoperative Device Use Questionnaire



Evaluation Date:
☐☐ / ☐☐ / ☐☐☐☐

[redacted]

**8. How many hours a day do you use your <u>overall</u> <u>preferred</u> listening mode (as indicated in question #1)?**

☐☐ Hours

**9. How easy has it been for you to adjust to listening with a hearing aid(s)?**

| Very easy | Moderately easy | Neither easy nor difficult | Moderately difficult | Very difficult | N/A or Not Sure |
|---|---|---|---|---|---|
| ○ | ○ | ○ | ○ | ○ | ○ |

**10. How easy has it been for you to manipulate your hearing aid(s)?**

| Very easy | Moderately easy | Neither easy nor difficult | Moderately difficult | Very difficult | N/A or Not Sure |
|---|---|---|---|---|---|
| ○ | ○ | ○ | ○ | ○ | ○ |

**11. Overall, sound seems the most pleasant and natural with...**

| Right HA | Left HA | Two HAs | Nothing |
|---|---|---|---|
| ○ | ○ | ○ | ○ |

**12. Overall, ease of listening is *greatest* with...**

| Right HA | Left HA | Two HAs | Nothing |
|---|---|---|---|
| ○ | ○ | ○ | ○ |

# Preoperative Device Use Questionnaire



Evaluation Date: ☐☐ / ☐☐ / ☐☐☐☐

Patient ID: [redacted]

**Please indicate your preferred way of listening for SPEECH in each of the following situations:**

| | Right HA | Left HA | Two HAs | Nothing | N/A or Not Sure |
|---|---|---|---|---|---|
| **13. Using the telephone:** | ○ | ○ | ○ | ○ | ○ |
| **14. Noisy environments:** | ○ | ○ | ○ | ○ | ○ |
| **15. Quiet environments:** | ○ | ○ | ○ | ○ | ○ |
| **16. One-on-one conversation:** | ○ | ○ | ○ | ○ | ○ |
| **17. In a small group (3-5 people):** | ○ | ○ | ○ | ○ | ○ |
| **18. In a large group (6+ people):** | ○ | ○ | ○ | ○ | ○ |
| **19. Listening to speech at a distance (e.g., at church, lecture hall):** | ○ | ○ | ○ | ○ | ○ |

**20. When using the telephone, do you use:**

○ Ear with hearing aid ○ Ear with no hearing aid ○ Both (i.e., with a loop)

**21. Please indicate your preferred type of MUSIC:**

○ Classical ○ Rock ○ Rap ○ Jazz ○ Country ○ Opera ○ Other*

**22. If you answered Other to question #21, please specify:** _____

**Please indicate your preferred way of listening to each of the following MUSIC types:**

| | Right HA | Left HA | Two HAs | Nothing | N/A or Not Sure |
|---|---|---|---|---|---|
| **23. Live music with singing:** | ○ | ○ | ○ | ○ | ○ |
| **24. Live music without singing:** | ○ | ○ | ○ | ○ | ○ |
| **25. Recorded music with singing (e.g., on car radio or home stereo):** | ○ | ○ | ○ | ○ | ○ |
| **26. Recorded music without singing (e.g., on car radio or home stereo):** | ○ | ○ | ○ | ○ | ○ |

# Preoperative Device Use Questionnaire



Evaluation Date: ☐☐ / ☐☐ / ☐☐☐☐

Patient ID: [redacted]

**27. Please indicate your profession:**

_____

**28. Please select the work environment that best describes your place of employment:**

- ◯ **Industrial**
- ◯ **Quiet office**
- ◯ **Noisy office**
- ◯ **Quiet outdoors**
- ◯ **Noisy outdoors**
- ◯ **Other***

**29. If Other, please specify:** _____

**Please indicate your preferred way of listening when ALONE in each of the following situations:**

| | Right HA | Left HA | Two HAs | Nothing | N/A or Not Sure |
|---|---|---|---|---|---|
| **30. Outdoors (birds, nature walk, etc.):** | ◯ | ◯ | ◯ | ◯ | ◯ |
| **31. Listening to music:** | ◯ | ◯ | ◯ | ◯ | ◯ |
| **32. At a shopping mall/grocery store:** | ◯ | ◯ | ◯ | ◯ | ◯ |
| **33. In your place of employment:** | ◯ | ◯ | ◯ | ◯ | ◯ |
| **34. At a theater:** | ◯ | ◯ | ◯ | ◯ | ◯ |

# Preoperative Device Use Questionnaire



Evaluation Date: ☐☐ / ☐☐ / ☐☐☐☐

Patient ID: [redacted]

**For your overall preferred way of listening (as indicated by question #1), please describe...**

**35. Your adjustment over time:**

| Very easy | Moderately easy | Neither easy nor difficult | Moderately difficult | Very difficult |
|---|---|---|---|---|
| ○ | ○ | ○ | ○ | ○ |

**36. What you *like* about wearing your overall preferred way of listening:**

_____

_____

**37. What you *dislike* about wearing your overall preferred way of listening:**

_____

_____

**Using your preferred way of listening, please rate your level of satisfaction for understanding SPEECH in each of the following situations:**

| | Very Satisfied | Satisfied | Neutral | Dissatisfied | Very Dissatisfied | Does Not Apply |
|---|---|---|---|---|---|---|
| **38. Using the telephone:** | ○ | ○ | ○ | ○ | ○ | ○ |
| **39. Noisy environments:** | ○ | ○ | ○ | ○ | ○ | ○ |
| **40. Quiet environments:** | ○ | ○ | ○ | ○ | ○ | ○ |
| **41. One-on-one conversation:** | ○ | ○ | ○ | ○ | ○ | ○ |
| **42. In a small group (3-5 people):** | ○ | ○ | ○ | ○ | ○ | ○ |
| **43. In a large group (6+ people):** | ○ | ○ | ○ | ○ | ○ | ○ |
| **44. Listening to speech at a distance (e.g., at church, lecture hall):** | ○ | ○ | ○ | ○ | ○ | ○ |

**Using your preferred way of listening, please rate your level of satisfaction when listening to MUSIC in the following situations:**

| | Very Satisfied | Satisfied | Neutral | Dissatisfied | Very Dissatisfied | Does Not Apply |
|---|---|---|---|---|---|---|
| **45. Live music with singing:** | ○ | ○ | ○ | ○ | ○ | ○ |
| **46. Live music without singing:** | ○ | ○ | ○ | ○ | ○ | ○ |
| **47. Recorded music with singing (e.g., on car radio or home stereo):** | ○ | ○ | ○ | ○ | ○ | ○ |
| **48. Recorded music without singing (e.g., on car radio or home stereo):** | ○ | ○ | ○ | ○ | ○ | ○ |

# Preoperative Device Use Questionnaire



Evaluation Date: ☐☐ / ☐☐ / ☐☐☐☐

Patient ID: [redacted]

**Using your preferred way of listening, please rate your level of satisfaction when ALONE in each of the following environments:**

| | Very Satisfied | Satisfied | Neutral | Dissatisfied | Very Dissatisfied | Does Not Apply |
|---|---|---|---|---|---|---|
| **49. Outdoors (bird, nature walk, etc.):** | ○ | ○ | ○ | ○ | ○ | ○ |
| **50. Listening to music:** | ○ | ○ | ○ | ○ | ○ | ○ |
| **51. At a shopping mall/grocery store:** | ○ | ○ | ○ | ○ | ○ | ○ |
| **52. In your place of employment:** | ○ | ○ | ○ | ○ | ○ | ○ |

**Using your <u>overall</u> <u>preferred</u> way of listening (as indicated in question #1), please rate your level of satisfaction with your ability to LOCATE SOUNDS in the following situations:**

| | Very Satisfied | Satisfied | Neutral | Dissatisfied | Very Dissatisfied | Does Not Apply |
|---|---|---|---|---|---|---|
| **53. Crossing a busy street:** | ○ | ○ | ○ | ○ | ○ | ○ |
| **54. Identifying an elevator signal:** | ○ | ○ | ○ | ○ | ○ | ○ |
| **55. Locating voice source (i.e. warning, referencing name):** | ○ | ○ | ○ | ○ | ○ | ○ |
| **56. Identifying location of emergency siren:** | ○ | ○ | ○ | ○ | ○ | ○ |

**Using your <u>overall</u> <u>preferred</u> way of listening (as indicated by question #1), please rate your level of satisfaction with the following items:**

| | Very Satisfied | Satisfied | Neutral | Dissatisfied | Very Dissatisfied | Does Not Apply |
|---|---|---|---|---|---|---|
| **57. Sound quality of my own voice:** | ○ | ○ | ○ | ○ | ○ | ○ |
| **58. Naturalness of speech:** | ○ | ○ | ○ | ○ | ○ | ○ |
| **59. Handling or manipulation:** | ○ | ○ | ○ | ○ | ○ | ○ |
| **60. Clarity of speech:** | ○ | ○ | ○ | ○ | ○ | ○ |
| **61. Clarity of environmental sounds:** | ○ | ○ | ○ | ○ | ○ | ○ |

# Preoperative Device Use Questionnaire



Evaluation Date: ☐☐ / ☐☐ / ☐☐☐☐

Patient ID: [redacted]

**Please rate your personal level of IMPORTANCE for each of the following items:**

| | Not Important | Slightly Important | Important | Very Important | Neutral or N/A |
|---|---|---|---|---|---|
| **62. Using the telephone:** | ○ | ○ | ○ | ○ | ○ |
| **63. Noisy environments:** | ○ | ○ | ○ | ○ | ○ |
| **64. Quiet environments:** | ○ | ○ | ○ | ○ | ○ |
| **65. One-on-one conversation:** | ○ | ○ | ○ | ○ | ○ |
| **66. In a small group (3-5 people):** | ○ | ○ | ○ | ○ | ○ |
| **67. In a large group (6+ people):** | ○ | ○ | ○ | ○ | ○ |
| **68. Listening to speech at a distance (e.g. at church, lecture hall):** | ○ | ○ | ○ | ○ | ○ |
| **69. Outdoors (bird, nature walk, etc.):** | ○ | ○ | ○ | ○ | ○ |
| **70. Live music with singing:** | ○ | ○ | ○ | ○ | ○ |
| **71. Live music without singing:** | ○ | ○ | ○ | ○ | ○ |
| **72. Recorded music with singing (e.g., on car radio or home stereo):** | ○ | ○ | ○ | ○ | ○ |
| **73. Recorded music without singing (e.g., on car radio or home stereo):** | ○ | ○ | ○ | ○ | ○ |
| **74. At a shopping mall/grocery** | ○ | ○ | ○ | ○ | ○ |
| **75. In your place of employment:** | ○ | ○ | ○ | ○ | ○ |
| **76. Crossing a busy street:** | ○ | ○ | ○ | ○ | ○ |
| **77. Identifying an elevator signal:** | ○ | ○ | ○ | ○ | ○ |
| **78. Locating voice source (i.e. warning, referencing name):** | ○ | ○ | ○ | ○ | ○ |
| **79. Identifying location of emergency siren:** | ○ | ○ | ○ | ○ | ○ |
| **80. Sound quality of my own voice:** | ○ | ○ | ○ | ○ | ○ |
| **81. Naturalness of speech:** | ○ | ○ | ○ | ○ | ○ |
| **82. Handling or manipulation:** | ○ | ○ | ○ | ○ | ○ |
| **83. Clarity of speech:** | ○ | ○ | ○ | ○ | ○ |
| **84. Clarity of environmental sounds:** | ○ | ○ | ○ | ○ | ○ |

# Preoperative Device Use Questionnaire



Evaluation Date: ☐☐ / ☐☐ / ☐☐☐☐

Patient ID: [redacted]

**Please consider the following questions as they relate to your overall preferred way of listening (as indicated in question #1):**

| | Never | Sometimes | Regularly | Usually | Always | N/A |
|---|---|---|---|---|---|---|
| **85. Do you become irritated if you cannot follow a conversation?** | ○ | ○ | ○ | ○ | ○ | ○ |
| **86. Do you go places where your hearing might represent a serious handicap?** | ○ | ○ | ○ | ○ | ○ | ○ |
| **87. Do you feel anxious when talking to strangers?** | ○ | ○ | ○ | ○ | ○ | ○ |
| **88. Does your hearing present a serious hinderance when speaking with your neighbors?** | ○ | ○ | ○ | ○ | ○ | ○ |
| **89. Does your hearing present a serious problem at parties?** | ○ | ○ | ○ | ○ | ○ | ○ |
| **90. Do you find it tiring to listen (without lipreading)?** | ○ | ○ | ○ | ○ | ○ | ○ |
| **91. Does your hearing undermine your self-confidence?** | ○ | ○ | ○ | ○ | ○ | ○ |

**92. Overall, I am satisfied with my performance with my overall preferred way of listening.**

| Very Satisfied | Satisfied | Neutral | Dissatisfied | Very Dissatisfied | Does Not Apply |
|---|---|---|---|---|---|
| ○ | ○ | ○ | ○ | ○ | ○ |

**93. In question #1, you indicated your overall preferred way of listening. Is this also the clearest way of listening overall?** ○ Yes ○ No*

***If No, which is your clearest way of listening overall?**

○ a. I use both hearing aids together

○ b. I use my left hearing aid

○ c. I use my right hearing aid

○ d. I don't use any hearing aids

Cochlear

# Postoperative Device Use Questionnaire



Evaluation Date (MM/DD/YYYY): ☐☐ / ☐☐ / ☐☐☐☐

Patient ID: [redacted]

Interval: ○ 6 Month ○ 12 Month

Clinic Name

Audiologist

**1. Since receiving your Nucleus Hybrid Cochlear Implant, which of the following statements best describes your <u>overall</u> <u>preferred</u> way of listening most of the time? Please refer to the attached diagram.** ***(Mark only one response)***

○ a. Hybrid Mode

○ b. Combined Mode

○ c. Bimodal

○ d. Acoustic only

○ e. Electric only

○ f. Nothing

**If you chose "d", "e" or "f" in question #1, please answer questions #2 - #5.**
**If you chose "a", "b" or "c", please skip to question #7.**

**In Question #1, you indicated that you use your CI alone, that you use your Hearing Aid alone, or that you do not use anything. Please indicate why:**
***(Mark all answers that apply)***

| | Apply | Does Not Apply | |
|---|---|---|---|
| **2.** | ○ | ○ | My performance is clearly best when using just one of the two systems (i.e. electric vs. acoustic). |
| **3.** | ○ | ○ | It is too inconvenient to wear the external parts of the CI, Acoustic Component (AC), and HA at the same time. |
| **4.** | ○ | ○ | I receive no additional benefit when wearing the CI, AC, and HA together. |
| **5.** | ○ | ○ | Sound from the CI, AC and HA does not blend. |

**If you chose "apply" in question #5, please answer question #6, then skip to question 12.**
**Otherwise, skip to question #7.**

**6. In Question #5, you indicated the sound from the CI, the AC and HA does not blend. Please specify:**

○ Sound within same ear ○ Sound in between ears

# Postoperative Device Use Questionnaire



**Interval:** ○ **6 Month** ○ **12 Month**

Patient ID: [redacted]

**7. How many hours a day do you use your <u>overall</u> <u>preferred</u> listening mode (as indicated in question #1)?**

☐☐ Hours

**8. How easy has it been for you to adjust to listening with two different systems (i.e., electric and acoustic)?**

| Very easy | Moderately easy | Neither easy nor difficult | Moderately difficult | Very difficult |
|---|---|---|---|---|
| ○ | ○ | ○ | ○ | ○ |

**9. How easy has it been for you to manipulate the sound processor (i.e., CI and AC)?**

| Very easy | Moderately easy | Neither easy nor difficult | Moderately difficult | Very difficult |
|---|---|---|---|---|
| ○ | ○ | ○ | ○ | ○ |

**10. The sound provided by the CI, AC and HA blend well together.**

| Strongly agree | Agree | Neutral | Disagree | Strongly disagree |
|---|---|---|---|---|
| ○ | ○ | ○ | ○ | ○ |

**11. The volume between the CI, AC and HA is well balanced.**

| Strongly agree | Agree | Neutral | Disagree | Strongly disagree |
|---|---|---|---|---|
| ○ | ○ | ○ | ○ | ○ |

**12. Overall, sound seems the most pleasant and natural with... (please refer to diagram)**

| Hybrid | Bimodal | Combined | CI Only | HA Only | Nothing |
|---|---|---|---|---|---|
| ○ | ○ | ○ | ○ | ○ | ○ |

**13. Overall, ease of listening is *greatest* with... (please refer to diagram)**

| Hybrid | Bimodal | Combined | CI Only | HA Only | Nothing |
|---|---|---|---|---|---|
| ○ | ○ | ○ | ○ | ○ | ○ |

# Postoperative Device Use Questionnaire



**Interval:** ○ **6 Month** ○ **12 Month**

Patient ID: [redacted]

**Please indicate your preferred way of listening for SPEECH in each of the following situations:**
***(Please refer to diagram)***

| | Hybrid | Bimodal | Combined | CI Only | HA Only | Nothing | N/A or Not Sure |
|---|---|---|---|---|---|---|---|
| **14. Using the telephone:** | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| **15. Noisy environments:** | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| **16. Quiet environments:** | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| **17. One-on-one conversation:** | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| **18. In a small group (3-5 people):** | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| **19. In a large group (6+ people):** | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| **20. Listening to speech at a distance (e.g., at church, lecture hall):** | ○ | ○ | ○ | ○ | ○ | ○ | ○ |

**21. When using the telephone, do you use:**

○ Implanted Ear ○ Non-Implanted Ear ○ Both (e.g., use neck loop)

**22. Please indicate your preferred type of Music:**

○ Classical ○ Rock ○ Rap ○ Jazz ○ Country ○ Opera ○ Other*

**23. If you answered Other to question #22, please specify:** _____

**Please indicate your preferred way of listening to each of the following MUSIC types:**
***(Please refer to diagram)***

| | Hybrid | Bimodal | Combined | CI Only | HA Only | Nothing | N/A or Not Sure |
|---|---|---|---|---|---|---|---|
| **24. Live music with singing:** | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| **25. Live music without singing:** | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| **26. Recorded music with singing (e.g., on car radio or home stereo):** | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| **27. Recorded music without singing (e.g., on car radio or home stereo):** | ○ | ○ | ○ | ○ | ○ | ○ | ○ |

# Postoperative Device Use Questionnaire



**Interval:** ○ **6 Month** ○ **12 Month**

Patient ID: [redacted]

**28. Please indicate your profession:**

_____

**29. Please select the work environment that best describes your place of employment:**

- ○ **Industrial**
- ○ **Quiet office**
- ○ **Noisy office**
- ○ **Quiet outdoors**
- ○ **Noisy outdoors**
- ○ **Other***

**30. If you chose Other in question #29, please specify:** _____

**Please indicate your preferred way of listening when ALONE in each of the following situations:**
***(Please refer to diagram)***

| | Hybrid | Bimodal | Combined | CI Only | HA Only | Nothing | N/A or Not Sure |
|---|---|---|---|---|---|---|---|
| **31. Outdoors (birds, nature walk, etc.):** | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| **32. Listening to music:** | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| **33. At a shopping mall/grocery store:** | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| **34. In your place of employment:** | ○ | ○ | ○ | ○ | ○ | ○ | ○ |
| **35. At a theater:** | ○ | ○ | ○ | ○ | ○ | ○ | ○ |

# Postoperative Device Use Questionnaire



Patient ID: [redacted]

**Interval:** ○ **6 Month** ○ **12 Month**

**For your overall preferred way of listening (as indicated by question #1), please describe...**

**36. Your adjustment over time:**

| Very easy | Moderately easy | Neither easy nor difficult | Moderately difficult | Very difficult |
|---|---|---|---|---|
| ○ | ○ | ○ | ○ | ○ |

**37. What you *like* about wearing your overall preferred way of listening:**

_____

_____

**38. What you *dislike* about wearing your overall preferred way of listening:**

_____

_____

**Using your preferred way of listening, please rate your level of satisfaction for understanding SPEECH in each of the following situations:**

| | Very Satisfied | Satisfied | Neutral | Dissatisfied | Very Dissatisfied | Does Not Apply |
|---|---|---|---|---|---|---|
| **39. Using the telephone:** | ○ | ○ | ○ | ○ | ○ | ○ |
| **40. Noisy environments:** | ○ | ○ | ○ | ○ | ○ | ○ |
| **41. Quiet environments:** | ○ | ○ | ○ | ○ | ○ | ○ |
| **42. One-on-one conversation:** | ○ | ○ | ○ | ○ | ○ | ○ |
| **43. In a small group (3-5 people):** | ○ | ○ | ○ | ○ | ○ | ○ |
| **44. In a large group (6+ people):** | ○ | ○ | ○ | ○ | ○ | ○ |
| **45. Listening to speech at a distance (e.g., at church, lecture hall):** | ○ | ○ | ○ | ○ | ○ | ○ |

**Using your preferred way of listening, please rate your level of satisfaction when listening to MUSIC in the following situations:**

| | Very Satisfied | Satisfied | Neutral | Dissatisfied | Very Dissatisfied | Does Not Apply |
|---|---|---|---|---|---|---|
| **46. Live music with singing:** | ○ | ○ | ○ | ○ | ○ | ○ |
| **47. Live music without singing:** | ○ | ○ | ○ | ○ | ○ | ○ |
| **48. Recorded music with singing (e.g., on car radio or home stereo):** | ○ | ○ | ○ | ○ | ○ | ○ |
| **49. Recorded music without singing (e.g., on car radio or home stereo):** | ○ | ○ | ○ | ○ | ○ | ○ |

# Postoperative Device Use Questionnaire



Patient ID: [redacted]

**Interval:** ○ **6 Month** ○ **12 Month**

**Using your preferred way of listening, please rate your level of satisfaction when ALONE in each of the following environments:**

| | Very Satisfied | Satisfied | Neutral | Dissatisfied | Very Dissatisfied | Does Not Apply |
|---|---|---|---|---|---|---|
| **50. Outdoors (bird, nature walk, etc.):** | ○ | ○ | ○ | ○ | ○ | ○ |
| **51. Listening to music:** | ○ | ○ | ○ | ○ | ○ | ○ |
| **52. At a shopping mall/grocery store:** | ○ | ○ | ○ | ○ | ○ | ○ |
| **53. In your place of employment:** | ○ | ○ | ○ | ○ | ○ | ○ |

**Using your <u>overall</u> <u>preferred</u> way of listening (as indicated in question #1), please rate your level of satisfaction with your ability to LOCATE SOUNDS in the following situations:**

| | Very Satisfied | Satisfied | Neutral | Dissatisfied | Very Dissatisfied | Does Not Apply |
|---|---|---|---|---|---|---|
| **54. Crossing a busy street:** | ○ | ○ | ○ | ○ | ○ | ○ |
| **55. Identifying an elevator signal:** | ○ | ○ | ○ | ○ | ○ | ○ |
| **56. Locating voice source (i.e. warning, referencing name):** | ○ | ○ | ○ | ○ | ○ | ○ |
| **57. Identifying location of emergency siren:** | ○ | ○ | ○ | ○ | ○ | ○ |

**Using your <u>overall</u> <u>preferred</u> way of listening (as indicated by question #1), please rate your level of satisfaction with the following items:**

| | Very Satisfied | Satisfied | Neutral | Dissatisfied | Very Dissatisfied | Does Not Apply |
|---|---|---|---|---|---|---|
| **58. Sound quality of my own voice:** | ○ | ○ | ○ | ○ | ○ | ○ |
| **59. Naturalness of speech:** | ○ | ○ | ○ | ○ | ○ | ○ |
| **60. Handling or manipulation:** | ○ | ○ | ○ | ○ | ○ | ○ |
| **61. Clarity of speech:** | ○ | ○ | ○ | ○ | ○ | ○ |
| **62. Clarity of environmental sounds:** | ○ | ○ | ○ | ○ | ○ | ○ |

# Postoperative Device Use Questionnaire



Patient ID:

**Interval:** ○ **6 Month** ○ **12 Month**

**Please rate your personal level of IMPORTANCE for each of the following items:**

| | Not Important | Slightly Important | Important | Very Important | Neutral or N/A |
|---|---|---|---|---|---|
| **63. Using the telephone:** | ○ | ○ | ○ | ○ | ○ |
| **64. Noisy environments:** | ○ | ○ | ○ | ○ | ○ |
| **65. Quiet environments:** | ○ | ○ | ○ | ○ | ○ |
| **66. One-on-one conversation:** | ○ | ○ | ○ | ○ | ○ |
| **67. In a small group (3-5 people):** | ○ | ○ | ○ | ○ | ○ |
| **68. In a large group (6+ people):** | ○ | ○ | ○ | ○ | ○ |
| **69. Listening to speech at a distance (e.g. at church, lecture hall):** | ○ | ○ | ○ | ○ | ○ |
| **70. Outdoors (bird, nature walk, etc.):** | ○ | ○ | ○ | ○ | ○ |
| **71. Live music with singing:** | ○ | ○ | ○ | ○ | ○ |
| **72. Live music without singing:** | ○ | ○ | ○ | ○ | ○ |
| **73. Recorded music with singing (e.g., on car radio or home stereo):** | ○ | ○ | ○ | ○ | ○ |
| **74. Recorded music without singing (e.g., on car radio or home stereo):** | ○ | ○ | ○ | ○ | ○ |
| **75. At a shopping mall/grocery store:** | ○ | ○ | ○ | ○ | ○ |
| **76. In your place of employment:** | ○ | ○ | ○ | ○ | ○ |
| **77. Crossing a busy street:** | ○ | ○ | ○ | ○ | ○ |
| **78. Identifying an elevator signal:** | ○ | ○ | ○ | ○ | ○ |
| **79. Locating voice source (i.e. warning, referencing name):** | ○ | ○ | ○ | ○ | ○ |
| **80. Identifying location of emergency siren:** | ○ | ○ | ○ | ○ | ○ |
| **81. Sound quality of my own voice:** | ○ | ○ | ○ | ○ | ○ |
| **82. Naturalness of speech:** | ○ | ○ | ○ | ○ | ○ |
| **83. Handling or manipulation:** | ○ | ○ | ○ | ○ | ○ |
| **84. Clarity of speech:** | ○ | ○ | ○ | ○ | ○ |
| **85. Clarity of environmental sounds:** | ○ | ○ | ○ | ○ | ○ |

# Postoperative Device Use Questionnaire



Patient ID: [redacted]

**Interval:** ○ **6 Month** ○ **12 Month**

**Please consider the following questions as they relate to your overall preferred way of listening (as indicated in question #1):**

| | Never | Sometimes | Regularly | Usually | Always | N/A |
|---|---|---|---|---|---|---|
| **86. Do you become irritated if you cannot follow a conversation?** | ○ | ○ | ○ | ○ | ○ | ○ |
| **87. Do you go places where your hearing might represent a serious handicap?** | ○ | ○ | ○ | ○ | ○ | ○ |
| **88. Do you feel anxious when talking to strangers?** | ○ | ○ | ○ | ○ | ○ | ○ |
| **89. Does your hearing present a serious hinderance when speaking with your neighbors?** | ○ | ○ | ○ | ○ | ○ | ○ |
| **90. Does your hearing present a serious problem at parties?** | ○ | ○ | ○ | ○ | ○ | ○ |
| **91. Do you find it tiring to listen (without lipreading)?** | ○ | ○ | ○ | ○ | ○ | ○ |
| **92. Does your hearing undermine your self-confidence?** | ○ | ○ | ○ | ○ | ○ | ○ |

**93. In question #1, you indicated your overall preferred way of listening. Is this also the clearest way of listening overall?** ○ Yes ○ No*

***If No, which is your clearest way of listening overall?**

○ a. Hybrid Mode ○ d. Acoustic only

○ b. Combined Mode ○ e. Electric only

○ c. Bimodal ○ f. Nothing

**94. Overall, I am satisfied with my performance with the Nucleus Hybrid Cochlear Implant.**

| Very Satisfied | Satisfied | Neutral | Dissatisfied | Very Dissatisfied | Does Not Apply |
|---|---|---|---|---|---|
| ○ | ○ | ○ | ○ | ○ | ○ |

**95. I am satisfied I made the decision to receive the Nucleus Hybrid Cochlear Implant.**

| Very Satisfied | Satisfied | Neutral | Dissatisfied | Very Dissatisfied | Does Not Apply |
|---|---|---|---|---|---|
| ○ | ○ | ○ | ○ | ○ | ○ |

**SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)**

## I. GENERAL INFORMATION

| | |
|---|---|
| Device generic name: | Cochlear Implant |
| Device trade name: | Nucleus® Hybrid L24 Implant System, consisting of:<br>• CI24REH Cochlear Implant<br>• Nucleus 6 Sound Processor (CP910 or CP920) with Acoustic Component, cable, coil, and accessories<br>• CR200 Series Remote Assistants (CR210 or CR230 for patient use; CR220 Intraoperative for professional use)<br>• Custom Sound v4 programming software |
| Applicant's name and address: | Cochlear Americas<br>13059 E Peakview Ave.<br>Centennial, CO 80111 |
| PMA number: | *To be completed by FDA* |
| Date of Panel recommendation: | *To be completed by FDA* |
| Date of notice of approval to the applicant: | *To be completed by FDA* |

## II. INDICATIONS FOR USE

The Nucleus® Hybrid L24 Implant System is intended for patients aged 18 years and older who have residual low-frequency hearing sensitivity and bilateral severe to profound high frequency sensorineural hearing loss, and who obtain limited benefit from bilateral hearing aids.

Typical preoperative hearing of candidates ranges from normal to moderate hearing loss in the low frequencies (thresholds no poorer than 60 dB HL at $\leq$ 500 Hz), and from severe to profound hearing loss at frequencies above 1500 Hz (threshold average of 2000, 3000, and 4000 Hz $\geq$ 75 dB HL).

The CNC word recognition score will be between 10% and 60% inclusively in the ear to be implanted in the preoperative aided condition, and in the contralateral ear will be equal to or better than that of the ear to be implanted but not more than 80% correct.

## III. CONTRAINDICATIONS

A cochlear implant is not indicated for individuals who have the following conditions:

1. Deafness due to lesions of the acoustic nerve or central auditory pathway
2. Active middle ear infections
3. Absence of cochlear development
4. Tympanic membrane perforation in the presence of active middle ear disease.

## IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the labeling for the Nucleus® Hybrid L24 implant and the Nucleus 6 Sound Processor.

## V. DEVICE DESCRIPTION

The Nucleus Hybrid L24 Implant is an electric-acoustic stimulation (EAS) cochlear implant system intended to address the needs of individuals who demonstrate residual low-frequency hearing sensitivity, but who have severe to profound mid and high-frequency sensorineural hearing loss. It provides electric (cochlear implant) stimulation to the mid to high frequency region of the cochlea, but also has the ability to provide acoustic (hearing aid) amplification in low-frequency regions for patient s with residual low-frequency hearing sensitivity. It consists of both internal and external components, as illustrated in Figure 1.

**Figure 1: The Cochlear Nucleus Hybrid Cochlear Implant system, consisting of the model Hybrid L24 Implant (top), Nucleus 6 Hybrid Sound Processor with Acoustic Component (bottom left), and two Remote Assistant options, the basic CR210 (bottom middle) or the full function CR230 (bottom right). Illustration not to scale.**

### *Nucleus® Hybrid™ L24 Implant*

The receiver/stimulator assembly and extracochlear electrodes of the Nucleus® Hybrid™ L24 Implant are identical to those of the marketed Cochlear Nucleus model CI24RE (Freedom™) cochlear implant. However, the intracochlear electrode array of the Hybrid L24 implant is

different than the conventional (straight [ST] and Contour Advance [CA]) electrode arrays used with Cochlear's other models of cochlear implants. While the Hybrid L24 electrode array has 22 active electrodes like Cochlear's conventional electrode arrays, it is shorter and thinner with an intention to preserve the integrity of the apical region of the cochlea (which mediates low frequencies) and thus to increase the possibility of retention of residual low-frequency hearing sensitivity. While conventional, longer electrode arrays marketed by Cochlear typically achieve insertion depths up to 25 mm, the Hybrid L24 electrode array is designed for an insertion depth of 15 to 16 mm.

***Cochlear™ Nucleus® 6 Sound Processor***

The Cochlear™ Nucleus® 6 Sound Processor includes an Acoustic Component that can provide conventional amplification for residual acoustic hearing sensitivity in the lower frequencies. Two versions of the Nucleus 6 sound processor are available: the CP910 and the CP920. These sound processors are identical except that the CP920 has an accessory port for use with accessories.

Both the electric (cochlear implant) and acoustic (hearing aid) sound processing are programmed using Custom Sound Suite software, version 4. Two remote controls are available for patient use: the CR210 basic Remote Assistant and the CR230 fully-featured Remote Assistant. A third remote control is also available only for use by professionals in the operating theater, the CR220 Intraoperative Remote Assistant.

## VI. ALTERNATIVE PRACTICES AND PROCEDURES

The alternative treatment of severe to profound bilateral high-frequency sensorineural hearing loss with residual low-frequency hearing is the use of conventional air conduction or, in some cases, frequency transposition hearing aids. Patients may also choose to forego obtaining a hearing device in lieu of pursuing rehabilitation via speechreading and/or sign language training. Each of these alternatives has its own advantages and disadvantages. A patient should fully discuss the alternatives with his/her physician and audiologist in order to select the treatment that best meets his/her expectations and lifestyle.

## VII. MARKETING HISTORY

The Nucleus Hybrid L24 implant combined with a previous generation sound processor (Freedom™ Hybrid™) has been marketed for use in both adults and children in the European community since 2008, in parts of Latin America and Asia-Pacific since 2009-2010, and in Canada since 2011. Since market introduction, approximately 315 Hybrid systems have been implanted worldwide. The Hybrid L24 system has not been withdrawn from any market for any reason related to safety or effectiveness.

## VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Like any ear surgery, cochlear implantation carries with it a certain amount of risk. Implantation with the Hybrid L24 has similar risks for recipients as implantation with other cochlear implants. Below is a list of potential adverse effects/complications associated with the implantation and use of the Hybrid L24 Cochlear Implant System:

- Decrease of residual acoustic hearing sensitivity
- Vertigo, dizziness, or balance problems that did not exist preoperatively or worsened postoperatively
- Facial nerve problems
- Meningitis
- Perilymphatic fistula
- Tinnitus that did not exist preoperatively or worsened postoperatively
- Implant migration/extrusion
- Skin flap issues
- Device-related programming problems or device failure

For the specific adverse events that occurred as part of the clinical study, see Section X.

## IX. SUMMARY OF PRECLINICAL STUDIES

Because the Nucleus Hybrid L24 Implant System represents modifications to the Nucleus 24 Cochlear Implant System currently marketed, the non-clinical studies that were undertaken to evaluate the safety and effectiveness of the Hybrid L24 Implant System relate to the following modifications:

- New Intracochlear electrode array
- New Nucleus 6 External Components
- New Remote Assistants

The results of the non-clinical studies are summarized below and demonstrate, with a reasonable degree of assurance, that the Hybrid L24 Implant System is safe and effective for its intended use.

**Intracochlear Electrode Array:**

Temporal Bone Insertion Studies*:*
Hybrid L24 electrodes were inserted into 18 temporal bones by experienced otologic surgeons using a standard posterior tympanotomy approach. The implanted temporal bones were subsequently processed for histological assessment and the temporal bones showed no evidence of trauma. Results also showed minimal resistance when inserting the electrode, full insertion depth could be achieved with a single stroke insertion, and the electrode did not buckle in the proximal region. The electrode therefore is considered to perform in human temporal bones in a safe and acceptable way.

Mechanical Robustness and Environmental Testing*:*
As the Hybrid L24 implant uses the same stimulator and coil assembly as the CI24RE cochlear implant, environmental tests performed on the CI24RE may be applied with confidence to the

Hybrid L24 implant. The only difference between the two implants (the intracochlear electrode array) had no possible impact on the environmental test results. The Hybrid L24's intracochlear electrode array was subjected to the following mechanical robustness testing:

- Multiple insertion testing
  Five Hybrid L24 electrode arrays were subjected to 50 insertion and removal cycles. All samples passed the mechanical and electrical acceptance criteria after the insertion and removal cycles.

- Linear and Angular Fatigue Test of the Electrode Array
  A total of 12 units were exercised through +/- 30º angular (four units) and +/- 10% of electrode length (eight units) at about 2 cycles per second, in a number of different test planes. The samples passed 2.5 million cycles, while maintaining continuity and showing no visible signs of damage.

- Severe Stress and Twist of the Electrode Lead:
  2 electrode leads were stretched by 10% and rotated 360º clockwise and 360º counter-clockwise over 10 cycles. The samples maintained continuity and showed no visible signs of damage.

- Severe Electrode Lead Shear Test:
  2 electrodes leads were clamped at a 90º angle to the longitudinal axis of the implant (all four possible orientations were tested). The face of the shear tool was placed perpendicular to the electrode lead at a distance of 1.2 mm from the titanium case. Electrical continuity of the lead was monitored, while the shear tool was pushed slowly (0.1mm/s) to the lead. The samples maintained continuity and showed no visible signs of damage.

Charge-Density Calculations: Taking into account the area and periphery of the smallest electrode surface, charge density calculations were completed to assure safe current stimulation by electrodes in the cochlea.

**External Components and Remote Assistants:**

Mechanical Robustness and Environmental Testing

- Cold Test
  The units were exposed to conditions specified in IEC 60068-2-1 Part 2 Test Ab: Starting Temperature: Ambient; Rate of Change: <1°C/min (Averaged over 5 min); Test Temperature: -40°C ± 3°C for 16 hours, all units were fully functional and no damage was noted.

- Dry Heat
  The units were exposed to conditions specified in IEC 60068-2-1 Part 2 Test Bb: Starting Temperature: Ambient; Rate of Change: <1°C/min (Averaged over 5 min) worksheet to

record rate; Test Temperature: +70°C ± 2°C for 16 hours, all units were fully functional and no damage was noted.

- Thermal Cycling
  The units were exposed to conditions specified in IEC 60068-2-1 Part 2 Test Nb: Temperature Range: -40°C to 70°C; Rate of Change: 1°C ± 0.2°C/min; Number of Cycles: 2; Exposure Time at Endpoints: 3 hours per cycle, all units were fully functional and no damage was noted.

- Cyclic Damp
  Samples were exposed to conditions specified in IEC 60068-2-1 Part 2 Test Dd: 55°C ± 2°C, 93±3% RH, for 12 hours, then 25°C ± 3°C, 95% RH, for 12 hours and repeated for a total of 6 cycles, with no significant damage noted.

- Low Pressure
  Samples were placed in a pressure chamber set at 100 hPa (7.25 psi) ± 5 % for 1 hour with no significant damage noted and all units remaining fully functional.

- Random Vibration
  Samples were subjected to random vibration (BS EN 45502-1:1998, Section 23.2 as per IEC 60068-2-64 Ed. 2.0 b:2008, Test Fh) at a frequency bandwidth of 5 to 150 Hz at an accelerated spectral density of $0.1g^2$/Hz for 30 minutes, across three orthogonal planes. No physical or electrical damage was observed.

- Free Fall
  Samples were subjected to a free fall drop test (EN 45502-2-3:2010, Section 23.1 as per IEC 60068-2-31 Ed. 2.0, 2008-05, Test Ec). The components remained fully functional.

- Ingress Protection Testing: External Components Only
  IP44 testing was conducted per IEC 60529 Ed. 2.1 b:2001. All configurations passed the testing.
  IP57 testing was conducted using the rechargeable battery pack per IEC 60529 Ed. 2.1 b:2001 All configurations passed the testing.

- Clamp Force
  External retention components were subjected to a test using a bite test clamp positioned in an Instron force tester. The force was gradually increased from 0 at a rate of 10N per second until the bite force reached 140N, and held for 5 seconds. The acceptance criteria were met and the samples showed no visible signs of significant damage.

- Overmould Strength Test
  Using a test jig and an Instron force tester, the strength of the overmould on external retention devices was analyzed by increasing force using a displacement rate of 1mm per second. Acceptance criteria were met and the maximum force reached during delamination of parts was greater than 30N.

- Retention Tests
  Several tests were set up to measure the force it takes to detach retention components. Acceptance criteria were met and the test subject was only detached with a force >22.5N.

- LED Light Test
  A light meter was used to measure sound processor LED alert light levels. Acceptance criteria were met and light levels were maintained between 100 and 1500 lux.

Electrical Testing – External Components

- Electrical Basic Functionality
  Verification testing demonstrated that the general electronic hardware of the CP900 series externals function in the manner intended.

- RF Link Electrical Verification
  Verification testing demonstrated that the RF link functions as intended, transmitting data and power from the sound processor to the implant.

- Mobile Phone Compatibility and RF Immunity
  Verification testing demonstrated the compatibility of the CP900 Sound Processor and devices that emit RF radiation.

- Radio Testing
  Verification testing demonstrated that the CP900 series sound processor meets the radio regulations (47 CFR Part 15, RSS – 210 issue 8, EN 300 328 as per R&TTE Directive 199/5EC and CEPT/ERC 70-03).

- EMC
  Verification testing demonstrated that CP900 Series meets EMC requirements: Radiated Emissions (CISPR 11), Electrostatic Discharge (IEC 61000-4-2), Radiated RF Field (IEC 61000-4-3), Conducted RF Disturbances (IEC 61000-4-6), Power Frequency Magnetic Field (IEC 61000-4-8), and Immunity (EN 45502-2-3 Clause 27.2 and Clause 27.3), Immunity of Hearing Aids to interferences generated by a wireless phone (IEC60118-13:2011).

- Wireless Range
  Verification testing demonstrated that the wireless range of the CP900 series functions as intended for patient use.

Electrical Testing – Remote Assistants

- Basic Functionality
  Verification testing demonstrated that the general electronic hardware of the remote assistants functions in the manner intended.

- EMC
  Verification testing demonstrated that the remote assistants meet CISPR11.

- Wireless Link, Immunity to RF
  Verification testing demonstrated accordance to FDA Draft Guidance (Radio Frequency Wireless Technology in Medical Devices, 2007) and IEC61000-4-3 procedure with a 20V/m level to simulate anticipated interference in a surgical operating theatre.

- Wireless Range Verification
  Verification demonstrated that the wireless range of the remote assistants function as intended for patient use.

- Radio Compliance
  Verification testing demonstrated the remote assistants function with firmware as intended.

Lithium Ion Battery Testing

- UL 1642
  5 samples of each lithium ion battery (compact and standard) were subjected to verification testing according to UL 1642. Acceptance criteria were met.

- IEC 62133
  Compact and Standard lithium ion batteries were subjected to verification testing according to IEC62133. Acceptance criteria were met.

**Hybrid L24 End to End Acoustic Verification Testing**
End-to-end testing including electrical and acoustical verification, acoustical system behavior and listening tests were completed to verify that the Hybrid L24 system functions as intended. Results demonstrate that the System functions as intended and is acceptable for clinical use.

**Biocompatibility**
Intracochlear Electrode Array:
All materials used in the Hybrid L24 are identical to those used in the CI24RE series introcochlear electrode arrays. The manufacturing process is also unchanged, along with the facilities used, such as cleanrooms, sterilization tools, and sealing machines. Given the changes in design have resulted in no change to manufacturing materials, processes, or equipment, biocompatibility testing performed on the CI24RE series implants may be applied with confidence to the Hybrid L24 implant.

CP900 External Components and Remote Assistants:
Biological evaluations/tests were conducted according to ISO 10993-5 and ISO 10993-10. No failures were observed. The materials contained within the CP900 system are therefore safe for use.

**Sterilization**

The Hybrid L24 implant has been adopted in Cochlear's Validated EtO Sterilization Process according to AAMI TIR28:2009, therefore demonstrating compliance with EN556-1:2001, ISO 11135-1:2007, ETO residual safety per ISO10993-7:2008 and the requirements for medical device packaging per ISO11607-1:2006.

## X. SUMMARY OF CLINICAL STUDY

A clinical study of the Nucleus Hybrid L24 Implant System was done in support of marketing approval for the device (IDE No. G070191). In this study, a previous generation sound processor, the Freedom Hybrid, was used; however, the newer Nucleus 6 Sound Processor that is being marketed as the external portion of the system is equivalent or better in both electric and acoustic stimulation capability.

### *Pivotal Clinical Study Design*

Major Design Characteristics

The clinical study that formed the basis for FDA's finding that the Nucleus Hybrid L24 Implant System is safe and effective for its intended use was a prospective, multi-center repeated-measures study with both objective and subjective performance data collected. There were 10 participating investigational sites from across the United States:

- NYU Medical Center in New York, New York
- Midwest Ear Institute in Kansas City, Missouri
- Mayo Clinic in Rochester, Minnesota
- Hearts for Hearing in Oklahoma City, Oklahoma
- Northwestern University in Chicago, IL
- Ohio State University in Columbus, Ohio
- Rocky Mountain Ear Center in Denver, Colorado
- University of Cincinnati in Cincinnati, Ohio
- University of Iowa in Iowa City, Iowa
- Center for Hearing and Balance in Chesterfield, Missouri

Due to the nature of cochlear implantation, the study could not be blinded. It was a single subject design where each subject served as his/her own control was utilized. This allows for comparison of preoperative performance with hearing aid(s) to postoperative performance with the Nucleus Hybrid L24 Implant System, with and without use of an additional hearing aid in the contralateral (non-implant) ear.

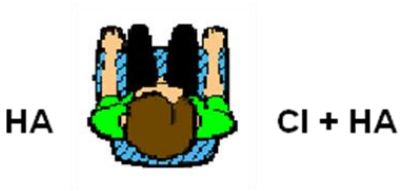
Data were collected preoperatively with hearing aid(s), and post-implantation with the Hybrid device in several listening configurations at the time of activation of the device, and at 3-, 6-, and 12-month postactivation intervals. Measurement of unaided (acoustic) hearing thresholds was accomplished over time to examine effects of the device on residual hearing sensitivity. Primary efficacy data were speech recognition scores in both quiet and background noise. Additional efficacy data were collected via a music perception test and subjective questionnaires.

Test conditions were defined as follows:

- Hybrid Stimulation – use of acoustic hearing, via amplification, in addition to electric hearing via a cochlear implant in the same ear

- Bimodal Stimulation – use of acoustic hearing, via amplification, in addition to electric hearing via a cochlear implant in the opposite ear

- Combined Stimulation (Everyday use) – use of acoustic hearing bilaterally, via amplification, in addition to electric hearing via a cochlear implant. That is, a combination of the Hybrid and Bimodal conditions




Clinical Endpoints and Success/Failure Criteria

The primary clinical endpoint for efficacy analysis was measured at 6 months postactivation because it has been well established that most cochlear implant recipients show progressive improvement in speech scores across the first 6 months after activation of their implant system. Secondary endpoints were defined to reflect individual subject improvements and to lend consistency to the trial results. Safety data were collected for the duration of the study.

Specifically, the co-primary efficacy endpoints for this study were the assessment of statistical significance of the within-subject differences for two speech recognition tests:

- Word and phoneme recognition in quiet as evaluated with the Consonant-Nucleus-Consonant (CNC) test (Peterson and Lehiste, 1962)[1]
- Sentence recognition in noise as evaluated with the AzBio test (Spahr *et al.*, 2011)[2].

Scores on both speech tests were obtained at the 6-month postactivation interval in the implanted ear with the device in Hybrid mode (acoustic-electric stimulation to the implant ear)[3], and

[1] Peterson, F, & Lehiste, I. (1962). J Speech Hearing Dis, 27(1): 62-70.
[2] Spahr, A, Dorman, M., Litvak, L, Van Wie, S, Gifford, R *et al.* (2011). Ear Hear 33(1): 112-117..
[3] Scores obtained in the cochlear implant (electric)-alone mode were used in place of Hybrid mode for those subjects who could not make of use of the acoustic component with the Hybrid device due to having acquired a profound or total hearing loss.

compared with preoperative assessment using a hearing aid in the implant ear. The primary endpoints were that mean performance with each of these measures would show significant benefit with use of the Hybrid device compared to the preoperative amplification condition.

The co-secondary efficacy endpoints were also measured at the 6-month postactivation interval. Specifically, the secondary endpoint would be met if more than 75% of subjects scored equal to or better in the Hybrid mode than preoperatively in the hearing-aid-alone condition on the CNC test, and that 75% would score equal to or better in the Hybrid mode than preoperatively with a hearing aid alone on the AzBio test.

Statistical Analysis Plan

*Sample Size Justification*

The sample size needed to achieve sufficient power to reject the null hypothesis was determined based on previous clinical trial data for earlier Hybrid implant models and the same or similar speech recognition test materials. Since a nonparametric test was to be used in the event of significant evidence of non-normal outcome data for the co-primary endpoints, a sample size 10% greater than that of a simple paired-mean comparison test was calculated due to the expected loss of power with a nonparametric test. Further, to protect against a loss of power due to missing data if some subjects were lost to follow-up, an additional 10% increase in the sample size was allowed for. Under these assumptions, the minimum sample size necessary to achieve 90% power for the two co-primary endpoints was 47, and thus the final sample size planned for this trial, 50 subjects, exceeded the minimum requirement for statistical power to provide assurance of adequate statistical power and greater justification for generalizability to the wider clinical population.

*Primary Efficacy Endpoint Analyses*

The significance of the mean differences in speech recognition scores between preoperative and the 6-month postoperative interval were analyzed using paired t-tests. The level of significance for these one-sided tests was 0.025. If there was significant evidence that the assumptions of the t-tests did not hold (i.e., $p < 0.05$ from a Shapiro-Wilk test of normality), then Wilcoxon signed-rank tests were used.

*Safety Data Analyses*

All adverse events were tabulated for number and frequency of events, with corresponding 95% exact binomial confidence limits and the number of events per patient-time (e.g., events per 10 patient years). This was compared qualitatively to previous cochlear implant studies. Time to first adverse event was summarized using Kaplan-Meier plots. Exploratory proportional hazards regression models were used to determine whether baseline factors were associated with risk for adverse events over the course of the study. Hazard ratios and 95% confidence intervals for these analyses were cited.

Individual audiometric data were examined across test intervals to assess any changes in hearing sensitivity and to characterize the impact of the procedure on residual hearing sensitivity in the low frequencies.

*Handling of missing data*

For primary analyses, missing 6-month postactivation data were imputed using the last-value – carried-forward approach. Sensitivity analyses were performed to assess the robustness of results to different assumptions underlying the missing data.

For the co-primary endpoints, both a best-case and worst-case analysis were performed. The most favorable (best-case) and least favorable (worst-case) change in CNC and AzBio scores observed in the complete data set were imputed for any missing values and the data re-analyzed using the full data with the imputed data added.

*Subgroup analyses and pooling results across sites*

The consistency of the primary endpoints was examined across subgroups of subjects defined by the following baseline characteristics: gender, race, duration of severe-to-profound hearing loss, baseline CNC scores, and previous history of otologic surgery. Similarly, the consistency of the primary endpoints was examined across investigational sites by testing for an effect of site in an ANOVA model. Potential variation between sites in the primary endpoints was explored by assessing whether or not there were differences in baseline characteristics between subjects at sites that might explain the results.

A specific subgroup of particular interest was subjects who experienced decreases in their low-frequency acoustic hearing thresholds postoperatively. To examine these subjects, analyses were performed on the primary endpoint (6 months postactivation) speech perception and music perception measures, separately for subjects with varying degrees of low frequency hearing loss; i.e. mild (26 through 40 dB HL), moderate (41 through 55 dB HL), moderate-severe (56 through 70 dB HL), severe (71 through 90 dB HL), profound (91+ dB HL), or total (no measurable hearing). This analysis was also performed based on outcomes at 3- and 12-month postactivation intervals.

Exploratory analyses were performed to determine if there were any factors predictive of low-frequency hearing loss, including duration of hearing loss, gender, and age. Additional exploratory analyses were also done to provide information regarding preservation of residual hearing with shorter electrode array models in general, by incorporating data from two other previous clinical studies: G990155 (Hybrid S8 cochlear implant) and G070016 (Hybrid S12 cochlear implant).

*Other Speech Recognition Assessments*

Device efficacy was also assessed for the Combined listening mode; i.e., use of the Hybrid device on the implant ear with acoustic input, combined with use of a hearing aid on the other

ear[4]. Specifically, within-subject differences in CNC and AzBio scores at postoperative intervals were compared to those measured preoperatively with bilateral hearing aids. The intention of these analyses was to provide an evaluation of outcomes for subjects using their "everyday" listening configuration of a Hybrid cochlear implant combined with a hearing aid in the non-implant ear.

To examine the impact of adding acoustic stimulation to the implant ear, a Cochlear Implant (electric)-alone condition was also evaluated, but only using the CNC test. Finally, a third speech recognition measure obtained was a 12-item forced choice spondee Speech Recognition Threshold (SRT) in noise test, measured in an adaptive paradigm to determine the signal-to-noise ratio (SNR) for 50% correct. These tests were only obtained preoperatively and at the 6-month postoperative interval.

*Assessment of Music Perception and Subjective Benefit*

Music perception ability was evaluated using the University of Washington Clinical Assessment of Music Perception (UW-CAMP) test battery. The UW-CAMP consists of three subtests each designed to provide an assessment of fundamental auditory skills important for music perception. One subtest provides an assessment of pitch perception, the second provides an assessment of melody recognition and the third subtest assesses the perception of timbre. The test battery also includes a questionnaire to evaluate music background and as well as appreciation of music.

Within-subject differences for the UW-CAMP music test scores in the Hybrid and Combined modes at the 6-month interval were compared to those taken in the preoperative unilateral and bilateral hearing aid conditions, respectively. Results were compared to outcomes for subjects using traditional cochlear implants to examine the usefulness to music perception of preserving low-frequency acoustic hearing in Hybrid cochlear implant recipients.

Finally, several questionnaires were used to assess perceived (subjective) benefit. They were administered preoperatively for bilateral hearing aid use, and postoperatively for the everyday listening mode (Combined mode for most subjects). Scores from these metrics provided secondary measures of device efficacy.

The questionnaires were:

- The Speech, Spatial, and Qualities of Speech Questionnaire or SSQ (anchored) [5], a self-assessment tool with three categories (speech hearing rating scale, spatial rating scale, and sound qualities rating scale).
- An "in-house" designed device usability metric, the Device Use Questionnaire or DUQ, used to determine subjective preferences with regards to device use in various listening environments.
- The Musical Background Questionnaire (MBQ[6]) adapted, given as a self-assessment tool that examines musical training prior to hearing loss, listening

[4] Scores obtained in the Bimodal mode will be used in place of Combined mode for those subjects who could not make use of the acoustic component of the Hybrid device due to having acquired a profound or total hearing loss.
[5] Noble, W. & Gatehouse, S. (2004). The Speech, Spatial and Qualities of Hearing Scale (SSQ). Intl J Audiol, 43(2), 85-99.

habits, quality and satisfaction of listening to music aided, and enjoyment of musical styles and different instrument timbres.

***Study Design***

Clinical Exclusion and Inclusion Criteria

Enrollment in the Hybrid study was limited to subjects who met the following selection criteria:

*Criteria for Inclusion:*

1. Eighteen years of age or older at the time of implantation.
2. Severe to profound (a threshold average of 2000, 3000, & 4000 Hz $\geq$ 75dB HL) sensorineural hearing loss for frequencies > 1500 Hz. Low-frequency thresholds up to and including 500 Hz should be no poorer than 60 dB HL. (See Figure 2).
3. CNC word recognition score (mean of two lists) between 10% and 60%, inclusive (i.e., 10% ≤ score ≤ 60%), in the ear to be implanted.
4. CNC word recognition score in the contralateral ear equal to, or better than, the ear to be implanted but not more than 80%.
5. English spoken as a primary language.

*Criteria for Exclusion:*

1. Duration of severe-to-profound hearing loss greater than 30 years.
2. Congenital hearing loss (for the purpose of this study, onset prior to 2 years-of-age).
3. Medical or psychological conditions that contraindicate undergoing surgery.
4. Ossification or any other cochlear anomaly that might prevent complete insertion of the electrode array.
5. Conductive overlay of 15 dB or greater at two or more frequencies, in the range 250 to 1000 Hz.
6. Hearing loss of neural or central origin.
7. Diagnosis of Auditory Neuropathy.
8. Active middle-ear infection.
9. Unrealistic expectations on the part of the subject, regarding the possible benefits, risks, and limitations that are inherent to the surgical procedure(s) and prosthetic devices.

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[6] Gfeller, K., Christ, A., Knutson, J. F., *et al.* (2000). Musical Backgrounds, Listening Habits, and Aesthetic Enjoyment of Adult Cochlear Implant Recipients. J Am Acad Audiol, 11, 390-406.

10. Unwillingness or inability of the candidate to comply with all investigational requirements.
11. Additional handicaps that would prevent or restrict participation in the audiological evaluations.

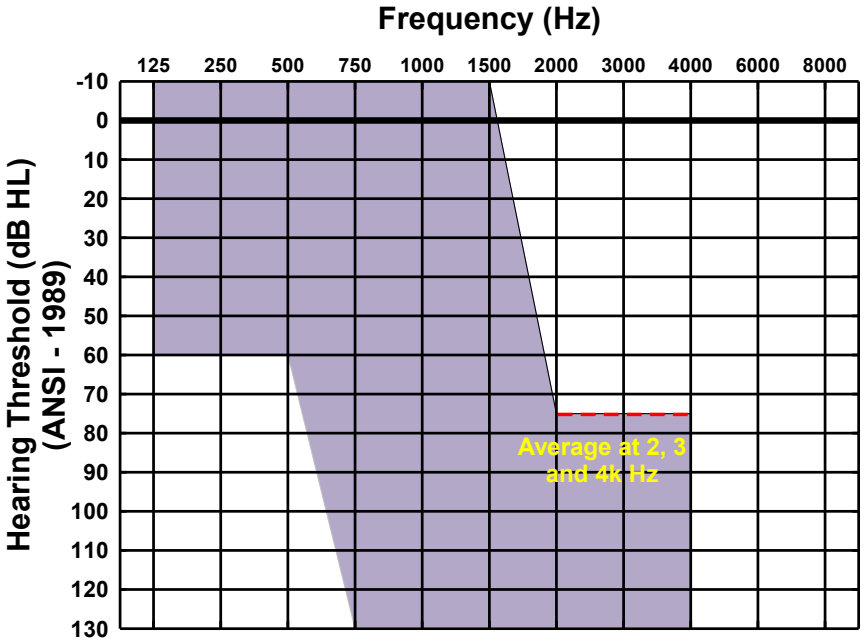


**Figure 2: Audiogram range for the subjects participating in the clinical trial**

*Brief Summary of Treatment and Follow-Up Protocols*

Table 1: Assessments/tasks completed at each test session summarizes the assessments/tasks completed at each test session. The investigation intervention involved pre-treatment assessment of candidacy, enrollment into the study, sasurements, implantation surgery, a healing period followed by fitting of the sound processor and activation of the implant (at 1-month postoperatively), and three post-treatment evaluations at approximately 3- 6- and 12-months postactivation.

The implantation surgery was similar to the procedures used for conventional cochlear implants, and utilized a cochleostomy approach. Intraoperative impedance telemetry was performed to verify electrode array integrity. The postoperative hospital stay was variable as determined by the surgeon. All surgical or device-related adverse events were recorded for the duration of the study.

Preoperatively, candidates were assessed in the unaided and aided (i.e., with hearing aids) conditions, unilaterally and bilaterally, to evaluate their appropriateness for entrance into the study and to establish baseline measures. Postoperatively, hearing thresholds in the implant ear were assessed at each test interval to examine the impact of the implant surgery on residual hearing preservation. Speech recognition testing was done in several unilateral and bilateral listening modes, including Hybrid (electric-acoustic [EAS] stimulation), Cochlear

Implant (CI/electric)-alone, Combined (Hybrid in the implant ear plus a hearing aid in the contralateral ear), and Bimodal (CI-only in the implant ear plus a hearing aid in the contralateral ear). Music perception was tested using the UW-CAMP in unilateral and bilateral modes. Subjective questionnaires asseed subjects' performance in everyday listening condition.

For CNC testing, two lists of words were presented at 60 dB A in quiet. Scores were obtained for both word and phoneme percent correct. For AzBio testing, two lists of sentences were presented in background noise with the target sentences fixed at 60 dB A and a fixed SNR of +5 dB (noise at 55 dB). The SRT in noise test was presented with target stimuli at 60 dB A from 0° azimuth (frontal) in a background of broadband noise or two competing talkers presented at +/- 90° azimuth (loudspeaker to the right or left). The UW-CAMP test battery was presented at 65 dB A.

**Table 1: Assessments/tasks completed at each test session**

| | Baseline Evaluation | Initial Device Activation | 3-month Postoperative | 6-month Postoperative | 12-month Postoperative |
|---|---|---|---|---|---|
| Informed Consent | X | | | | |
| Medical and Hearing History | X | | | | |
| Verification of Hearing Aid functioning | X | | X | X | X |
| Unaided Hearing Thresholds and Tympanometry | X | X | X | X | X |
| Aided Audiometric Thresholds | X | X | X* | X* | X* |
| Aided CNC test in quiet | X | | X | X | X |
| Aided AzBio sentences-in-noise test | X | | X | X | X |
| Adaptive SRT in noise | X | | | X | |
| Aided UW-CAMP music perception | X | | | X | |
| Questionnaires (SSQ, DUQ, MBQ) | X | | | X | X |
| Psychophysical Ts and Cs and electrical impedance | | X | X | X | X |
| Adverse event reporting | X | X | X | X | X |

*Aided thresholds were only retested if there was a change in unaided hearing sensitivity at that interval compared to the previous interval.

B. Accountability of PMA cohort

One hundred subjects were consented to be evaluated for participation in the clinical study, but only 50 were enrolled and implanted. Of the 100 subjects:

- 22 failed the screening because they did not meet study requirements.
- 28 were potential candidates, but withdrew and/or did not proceed with implantation either because they were unable to secure insurance, they decided to pursue other options (nonsurgical or a traditional cochlear implant), or the maximum number of study subjects had already been reached prior to their implant surgery.

Of the 50 subjects who were implanted:

- 50 subjects had devices activated and completed the 3-month postactivation test interval.
- 49 subjects completed the 6-month evaluation (primary endpoint).
    - One subject did not reach the 6-month test interval because he was reimplanted with a conventional cochlear implant (Nucleus Freedom) due to loss of residual hearing sensitivity.
- 46 subjects completed the 12-month evaluation, the final visit for collection of safety and effectiveness data to serve as the basis for the PMA submission, and the time of database lock.
    - Two subjects withdrew from the study prior to the 12-month test interval because they were diagnosed with serious medical conditions (pancreatic cancer for one, and advancing dementia for the other) unrelated to the device or procedure.
- One subject did not reach the 12-month test interval because he was also reimplanted with a conventional cochlear implant (Nucleus Freedom) due to loss of residual hearing sensitivity between 6 and 12 months postoperatively.

C. Study Population Demographics

Key demographics of the study population are shown in Table 2.

**Table 2: Demographics for the 50 study subjects**

| Variable | Mean | Standard Deviation | Range |
|---|---|---|---|
| Age at implantation (years) | 64 | 15 | 23 – 86.2 |
| Duration of hearing loss of any degree (years) | 28 | 15 | 6 - 84 |
| Duration of severe-to-profound high-frequency hearing loss (years) | 13 | 7 | 1.6 – 30.1* |
| | **Male** | **Female** | |
| Gender | 50% | 50% | |

* One subject met the requirement of <30 years duration of severe to profound high-frequency loss at candidacy assessment but was slightly over 30 years duration by the time surgery was completed.

D. Safety and Effectiveness Results

*Safety*

Adverse Events

The primary safety endpoint was defined as any surgical and/or device-related event, to be reported as the number and proportion of individuals experiencing the adverse event across the duration of the study. There were no unanticipated adverse events.

This study involved implanting subjects with residual low-frequency hearing so, for the purposes of adverse event reporting, any change in hearing that resulted in a profound (> 90 dB HL) or total (no measurable hearing) loss of low-frequency hearing (averaged over the frequency range 125 through 1000 Hz inclusively) in the implanted ear was considered an anticipated adverse event and included in the adverse event tabulations and analyses. Adverse events observed during the clinical study are shown in Table 3 below. Some subjects had more than one event, so the number occurring does not necessarily represent the number of subjects impacted.

**Table 3: Adverse Events**

| Adverse Event | Number Occurring | Number Resolved/Closed |
|---|---|---|
| ***Profound/Total loss of hearing*** | 22 | 0 |
| ***Increased Tinnitus*** | 6 | 6 |
| ***Tinnitus not present preoperatively*** | 6 | 6 |
| ***Increased tinnitus with change in hearing*** | 2 | 2 |
| ***Device Related (Opens/Shorts)*** | 11 | 11 |
| ***Dizziness*** | 3 | 3 |
| ***Dizziness with change in hearing*** | 2 | 2 |
| ***Imbalance*** | 1 | 1 |
| ***Imbalance with change in hearing*** | 1 | 1 |
| ***Vertigo*** | 1 | 1 |
| ***Vertigo with change in hearing*** | 1 | 1 |
| ***Sound Quality Issues*** | 2 | 2 |
| ***Decreased Performance*** | 1 | 1 |
| ***Increased impedances with change in hearing sensitivity*** | 1 | 1 |
| ***Overstimulation*** | 1 | 1 |
| ***Other**** | 4 | 4 |

** "Other" includes 2 reports of transient skin irritation due to externals, 1 case of pain associated with middle ear effusion, and 1 case of a local stitch infection.*

These adverse events and their rate of occurrence are consistent in character and severity to those reported for conventional cochlear implants.

Acoustic Hearing Preservation

Forty-eight[7] subjects completed audiometric assessments for the 6-month postactivation primary endpoint. Comparing preoperative to postoperative thresholds using a five frequency average from 125 through 1000 Hz inclusively:

- 27 experienced a decrease in low-frequency hearing ≤ 30 dB
  - 12 experienced a decrease in low-frequency hearing ≤ 10 dB
  - 12 experienced a decrease in low-frequency hearing >10 and ≤ 20 dB
  - 3 experienced a decrease in low-frequency hearing >20 and ≤30 dB
- 21 experienced a decrease in low-frequency hearing > 30 dB

Over the entire study period, 28 of 50 subjects experienced changes in low-frequency hearing of more than 30 dB. Four of these cases improved such that low-frequency thresholds were again within 30 dB of preoperative levels as of the most recent evaluation for each subject.

Table 4 below summarizes the low frequency pure tone average categorized by degree of loss experienced by the subjects at the end of the study.

**Table 4: Low frequency pure tone average categorized by degree of loss at study end**

| **Degree of Low Frequency Pure Tone Average (125-1kHz)** | **Number of Subjects** |
|---|---|
| Moderate (41 through 55 dB HL) | 15 (31%) |
| Moderate to Severe (56 through 70 dB HL) | 9 (19%) |
| Severe (71 through 90 dB HL) | 9 (19%) |
| Profound (> 90 dB HL) | 10 (21%) |
| Total (Nonmeasurable) | 5 (10%) |

*Effectiveness*

Primary Endpoint Analyses

All primary endpoints were met.

The pre- to postoperative change for the Hybrid mode at the 6-month postactivation endpoint failed the Shapiro-Wilk test for normality ($p < 0.05$) and was therefore subjected to a Wilcoxon signed-rank test for both the CNC and AzBio measures. As shown in Table 5 below, significant improvement was noted for both test measures. On average, subjects experienced a significant improvement of 36.6% for CNC word recognition and 32.8% for AzBio sentences in noise.

[7] One subject evaluated at 3 months with a profound loss of hearing and was not assessed audiometrically at 6 months (but was assessed for efficacy). Another subject, also evaluated at 3 months with a profound loss of hearing, withdrew prior to the 6-month evaluation.

**Table 5: Statistical summary for co-primary endpoints**

| (N=49)[#] | Acoustic Alone Preoperative | Hybrid Mode 6 Months Postactivation | Percentage Point Change | P-Value* |
|---|---|---|---|---|
| | Mean ± S.D. | Mean ± S.D. | Mean ± S.D. (95% C.I) | |
| **Word scores** | 28.8% ± 14.6% | 65.4% ± 25.4% | 36.6 ± 26.2 (29.1, 44.1) | p < 0.0001 |
| **AzBio scores** | 16.3% ± 14.4% | 49.2% ± 30.8% | 32.8 ± 29.1 (24.5, 41.2) | p < 0.0001 |

[#] One subject withdrew prior to the 6-month interval and was not included in the analyses.
*Signed-rank p-value

The 3-month data for the one subject who did not reach the 6-month testing period due to reimplantation with a conventional cochlear implant after loss of residual hearing was carried forward as per the statistical analysis plan.

Secondary Endpoint Analyses

Secondary efficacy endpoint analyses were based on binomial comparisons[8] of pre- and postoperative speech scores for the CNC test, scored for both word and phoneme correct, and the AzBio test. Binomial comparisons of individual scores obtained in the Hybrid mode at 6 months postactivation (key endpoint) were compared with those obtained preoperatively with a hearing aid in the ear to be implanted, to determine the proportion of subjects performing equal to or better than the preoperative untreated condition.

**As shown in**

Table 6, the secondary endpoints (>75% scoring equal to or better than preoperative) were met and exceeded for both metrics. When the Combined mode at 6 months is considered in the analysis, an even higher proportion of subjects show significant improvement. Table 7 shows the proportion of subjects with postoperative score better than preoperative at the 6 month study interval.

[8] Thornton, A.R. & Raffin, M.J.M. (1978). Speech discrimination scores modeled as a binomial variable. J Speech Hear Res, 21: 507 518.

**Table 6: Proportion of subjects with postoperative score equal to or better than preoperative at the 6 month study interval**

| Listening Mode: | CNC Words | CNC Phonemes | AzBio in Noise |
|---|---|---|---|
| **Hybrid (Study Endpoint)** | 96.0% | 91.8% | 89.8% |
| **Combined (Everyday Use)** | 100% | 100% | 100% |

**Table 7: Proportion of subjects with postoperative score better than preoperative at the 6 month study interval**

| Listening Mode: | CNC Words | CNC Phonemes | AzBio in Noise |
|---|---|---|---|
| **Hybrid (Study Endpoint)** | 81.6% | 85.7% | 73.5% |
| **Combined (Everyday Use)** | 87.8% | 89.9% | 83.7% |

Other Assessments

*Speech recognition at 6 months postactivation*

The co-primary efficacy endpoints for this study were the assessment of the within-subject difference in CNC words and AzBio sentences-in-noise parameters in the implanted ear at 6 months postactivation (with the device in Hybrid Mode[9]) compared with the preoperative assessment (Acoustic Alone).

[9] Scores obtained in the Hybrid cochlear implant alone mode were used in place of Hybrid Mode for those subjects who did not make of use of acoustic hearing in the implanted ear.

Speech perception data are available on 50 subjects, for at least one postoperative evaluation. Fifty subjects completed the 3-month postactivation interval, 49[10]/50 subjects completed the 6-month postactivation interval, and 46[11]/50 subjects completed the 12-month postactivation interval.

As shown in Table 8 below, significant improvement was noted for both test measures. On average, subjects experienced a significant improvement of 36.6 percentage points for CNC word recognition and 32.8 percentage points for AzBio sentences in noise.

**Table 8: Pre to post operative change at the 6 month postactivation endpoint**

| (N=49)[#] | Acoustic Alone Preoperative | Hybrid Mode 6 Months Postactivation | Percentage Point Change | P-Value* |
|---|---|---|---|---|
| | Mean ± S.D. | Mean ± S.D. | Mean ± S.D. (95% C.I) | |
| **Word scores** | 28.4% ± 14.7% | 65.4% ± 25.4% | 37.0 ± 26.6 (29.4, 44.6) | p < 0.0001 |
| **AzBio scores** | 16.3% ± 14.4% | 49.2% ± 30.8% | 32.8 ± 29.1 (24.5, 41.2) | p < 0.0001 |

*Student's t-test p-value; signed-rank p-value if normality assumption failed.
[#]One subject withdrew prior to the 6-month interval and was not included in the analyses.

*Speech recognition across time*

For the subjects with CNC data:

- Preoperative CNC word scores obtained with a unilateral hearing aid in the ear to be implanted ranged from 9% to 64%, with a mean score of 28.8% (N=50),
- At the 3 month postactivation test interval, performance in the Hybrid Mode[12] ranged from 3% to 93%, with a mean of 58.5% (N=50),
- At the 6-month endpoint, scores ranged from 8% to 98% with a mean of 65.4% (N=49), and
- At 12 months, scores ranged from 5% to 97% with a mean of 69.4% (N=46).

By 12 months postactivation, binomial comparisons of the Hybrid mode versus preoperative hearing aid showed that 86.7% of the 46 subjects performed significantly better ($p < .05$) postoperatively. Five subjects showed significant decrements and one subject showed no

[10] One subject withdrew prior to the 6-month interval. Another subject completed speech perception testing but did not complete an audiometric evaluation; hence the number of subjects at the 6-month evaluation is 49 for efficacy measures and 48 as for the hearing sensitivity data.
[11] One subject withdrew prior to the 6-month interval. Three subjects withdrew prior to the 12-month interval.
[12] For patients who had a profound or total loss of residual heating, preoperative hearing aid scores were compared with the postoperative Hybrid cochlear implant-alone condition.

significant pre- to postoperative change. All pre-to-postoperative mean differences were significant.

For everyday use (a combination of all available acoustic and electric stimulation) listening, the CNC data show:

- Preoperative CNC word scores obtained with bilateral hearing aids ranged from 2% to 81%, with a mean score of 44.9% (N=50),
- At the 3-month postactivation test interval, performance in the Combined mode [13] ranged from 27% to 96%, with a mean of 75.8% (N=50),
- At 6 months scores ranged from 35% to 98% with a mean of 79.4% (N=49), and
- At 12 months scores ranged from 44% to 98% with a mean of 82.0% (N=46).

All pre-to-post operative mean differences were significant (including the pre- to 6-month endpoint comparison) based on paired t-tests. By 12 months postactivation, binomial comparisons of the Combined mode versus the preoperative bilateral hearing aids score showed that 86.7% of the 46 subjects performed significantly better postoperatively. Six subjects showed no significant pre- to postoperative changes. No subject showed a significant decrement.

CNC phoneme recognition scores showed a similar trend to the word recognition scores.

For the subjects with AzBio data:

- Preoperative AzBio sentence scores obtained with a hearing aid in the ipsilateral ear (i.e., the ear to be implanted) ranged from 0% to 64.1%, with a mean score of 16.3% (N=50),
- At the 3 month postactivation test interval, performance in the Hybrid mode[14] ranged from 0% to 88.7%, with a mean of 44.6% (N=49),
- At 6 months scores ranged from 0% to 91.5% with a mean of 49.2% (N=49), and
- At 12 months scores ranged from 0% to 90.2% with a mean of 51.5% (N=46).

All pre-to-postoperative mean differences were significant based on paired t-tests. By 12 months postactivation, binomial comparisons of the Hybrid mode versus hearing aid preoperatively showed that 71.7% of the 46 subjects performed significantly better postoperatively. Five subjects showed significant decrements and 8 subjects showed no significant pre- to postoperative changes.

For everyday use (a combination of all available acoustic and electric stimulation), the AzBio data showed:

- Preoperative AzBio sentence scores obtained with bilateral hearing aids ranged from 0% to 76.5%, with a mean score of 29.6% (N=50),
- At the 3 month postactivation test interval, performance in the Combined mode[15] ranged from 0% to 97.3%, with a mean of 62.2% (N=48[16]),

[13] For subjects with total or profound hearing loss, the comparison was with the bimodal condition.
[14] For subjects with total or profound hearing loss, the comparison was with the cochlear implant-alone condition.
[15] For subjects with total or profound hearing loss, the comparison was with the bimodal condition.

- At 6 months scores ranged from 3.6% to 92.7% with a mean of 62.6% (N=49), and
- At 12 months scores ranged from 3.6% to 97.5% with a mean of 66.3% (N=46).

All pre-to-postoperative mean differences were significant based on paired t-tests. By 12 months postactivation, binomial comparisons of the Combined mode versus bilateral hearing aid scores preoperatively showed that 89.1% of the 46 subjects performed significantly better postoperatively. Three subjects showed no significant pre- to postoperative changes. Two subjects showed significant decrements.

*Efficacy Outcomes as a Function of Hearing Loss*

Mean preoperative (hearing aid in the implant ear) and 6-month postactivation (Hybrid mode[17]) unilateral CNC and AzBio scores as a function of the degree of low-frequency hearing loss were considered at the 6-month endpoint. Analysis of variance showed a significant effect for degree of hearing loss. That is, the degree of pre- to postoperative improvement did depend on the degree of acoustic hearing sensitivity maintained at the 6-month test interval. However, when using the Hybrid implant ear alone, significant improvement in speech perception is possible for all levels of hearing loss, albeit particularly for those subjects who maintained severe or better levels of hearing at the 6-month endpoint.

In their everyday listening, subjects use the Hybrid cochlear implant[18] in concert with a hearing aid in the contralateral, non-implant ear; i.e., the Combined listening mode. As shown in Figure 3, significant improvement was observed for the subjects using the Combined mode compared to their performance with bilateral hearing aids, across all degrees of postoperative hearing levels. Table 9 shows mean absolute scores as well as mean improvements on the CNC and AzBio test measures relative to the degree of postoperative hearing.

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[16]AzBio test at 3 months was not measured on one subject, and the score for one subjects was excluded as a statistical outlier.

[17] For subjects with profound or total hearing loss, the comparison was to cochlear implant-alone.

[18] For subjects with profound or total hearing loss, the comparison was to the Bimodal mode.

**Table 9: Mean absolute scores and as mean improvements on the CNC and AzBio test measures relative to the degree of postoperative hearing.**

| | Moderate | Moderate to Severe | Severe | Profound | Total Loss |
|---|---|---|---|---|---|
| **Mean Improvement on CNC** | 44.2% | 35.4% | 32.9% | 19.6% | 39.0% |
| **Mean Score on CNC** | 83.3% | 81.4% | 83.8% | 66.6% | 80.8% |
| **Mean Improvement on AZBio in noise** | 44.5% | 38.4% | 39.0% | 12.7% | 25.2% |
| **Mean score on AzBio in noise** | 73.4% | 70.5% | 62.5% | 44.1% | 58.7% |

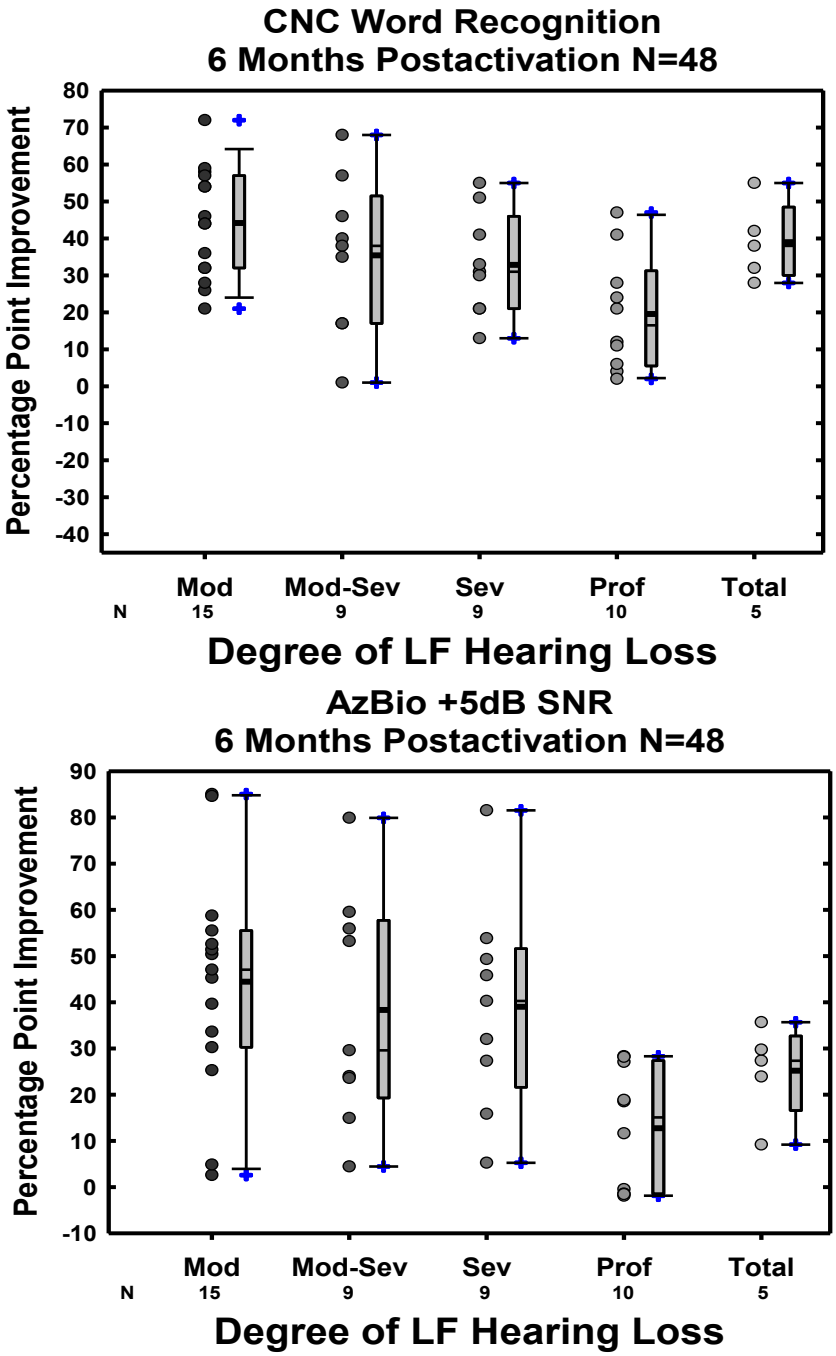


**Figure 3: Mean Pre-to 6-Month postactivation Combined Mode outcomes for the CNC word test (upper) and AzBio in Noise Test (lower), as a function of degree of hearing loss at the 6-Month endpoint**

*Aided Thresholds*

Aided thresholds were significantly better with the Hybrid cochlear implant than with preoperative amplification. All subjects in this study showed improvements in aided thresholds in the high frequencies because hearing aids were not able to overcome the severe to profound degree of their acoustic hearing impairment in this audiometric region.

*UW-CAMP*

The University of Washington Clinical Assessment of Music Perception (UW-CAMP) music test battery was used to assess music perception abilities. The UW-CAMP consists of three subtests each designed to provide an assessment of fundamental auditory skills important for music perception: pitch discrimination, melody recognition and timbre. The UW-CAMP was administered ipsilaterally for the implanted ear and bilaterally at the preoperative baseline and 6-month endpoint evaluations.

<u>Pitch</u>

In an ipsilateral condition:

- Average preoperative pitch discrimination thresholds obtained Acoustic Alone, with a hearing aid in the ipsilateral ear (i.e., the ear to be implanted), ranged from 0.5 to 4.8 semitones, with a mean of 1.1 semitones (N=50),
- At the 6 month postactivation test interval, performance in the Hybrid Mode (i.e., Cochlear Implant + Ipsilateral Acoustic[19]) ranged from 0.5 to 8.9 semitones, with a mean of 1.5 semitones (N=46[20]).

In a bilateral condition:

- Average preoperative pitch discrimination thresholds obtained in the Bilateral Acoustic condition, with bilateral hearing aids, ranged from 0.5 to 6.3 semitones, with a mean of 1.1 semitones (N=50),
- At the 6 month postactivation test interval, performance in the Combine Mode (i.e., Cochlear Implant + Bilateral Acoustic[21]) ranged from 0.5 to 3.7 semitones, with a mean of 1.1 semitones (N=46[20]).

Normally hearing individuals can discriminate tones that are 1 semitone apart on average, whereas traditional cochlear implant recipients require the tones to be 3 semitones apart, on average. Hybrid users performed at levels similar to that observed to normally hearing subjects and considerably better than that observed for the traditional cochlear implant users. In addition, the Hybrid users maintained their pitch discrimination abilities, on average pre- to postoperatively for the treated ear (Acoustic Alone vs. Hybrid Mode) and when considering

[19] For some subjects, the Hybrid Mode was not tested at 6 months as the best unilateral listening mode because the subjects experienced profound or total loss of hearing. Thus, preoperative Acoustic Alone scores were compared with the postoperative Hybrid cochlear implant alone as the best unilateral listening condition.

[20] The score for one subject did not save due to a software error, one subject was not assessed he did not understand the task (and was subsequently diagnosed with advancing dementia), another subject did not complete the test due to time constraints, and one subject was reimplanted prior to the 6-month interval.

[21] For some subjects the Combined Mode was not tested at 6 months as the best bilateral listening mode because the subjects experienced profound or total loss of hearing. Thus, preoperative Bilateral Acoustic scores were compared with the postoperative Bimodal Mode as the best bilateral listening condition.

scores for the bilateral condition (Bilateral Acoustic vs. Combined Mode). No significant changes ($p > 0.05$) were noted when comparing Acoustic Alone (preoperatively) and Hybrid Mode (two middle bars) as well as Bilateral Acoustic (preoperatively) and Combined Mode (two bars to the right).

Melody Recognition

- Implanted Ear
  - Preoperative melody recognition scores obtained Acoustic Alone ranged from 11.1% to 100%, with a mean of 66.2% (N=50),
  - At the 6 month postactivation test interval, performance in the Hybrid Mode[22] also ranged from 11.1% to 100%, with a mean of 65.9% (N=47[23]).
- Everyday Condition
  - Preoperative melody recognition scores obtained in the Bilateral Acoustic condition ranged 13.9% to 100%, with a mean of 66.3% (N=50),
  - At the 6 month postactivation test interval, performance in the Combined Mode[24] ranged from 16.7% to 100%, with a mean of 66.7% (N=46[25]).

The Hybrid users maintained their melody recognition abilities, on average pre- to postoperatively for the treated ear (Acoustic Alone vs. Hybrid Mode) and for the bilateral condition (Bilateral Acoustic vs. Combined Mode). No significant changes ($p > 0.05$) were noted when comparing Acoustic Alone (preoperatively) and Hybrid Mode as well as Bilateral Acoustic (preoperatively) and Combined Mode.

Timbre

In the ipsilateral condition:

- Preoperative timbre recognition scores obtained Acoustic Alone ranged from 12.5% to 91.7%, with a mean of 50.8% (N=50),
- At the 6 month postactivation test interval, performance in the Hybrid Mode[22] ranged from 8.3% to 100%, with a mean of 56.6% (N=47[23]).

In a bilateral condition:

[22] For some subjects, the Hybrid Mode was not tested at 6 months as the best unilateral listening mode because the subjects experienced profound or total loss of hearing. Thus, preoperative Acoustic Alone scores were compared with the postoperative Hybrid cochlear implant alone as the best unilateral listening condition.
[23] One subject was not assessed as this subject did not understand the task (and was subsequently diagnosed with advancing dementia), another subject did not complete the test due to time constraints, and another subject was reimplanted prior to the 6-month interval.
[24] For some subjects the Combined Mode was not tested at 6 months as the best bilateral listening mode because the subjects experienced profound or total loss of hearing. Thus, preoperative Bilateral Acoustic scores were compared with the postoperative Bimodal Mode as the best bilateral listening condition.
[25] The score for one subject did not save due to a software error, one subject was not assessed as this subject did not understand the task (and was subsequently diagnosed with advancing dementia), one subject did not complete the test due to time constraints, and another subject was reimplanted prior to the 6-month interval.

- Preoperative timbre recognition scores obtained in the Bilateral Acoustic condition ranged 8.3% to 100%, with a mean of 56.2% (N=50),
- At the 6 month postactivation test interval, performance in the Combined Mode[26] ranged from 20.8% to 91.7%, with a mean of 57.0% (N=46[27]).

Hybrid users maintained their melody recognition abilities, on average pre- to postoperatively for the treated ear (Acoustic Alone vs. Hybrid Mode) and for the bilateral condition (Bilateral Acoustic vs. Combined Mode). No significant changes ($p > 0.05$) were noted when comparing Acoustic Alone (preoperatively) and Hybrid Mode as well as Bilateral Acoustic (preoperatively) and Combined Mode.

*Questionnaires*

SSQ

The Speech, Spatial, and Qualities of Speech Questionnaire or SSQ was administered as a self-assessment of hearing (dis)abilities across a range of listening situations that fall within three hearing domains. Forty-nine questions address various aspects of hearing: speech hearing (14 questions concerning hearing speech in a variety of listening situations), spatial hearing (17 questions concerning direction, distance and movement of sound and ability to segregate sounds), and sound qualities (18 questions concerning ease of listening, and naturalness, clarity, identification of different speakers, musical pieces and instruments as well as everyday sounds). Each question is scored by the reader using a line marked from 0 through 10, where 0 corresponds to minimal ability and 10 corresponds to complete ability.

Fifty subjects completed the SSQ preoperatively, 48 completed it at 6 months postactivation, and 46 completed it at the 12-month postactivation interval. For each subscale and the averaged total score, comparison was made between the preoperative and postoperative bilateral conditions[28].

*Speech Hearing Subscale*

- Preoperative SSQ scores obtained in the preoperative bilateral hearing aids condition ranged from 0.8 to 6.2, with a mean score of 3.2 (N=50).
- At the 6-month evaluation in the Combined mode, scores ranged from 0.7 to 8.8 with a mean of 5.4 (N=48[29]), and
- At 12 months, scores in the Combined mode ranged from 1.4 to 8.8 with a mean of 5.6 (N=46[30]).

[26] Note that for some subjects the Combined Mode was not tested at 6 months as the best bilateral listening mode because the subjects experienced profound or total loss of hearing.. Thus, preoperative Bilateral Acoustic scores were compared with the postoperative Bimodal Mode as the best bilateral listening condition.
[27] The score for one subject did not save due to a software error, one subject was not assessed as this subject did not understand the task (and was subsequently diagnosed with advancing dementia), one subject did not complete the test due to time constraints, and another subject was reimplanted prior to the 6-month interval.
[28] For subjects who had profound or total loss of hearing, the Bimodal mode was the postoperative comparison.
[29] Two subjects did not complete the SSQ at the 6-month evaluation before having revision surgery to receive a traditional cochlear implant.
[30] Two subjects did not complete the 12-month evaluations with the Hybrid cochlear implant after receiving traditional cochlear implants. Two subjects withdrew from the study for medical reasons.

Pre-to-postoperative mean differences were significant based on paired t-tests[31]. By 12 months postactivation, individual comparisons of the Combined mode score versus the bilateral hearing aids score preoperatively showed that 86.7% of the 46 subjects performed significantly better postoperatively. Five subjects showed a significant decrement and one subject showed no significant pre- to postoperative change.

*Spatial Hearing Scale*

- Preoperative SSQ scores obtained in the preoperative bilateral hearing aids condition ranged from 1.4 to 9.2, with a mean score of 4.5 (N=50),
- At the 6-month evaluation in the Combined mode, scores ranged from 1.1 to 8.3 with a mean of 5.5 (N=48[29]), and
- At 12 months, scores in the Combined Mode ranged from 1.6 to 8.5 with a mean of 5.7 (N=46[30]).

Pre-to-postoperative mean differences were significant based on paired t-tests. By 12 months postactivation, individual comparisons of the Combined mode score and preoperative bilateral hearing aids score showed that 86.7% of the 46 subjects with speech perception data available performed significantly better postoperatively. Five subjects showed a significant decrements and 1 subject showed no significant pre- to postoperative change.

*Sound Qualities Scale*

- Preoperative SSQ scores obtained in the Bilateral Acoustic condition ranged from 1.6 to 8.1, with a mean score of 5.0 (N=50),
- At the 6-month evaluation in the Combined mode, scores ranged from 2.7 to 9.1 with a mean of 6.3 (N=48[29]), and
- At 12 months, scores in the Combined Mode ranged from 2.5 to 8.9 with a mean of 6.5 (N=46[30]).

Pre-to-postoperative mean differences were significant based on paired t-tests. By 12 months postactivation, individual comparisons of the preoperative Combined mode score and preoperative bilateral hearing aid score showed that 86.7% of the 46 subjects performed significantly better postoperatively. Five subjects showed a significant decrement and one subject showed no significant pre- to postoperative change.

*Total SSQ Score*

- Preoperative SSQ scores obtained in the bilateral hearing aids condition ranged from 1.3 to 7.8, with a mean score of 4.2 (N=50),
- At the 6-month evaluation in the Combined mode, scores ranged from 2.5 to 8.5 with a mean of 5.7 (N=48[29]), and
- At 12 months, scores in the Combined mode ranged from 2.5 to 8.4 with a mean of 5.9 (N=46[30]).

[31] If there was significant evidence that the assumptions of the t-test were not met (i.e., $p < 0.05$ for a Shapiro-Wilk test of normality), a Wilcoxon signed-rank test was used instead.

Pre-to-postoperative mean differences were significant based on paired t-tests. By 12 months postactivation, individual comparisons of the postoperative Combined mode score and preoperative bilateral hearing aids score showed that 86.7% of the 46 subjects performed significantly better postoperatively. Five subjects showed significant decrements and 1 subject showed no significant pre- to postoperative change.

DUQ

An "in-house" designed device usability metric, the Device Use Questionnaire or DUQ, was administered to determine subjective preferences with regards to device use in various listening environments. Fifty subjects completed the DUQ preoperatively, 48[32] completed the DUQ at 6 months postactivation, and 46[33] completed the DUQ at the 12-month postactivation interval. A brief summary of key responses is given here.

Preoperatively, 76.0% reported the use of bilateral hearing aids as the overall preferred way of listening most of the time. Seventy-six percent also reported being "dissatisfied" or "very dissatisfied" with their hearing aid performance.

Postoperatively at 12 months, 65.2% preferred for everyday listening the Combined mode, 19.6% preferred the Bimodal mode, and 13.0% preferred listening in the Hybrid mode unilaterally. For adjusting to listening with the system, 80.4% reported that it was "very easy" or "moderately easy". A majority of subjects reported that sound was most pleasant and natural, and that overall ease of listening was greatest in the Combined mode. Of the 46 subjects, 78.2% reported being "very satisfied or satisfied" with their performance at 12 months with the Hybrid L24 implant system, and 80.4% reported being "very satisfied" or "satisfied" with their decision to be implanted.

MBQ

The test battery included a questionnaire to evaluate music background and experience as well as the appreciation of music, known as the Musical Background Questionnaire (MBQ). Forty eight subjects[32] completed the MBQ both preoperatively, and at 6 months postactivation.

Preoperative Results:

- 72.0% reported their preferred way of listening to music was with bilateral hearing aids, while 22.0% preferred to listen to music with no hearing aids and the remaining subjects, and only 6.0% preferred listening with only a unilateral aid.
- With their hearing loss and best listening condition, subjects chose to listen to music:
  - 6% never
  - 44.0% less 3 hours per week
  - 32.0% 3-5 hours per week
  - 8.0% 6-8 hours per week

[32] The 48 subjects were the same 48 subjects that completed the DUQ, MBQ, and SSQ at the 6 month interval.
[33] The 46 subjects were the same 46 subjects that completed the SSQ and DUQ at the 12 month interval.

        - 10.0%  9 or more hours per week
    - With their hearing loss in the best listening condition:
        - 6.0%  avoid music
        - 58% listen, but find music difficult to understand
        - 16% find music very enjoyable
        - 10.0% listen, and find music important
        - 2.0% never really listen to music
        - 8.0% listen, but find music unimportant

Postoperative Results

- Subjects preferred to listen to music in the following conditions
    - 54.2% in the Combined condition
    - 29.2% in the Bimodal condition
    - 4.2% in the cochlear implant-alone condition
    - 4.2% in the Hybrid condition
    - 4.2% in a hearing aid only condition (no CI)
    - 4.2% using no amplification or CI
- When asked how often they choose to listen to music after their implant ,in their best listening condition, subjects reported
    - 33.3% less than 3 hours per week
    - 33.3% 3-5 hours per week
    - 12.5% 6-8 hours per week
    - 20.8% 9 or more hours per week

Subjects were also asked to indicate how music sounds currently with respect to different rating scales.  Based on mean ratings, music was rated more favorably for the postoperative condition compared to preoperative in some comparisons (empty vs full, unpleasant vs pleasant, unnatural versus natural), less favorably in a couple comparisons (sounds like music, like versus dislike the sound), and poorer in a couple comparison (clear versus fuzzy, easy to follow versus difficult). Despite this, subjects on average chose to listen to music more following implantation.

## XI. OVERALL CONCLUSIONS FROM THE CLINICAL STUDY

The valid scientific evidence presented in the preceding sections provides reasonable assurance that the Nucleus Hybrid L24 Implant System is safe and effective for the target population of patients (18 years of age and older) who have residual low-frequency hearing sensitivity and bilateral severe to profound high frequency sensorineural hearing loss, and who obtain limited benefit from bilateral hearing aids.

### A. Safety Conclusions

The risks associated with the use of the device and implantation procedure were found to be consistent with previous cochlear implant surgery (Freedom cochlear implant P970051/S028) in terms of type, frequency and severity.  Most of the adverse events reported were transient and occurred at low incidence rates and included tinnitus (occurring or increasing post-implantation), dizziness, electrode array ‘opens/shorts’, vertigo, sound quality and performance issues.  All were resolved or closed by the end of

the study. An additional event[34] captured with the Hybrid L24 subjects was post-implant changes in low-frequency residual hearing. Twenty-four out of the 50 Hybrid L24 subjects experienced a profound to total loss of low-frequency residual hearing at the implant ear at some point during the study. Four of those individuals underwent explantation with reimplantation of another cochlear implant with a longer electrode array. One patient was reimplanted before the 6 month endpoint, one was reimplanted between the 6 and 12 month endpoints, and two were reimplanted after the 12 month endpoint. This revision surgery is also an expected complication of current cochlear implant procedures.

## B. Effectiveness Conclusions

In this study 48/50 protocol patients completed the 6 months primary (speech perception) endpoint for data capture. On average, subjects experienced a significant improvement of 36.6% in CNC word recognition and 32.8% for AzBio sentences in noise as compared to their preoperative hearing aid scores. Secondary endpoint analyses (binomial comparisons of pre- and postoperative speech scores for the same tests) were to determine the proportion of subjects performing equal to or better than the preoperative hearing aid condition. The CNC word and phoneme recognition scores indicated 96% and 91.8%, respectively, with AzBio sentences at 89.8% of patients either improved or performed equivalently. These objective test measures were supported by the self-assessment questionnaires that were only designed to address the 'everyday' or 'combined mode' listening situation. The SSQ, that was administered across a range of listening situations and reported within three hearing domains at 12 months postoperatively, indicated that for all three subscales, *Speech Hearing*, *Spatial Hearing and Sound Qualities*, 86.7% of patients performed significantly better than with their preoperative bilateral hearing aids. A further measure of performance, the UW-CAMP, indicated Hybrid L24 recipients performed closer to 'acoustic' listeners than cochlear implant (electric) listeners thereby enjoying the melodic aspects of music. The outcome of a self-satisfaction survey (DUQ) also was consistent in supporting the effectiveness of the device at 12 months with 80.4% reporting they were 'satisfied/very satisfied' with their decision to be implanted and 78.2% 'satisfied/very satisfied' with their performance. This is compared to 76% of patients 'dissatisfied/very dissatisfied' with their hearing aids when assessed preoperatively.

In conclusion, the study data, objective and self-assessment, indicate that the Cochlear Nucleus Hybrid L24 Implant is an effective therapy for its indication providing most patients (≥ 75%) the opportunity for improvements in speech understanding in quiet and noise and should also provide them additional benefit in listening to music and in spatial hearing and sound quality as compared to acoustic hearing aids.

## C. Benefit-Risk Conclusions

[34] This is not generally measured post-implantation nor reported as an adverse event in current cochlear implant surgeries as labeling indicates that with insertion of the longer electrode arrays patients can expect to lose all residual hearing.

The probable benefits of the device are based on data collected in a clinical study to support PMA approval as described above. The clinical study demonstrated several benefits as compared to the most common alternative treatment (air conduction hearing aids) for this type and degree of hearing loss including improvements in word and phoneme understanding in quiet and sentence understanding in noise. These improvements are likely to be experienced by most candidates who meet the indication. For those patients experiencing profound to total losses of residual hearing at the implant ear, some may elect to undergo a further surgical revision for reimplantation with a cochlear implant with a longer electrode array. 18/24 of the study subjects who did experience that significant loss in low-frequency hearing continued use with the Hybrid L24 most commonly in the bimodal mode but also in a combined mode or unilateral ('electric alone') mode and exhibited significant benefit.

### D. Overall Conclusions

The data in this application support the reasonable assurance of safety and effectiveness of this device for the indications for use. Based on the clinical study results, it is reasonable to conclude that the clinical benefits with use of the Nucleus Hybrid L24 Implant System in terms of improvement in speech understanding in quiet and noise, and the likelihood of increased satisfaction with sound quality and in performance in spatial hearing outweigh the risks associated with the device and surgical procedure through one-year of follow-up when used in the indicated population in accordance with the directions for use.

## XII. PANEL RECOMMENDATIONS

*To be completed by FDA*

## XIII. CDRH DECISION

*To be completed by FDA*

## XIV. APPROVAL SPECIFICATIONS

Directions for use:

See device labeling.

Hazards to Health from Use of the Device:

See Indications and Contraindications, Warnings, Precautions, and Adverse Events in the device labeling.

Nucleus® Hybrid L24 Implant System
Physician's Package Insert

Symbols

| | |
|---|---|
| | Note: Important information or advice.<br>Can avoid inconvenience. |
| | **Warning (harmful)**<br>Potential safety hazards and serious adverse reactions.<br>Could cause harm to person. |

This document contains important information such as indications and contraindications that applies to the following cochlear implant systems:

- Nucleus® Hybrid L24 cochlear implant

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## Device description

Cochlear Nucleus implant systems are designed to provide useful hearing and include both implanted and external components. The implant is surgically implanted under the skin behind the ear. It includes a receiver/stimulator to receive and decode the electrical signals and an electrode array to deliver these signals to the cochlea. The external components include the following sound processors:
Nucleus CP900 series with associated accessories and cables.

A cochlear implant system converts sound in the environment into electrical code and transmits this code to the auditory nerve, and on to the brain where it is interpreted as sound.

## Indications

The cochlear implant is intended to restore a level of auditory sensation via electrical stimulation of the high-frequency region of the auditory nerve, while preserving existing low-frequency acoustic hearing. For patients with postoperative residual low-frequency hearing sensitivity, the Nucleus 6 sound processor also can provide acoustic amplification.

The Nucleus Hybrid L24 cochlear implant is intended for use in patients 18 years or older who have residual low-frequency hearing sensitivity and bilateral severe to profound high frequency sensorineural hearing loss, and who obtain limited benefit from bilateral hearing aids. Typical preoperative hearing of candidates ranges from normal to moderate hearing loss in the low frequencies (thresholds no poorer than 60 dB HL at ≤ 500 Hz), and from severe to profound hearing loss at frequencies above 1500 Hz (threshold average of 2000, 3000, and 4000 Hz ≥ 75 dB HL). The CNC word recognition score will be between 10% and 60% inclusively in the ear to be implanted in the preoperative aided condition, and in the contralateral ear will be equal to or better than that of the ear to be implanted but not more than 80% correct.
For patients with post-operative residual low-frequency acoustic hearing, the Nucleus 6 sound processor has an acoustic component that fits into the concha and canal of the outer ear. Prospective candidates should also be well motivated and have appropriate expectations of the potential benefits of an implant with or without an acoustic component.

## Contraindications

A cochlear implant is not indicated for individuals who have the following conditions:
1. Deafness due to lesions of the acoustic nerve or central auditory pathway
2. Active middle ear infections

3. Absence of cochlear development
4. Tympanic membrane perforation in the presence of active middle ear disease.

## Warnings

### Medical treatments generating induced currents

Some medical treatments generate induced currents that may cause tissue damage or permanent damage to the implant.

Warnings for specific treatments are given below.

Electrosurgery

Electrosurgical instruments are capable of inducing radio frequency currents that could flow through the electrode array. Monopolar electrosurgical instruments must not be used on the head or neck of an implant patient as induced currents could cause damage to cochlear tissues or permanent damage to the implant. Bipolar electrosurgical instruments may be used on the head and neck of patients; however, the cautery electrodes must not contact the implant and should be kept more than 1 cm (~0.5 in.) from the extracochlear electrodes.

Diathermy

Do not use therapeutic or medical diathermy (thermopenetration) using electromagnetic radiation (magnetic induction coils or microwave). High currents induced into the electrode lead can cause tissue damage to the cochlea or permanent damage to the implant. Medical diathermy using ultrasound may be used below the head and neck.

Neurostimulation

Do not use neurostimulation directly over the implant. High currents induced into the electrode lead can cause tissue damage to the cochlea or permanent damage to the implant.

Electroconvulsive therapy

Do not use electroconvulsive therapy on an implant patient under any circumstances. Electroconvulsive therapy may cause tissue damage to the cochlea or damage to the implant.

Ionizing radiation therapy

Do not use ionizing radiation therapy directly over the implant because it may cause damage to the implant.

## Magnetic Resonance Imaging (MRI)

MRI is contraindicated except under the circumstances described below. Do not allow a patient with an implant to be in a room where an MRI scanner is located except under the following special circumstances.

Warning: The magnet must be surgically removed prior to undertaking MRI as tissue damage may occur if the recipient is exposed to MRI with the magnet in place.

Warning: The patient must take off the sound processor and headset before entering a room where an MRI scanner is located.

Non-clinical testing has demonstrated the Hybrid L24 implant is MR Conditional only after the magnet has been surgically removed. It can be scanned safely under the following conditions:

- Magnet must be surgically removed prior to MRI scan
- Static magnetic field of 1.5 tesla
- Spatial gradient field of 260 Gauss/cm or less
- Maximum whole body averaged Specific Absorption Rate (SAR) of 0.5W/Kg maximum above the bottom of the sternum and 2W/kg maximum below the bottom of the sternum for 15 minutes of scanning as per the diagram below. The quality of MRI will be affected by the metal in the implant. Image shadowing may extend as far as 6 cm (~ 2 ½ in.) from the implant (under the following scan sequence: T2-weighted Fast Spin Echo), thereby resulting in loss of diagnostic information in the vicinity of the implant. For more information about magnet removal, refer to the Surgeon's Guide or contact Cochlear.

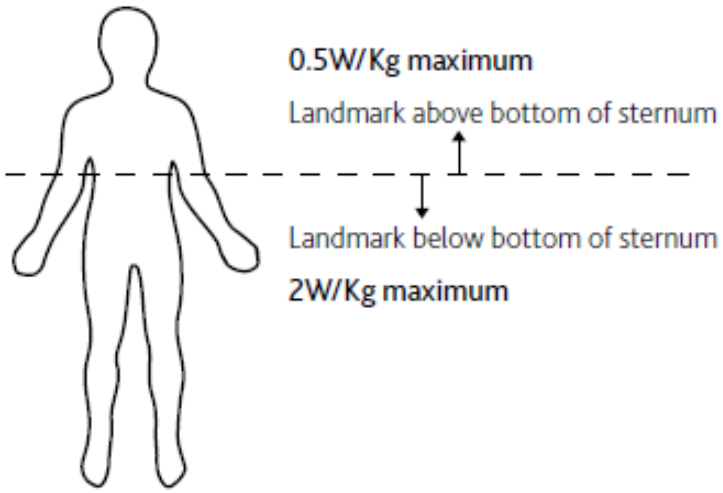



Figure 1: Whole average body SAR limits for 15 minutes scan time

In non-clinical testing, an equivalent implant produced a temperature rise of less than 1.2 °C at a maximum whole body averaged SAR of 0.5 W/kg, as assessed by calorimetry for 6 minutes of MR scanning in a 1.5T GE Signa whole body coil when landmarked above the bottom of the sternum.
In non-clinical testing, an equivalent implant produced a temperature rise of less than 1.9 °C at a maximum whole body averaged SAR of 2 W/kg, as assessed by calorimetry for 6 minutes of MR scanning in a 1.5 T GE Signa whole body coil when landmarked below the bottom of the sternum

### Meningitis

Prior to implantation, candidates should consult their primary care physician and implanting surgeon regarding vaccination status against organisms that cause meningitis. Meningitis is a known risk of inner ear surgery and candidates should be appropriately counselled of this risk.
In addition, certain preoperative conditions may increase the risk of meningitis with or without an implant. These conditions include:

- Mondini's syndrome and other congenital cochlear malformations
- Concurrent Cerebrospinal Fluid (CSF) shunts or drains
- Recurrent episodes of bacterial meningitis prior to implantation
- Perilymph fistulas and skull fracture/defect with CSF communication.

### Residual hearing

Most patients maintain audiometric thresholds at the lower frequencies in the implanted ear. For some patients, a total loss of acoustic hearing in the implanted ear may occur.

### Long term effects of electrical stimulation

Most patients can benefit from electrical stimulation levels that are considered safe, based on animal experimental data. For some patients, the levels needed to produce the loudest sounds exceed these levels. The long-term effects of such stimulation in humans are unknown.

### Small parts hazard

Patients and caregivers should be counseled that the external implant system contains small parts that may be hazardous if swallowed or may cause choking if inhaled.

### Head trauma

A blow to the head in the area of the implant may damage the implant and result in its failure. For recommendations on how to minimize the chance of experiencing head trauma see http://www.cdc.gov/ncipc/pubres/tbi_toolkit/patients/preventing.htm

### Use of batteries and battery ingestion

When using disposable batteries, only use battery types recommended by your clinician or Cochlear. Other types may not have sufficient energy to allow your processor to operate for a long time. Cochlear does not recommend the use of silver oxide or alkaline batteries.

Batteries can be harmful if swallowed. Ensure that batteries are kept out of reach of young children and pets. If swallowed, seek prompt medical attention at the nearest emergency center.

### Rechargeable Batteries

In certain circumstances, rechargeable batteries can become VERY HOT, and could cause injury. Remove your processor immediately if it becomes unusually warm or hot, and seek advice from your clinician. Caregivers should touch their recipient's processor to check for heat if the recipient is showing signs of discomfort. Rechargeable batteries should NEVER be worn beneath clothing (including scarves and headwear covering the ears). Use of the rechargeable battery is contraindicated in patients who cannot remove the device by themselves, or notify a caregiver that the device has become hot.

### Overheating of external devices

Remove your processor immediately if it becomes unusually warm or hot, and seek advice from your clinician. Caregivers should touch their recipient's processor to check for heat if the recipient is showing signs of discomfort. The manufacturer only recommends the use of Cochlear rechargeable battery modules and zinc air disposable batteries. The processor is not intended to be used with silver oxide batteries. In some circumstances, the use of these batteries could result in severe burns. A dangerous amount of heat can be generated by these batteries in conditions where heat cannot dissipate, especially if the device is being held against the skin by clothing or a retention device. In addition, use of silver oxide batteries may damage your processor.

## Precautions

If you experience a significant change in performance or the sound becomes uncomfortable, turn off your processor and contact your implant center.
Use the cochlear implant system only with the approved devices and accessories listed in the user guide. The processor and other parts of the system contain complex electronic parts. These parts are durable but must be treated with care. The processor must not be opened by anyone other than Cochlear's qualified service personnel or the warranty will be invalidated. Each processor is programmed specifically for each implant. Never wear another person's processor or lend yours to another user. If you have two processors (one for each ear), always wear the processor programmed for your left ear on the left, and the processor programmed for your right ear on the right. Using the wrong processor could result in loud or distorted sounds that, in some instances, may cause extreme discomfort. Do not operate the processor at temperatures above +40 °C (+104 °F) or less than +5 °C (+41 °F). Do not store the processor at temperatures above +50 °C (+122 °F) or less than -20 °C (-4 °F). The processor's sound quality may be intermittently distorted when you are within approximately 1.6 km or 1 mile of a radio or television transmission tower. Additional sources of interference include, but are not limited to:

- Security systems
- Industrial machinery and power systems
- Mobile communications equipment (including cellular telephones)
- Certain kinds of hand-held, two-way radios (including Citizen Band, Family Radio Service, and Amateur Band).

To reduce or eliminate the interference, move away from the source. If your processor stops working, turn the power switch off and then back on. This effect is temporary and will not damage the processor.

### Theft and metal detection systems

Devices such as airport metal detectors and commercial theft detection systems produce strong electromagnetic fields. Some cochlear implant recipients may experience a distorted sound sensation when passing through or near one of these devices. To avoid this, turn off the processor when in the vicinity of one of these devices. The materials used in the cochlear implant may activate metal detection systems. For this reason, recipients should carry the Cochlear Implant Patient Identification Card with them at all times.

### Electrostatic discharge

A discharge of static electricity can damage the electrical components of the cochlear implant system or corrupt the program in the processor. If static electricity is present (e.g. when putting on or removing clothes over the head or getting out of a vehicle), cochlear implant recipients should touch something conductive (e.g. a metal door handle) before the cochlear implant system contacts any object or person. Prior to engaging in activities that create extreme electrostatic discharge, such as playing on

plastic slides, the processor should be removed. Clinicians should use an anti-static shield on the computer monitor when programming a cochlear implant recipient.

### Mobile telephones

Some types of digital mobile telephones, e.g. Global System for Mobile communications (GSM) as used in some countries, may interfere with the operation of the external equipment. As a result, cochlear implant recipients may perceive a distorted sound sensation when in close proximity, 1–4 m (~3–12 ft), to a digital mobile telephone in use.

## Summary of Hybrid L24 Implant System Clinical Trial

Beginning in 2007, a repeated-measures, single-subject clinical trial was initiated to investigate the safety and effectiveness of the Hybrid L24 Cochlear Implant System, a cochlear implant that incorporates both electric and acoustic stimulation. Fifty subjects with severe to profound high-frequency loss but significant levels of low-frequency acoustic hearing were enrolled into this multicenter study, involving ten invitational sites from across the Unites States. Effectiveness of the Hybrid L24 system was assessed by comparing preoperative hearing performance with hearing aid(s) to postoperative performance with the Hybrid L24 system. Postoperative hearing performance was measured at device activation and 3, 6, and 12 months post activation intervals with the Hybrid L24 system, with and without use of an additional hearing aid in the contralateral (non-implant) ear in several listening conditions. Measurement of unaided (acoustic) hearing thresholds was accomplished over time to examine effects of the device on residual hearing sensitivity.

Primary efficacy data were speech recognition scores in both quiet and background noise. The primary clinical endpoint for efficacy analysis was measured at 6 months postactivation through assessment of statistical significance of the within-subject differences for the CNC word test and sentence recognition in noise as evaluated with the AzBio test. Scores on both speech tests were obtained at the 6-month postactivation interval in the implanted ear with the device in Hybrid mode (acoustic-electric stimulation to the implanted ear) and compared with preoperative assessment using a hearing aid in the implanted ear. The primary endpoints were that mean performance with each of these measures would show significant benefit with use of the Hybrid device compared to the preoperative amplification condition.

Device efficacy was also assessed for the Combined listening mode; i.e., use of the Hybrid device on the implant ear with acoustic input, combined with use of a hearing aid on the other ear. Specifically, within-subject differences in CNC and AzBio scores at postoperative intervals were compared to those measured preoperatively with bilateral hearing aids. The intention of these analyses was to provide an evaluation of outcomes

for subjects using their "everyday" listening configuration of a Hybrid cochlear implant combined with a hearing aid in the non-implant ear.

To examine the impact of adding acoustic stimulation to the implant ear, a Cochlear Implant (electric)-alone condition was also evaluated, but only using the CNC test.

Additional efficacy data were collected via a music perception test and subjective questionnaires.

## Results of Hybrid L24 Implant System Clinical Trial

### Acoustic Hearing Preservation

Forty-eight subjects completed audiometric assessments for the 6-month postactivation primary endpoint. Comparing preoperative to postoperative thresholds using a five frequency average from 125 through 1000Hz, inclusively, 27 experienced a decrease in low-frequency hearing ≤ 30 dB. Of those 27, 12 experienced a decrease in low-frequency hearing ≤ 10 dB, 12 experienced a decrease in low-frequency hearing >10 and ≤ 20 dB, and 3 experienced a decrease in low-frequency hearing >20 and ≤30 dB. 21 experienced a decrease in low-frequency hearing > 30 dB. Over the entire study period, 28 of 50 subjects experienced changes in low-frequency hearing of more than 30 dB. Four of these cases improved such that low-frequency thresholds were again within 30 dB of preoperative levels as of the most recent evaluation for each subject.

Table 1 below summarizes the low frequency pure tone average categorized by degree of loss experienced by the subjects at the end of the study.

**Table 1: Low frequency pure tone average categorized by degree of loss at study end**

| Degree of Low Frequency Pure Tone Average (125-1kHz) | Number of Subjects |
|---|---|
| Moderate (41 through 55 dB HL) | 15 (31%) |
| Moderate to Severe (56 through 70 dB HL) | 9 (19%) |
| Severe (71 through 90 dB HL) | 9 (19%) |
| Profound (> 90 dB HL) | 10 (21%) |
| Total (Nonmeasurable) | 5 (10%) |

### Effectiveness Analysis

**Primary Endpoint Analysis**

All primary endpoints were met. As shown in Table 2 below, significant improvement was noted for both test measures. On average, subjects experienced a significant improvement of 36.6% for CNC word recognition and 32.8% for AzBio sentences in noise.

**Table 2: Statistical summary for co-primary endpoints**

| (N=49)[#] | Acoustic Alone Preoperative | Hybrid Mode 6 Months Postactivation | Percentage Point Change | P-Value* |
|---|---|---|---|---|
| | Mean ± S.D. | Mean ± S.D. | Mean ± S.D. (95% C.I) | |
| **Word scores** | 28.8% ± 14.6% | 65.4% ± 25.4% | 36.6 ± 26.2 (29.1, 44.1) | p < 0.0001 |
| **AzBio scores** | 16.3% ± 14.4% | 49.2% ± 30.8% | 32.8 ± 29.1 (24.5, 41.2) | p < 0.0001 |

[#] One subject withdrew prior to the 6-month interval and was not included in the analyses.
*Signed-rank p-value

The 3-month data for the one subject who did not reach the 6-month testing period due to reimplantation with a conventional cochlear implant after loss of residual hearing was carried forward as per the statistical analysis plan.

**Secondary Endpoint Analysis**

Secondary efficacy endpoint analyses were based on binomial comparisons of pre- and postoperative speech scores for the CNC test, scored for both word and phoneme correct, and the AzBio test. Binomial comparisons of individual scores obtained in the Hybrid mode at 6 months postactivation (key endpoint) were compared with those obtained preoperatively with a hearing aid in the ear to be implanted, to determine the proportion of subjects performing equal to or better than the preoperative untreated condition.

As shown in Table 3, the secondary endpoints (>75% scoring equal to or better than preoperative) were met and exceeded for both metrics. When the Combined mode at 6 months is considered in the analysis, an even higher proportion of subjects show significant improvement. Table 4 shows the proportion of subjects with postoperative score better than preoperative at the 6 months study interval.

**Table 3: Proportion of subjects with postoperative score equal to or better than preoperative at the 6 month study interval**

| Listening Mode: | CNC Words | CNC Phonemes | AzBio in Noise |
|---|---|---|---|
| **Hybrid (Study Endpoint)** | 96.0% | 91.8% | 89.8% |
| **Combined (Everyday Use)** | 100% | 100% | 100% |

**Table 4: Proportion of subjects with postoperative score better than preoperative at the 6 month study interval**

| Listening Mode: | CNC Words | CNC Phonemes | AzBio in Noise |
|---|---|---|---|
| **Hybrid (Study Endpoint)** | 81.6% | 85.7% | 73.5% |
| **Combined (Everyday Use)** | 87.8% | 89.9% | 83.7% |

**Speech Recognition Across Time**

CNC postoperative data:

- Preoperative CNC word scores obtained with a unilateral hearing aid in the ear to be implanted ranged from 9% to 64%, with a mean score of 28.8% (N=50),
- At the 3 month postactivation test interval, performance in the Hybrid Mode ranged from 3% to 93%, with a mean of 58.5% (N=50),
- At the 6-month endpoint, scores ranged from 8% to 98% with a mean of 65.4% (N=49), and
- At 12 months, scores ranged from 5% to 97% with a mean of 69.4% (N=46).

All pre-to-post operative mean differences were significant (including the pre- to 6-month endpoint comparison) based on paired t-tests. By 12 months postactivation,

binomial comparisons of the Combined mode versus the preoperative bilateral hearing aids score showed that 86.7% of the 46 subjects performed significantly better postoperatively. Six subjects showed no significant pre- to postoperative changes. No subject showed a significant decrement.

CNC phoneme recognition scores showed a similar trend to the word recognition scores.

AzBio Postoperative Data:

- Preoperative AzBio sentence scores obtained with a hearing aid in the ipsilateral ear (i.e., the ear to be implanted) ranged from 0% to 64.1%, with a mean score of 16.3% (N=50),
- At the 3 month postactivation test interval, performance in the Hybrid mode ranged from 0% to 88.7%, with a mean of 44.6% (N=49),
- At 6 months scores ranged from 0% to 91.5% with a mean of 49.2% (N=49), and
- At 12 months scores ranged from 0% to 90.2% with a mean of 51.5% (N=46).

By 12 months postactivation, binomial comparisons of the Hybrid mode versus hearing aid preoperatively showed that 71.7% of the 46 subjects performed significantly better postoperatively. Five subjects showed significant decrements and 8 subjects showed no significant pre- to postoperative changes.

For everyday use (a combination of all available acoustic and electric stimulation), the AzBio data showed:

- Preoperative AzBio sentence scores obtained with bilateral hearing aids ranged from 0% to 76.5%, with a mean score of 29.6% (N=50),
- At the 3 month postactivation test interval, performance in the Combined mode ranged from 0% to 97.3%, with a mean of 62.2% (N=48),
- At 6 months scores ranged from 3.6% to 92.7% with a mean of 62.6% (N=49), and
- At 12 months scores ranged from 3.6% to 97.5% with a mean of 66.3% (N=46).

All pre-to-postoperative mean differences were significant based on paired t-tests. By 12 months postactivation, binomial comparisons of the Combined mode versus bilateral hearing aid scores preoperatively showed that 89.1% of the 46 subjects performed significantly better postoperatively. Three subjects showed no significant pre- to postoperative changes. Two subjects showed significant decrements.

**Efficacy Outcomes as a Function of Hearing Loss**

Mean preoperative (hearing aid in the implant ear) and 6-month postactivation (Hybrid mode) unilateral CNC and AzBio scores as a function of the degree of low-frequency

hearing loss were considered at the 6-month endpoint. Analysis of variance showed a significant effect for degree of hearing loss. That is, the degree of pre- to postoperative improvement did depend on the degree of acoustic hearing sensitivity maintained at the 6-month test interval. However, when using the Hybrid implant ear alone, significant improvement in speech perception is possible for all levels of hearing loss, albeit particularly for those subjects who maintained severe or better levels of hearing at the 6-month endpoint.

In their everyday listening, subjects use the Hybrid cochlear implant in concert with a hearing aid in the contralateral, non-implant ear; i.e., the Combined listening mode. As shown in **Error! Reference source not found.**, significant improvement was observed for the subjects using the Combined mode compared to their performance with bilateral hearing aids, across all degrees of postoperative hearing levels. **Error! Reference source not found.** shows mean absolute scores as well as mean improvements on the CNC and AzBio test measures relative to the degree of postoperative hearing.

**Table 5: Mean Absolute Scores and as Mean Improvements on the CNC and AzBio Test Measures Relative to the Degree of Postoperative Hearing**

| | Moderate | Moderate to Severe | Severe | Profound | Total Loss |
|---|---|---|---|---|---|
| **Mean Improvement on CNC** | 44.2% | 35.4% | 32.9% | 19.6% | 39.0% |
| **Mean Score on CNC** | 83.3% | 81.4% | 83.8% | 66.6% | 80.8% |
| **Mean Improvement on AZBio in noise** | 44.5% | 38.4% | 39.0% | 12.7% | 25.2% |
| **Mean score on AzBio in noise** | 73.4% | 70.5% | 62.5% | 44.1% | 58.7% |

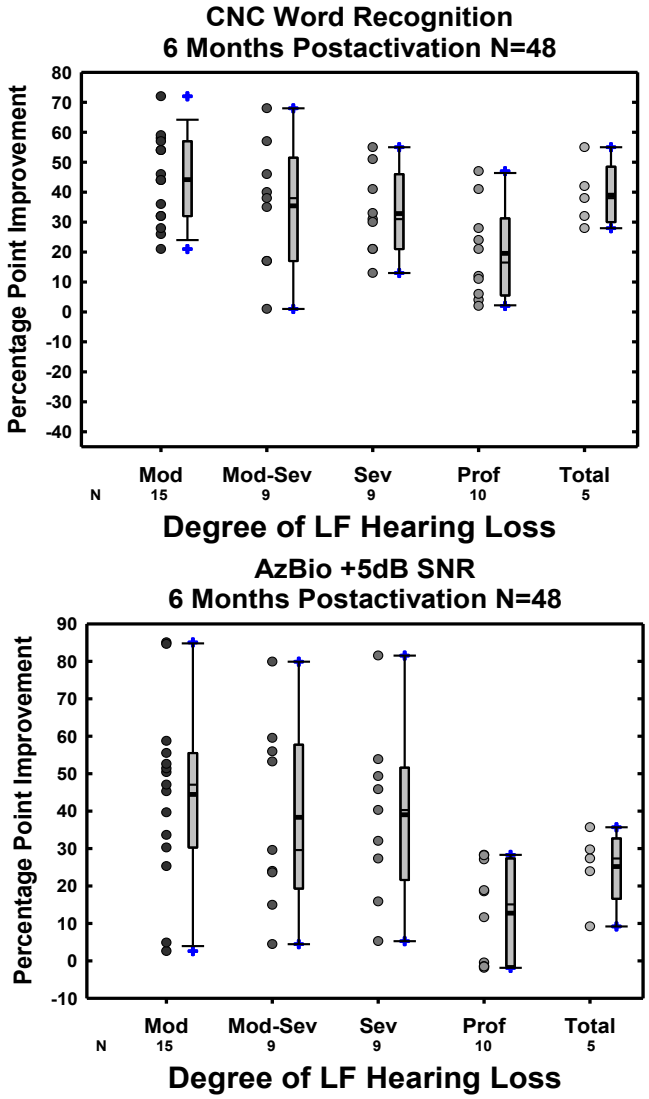



**Figure 1: Mean Pre- to 6-Month Postactivation Combined Mode Outcomes for the CNC Word Test (Upper) and AzBio in Noise Test (Lower), as a function of degree of hearing loss at the 6-Month endpoint.**

Aided Tresholds

Aided thresholds were significantly better with the Hybrid cochlear implant than with preoperative amplification. All subjects in this study showed improvements in aided thresholds in the high frequencies because hearing aids were not able to overcome the severe to profound degree of their acoustic hearing impairment in this audiometric region.

UW-CAMP

The University of Washington Clinical Assessment of Music Perception (UW-CAMP) music test battery was used to assess music perception abilities. The UW-CAMP consists of three subtests each designed to provide an assessment of fundamental auditory skills important for music perception: pitch discrimination, melody recognition and timbre. The UW-CAMP was administered ipsilaterally for the implanted ear and bilaterally at the preoperative baseline and 6-month endpoint evaluations.

Pitch:

In an ipsilateral condition:

- Average preoperative pitch discrimination thresholds obtained Acoustic Alone, with a hearing aid in the ipsilateral ear (i.e., the ear to be implanted), ranged from 0.5 to 4.8 semitones, with a mean of 1.1 semitones (N=50),
- At the 6 month postactivation test interval, performance in the Hybrid Mode (i.e., Cochlear Implant + Ipsilateral Acoustic) ranged from 0.5 to 8.9 semitones, with a mean of 1.5 semitones (N=46).

In a bilateral condition:

- Average preoperative pitch discrimination thresholds obtained in the Bilateral Acoustic condition, with bilateral hearing aids, ranged from 0.5 to 6.3 semitones, with a mean of 1.1 semitones (N=50),
- At the 6 month postactivation test interval, performance in the Combine Mode (i.e., Cochlear Implant + Bilateral Acoustic) ranged from 0.5 to 3.7 semitones, with a mean of 1.1 semitones (N=46).

Normally hearing individuals can discriminate tones that are 1 semitone apart on average, whereas traditional cochlear implant recipients require the tones to be 3 semitones apart, on average. Hybrid users performed at levels similar to that observed to normally hearing subjects and considerably better than that observed for the traditional cochlear implant users. In addition, the Hybrid users maintained their pitch discrimination abilities, on average pre- to postoperatively for the treated ear (Acoustic Alone vs. Hybrid Mode) and when considering scores for the bilateral condition (Bilateral Acoustic vs. Combined Mode). No significant changes ($p > 0.05$) were noted when comparing Acoustic Alone (preoperatively) and Hybrid Mode (two middle bars) as well as Bilateral Acoustic (preoperatively) and Combined Mode (two bars to the right).

Melody Recognition:

Implanted Ear

- Preoperative melody recognition scores obtained Acoustic Alone ranged from 11.1% to 100%, with a mean of 66.2% (N=50),
- At the 6 month postactivation test interval, performance in the Hybrid Mode also ranged from 11.1% to 100%, with a mean of 65.9% (N=47).

Everyday Condition

- Preoperative melody recognition scores obtained in the Bilateral Acoustic condition ranged 13.9% to 100%, with a mean of 66.3% (N=50),
- At the 6 month postactivation test interval, performance in the Combined Mode ranged from 16.7% to 100%, with a mean of 66.7% (N=46).

The Hybrid users maintained their melody recognition abilities, on average pre- to postoperatively for the treated ear (Acoustic Alone vs. Hybrid Mode) and for the bilateral condition (Bilateral Acoustic vs. Combined Mode). No significant changes ($p > 0.05$) were noted when comparing Acoustic Alone (preoperatively) and Hybrid Mode as well as Bilateral Acoustic (preoperatively) and Combined Mode.

Timbre:

In the ipsilateral condition:

- Preoperative timbre recognition scores obtained Acoustic Alone ranged from 12.5% to 91.7%, with a mean of 50.8% (N=50),
- At the 6 month postactivation test interval, performance in the Hybrid Moderanged from 8.3% to 100%, with a mean of 56.6% (N=47).

In a bilateral condition:

- Preoperative timbre recognition scores obtained in the Bilateral Acoustic condition ranged 8.3% to 100%, with a mean of 56.2% (N=50),
- At the 6 month postactivation test interval, performance in the Combined Mode ranged from 20.8% to 91.7%, with a mean of 57.0% (N=46).

Hybrid users maintained their melody recognition abilities, on average pre- to postoperatively for the treated ear (Acoustic Alone vs. Hybrid Mode) and for the bilateral condition (Bilateral Acoustic vs. Combined Mode). No significant changes ($p > 0.05$) were noted when comparing Acoustic Alone (preoperatively) and Hybrid Mode as well as Bilateral Acoustic (preoperatively) and Combined Mode.

**Questionnaires**

<u>Speech, Spatial, and Qualities of Speech Questionnaire (SSQ)</u>

The SSQ was used as a subject self-assessment of hearing (dis)abilities across a range of listening situations that fall within three hearing domains: speech hearing rating scale, spatial rating scale, and sound qualities rating scale. Forty-nine questions address various aspects of hearing: speech hearing (14 questions concerning hearing speech in a variety of listening situations), spatial hearing (17 questions concerning direction, distance and movement of sound and ability to segregate sounds), and sound qualities

(18 questions concerning ease of listening, and naturalness, clarity, identification of different speakers, musical pieces and instruments as well as everyday sounds). Each question is scored by the reader using a line marked from 0 through 10, where 0 corresponds to minimal ability and 10 corresponds to complete ability.

Fifty subjects completed the SSQ preoperatively, 48 completed it at 6 months postactivation, and 46 completed it at the 12-month postactivation interval. For each subscale and the averaged total score, comparison was made between the preoperative and postoperative bilateral conditions.

Speech Hearing Subcale

- Preoperative SSQ scores obtained in the preoperative bilateral hearing aids condition ranged from 0.8 to 6.2, with a mean score of 3.2 (N=50).
- At the 6-month evaluation in the Combined mode, scores ranged from 0.7 to 8.8 with a mean of 5.4 (N=48), and
- At 12 months, scores in the Combined mode ranged from 1.4 to 8.8 with a mean of 5.6 (N=46).

By 12 months postactivation, individual comparisons of the Combined mode score versus the bilateral hearing aids score preoperatively showed that 86.7% of the 46 subjects performed significantly better postoperatively. Five subjects showed a significant decrement and one subject showed no significant pre- to postoperative change

Spatial Hearing Scale

- Preoperative SSQ scores obtained in the preoperative bilateral hearing aids condition ranged from 1.4 to 9.2, with a mean score of 4.5 (N=50),
- At the 6-month evaluation in the Combined mode, scores ranged from 1.1 to 8.3
  with a mean of 5.5 (N=48**Error! Bookmark not defined.**), and
- At 12 months, scores in the Combined Mode ranged from 1.6 to 8.5 with a mean of 5.7 (N=46**Error! Bookmark not defined.**).

Pre-to-postoperative mean differences were significant based on paired t-tests. By 12 months postactivation, individual comparisons of the Combined mode score and preoperative bilateral hearing aids score showed that 86.7% of the 46 subjects with speech perception data available performed significantly better postoperatively. Five subjects showed a significant decrements and 1 subject showed no significant pre- to postoperative change.

Sound Qualities Scale

- Preoperative SSQ scores obtained in the Bilateral Acoustic condition ranged from 1.6 to 8.1, with a mean score of 5.0 (N=50),
- At the 6-month evaluation in the Combined mode, scores ranged from 2.7 to 9.1 with a mean of 6.3 (N=48**Error! Bookmark not defined.**), and
- At 12 months, scores in the Combined Mode ranged from 2.5 to 8.9 with a mean of 6.5 (N=46**Error! Bookmark not defined.**).

Pre-to-postoperative mean differences were significant based on paired t-tests. By 12 months postactivation, individual comparisons of the preoperative Combined mode score and preoperative bilateral hearing aid score showed that 86.7% of the 46 subjects performed significantly better postoperatively. Five subjects showed a significant decrement and one subject showed no significant pre- to postoperative change.

Total SSQ Score

- Preoperative SSQ scores obtained in the bilateral hearing aids condition ranged from 1.3 to 7.8, with a mean score of 4.2 (N=50),
- At the 6-month evaluation in the Combined mode, scores ranged from 2.5 to 8.5 with a mean of 5.7 (N=48**Error! Bookmark not defined.**), and
- At 12 months, scores in the Combined mode ranged from 2.5 to 8.4 with a mean of 5.9 (N=46**Error! Bookmark not defined.**).

Pre-to-postoperative mean differences were significant based on paired t-tests. By 12 months postactivation, individual comparisons of the postoperative Combined mode score and preoperative bilateral hearing aids score showed that 86.7% of the 46 subjects performed significantly better postoperatively. Five subjects showed significant decrements and 1 subject showed no significant pre- to postoperative change.

DUQ

An “in-house” designed device usability metric, the Device Use Questionnaire (DUQ), was administered to determine subjective preferences with regards to device use in various listening environments. Fifty subjects completed the DUQ preoperatively, 48 completed the DUQ at 6 months postactivation, and 46 completed the DUQ at the 12-month postactivation interval. Preoperatively, 76.0% reported the use of bilateral hearing aids as the overall preferred way of listening most of the time. Seventy-six percent also reported being “dissatisfied” or “very dissatisfied” with their hearing aid performance. Postoperatively at 12 months, 65.2% preferred for everyday listening the

Combined mode, 19.6% preferred the Bimodal mode, and 13.0% preferred listening in the Hybrid mode unilaterally. For adjusting to listening with the system, 80.4% reported that it was "very easy" or "moderately easy". A majority of subjects reported that sound was most pleasant and natural, and that overall ease of listening was greatest in the Combined mode. Of the 46 subjects, 78.2% reported being "very satisfied or satisfied" with their performance at 12 months with the Hybrid L24 implant system, and 80.4% reported being "very satisfied" or "satisfied" with their decision to be implanted.

MBQ

The Musical Background Questionnaire (MBQ) is a self-assessment questionnaire that examines musical training prior to hearing loss, listening habits with hearing aids, satisfaction with hearing aids for music listening, quality of music with hearing aids, enjoyment of musical styles with hearing aids, enjoyment of different instrumental timbres with hearing aids.

The test battery included a questionnaire to evaluate music background and experience as well as the appreciation of music, known as the Musical Background Questionnaire (MBQ). Forty eight subjects completed the MBQ both preoperatively, and at 6 months postactivation.

Preoperative Results:

- 72.0% reported their preferred way of listening to music was with bilateral hearing aids, while 22.0% preferred to listen to music with no hearing aids and the remaining subjects, and only 6.0% preferred listening with only a unilateral aid.
- With their hearing loss and best listening condition, subjects chose to listen to music:
  - 6% never
  - 44.0% less 3 hours per week
  - 32.0% 3-5 hours per week
  - 8.0% 6-8 hours per week
  - 10.0% 9 or more hours per week
- With their hearing loss in the best listening condition:
  - 6.0% avoid music
  - 58% listen, but find music difficult to understand
  - 16% find music very enjoyable
  - 10.0% listen, and find music important
  - 2.0% never really listen to music
  - 8.0% listen, but find music unimportant

Postoperative Results

- Subjects preferred to listen to music in the following conditions
  - 54.2% in the Combined condition
  - 29.2% in the Bimodal condition
  - 4.2% in the cochlear implant-alone condition

        - 4.2% in the Hybrid condition
        - 4.2% in a hearing aid only condition (no CI)
        - 4.2% using no amplification or CI
    - When asked how often they choose to listen to music after their implant ,in their best listening condition, subjects reported
        - 33.3% less than 3 hours per week
        - 33.3% 3-5 hours per week
        - 12.5% 6-8 hours per week
        - 20.8% 9 or more hours per week

Subjects were also asked to indicate how music sounds currently with respect to different rating scales. Based on mean ratings, music was rated more favorably for the postoperative condition compared to preoperative in some comparisons (empty vs full, unpleasant vs pleasant, unnatural versus natural), less favorably in a couple comparisons (sounds like music, like versus dislike the sound), and poorer in a couple comparison (clear versus fuzzy, easy to follow versus difficult). Despite this, subjects on average chose to listen to music more following implantation.

## Safety

Adverse Events

The primary safety endpoint was defined as any surgical and/or device-related event, to be reported as the number and proportion of individuals experiencing the adverse event across the duration of the study. There were no unanticipated adverse events. This study involved implanting subjects with residual low-frequency hearing so, for the purposes of adverse event reporting, any change in hearing that resulted in a profound (> 90 dB HL) or total (no measurable hearing) loss of low-frequency hearing (averaged over the frequency range 125 through 1000 Hz inclusively) in the implanted ear was considered an anticipated adverse event and included in the adverse event tabulations and analyses. Adverse events observed during the clinical study are shown in **Error! Reference source not found.** below. Some subjects had more than one event, so the number occurring does not necessarily represent the number of subjects impacted.

**Table 6: Adverse Events**

| Adverse Event | Number Occurring | Number Resolved/Closed |
|---|---|---|
| ***Profound/Total loss of hearing*** | 22 | 0 |
| ***Increased Tinnitus*** | 6 | 6 |
| ***Tinnitus not present preoperatively*** | 6 | 6 |
| ***Increased tinnitus with change in hearing*** | 2 | 2 |
| ***Device Related (Opens/Shorts)*** | 11 | 11 |
| ***Dizziness*** | 3 | 3 |

| | | |
|---|---|---|
| ***Dizziness with change in hearing*** | 2 | 2 |
| ***Imbalance*** | 1 | 1 |
| ***Imbalance with change in hearing*** | 1 | 1 |
| ***Vertigo*** | 1 | 1 |
| ***Vertigo with change in hearing*** | 1 | 1 |
| ***Sound Quality Issues*** | 2 | 2 |
| ***Decreased Performance*** | 1 | 1 |
| ***Increased impedances with change in hearing sensitivity*** | 1 | 1 |
| ***Overstimulation*** | 1 | 1 |
| ***Other**** | 4 | 4 |

** "Other" includes 2 reports of transient skin irritation due to externals, 1 case of pain associated with middle ear effusion, and 1 case of a local stitch infection.*

These adverse events and their rate of occurrence are consistent in character and severity to those reported for conventional cochlear implants.

## Other information

### Patient counseling

Preoperative counseling
Prospective cochlear implant candidates should be counseled regarding potential benefits, warnings, precautions and adverse effects of cochlear implantation, using the information in this document.

### Storage, handling and sterilization

Implants should be stored at normal room temperature. Implants may be stored at temperatures between -4 °F and +120 °F (-20 °C and +50 °C). The 'use by' date is stamped on the outside package. If it has expired, return the device to Cochlear. Handle the implant packages with care. Severe impact may rupture the inner sterile package. Cochlear implants are supplied sterile in gas-permeable packaging. The titanium plugs and replacement magnets are supplied separately in sterile gas-permeable packaging. These are single use items. The sterile package contains information indicating ethylene oxide processing. Before opening the sterile package, inspect it carefully. If the package is ruptured, or exposure to ethylene oxide processing is not indicated, please return the package to Cochlear.

## Information for use and recommended training

Physicians should be very experienced in mastoid surgery and the facial recess approach to the oval window and round window. It is important that physicians be trained in the implantation procedure for the Hybrid L24 implant. It is strongly recommended that the surgeon work with an experienced team of audiology, speech-language, rehabilitation, education and psychology professionals. It is recommended that audiology professionals attend a training program for this device.

Cochlear Americas conducts periodic training courses. For product-specific information, refer to the Surgeon's Guide supplied with each implant.

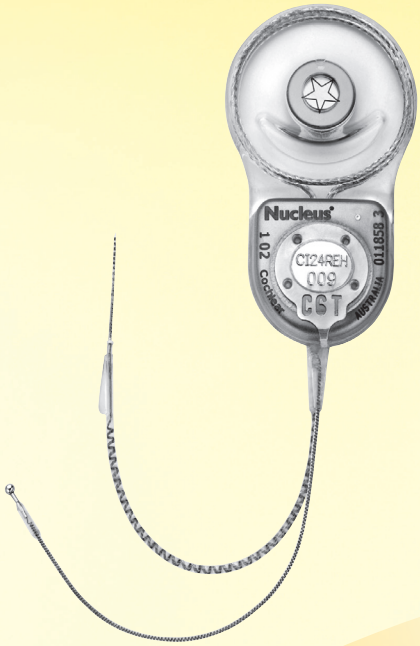
CI24REH

# Cochlear™

## Nucleus® Hybrid L24 implant

CI24REH

Surgeon's Guide




Hear now. And always

Cochlear®

# Symbols

| | |
|---|---|
| | NOTE<br>Important information or advice. |
| | CAUTION (no harm)<br>Special care to be taken to ensure safety and effectiveness.<br>Could cause damage to equipment. |
| | WARNING (harmful)<br>Potential safety hazards and serious adverse reactions.<br>Could cause harm to person. |

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# Introduction

This guide explains a surgical procedure for implanting the device. Other surgical approaches and variations are practised and may be considered more appropriate in certain circumstances. This guide also does not take account of any particular circumstance(s) or factor(s) relevant to an individual patient or case. The appropriate surgical procedure in each case is to be determined by the relevant physician exercising independent medical judgment and after considering all relevant circumstances, factors and information.

⚠ CAUTION

- Surgeons implanting this device should be experienced in cochlear implant surgery.
- Please ensure you are thoroughly familiar with all product labelling.
- When using sharp instruments near the device, take great care to avoid nicking or damaging the case, insulation, or electrode lead.

Please read the Physician's Package Insert and the Important Information Booklet. They contain important information on MRI, indications, contraindications, adverse effects, warnings and precautions.

## The Hybrid L24 implant

The Hybrid L24 implant has a receiver/stimulator, which receives and decodes the electrical signal from the sound processor, and an electrode array, which delivers the signal to the cochlea.

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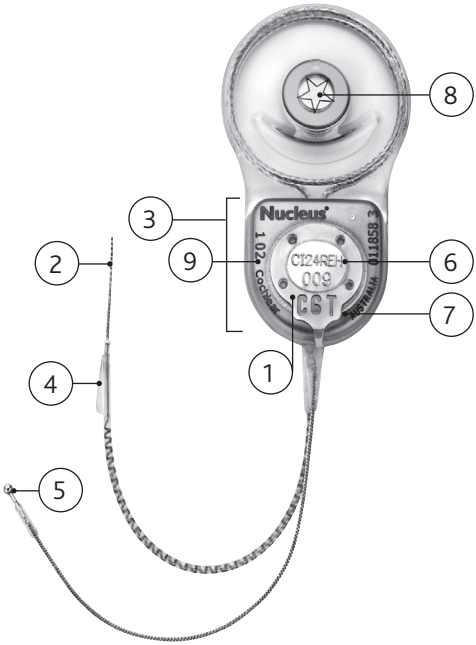
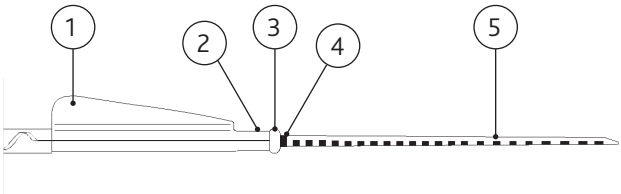



1 Receiver/stimulator
2 Intracochlear electrode array
3 Extracochlear electrode (plate)
4 Handle
5 Extracochlear electrode (ball)
6 Model (CI24REH)
7 Radiopaque characters
Manufacturer (C = Cochlear)
Model (6 = Hybrid L24)
Year made (T = 2004 and later)
8 Magnet (star on skin side)
9 Serial no. (e.g. 102 014 0889032)

Figure 1: Hybrid L24 implant (skin side)




1 Silicone wing
2 Platinum stiffener
3 White silicone stopper
4 Platinum band
5 22 modular facing electrodes

Figure 2: Hybrid L24 implant electrode array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# Surgical Tools

## Surgical tools for the Hybrid L24 implant

The CI24R/CI24RE Surgical Tool Kit (Z60523) is appropriate for use with the Hybrid L24 implant. All tools are stainless steel and sterilisable (according to your institution's policies).

### BTE Template (Z33011)

Used to ensure the implant is positioned with sufficient space for an ear level sound processor.

Figure 3: BTE Template

### Implant Template (Z33019)

Used to determine/check the shape of the well excavation and the position of the implant.

Figure 4: Implant Template

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## Bone Recess Template (Z60479)

Used to mark the well on the skull, and measure the depth of the well after drilling.

Figure 5: Bone Recess Template

## Array Exit Marking Template (Z33017)

Used to check the size of the well excavation, select the final position of the implant by rotating the tool in the well, and mark the exit position and width of the channel for the electrode array and extracochlear lead.

Figure 6: Array Exit Marking Template


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### Recess Checking Gauge (Z60480)

Used to mark the well on the skull, and measure the depth of the well after drilling.

Figure 7: Recess Checking Gauge

## Other tools

### Non-sterile Silicone Implant Template (Z33020)

Used to determine/check the optimum implant position and trace it onto the skin prior to incision.

⚠ CAUTION

Do not sterilise. Do not use in the sterile field. Single-use item.

Figure 8: Non-sterile Silicone Implant Template

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## AOS (Advance Off-Stylet™) Forceps (Z60770)

Aids insertion of the electrode array into the cochlea. With curved tip ends that gently cup the array, improve stability and minimise rotation.

Figure 9: AOS Forceps


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# Surgical Procedure

## General surgical issues

Meningitis is a known risk of inner ear surgery. Candidates should be appropriately counselled of this risk and the vaccination status against organisms that cause meningitis. Broad-spectrum antibiotic coverage should be determined by the surgeon, to be consistent with best practice.

## 1. Pre-incision: non-sterile field

1. Place the BTE Template in position on the ear. Ensure there will be sufficient clearance between the receiver/stimulator and an ear level sound processor so that the sound processor will not rest on the receiver/stimulator. Typical separation is at least 10 mm.
2. Ensure the incision is large enough to accommodate the implant.
3. Prior to incision, the incision line may be infiltrated with 1 % Lidocaine with 1:100 000 or 1:200 000 adrenaline/epinephrine unless contraindicated.

## 2. Incision

⚠ WARNING

If the patient has an implant in the other ear, monopolar electrosurgical instruments must not be used (bipolar electrosurgical instruments may be used).

1. Make the incision down to the avascular plane of the periosteum and temporalis fascia, and form a flap (a monopolar cutting current may be used). Stabilise the flap using retraction as necessary.
2. Create an anteriorly-based large palva flap.
3. Elevate a sub periosteal pocket for the receiver/stimulator. After placing the receiver/stimulator in the sub periosteal pocket, it can be secured further by a variety of methods.
4. Elevate a separate, sub periosteal pocket against the bone under the temporalis muscle for the extracochlear electrode ball between the skull and the periosteum.

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# 3. Mastoidectomy and well

The mastoidectomy is described next. Some surgeons prefer to drill the well first.

## The mastoidectomy

Create an adequate mastoidectomy cavity, allowing an overhang both superiorly and posteriorly to accommodate any redundant proximal electrode lead.

## The well

1. Mark the well using the circular Bone Recess Template and/or the Implant Recess Template.
2. Drill the well bed. The round drill bed allows for some rotation of the receiver/stimulator, to achieve optimal placement.
3. Use the Bone Recess Template to check the well's final dimensions.
4. Place the Array Exit Marking Template in the well and rotate it to the optimum position.
5. Mark the exit of the electrode array.
6. Drill a channel to connect the well and the mastoid cavity. The channel will help to protect the electrode array against trauma.
7. Use the Recess Checking Gauge to check the position of the array exit.


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# 4. Facial recess

1. Open the facial recess ensuring it gives as much visibility and access as possible. Opening up the facial recess fully and widely is the key to ensuring ease of placing the cochlear electrode. When done correctly, the recess allows easy access and the correct angles of insertion. The horizontal canal and short process of the incus should be clearly visualised.
2. Identify the facial nerve, but do not expose it. The facial nerve should be identified and bone removed anterior to it and anterior/inferiorly and anterior/medially. In addition, the bone lateral to it should be removed as well, coupled with a thin exterior auditory canal.
3. Identify the chorda tympani nerve.

   The posterior portion of the middle ear, including the stapedius tendon, promontory and round window niche (RWN), should be clearly visualised.

   The view of the round window membrane is normally obstructed by a bony overhang of the lateral margin of the round window niche. In addition, a false membrane often covers the true membrane.

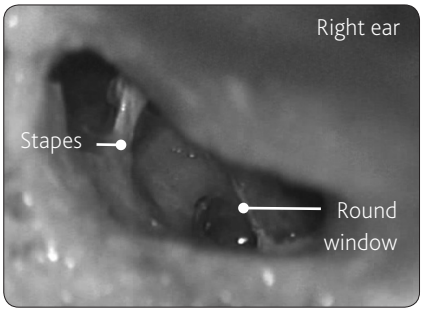


Figure 10: Pre removal of the bony overhang on the lateral rim of the round window

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4. Remove the bony overhang using a 1.0 mm or a 1.5 mm diamond burr. Once the bone has been removed, the posterior portion of the middle ear, including the stapedius tendon, promontory and round window niche (RWN), should be clearly visualised.

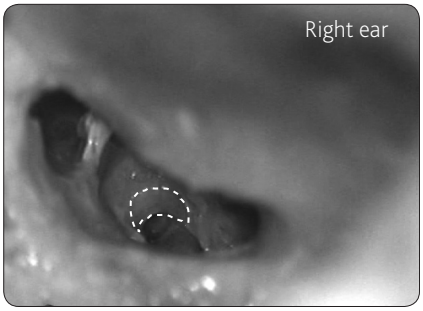


Figure 11: Post removal of the bony overhang on the lateral rim of the round window

## 5. Preparing the round window or cochleostomy

The Hybrid L24 implant electrode is compatible with both the round window (method 1) and traditional cochleostomy (method 2) approaches. This section describes the preparation of the site for both approaches. See later section for details on inserting the electrode array.

NOTE
Do not actually open the round window or cochleostomy until ready to insert the electrode.


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# Method 1 — round window

1. Visualise the stapes to confirm the site of the round window, and visualise the round window membrane. It is approximately 2 mm inferior and slightly posterior to the oval window.

   The round window membrane may be obscured by the overhang of the lateral margin of the niche. It may be necessary to drill away the overhang to see the round window membrane.

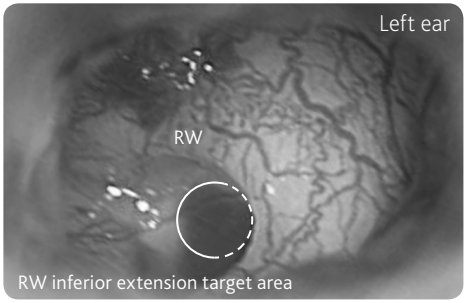


Figure 12: Round window target area

2. Remove the false membrane.
3. Immediately prior to inserting the electrode, a straight incision is made inferiorly in the round window from anterior to posterior.

NOTE
The diameter of the incision must be at least equal to the diameter of the electrode at the proximal end i.e. 0.6 mm diameter.

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# Method 2 — cochleostomy

1. Visualise the stapes to confirm the site of the round window, and visualise the round window membrane. It is approximately 2 mm inferior and slightly posterior to the oval window.

   The round window membrane may be obscured by the overhang of the lateral margin of the niche. It may be necessary to drill away the overhang to see the round window membrane.

2. Perform a cochleostomy into the scala tympani using a 1.4 mm or 1.0 mm diameter diamond burr at low speed.

   Position the cochleostomy inferior and slightly anterior to the round window membrane. It should be close to, or incorporating, the round window niche. A slight blue line of endosteum should become visible as the bone is being thinned for the cochleostomy This indicates the location of the scala tympani.

   Drilling too far anteriorly or superiorly will result in the endosteum appearing white and the scala media or vestibuli may be entered. Drilling too far inferiorly will miss the cochlea entirely and a hypotympanic air cell may be entered, leading to incorrect electrode placement.

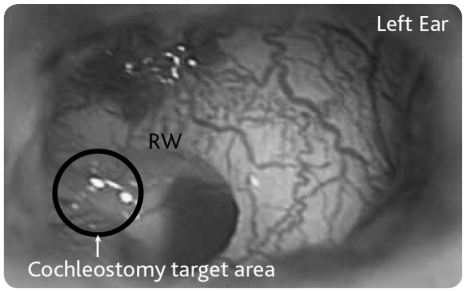


Figure 13: Cochleostomy target area


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3. Drill sufficient bone with the 1.4 mm or 1.0 mm diameter diamond burr to expose at least 0.65–0.75 mm of endosteum. A 0.5 mm diameter diamond burr or a small foot plate hook (0.2 mm diameter) may be used to remove the final layer of bone.

CAUTION

A cochleostomy size of 0.6–0.7 mm is preferred. This size accommodates the diameter of the electrode adjacent to the stopper. A cochleostomy size greater than 1.2 mm may result in the unwanted insertion of the stopper into the cochlea.

The following should be performed immediately prior to insertion of the electrode:

1. Open the endosteum with a hook or needle.
2. Using stapes footplate instruments, remove any sharp edge of bone which might snag the electrode.

NOTE

Do not suction the perilymph.

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# 6. Inspecting the implant and electrodes

1. Remove the implant's outer packaging.
2. Break the seal on the outer tray, and without touching the device, confirm the inner packaging is not damaged, and that exposure to ethylene oxide processing is indicated.
3. Remove the sterile tray and confirm the implant is not damaged.
4. Lift the implant from the sterile packaging tray.

NOTE
Leave the protective tube on the array until just prior to insertion.

CAUTION
Monopolar electrosurgical instruments must not be used on the neck and head of a cochlear implant patient from this point. Bipolar electrosurgical instruments may be used; however, the cautery electrodes must not contact the implant and should be kept more than 1 cm from the extracochlear electrodes.


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## 7. Securing the device

Place the pedestal of the receiver/stimulator in the well, and place the electrode lead in the centre of the channel.

⚠ CAUTION

If rotating the implant in its bed, take care not to pinch the electrode lead between the edge of the bone channel and the pedestal.

If desired, secure the package with a suture using a non-absorbable synthetic material.

⚠ CAUTION

Do not suture directly over the magnet in case the magnet requires removal at a later date.

## 8. Securing the extracochlear electrode

Carefully place the extracochlear electrode against the bone under the temporalis muscle, minimising mechanical stress on the electrode lead. Do not place it in the temporalis muscle.

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# 9. Inserting the electrode array

The forceps should be used to slowly insert the electrode array into the round window or cochleostomy, holding the electrode by the handle.

NOTE

- Use minimal force and insert the electrode slowly. A slow insertion reduces the risk of intracochlear trauma and allows displacement of the perilymph.
- Do not suction the perilymph from within, or near, the round window or cochleostomy.

1. Carefully remove the protective tube from the electrode array. Do not squeeze or stretch the array.
2. Holding the electrode by the handle, guide the tip toward the cochleostomy or round window ensuring that the half-band electrodes remain oriented toward the modiolus. The handle can be used to identify electrode orientation, as it is located on the opposite side of the electrode array. Advance the electrode slowly so that the first few electrodes are inserted.
3. Using the handle to maintain orientation, continue slowly inserting the electrode up to the white silicone stopper.
4. Stabilise the lead to prevent movement of the electrode array in the cochlea.


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# 10. Securing and sealing the intracochlear electrode array

⚠ CAUTION

Immediately after electrode insertion and before arranging the excess proximal electrode lead in the mastoid cavity, it is important to immobilise the electrode by continuously holding it by the handle. Movement of the excess lead could result in the electrode twisting and potentially damaging structures, or possibly freeing itself from the cochlea.

The electrode array may be secured to limit the risk of migration. The method of fixation, and choice of fixation points, will depend on surgical access and the surgeon's discretion.

Pack completely around the electrode in the cochleostomy or round window with an autograft consisting of strips of fascia or pericranium to ensure there are no gaps in the seal. If there is a perilymph leak, extra tissue may be needed to ensure that the seal is tight.

Coil the excess redundant proximal electrode lead inside the mastoid cavity under the bony overhangs.

Place any excess loop of the extracochlear electrode in the mastoid cavity. If the leads are able to migrate into subcutaneous tissue they may be subject to excessive movement and fatigue. To avoid this, ensure the leads are secure within the cavity, but do not suture over the leads with fine gauge sutures.

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## 11. Intraoperative measurements

Intraoperative measurements via telemetry may now be performed. Put the transmitting coil in a sterile sheath, replace the flap and place the coil on top of the implant.

NOTE
The implant transmitting range is 2–10 mm. The implant may not function properly if the coil is directly on top of the receiver/stimulator.

## 12. Closure

The facial recess may be packed with soft tissue. Suture the palva flap over the proximal portion of the intracochlear electrode lead. Close the wound in layers. Drainage is not recommended. Apply a large mastoid dressing.


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# Magnetic Resonance Imaging

## Overview

The Hybrid L24 implant is designed to withstand Magnetic Resonance Imaging (MRI) at field strengths described in the Warnings and Precautions sections of the Important Information Booklet and Physician's Package Insert. At some field strengths in some regions, the magnet must be removed surgically before the patient undergoes an MRI procedure. The magnet must be removed at all field strengths in the USA.

If inspecting near the implant, removal of the magnet should be considered as MR image quality may be compromised with it in place.

Read the MRI section of the Important Information Booklet or Physician's Package Insert before following the instructions below.

⚠ CAUTION

- Take care when removing or inserting the magnet (or plug) so the implant silicone is not damaged: exert minimal force; always use a blunt instrument – such as an elevator – to lift the lip of the silicone elastomer recess; and minimise the pressure applied to the implant coil.
- Magnets for the Hybrid L24 implant are a different size to magnets for the CI500 Series. Ensure that the correct magnet (Z50101) is used.
- Plugs for the Hybrid L24 implant are a different size to plugs for the CI500 Series. Ensure that the correct plug (Z50100) is used.

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# Removing the magnet before implantation

If a new recipient has a condition that will require future MRI examinations, it may be appropriate to replace the magnet with a non-magnetic titanium plug before the device is implanted.

The replacement procedure should take place under sterile conditions.

To replace the magnet prior to implantation:

1. In sterile conditions, remove the cochlear implant from its sterile packaging and place it on a flat and stable surface, with the star symbol on the magnet facing up. Do not remove the electrode array protective tube.
2. Using an elevator, or similar instrument, lift the tip of the silicone elastomer recess around the magnet and remove the magnet from the implant. When removing the magnet, minimise the pressure applied to the antenna of the implant.
3. Remove the sterile non-magnetic plug from its packaging and insert it into the recess. Lift the lip of the recess using an elevator and press the plug into position, being careful not to exert undue pressure on the implant.
4. The cochlear implant is now ready for implantation.

Replace the magnet when there is no further need for MRI examinations, following the procedures below.

To wear an external transmitter coil while the implant has no magnet in place, the patient must wear a retainer disc.


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# Removing the magnet after implantation

Remove the magnet in sterile conditions, using either general or local anaesthetic. To avoid damaging the magnet pocket, when removing the magnet use blunt instruments.

1. Make a small incision ensuring there is good access to the magnet.

⚠ CAUTION

- Do not use monopolar electrosurgical instruments.
- Keep bipolar electrosurgical instrumements at least 1 cm away from the extracochlear electrodes.

2. Cut through any fibrous growth around the implant and expose the magnet.
3. Using an elevator or similar instrument, carefully lift the lip of the silicone elastomer recess and remove the magnet. If a retaining suture runs across the magnet, move the suture out of the way.

The surgical technique then differs according to whether the patient requires a single MRI examination or multiple examinations over a period of time.

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# Single MRI

For a single MRI examination:

1. Make a small incision (see previous section) and remove the magnet.
2. Leave the magnet recess empty and apply a dry sterile dressing, without closing the wound.
3. The recess may remain empty with sterility maintained for a period of up to four hours.
4. Take the patient for the MRI examination.
5. After the MRI has been taken, insert a sterile replacement magnet with the star symbol (denoting polarity) facing up.
6. Use the elevator to lift the lip of the recess and position the magnet.
7. Close the wound in layers.


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# Multiple MRI

For implant users requiring multiple MRI examinations over a period of time, the implant magnet is removed and replaced with a sterile non-magnetic titanium plug. In the magnet's absence, the plug prevents fibrous tissue growing into the recess. Such growth makes later magnet replacement difficult.

The patient must wear a retainer disc to hold their external transmitter coil in place when the magnet has been removed.

When there is no further need for MRI examinations, the plug is removed and replaced by a magnet.

The titanium plug and replacement magnet are supplied separately in sterile packs. Both are single-use items.

To insert a sterile non-magnetic plug in the recess:

1. Make a small incision (see earlier section) and remove the magnet.
2. Lift the lip of the recess using an elevator and press the non-magnetic plug into position, being careful not to exert undue pressure on the implant.

⚠ CAUTION

Plugs for the Hybrid L24 implant are a different size to plugs for the CI500 Series. Ensure that the correct plug (Z50100) is used.

3. Close the wound in layers.

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When MRI is no longer a regular necessity:

1. Make a small incision (see earlier section) exposing the magnet recess.
2. Remove the non-magnetic plug, using the above procedure.
3. Insert a sterile replacement magnet with the star symbol (denoting polarity) facing up. Use an elevator to lift the lip of the recess and position the magnet.

CAUTION

Magnets for the Hybrid L24 implant are a different size to magnets for the CI500 Series. Ensure that the correct magnet (Z50101) is used.

4. Close the wound in layers.

For additional information about magnet removal, contact Cochlear.


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# General Information

## Post-operative management

Monitor the patient as for all procedures involving general anaesthesia. Keep the pressure dressing on for one day, then inspect the wound and apply another dressing for five days. Remove sutures on approximately the 10th day.

The initial fitting procedure for the sound processor should be scheduled three to four weeks after the operation. Fitting should be checked at three months, six months and one year postoperatively, then at yearly intervals (or more frequently if required by the condition of the patient).

## Explantation

In rare circumstances, it may be necessary to explant a cochlear implant. Please follow the guidelines below.

- Contact Cochlear to order a Retrieved Device Kit (Z25017). The kit must be used to transport the explanted device to Cochlear.
- Before explanting the device, examine it for any defects, and note these on the form provided with the kit.

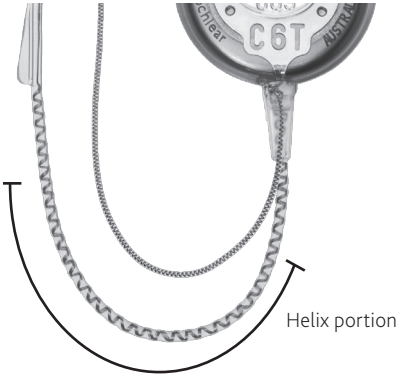


Fig 14: Helix portion of electrode lead

- Try to keep the explanted device intact and undamaged.
- Cut the intracochlear electrode lead if this will make it easier to remove the device without damaging it. The cut should be in the helix portion of the electrode lead.
- If the extracochlear electrode (ball) is difficult to remove, cut the extracochlear lead and leave the ball in place.

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- If the intracochlear electrode array is removed from the cochlea, return it in the kit, even if it is damaged.
- If removal would cause excessive trauma, leave the distal end of the extracochlear electrode lead (with the ball electrode) in place.
- Return the kit containing the explanted device to Cochlear.

## Problem reporting

Legislation on medical devices requires the manufacturer to report adverse events to the appropriate authorities. Should such an incident occur, notify the nearest Cochlear office or its official distributor as soon as possible.

## Warranty

To the purchaser: the law in some countries requires that the written warranty for this cochlear implant must be made available for the patient's review before it is sold to her/him. The Cochlear terms and conditions of warranty should therefore be given to the patient before implantation of the cochlear implant. The warranty is included in the document pack.

## Registration

Please ensure the registration card is completed and returned to Cochlear within 30 days of receiving the product. The patient should also complete the supplied patient identification card and carry it with them at all times.


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# Hybrid L24 implant specifications

## Electrodes

- 22 half-banded platinum electrodes, moulded with a silicone elastomer carrier, located towards the distal end of a 16 mm active array (tip to stopper).
- Proximal diameter of 0.55 x 0.4 mm tapering to a distal diameter of 0.35 x 0.25 mm.
- Two extracochlear electrodes: one platinum plate attached to the receiver/stimulator package, and a separate 1.5 mm (typical) diameter ball electrode on an 80 mm lead.
- A white silicone stopper limits intracochlear placement to the desired depth.

## Receiver/stimulator

- Hermetically sealed titanium case
- Case dimensions: 25 mm x 19.3 mm x 4.9 mm
- Coil dimensions: 30.6 mm diameter x 6.9 mm thick
- Weight 9.5 g (including electrode array).

## Operating characteristics

- Power and data received by a 5 MHz inductive link from the sound processor headset coil
- Delivers biphasic current pulses
- Delivers monopolar, bipolar or common ground stimulation
- Delivers stimulus amplitudes from 0 to 1.75 mA
- Delivers stimulus duration from 9.6 µs to 400 µs per phase.

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# Certification and applied standards

The Nucleus® cochlear implant system and the Cochlear™ Hybrid™ System fulfil the essential requirements listed in Annex 1 of the EC directive 90/385/EEC on Active Implantable Medical Devices as last amended by EC Directive 93/68/EEC. Both systems were approved for CE-Mark according to Annex 2 by Notified Body 0197; the Nucleus® cochlear implant system in 1993, 1996, 2001, 2004 and 2005, and the Cochlear™ Hybrid™ System in 2008.

CE 0197


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# Symbols used on implant packaging

| Symbol | Meaning |
|---|---|
| | Fragile, handle with care |
| | Read operator's manual |
| | Do not re-use |
| | Date of manufacture |
| | Manufacturer |
| | Use-by date |
| -20°C (-4°F) +50°C (+122°F) | Temperature limit |
| STERILE EO | Sterilised using ethylene oxide |
| Rx Only | Caution: US law restricts this device to sale by, or on the order of, a physician |
| REF | Catalogue number |
| SN | Serial number |
| LOT | Batch code |
| CE 0197 | CE registration mark |

Table 1: Symbols used on implant packaging



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| Symbol | Meaning |
|---|---|
| | Keep dry |
| | Do not use if package is damaged |
| | Caution |
| | Do not resterilise |

Table 1: Symbols used on implant packaging


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Cochlear™

# Nucleus® Hybrid™ L24 implant CI24REH

## Important Information: Warnings, Precautions and Electromagnetic Compatibility

Hear now. And always

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# Symbols

| | |
|---|---|
| | **Note**<br>Important information or advice.<br>Can avoid inconvenience. |
| | **Caution (no harm)**<br>Special care to be taken to ensure safety and effectiveness.<br>Could cause damage to equipment. |
| | **Warning (harmful)**<br>Potential safety hazards and serious adverse reactions.<br>Could cause harm to person. |

This document contains important information such as warnings, precautions and privacy that applies to the following cochlear implant systems:

- Cochlear™ Nucleus® Hybrid™ L24 implant (CI24REH)

Read this document carefully to ensure that you understand the care of your system.

Discuss this information with your physician before undergoing any major medical procedure.

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# Warnings

## Medical treatments generating induced currents

Some medical treatments generate induced currents that may cause tissue damage or permanent damage to the implant. Warnings for specific treatments are given below.

### Electrosurgery

Electrosurgical instruments are capable of inducing radio frequency currents that could flow through the electrode array. Monopolar electrosurgical instruments must not be used on the head or neck of an implant patient as induced currents could cause damage to cochlear tissues or permanent damage to the implant. Bipolar electrosurgical instruments may be used on the head and neck of patients; however, the cautery electrodes must not contact the implant and should be kept more than 1 cm (~½ in.) from the extracochlear electrodes.

### Diathermy

Do not use therapeutic or medical diathermy (thermopenetration) using electromagnetic radiation (magnetic induction coils or microwave). High currents induced into the electrode lead can cause tissue damage to the cochlea or permanent damage to the implant.

Medical diathermy using ultrasound may be used below the head and neck.

### Neurostimulation

Do not use neurostimulation directly over the implant. High currents induced into the electrode lead can cause tissue damage to the cochlea or permanent damage to the implant.

### Electroconvulsive therapy

Do not use electroconvulsive therapy on an implant patient under any circumstances. Electroconvulsive therapy may cause tissue damage to the cochlea or damage to the implant.

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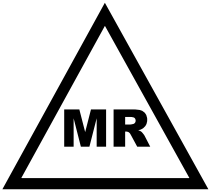
## Ionizing radiation therapy

Do not use ionizing radiation therapy directly over the implant because it may cause damage to the implant.

# Magnetic Resonance Imaging (MRI)




MRI is contraindicated except under the circumstances described below. Do not allow a patient with an implant to be in a room where an MRI scanner is located except under the following special circumstances.

**Warning**
The magnet must be surgically removed prior to undertaking MRI as tissue damage may occur if the recipient is exposed to MRI with the magnet in place.

**Warning**
The patient must take off the sound processor and headset before entering a room where an MRI scanner is located.

Non-clinical testing has demonstrated the CI24REH is MR Conditional only after the magnet has been surgically removed. It can be scanned safely under the following conditions:

- Magnet must be surgically removed prior to MRI scan
- Static magnetic field of 1.5 tesla
- Spatial gradient field of 260 Gauss/cm or less
- Maximum whole body averaged Specific Absorption Rate (SAR) of 0.5W/kg maximum above the bottom of the sternum and 2 W/kg maximum below the bottom of the sternum for 15 minutes of scanning as per the diagram below.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The quality of MRI will be affected by the metal in the implant. Image shadowing may extend as far as 6 cm (~ 2 ½ in.) from the implant (under the following scan sequence: T2-weighted Fast Spin Echo), thereby resulting in loss of diagnostic information in the vicinity of the implant.

For more information about magnet removal, refer to the Surgeon's Guide or contact Cochlear.

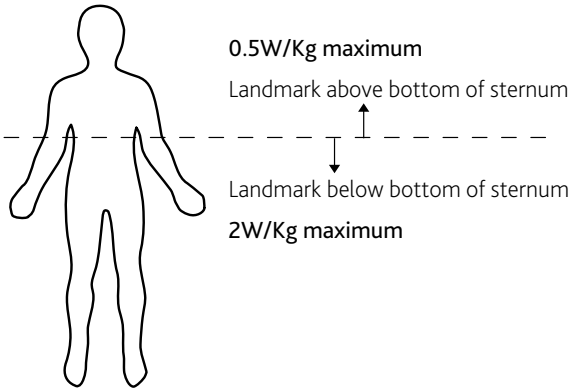


Figure 1: Whole average body SAR limits for 15 minutes scan time

In non-clinical testing, an equivalent implant produced a temperature rise of less than 1.2 °C at a maximum whole body averaged SAR of 0.5 W/kg, as assessed by calorimetry for 6 minutes of MR scanning in a 1.5 T GE Signa whole body coil when landmarked above the bottom of the sternum.

In non-clinical testing, an equivalent implant produced a temperature rise of less than 1.9 °C at a maximum whole body averaged SAR of 2 W/kg, as assessed by calorimetry for 6 minutes of MR scanning in a 1.5 T GE Signa whole body coil when landmarked below the bottom of the sternum.

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## Meningitis

Prior to implantation, candidates should consult their primary care physician and implanting surgeon regarding vaccination status against organisms that cause meningitis. Meningitis is a known risk of inner ear surgery and candidates should be appropriately counseled of this risk. In addition, certain preoperative conditions may increase the risk of meningitis with or without an implant. These conditions include:

- Mondini's syndrome and other congenital cochlear malformations
- Concurrent Cerebrospinal Fluid (CSF) shunts or drains
- Recurrent episodes of bacterial meningitis prior to implantation
- Perilymph fistulas and skull fracture/defect with CSF communication.

## Residual hearing

Most patients maintain audiometric thresholds in the implanted ear. For some patients, a total loss of acoustic hearing in the implanted ear may occur.

## Long-term effects of electrical stimulation

Most patients can benefit from electrical stimulation levels that are considered safe, based on animal experimental data. For some patients, the levels needed to produce the loudest sounds exceed these levels. The long-term effects of such stimulation in humans are unknown.

## Small parts hazard

Caregivers should be counseled that the external implant system contains small parts that may be hazardous if swallowed or may cause choking if ingested or inhaled.

## Head trauma

A blow to the head in the area of the implant may damage the implant and result in its failure.


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## Use of batteries and battery ingestion

When using disposable batteries, only use battery types recommended by your clinician or Cochlear. Other types may not have sufficient energy to allow your processor to operate for a long time. Cochlear does not recommend the use of silver oxide or alkaline batteries.

Batteries can be harmful if swallowed. Ensure that batteries are kept out of reach of young children. If swallowed, seek prompt medical attention at the nearest emergency center.

## Rechargeable batteries

In certain circumstances, rechargeable batteries can become VERY HOT, and could cause injury. Remove your processor immediately if it becomes unusually warm or hot, and seek advice from your clinician. Caregivers should touch the recipient's processor to check for heat if the recipient is showing signs of discomfort. Rechargeable batteries should NEVER be worn beneath clothing (including scarves and headwear covering the ears). Use of the rechargeable battery is contraindicated in patients who cannot remove the device by themselves, or notify a caregiver that the device has become hot.

## Overheating of external devices

Remove your processor immediately if it becomes unusually warm or hot, and seek advice from your clinician. Caregivers should touch their recipient's processor to check for heat if the recipient is showing signs of discomfort.

The manufacturer only recommends the use of Cochlear rechargeable battery modules and zinc air disposable batteries.

The processor is not intended to be used with silver oxide batteries. In some circumstances, the use of these batteries could result in severe burns. A dangerous amount of heat can be generated by these batteries in conditions where heat cannot dissipate, especially if the device is being held against the skin by clothing or a retention device. In addition, use of silver oxide batteries may damage your processor.

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# Precautions

If you experience a significant change in performance or the sound becomes uncomfortable, turn off your processor and contact your implant center.

Use the implant system only with the approved devices and accessories listed in the user guide.

Your processor and other parts of the system contain complex electronic parts. These parts are durable but must be treated with care. The opening of your processor by anyone other than Cochlear's qualified service personnel invalidates the warranty.

Each processor is programmed specifically for each implant. Never wear another person's processor or lend yours to another user.
If you have two processors (one for each ear), always wear the processor programmed for your left ear on the left, and the processor programmed for your right ear on the right. Using the wrong processor could result in loud or distorted sounds that, in some instances, may cause extreme discomfort.

Do not operate your processor at temperatures above +40 °C (+104 °F) or less than +5 °C (+41 °F).

Do not store your processor at temperatures above +50 °C (+122 °F) or less than -20 °C (-4 °F).

Your processor's sound quality may be intermittently distorted when you are within approximately 1.6 km or 1 mile of a radio or television transmission tower. Additional sources of interference include, but are not limited to:

- Security systems
- Industrial machinery and power systems
- Mobile communications equipment (including cellular telephones)
- Certain kinds of hand-held, two-way radios (including Citizen Band, Family Radio Service, and Amateur Band).

To reduce or eliminate the interference, move away from the source. If your processor stops working, turn the power switch off and then back on. This effect is temporary and will not damage your processor.

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## Theft and metal detection systems

Devices such as airport metal detectors and commercial theft detection systems produce strong electromagnetic fields. Some implant recipients may experience a distorted sound sensation when passing through or near one of these devices. To avoid this, turn off your processor when in the vicinity of one of these devices.

The materials used in the implant may activate metal detection systems. For this reason, recipients should carry the Cochlear Implant Patient Identification Card with them at all times.

## Electrostatic discharge

A discharge of static electricity can damage the electrical components of the implant system or corrupt the program in your processor.

If static electricity is present (e.g. when putting on or removing clothes over the head or getting out of a vehicle), implant recipients should touch something conductive (e.g. a metal door handle) before the implant system contacts any object or person.

Prior to engaging in activities that create extreme electrostatic discharge, such as playing on plastic slides, the processor should be removed. Clinicians should use an anti-static shield on the computer monitor when programming an implant recipient.

## Mobile telephones

Some types of digital mobile telephones, e.g. Global System for Mobile communications (GSM) as used in some countries, may interfere with the operation of the external equipment. As a result, implant recipients may perceive a distorted sound sensation when in close proximity, 1–4 m (~3–12 ft), to a digital mobile telephone in use.

## Air travel

Transmitting devices such as mobile/cell phones are required to be switched off on aircraft. If you have a remote control (remote assistant) for your processor, it should also be switched off because it is transmitting high frequency radio waves when switched on.


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## Scuba diving

| Implant type | Maximum depth |
|---|---|
| CI24REH implant | 40 m (~131 ft) |

Table 1: Maximum diving depths when wearing implants

Recipients should seek medical advice before participating in a dive for conditions that might make diving contraindicated, e.g. middle ear infection, etc. When wearing a mask, avoid pressure over the implant site.

## Sleeping

Do not wear your processor while sleeping, as you may not become aware of your processor becoming unusually warm or hot.

Do not allow recipients with disabilities to wear their processor while sleeping.

## Retention aids

When using retention aids such as the Snugfit™ or LiteWear, be aware that it may take longer to remove the processor if the processor becomes unusually warm or hot.

Do not attach the LiteWear beneath layers of clothing.

## Electromagnetic interference with medical devices

Cochlear Nucleus Remote Assistants meet defined international Electromagnetic Compatibility (EMC) and emission standards. However, because the remote assistant radiates electromagnetic energy, it is possible that it could interfere with other medical devices such as cardiac pacemakers and implantable defibrillators when used nearby. It is recommended that the remote assistant is kept at least 6 in. (~15.2 cm) away from devices which could be subject to electromagnetic interference. For added assurance, please also consult the recommendations provided by the device manufacturer.

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# Electromagnetic Compatibility (EMC)

## Guidance and manufacturer's declaration

The Nucleus Series Sound Processor and Remote Assistant are intended for use in the electromagnetic environments specified in this document.

They have been tested and found to be in compliance as shown. You should take care to use your processor as described.

## Electromagnetic emissions

| Emission test | Compliance | Guidance |
|---|---|---|
| RF emissions<br>CISPR 11 | Group 1 | RF energy is only used for its internal function. The RF emissions are very low and not likely to cause any interference in nearby electronic equipment. |
| RF emissions<br>CISPR 11 | Class B | The device is suitable for use in all establishments, including domestic establishments and those directly connected to public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions<br>IEC 61000-3-2 | Not applicable | |
| Voltage fluctuations/ flicker emissions<br>IEC 61000-3-3 | | |

Table 2: Electromagnetic emissions

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# Electromagnetic immunity

| Immunity test | IEC 60601 test level | Compliance level | Guidance |
|---|---|---|---|
| Electrostatic discharge (ESD) IEC 61000-4-2 | ±6 kV contact<br>±8 kV air | ±6 kV contact<br>±8 kV air | Refer to *Electrostatic Discharge* section |
| Electrical fast transient/burst IEC 61000-4-4 | Not applicable | | |
| Surge IEC 61000-4-5 | | | |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | | | |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields be at levels characteristic of a typical location in a typical commercial or hospital environment |
| Conducted RF IEC 61000-4-6<br>Radiated RF IEC 61000-4-3 | Not applicable<br>3 V/m 80 MHz to 2.5 GHz | 3 V/m | Refer to the<br>• Warnings and Precautions, and<br>• guidance below |

Table 3: Electromagnetic immunity


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## Guidance

Portable and mobile RF communications equipment should be used no closer to any part of the devices, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Recommended separation distance (d):

$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz

$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz

where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b]

Interference may occur in the vicinity of equipment marked with the following symbol:

**Note**

1. At 80 MHz and 800 MHz, the higher frequency range applies.
2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Explanatory notes:

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the processor is used exceeds the applicable RF compliance level above, the processor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the processor.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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# Recommended separation distances

Your processor is intended for use in an electromagnetic environment where the radiated RF disturbances are controlled.

To prevent electromagnetic interference, maintain a minimum distance between the portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

| **Rated maximum output power of transmitter (W)** | **Separation distance according to frequency of transmitter (m)** | | |
|---|---|---|---|
| | **150 kHz to 80 MHz** $d = 1.2\sqrt{P}$ | **80 MHz to 800 MHz** $d = 1.2\sqrt{P}$ | **800 MHz to 2.5 G Hz** $d = 2.3\sqrt{P}$ |
| 0.01 | Not applicable | 0.12 | 0.23 |
| 0.1 | | 0.38 | 0.73 |
| 1 | | 1.2 | 2.3 |
| 10 | | 3.8 | 7.3 |
| 100 | | 12 | 23 |

Table 4: Recommended separation distances

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

**Note**

1. At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.


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*Hear now. And always*

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**DRAFT**

# POST APPROVAL STUDY-Extended Duration

**P130016**

**Nucleus® Hybrid™ L24**
**Implant System**

**CORP-XXXX-HYB-PMA**

Study Sponsor:

Cochlear Americas
**13059 East Peakview Avenue**
Centennial, CO 80111

**CONFIDENTIAL - DO NOT COPY**

This protocol contains confidential proprietary information with respect to Cochlear products and clinical trials. I agree to hold this information in confidence and not to disclose it to any third parties for the shortest of the following periods of time: three years from the date of this agreement, the time at which this information becomes a matter of public knowledge, or the time at which a formal agreement for that purpose has been entered into by the parties.

**Investigator Responsibilities**

I, the undersigned, am responsible for the conduct of the study at the site below and by my signature below, I confirm that I have read, understand and will strictly adhere to the study protocol, "Evaluation of the Nucleus Hybrid L24 Cochlear Implant System - Post Approval Study-Extended Duration."

---

Clinical Investigational Site

---

Primary Investigator's Name (print)

---

Title

---

Signature

---

Sponsor Representative

---

Title

---

Signature

**Nucleus® Hybrid™ L24 Implant System**

**Post Approval Study – Extended Duration**

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## TERMS, DEFINITIONS, AND ABBREVIATIONS

| Term/Abbreviation | Definition |
|---|---|
| **Acoustic Alone** | Pre- or postoperative condition referring to the use of acoustic hearing alone, with or without amplification, ipsilateral to the implanted ear (i.e., in the same ear as the implant). |
| **Acoustic Component** | An optional component for the sound processor used with the Hybrid L24 implant, which provides amplification in the low frequencies for those patients who have residual hearing, postoperatively. |
| **AzBio Test**[1] | A sentence-level speech recognition test delivered in background noise at a +10 dB SNR |
| **Everyday Listening Condition** | Postoperative listening condition referring to either Combined Mode (defined below) or Bimodal Mode (defined below); |
| **Bilateral Acoustic** | Pre-operative condition referring to the use of bilateral acoustic hearing (i.e., acoustic hearing in both ears), with or without amplification. |
| **Bimodal Mode** | Use of acoustic hearing, with or without amplification, in addition to electric hearing via a cochlear implant in the contralateral (opposite) ear. |
| **BTE** | Behind-The-Ear. |
| **CI** | Cochlear Implant |
| **CNC Word List**[2] | A word recognition test delivered in quiet |
| **Combined Mode** | Use of acoustic hearing bilaterally, with or without amplification, in addition to electric hearing via a hybrid implant. |
| **CRF** | Case Report Form. |
| **Cochlear Implant Alone** | Stimulation delivered by the cochlear implant alone. |
| **Hybrid Mode** | Combination of acoustic and electric hearing, in the same (ipsilateral) ear. |
| **ITE** | In-The-Ear. |
| **MAP** | A program that defines the individualized fitting parameters of recipients for a specific speech coding strategy. |
| **Nucleus® Custom Sound™** | Clinical programming software for Nucleus cochlear implant systems. |
| **Nucleus® Freedom™ for Hybrid™ sound processor** | BTE sound processor used in the Nucleus Hybrid L24 IDE clinical study; often abbreviated as 'Freedom Hybrid sound processor' or 'Hybrid sound processor.' |

[1] Spahr, A, Dorman, M., Litvak, L, Van Wie, S, Gifford, R *et al.* (2011). Ear Hear 33(1): 112-117.
[2] Consonant-Nucleus-Consonant Test; Peterson, F.E. & Lehiste, I. (1962). Revised CNC lists for auditory tests. Journal of Speech and Hearing Disorders, 27(1): 62-70.

| | |
|---|---|
| **Signal-to-Noise Ratio** | The level relationship (ratio) of the target (signal) to the noise (e.g., if the target speech is 60 dBA and the noise is 50 dBA then the SNR = +10 dB). |

**Evaluation of the Nucleus® Hybrid™ L24 Implant System**

***Post Approval Study – Extended Duration***

**BACKGROUND**

The Hybrid L24 Implant System (P130016) was the subject of a pivotal clinical trial (IDE G070191) from 2007-2012. The data on the 50 subjects in support of safety and effectiveness of the device was submitted in June 2013 as part of PMA #130016. As part of the PMA approval, a Post Approval Study to monitor the extended (5 years) safety and effectiveness of the device in the original study population was designed.

**Device Description**

The Hybrid L24 Implant System, indicated for individuals with normal to moderate low-frequency hearing sensitivity and a severe to profound high-frequency sensorineural hearing loss, provides electric-acoustic (E+A) stimulation via a combination of internal and external components. The components consist of the Hybrid L24 implant (model CI24REH); an external sound processor (CP910/920) with or without an accessory port; a remote assistant (CR210/230) and specialized Custom Sound software.

**Indications for Use**

As all study subjects will have met the IDE G070191 pivotal study requirements of inclusion/exclusion and Indications for Use, the following is for informational use only. The Nucleus Hybrid L24 Implant System is intended for use in individuals 18 years or older who have thresholds in the normal to moderate range in the low frequencies with a severe to profound sensorineural loss in the high frequencies. Typical candidates will have the following in the ear to be implanted:

- Normal to moderate hearing loss in the low frequencies with thresholds up to 60 dB HL through 500 Hz;
- Severe to profound hearing loss at frequencies >1500 Hz (threshold average of 2000, 3000, and 4000 Hz ≥ 75 dB HL);
- CNC word recognition score between 10% and 60% inclusively in the preoperative aided condition.

The contralateral ear is typically equal to or better than the ear to be implanted but not more than 80% correct on CNC (words). For individuals with post-implant low frequency hearing, the sound processor provides acoustic amplification with electric stimulation for the high frequencies. Prospective candidates should also have appropriate expectations of the benefits of an implant with or without an acoustic component.

A Hybrid L24 Implant System is contraindicated for individuals with the following conditions:

- Deafness due to lesions of the acoustic nerve or central auditory pathway
- Active middle ear infections
- Absence of cochlear development
- Duration of severe to profound hearing loss > 30 years

## STUDY PURPOSE

The purpose of this study is to conduct extended duration (5 years post-implant) monitoring of the safety and effectiveness of the Hybrid L24 Implant System. This study will be comprised of a cohort (up to 47[3]) of current Hybrid subjects from IDE G070191 who have agreed to participate in a further evaluation of an approved sound processor with new, investigational features. In parallel to their participation in that IDE supplement (G070191/S026), study subjects will be asked to participate in this extended duration study up to five years post-activation.

## STUDY OBJECTIVES AND HYPOTHESES

### Study Design

This study will be conducted as a prospective, non-controlled, non-randomized, multicenter study.

### Study Population

Up to 47 subjects from the original study (G070191) population for the Hybrid L24 will be invited to participate. These subjects will also be given the opportunity to participate in an IDE for the N6 speech processor with new (investigational) features. It is expected that participation in that study will facilitate enrollment in this post approval study. The study cohort will consist of up to 47 adult subjects from IDE G070191 representing the 10 implanting centers. All study subjects will have met the following criteria as it was required for enrollment into the pivotal study.

Study Inclusion Criteria

- Subjects 18 years of age and older;
- Subjects will present with normal to moderate low-frequency hearing with a severe to profound sensorineural loss in the high frequencies. For the ear to be implanted, candidates will have the following:
  - normal to moderate hearing loss in the low frequencies with thresholds up to 60 dB HL through 500 Hz;
  - severe to profound hearing loss at frequencies >1500 Hz (threshold average of 2000, 3000, and 4000 Hz $\geq$ 75 dB HL);
  - CNC word recognition score between 10% and 60% inclusively in the preoperative aided condition;
- The contralateral (non-treated) ear will be equal to or better than the ear to be implanted but not more than 80% correct on CNC (words);
- Subjects not currently hearing aid users should participate in a 30-day trial with hearing aids prior to study enrollment;
- Subject should have appropriate expectations of the benefits of an implant with or without an acoustic component.

Study Exclusion Criteria

[3] Subjects deemed eligible for that IDE (Go7l191/S026)

- Deafness due to lesions of the acoustic nerve or central auditory pathway;
- Active middle ear infections;
- Absence of cochlear development;
- Duration of severe-to-profound hearing loss > 30 years.
- Existing implant in the contralateral ear

**Primary and Secondary Outcomes**

The primary safety outcome of this study will be based on the monitoring of type and frequency of adverse events over the extended duration (5 years post-implant) of continued Hybrid L24 use. An adverse event will be considered to be device-related when, in the judgment of the Primary Investigator, there is a logical connection between the use of the device (including the surgical procedure) and the occurrence of the event. Those adverse events (by type and frequency of occurrence) will be expected to be consistent with that reported in the pivotal study.

The long-term effectiveness of the device will be assessed based on individual performance as measured by speech perception tests over the course of the 60 months study duration. These tests (CNC words in quiet and AzBio sentences +10dB S/R) will be administered at the study enrollment interval (Baseline) and at each annual follow-up interval until study completion at 60 months, post-implant. Outcomes will be based on a comparison between the hearing aid (preop) and 60 Month (postimplant) speech perception data.

**Primary Endpoints**

The primary safety endpoint will be the comparison of the type and frequency of adverse events (and serious adverse events) occurring over the course of this study (up to 60 months) as compared to the pivotal clinical study for the Hybrid L24 (G070191).

The co-primary efficacy endpoints for this study will be the assessment of statistical significance of the within-subject differences for two speech recognition tests:

- Word recognition in quiet as evaluated with the Consonant-Nucleus-Consonant (CNC) test (Peterson and Lehiste, 1962);
- Sentence recognition in noise (+10dB) as evaluated with the AzBio test (Spahr *et al.*, 2011).

Scores on both speech tests will be obtained at this study Baseline (time of enrollment) and annually until study completion at 60 months. To be consistent with the data included in the *Post Approval Study – Newly Implanted* for the Hybrid L24, the above referenced speech recognition metrics will be used. These tests were part of the efficacy battery for the pivotal study (G070191) for these study subjects as well as part of the Minimum Speech Test Battery (MSTB) published in 2011 as a joint effort of the cochlear implant industry and the audiologic/otologic professional community. These test materials are provided free of charge to any cochlear implanting center and include calibration and instructions for use.

The primary endpoints will be that mean performance with each of these measures would show significant benefit with use of the Hybrid device (Hybrid mode and Everyday Listening condition) compared to the preoperative amplification condition at the end of the 60 months study period.

**Data Analysis**

- **Analysis of Safety**

  - Adverse Events and Serious Adverse Events will be expressed as events per patient – time.
  - All adverse event rates will be reported as the number and frequency of events with corresponding 95% exact binomial confidence limits and the number of events per patient-time (e.g., events per 10 patient years), and compared qualitatively to previous cochlear implant studies.
  - Time to first adverse event (including total losses of residual hearing) will be summarized using Kaplan Meier plots. Exploratory proportional hazards regression models will be used to determine whether baseline factors are associated with risk for adverse events over follow-up. Hazard ratios and 95% confidence intervals for these analyses will be cited.

- **Analysis of Efficacy**

  The significance of the mean differences in speech recognition scores between preoperative and the 60 months postactivation interval (study completion) will be analyzed using paired t-tests. If there was significant evidence that the assumptions of the t-tests did not hold (i.e. $p < 0.05$ from a Shapiro-Wilk test of normality), then Wilcoxon signed rank tests will be used.

**Adverse Events**

For purposes of this protocol, adverse events will be consistent with complaint reporting for similar approved technologies under 21 CFR 820.198. The sponsor expects an increase in the percent AEs reported per the installed base given the required reporting under this protocol.

As for loss of hearing sensitivity at the implant ear, this data will be trended in a similar fashion to the pivotal protocol (G070191) but will not be considered an adverse event unless the loss reaches a profound level (PTA average of 90 dB or greater for frequencies 125-1000Hz), total loss and/or explantation. Should an explantation occur, the sponsor will treat this as a serious injury with reporting occurring under the Medical Device Reporting regulations (21 CFR Part 803) in addition to inclusion in the annual update report on the PAS.

**Length of Follow-up**

Subjects will be followed for five (5) years post-activation.

## DATA COLLECTION PROCEDURES

As most cochlear implant patients routinely return for annual follow-up/programming visits, the yearly data collection is not anticipated to place a burden on sites or subjects. Conservatively, it

is anticipated that there could be a 30% lost-to-follow-up rate[4]. Attempts will be made to enroll as many of the study eligible candidates (n=47) as possible. As indicated above, study candidates will be approached in parallel to their enrollment into the IDE to evaluate new sound processor features for the Hybrid L24 system. Study duration is not expected to exceed 36 months as all current Hybrid L24 study subjects will have been implanted at least two years by the time of PMA approval and PAS initiation and enrollment.

**Data Collection Forms**

Study subjects will be required to sign an Informed Consent.

The Post Approval Study will require IRB approval. Study initiation will not begin before IRB approval is received at the respective institutions.

**Reporting Requirements for Interim/Final Reports**

The sponsor will submit annual interim reports beginning one year from the date of the *Post Approval Study – Extended Duration* protocol. These interim reports will contain the following information:

- Study enrollment by site
- Data collected relative to the primary and secondary endpoints
- Adverse events related to the device/procedure

**Test Metrics and Procedures-**

The following data will be gathered for each study subject following study enrollment and is summarized in table 1:

<u>Baseline (considered to be at time of study enrollment)</u>

- Otologic/medical questionnaire (health history);
- Unaided audiometric threshold measures, for each ear;
- Aided CNC Words presented in quiet at 60 dBA;
- Aided AzBio sentences presented at 60 dBA with +10dB SNR;
    - Each speech perception metric will be administered in the following two conditions:
        - Unilateral Condition: Hybrid mode or CI alone if subject no longer utilizes the acoustic component.
        - Everyday Listening Condition: Combined, Bimodal, Hybrid or CI alone
- Modified device use questionnaire;
- Health Utility Index (HUI);

<u>Annual Follow-ups</u>

[4] Based on sponsor experience with previous post-market studies

- Otologic/medical questionnaire (health history);
- Unaided audiometric threshold measures, for each ear;
- CNC Words presented in quiet at 60 dBA,
- AzBio sentences presented at 60 dBA with +10dB SNR;
    - Each speech perception metric will be administered in the following two conditions:
        - Unilateral Condition: Hybrid mode or CI alone if subject no longer utilizes the acoustic component.
        - Everyday Listening Condition: Combined, Bimodal, Hybrid or CI alone
- Modified device use questionnaire
- Health Utility Index (HUI).

Unaided audiometric thresholds will be obtained for each ear, *with insert earphones*, using the standard audiometric technique for pure-tone air-conduction testing.

Testing, for each ear, will include the following:

- Air conduction thresholds at 125, 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, and 8000 Hz;
- Bone conduction thresholds at 250, 500, 750, 1000, 1500, 2000, and 4000 Hz;
- Tympanometry at each ear.

**External Equipment Check**

Prior to any efficacy testing (e.g. speech perception testing) an assessment of the external hardware- CP900 sound processor, CP900 accessories and the acoustic component will be made

If any clinically significant change in unaided thresholds is noted then the amplification fitting(s) will be re-evaluated and adjustments made if necessary.

Table 1- Summary of Measures

| | Baseline Evaluation | Baseline + 12mos Post-activation | Baseline + 24mos Post-activation | Baseline + 36mos Post-activation |
|---|---|---|---|---|
| **Informed Consent** | X | | | |
| **Otologic & Medical History** | X | X | X | X |
| **Verification of Acoustic Component Function** | X | X | X | X |
| **Unaided Hearing Thresholds and Tympanometry** | X | X | X | X |
| **Processor Hardware Performance Check** | | X | X | X |
| **CNC test (Unilatral & Everyday)** | X | X | X | X |
| **AzBio-+10 S/R (Unilateral & Everyday)** | X | X | X | X |
| **Modified device use questionnaire** | X | X | X | X |
| **HUI** | X | X | X | X |

**Interim Evaluation intervals**

Should a subject report a decrement in performance and should that decrement in performance not be directly related to a simple hardware problem all specified interval testing will be conducted. Additionally, an otologic/medical case history will be taken.

**Evaluation Prior to Re-implantation with a Long Electrode**

In order to ensure that accurate information is gathered for any subjects electing to undergo explantation and re-implantation with a long array due, additional data will be collected prior to re-implantation. This evaluation will include the following information and will follow the procedures as described in the annual evaluation schedule:

- Audiometric testing

- Word recognition testing
- Psychophysical and electrical impedance measurements
- Otologic /medical questionnaire

If explantation occurs, in addition to being considered a serious injury, an MDR will be filed per 21 CRF 803.

**Study Completion**

Completed Subjects

Study subjects will be considered 'complete' when all assessments through 5 years postactivation have been performed in accordance with the study protocol. For subjects explanted, they will continue to be monitored on an annual basis whether reimplanted or not.

Discontinued Subjects

Any subject may voluntarily discontinue the PAS at any time without prejudice. The Investigator may discontinue a subject from the study at any time if (s)he considers that remaining in the study compromises the subject's health or the subject is not sufficiently cooperative. In either event, reason(s) for discontinuation should be recorded on a study withdrawal form, provided as part of the CRFs for the study.

Possible reasons for study discontinuation include the following:

- AE necessitating discontinuation from the study.
- The subject is lost to follow-up.
- Voluntary decision to withdraw consent made by the subject[5].
- Investigator decision[6].
- Other reason.

In case of a subject lost-to-follow-up, the Investigator must document a 'good faith' effort to attempt contacting the subject (or relative/family contact) by phone, email or letter multiple times. If attempts are unsuccessful, the 'subject withdrawal' form is to be completed in the study file and reported, as appropriate, in required reports to the Sponsor, IRB and FDA.

## ACCESS TO STUDY DOCUMENTS AND STUDY MONITORING

The Sponsor will designate appropriately trained monitors to review the progress of this supplemental study and assure the quality and integrity of data accumulated. All data generated

[5] Withdrawal of consent is defined as the subject's voluntary decision to revoke consent to continue participation in the study.

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and the source documents from which they originated are open to inspection by the Sponsor or its representative, the FDA, and other regulatory agencies.

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The Hybrid L24 Implant System represents a new treatment option, for a patient population that has few current therapeutic alternatives for ski-slope hearing loss. High frequency sound, crucial for speech discrimination, is provided electrically by the Hybrid L24 Implant while residual low frequency hearing is amplified by the acoustic component. The two modes of stimulation are processed and provided simultaneously by the externally worn Nucleus 6 Sound Processor.

Subjects with ski-slope hearing loss that participated in the pivotal Hybrid L24 clinical study were able to combine both low (acoustic) and high frequency (electric) information, from one or both ears, provided by the Hybrid L24 Implant System. Results indicated significant speech perception improvements in quiet and in noise when compared to preoperative performance. At study endpoint (6 months post activation), 100% of subjects showed equal or greater speech perception performance when listening with both ears (Hybrid + hearing aid in the opposite ear); greater than or equal to 90% of subjects when listening in the Hybrid Mode (electric and acoustic in the same ear).

As documented in the pivotal IDE study results, a percentage of individuals will lose their preoperative low frequency acoustic hearing subsequent to implantation with the Hybrid L24 Implant. This known risk is disclosed in the Hybrid L24 implant system labeling and is strongly recommended as an integral component of preoperative surgical and device counseling. Irrespective of the postoperative hearing status, most individuals can still be expected to receive substantial functional and speech recognition benefit on a daily basis when compared to their preoperative listening configuration of two hearing aids. The pivotal IDE study results also demonstrated the absence of unreasonable risk of illness or injury associated with the use of the device for its intended uses and conditions of use.

For those subjects consenting to participate in this Post Approval Study the probable benefits to health from use of the Hybrid device for its intended uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks.

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**DRAFT**

# POST APPROVAL STUDY-Newly Implanted

**P130016**

**Nucleus® Hybrid™ L24**
**Implant System**

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**CORP-5180-HYB-PMA**
**Revision 2**

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Study Sponsor:


Cochlear Americas
**13059 East Peakview Avenue**
Centennial, CO 80111



**CONFIDENTIAL - DO NOT COPY**

This protocol contains confidential proprietary information with respect to Cochlear products and clinical trials. I agree to hold this information in confidence and not to disclose it to any third parties for the shortest of the following periods of time: three years from the date of this agreement, the time at which this information becomes a matter of public knowledge, or the time at which a formal agreement for that purpose has been entered into by the parties.

**Investigator Responsibilities**

I, the undersigned, am responsible for the conduct of the study at the site below and by my signature below, I confirm that I have read, understand and will strictly adhere to the study protocol, "Evaluation of the Nucleus Hybrid L24 Cochlear Implant System - - Post Approval Study – Newly Implanted."

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Clinical Investigational Site

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Primary Investigator's Name (print)

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Title

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Signature

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Sponsor Representative

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Title

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Signature

**Nucleus® Hybrid™ L24 Implant System**

**Post Approval Study – Newly Implanted**

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## TERMS, DEFINITIONS, AND ABBREVIATIONS

| Term/Abbreviation | Definition |
|---|---|
| **Acoustic Alone** | Pre- or postoperative condition referring to the use of acoustic hearing alone, with or without amplification, ipsilateral to the implanted ear (i.e., in the same ear as the implant). |
| **Acoustic Component** | An optional component for the sound processor used with the Hybrid L24 implant, which provides amplification in the low frequencies for those patients who have residual hearing, postoperatively. |
| **AzBio Test**[1] | A sentence-level speech recognition test delivered in background noise at a +10 dB SNR |
| **Everyday Listening Condition** | Postoperative listening condition referring to either Combined Mode (defined below) or Bimodal Mode (defined below); |
| **Bilateral Acoustic** | Pre-operative condition referring to the use of bilateral acoustic hearing (i.e., acoustic hearing in both ears), with or without amplification. |
| **Bimodal Mode** | Use of acoustic hearing, with or without amplification, in addition to electric hearing via a cochlear implant in the contralateral (opposite) ear. |
| **BTE** | Behind-The-Ear. |
| **CI** | Cochlear Implant |
| **CNC Word List**[2] | A word recognition test delivered in quiet |
| **Combined Mode** | Use of acoustic hearing bilaterally, with or without amplification, in addition to electric hearing via a hybrid implant. |
| **CRF** | Case Report Form. |
| **Cochlear Implant Alone** | Stimulation delivered by the cochlear implant alone. |
| **Hybrid Mode** | Combination of acoustic and electric hearing, in the same (ipsilateral) ear. |
| **ITE** | In-The-Ear. |
| **MAP** | A program that defines the individualized fitting parameters of recipients for a specific speech coding strategy. |
| **Nucleus® Custom Sound™** | Clinical programming software for Nucleus cochlear implant systems. |

[1] Spahr, A, Dorman, M., Litvak, L, Van Wie, S, Gifford, R *et al.* (2011). Ear Hear 33(1): 112-117.
[2] Consonant-Nucleus-Consonant Test; Peterson, F.E. & Lehiste, I. (1962). Revised CNC lists for auditory tests. Journal of Speech and Hearing Disorders, 27(1): 62-70.

| | |
|---|---|
| **Nucleus® Freedom™ for Hybrid™ sound processor** | BTE sound processor used in the Nucleus Hybrid L24 IDE clinical study; often abbreviated as 'Freedom Hybrid sound processor' or 'Hybrid sound processor.' |
| **Signal-to-Noise Ratio** | The level relationship (ratio) of the target (signal) to the noise (e.g., if the target speech is 60 dBA and the noise is 50 dBA then the SNR = +10 dB). |

**Evaluation of the Nucleus® Hybrid™ L24 Implant System**

***Post Approval Study***

**BACKGROUND**

The Hybrid L24 Implant System (P130016) was the subject of a pivotal clinical trial (IDE G070191) from 2007-2012. The data on the 50 subjects in support of safety and effectiveness of the device was submitted in June 2013 as part of PMA #130016. As part of the PMA approval, a Post Approval Study to monitor the long-term (3 years) safety and effectiveness of the device in a cohort of newly implanted subjects was designed.

**Device Description**

The Hybrid L24 Implant System, indicated for individuals with normal to moderate low-frequency hearing sensitivity and a severe to profound high-frequency sensorineural hearing loss, provides electric-acoustic (E+A) stimulation via a combination of internal and external components. The components consist of the Hybrid L24 implant (model CI24REH); an external sound processor (CP910/920) with or without an accessory port; a remote assistant (CR210/230) and specialized Custom Sound software.

**Indications for Use**

The Nucleus Hybrid L24 Implant System is intended for use in individuals 18 years or older who have thresholds in the normal to moderate range in the low frequencies with a severe to profound sensorineural loss in the high frequencies. Typical candidates will have the following in the ear to be implanted:

- Normal to moderate hearing loss in the low frequencies with thresholds up to 60 dB HL through 500 Hz;
- Severe to profound hearing loss at frequencies >1500 Hz (threshold average of 2000, 3000, and 4000 Hz ≥ 75 dB HL);
- CNC word recognition score between 10% and 60% inclusively in the preoperative aided condition.

The contralateral ear is typically equal to or better than the ear to be implanted but not more than 80% correct on CNC (words). For individuals with post-implant low frequency hearing, the sound processor provides acoustic amplification with electric stimulation for the high frequencies. Prospective candidates should also have appropriate expectations of the benefits of an implant with or without an acoustic component.

A Hybrid L24 Implant System is contraindicated for individuals with the following conditions:

- Deafness due to lesions of the acoustic nerve or central auditory pathway
- Active middle ear infections
- Absence of cochlear development
- Duration of severe to profound hearing loss > 30 years

## STUDY PURPOSE

The purpose of this study is to conduct long term monitoring (36 months) of the safety and effectiveness of the Hybrid L24 Implant System. This study will be a prospective study of a cohort of newly implanted subjects.

## STUDY OBJECTIVES AND HYPOTHESES

### Study Design

This study will be conducted as a prospective, non-controlled, non-randomized, multicenter study.

### Study Population

Subjects will include a minimum of 50 individuals, 18 years of age and above, who will be implanted with the Hybrid L24 implant. The study cohort will consist of newly implanted (post PMA approval) Hybrid L24 recipients from up to 25 investigative centers.

Study Inclusion Criteria

- Subjects 18 years of age and older;
- Subjects will present with normal to moderate low-frequency hearing with a severe to profound sensorineural loss in the high frequencies. For the ear to be implanted, candidates will have the following:
  - normal to moderate hearing loss in the low frequencies with thresholds up to 60 dB HL through 500 Hz;
  - severe to profound hearing loss at frequencies >1500 Hz (threshold average of 2000, 3000, and 4000 Hz $\geq$ 75 dB HL);
  - CNC word recognition score between 10% and 60% inclusively in the preoperative aided condition;
- The contralateral (non-treated) ear will be equal to or better than the ear to be implanted but not more than 80% correct on CNC (words);
- Subjects not currently hearing aid users should participate in a 30-day trial with hearing aids prior to study enrollment;
- Subject should have appropriate expectations of the benefits of an implant with or without an acoustic component.

Study Exclusion Criteria

- Deafness due to lesions of the acoustic nerve or central auditory pathway;
- Active middle ear infections;
- Absence of cochlear development;
- Duration of severe-to-profound hearing loss > 30 years.
- Existing implant in the contralateral ear

**Primary and Secondary Outcomes**

The primary safety outcome of this study is related to the long term safety (three years) of the Hybrid L24 implant. Safety of the Hybrid L24 implant will be monitored based on type and frequency of adverse events. An adverse event will be considered to be device-related when, in the judgment of the Primary Investigator, there is a logical connection between the use of the device (including the surgical procedure) and the occurrence of the event. Those adverse events (by type and frequency of occurrence) will be expected to be consistent with that reported in the pivotal study.

The long-term effectiveness of the device will be assessed based on individual performance as measured by speech perception tests over the course of the 36 months study duration. These tests (CNC words in quiet and AzBio sentences +10dB S/R) will be administered aided at the preop and postactivation intervals and outcomes will be based on a comparison between the hearing aid (preop) and 36 Month (postactivation) speech perception data.

**Primary Endpoints**

The primary safety endpoint will be the comparison of the type and frequency of adverse events (and serious adverse events) occurring over the course of this study (36 months) as compared to the pivotal clinical study for the Hybrid L24 (G070191).

The co-primary efficacy endpoints for this study will be the assessment of statistical significance of the within-subject differences for two speech recognition tests:

- Word recognition in quiet as evaluated with the Consonant-Nucleus-Consonant (CNC) test (Peterson and Lehiste, 1962);
- Sentence recognition in noise (+10dB) as evaluated with the AzBio test (Spahr *et al.*, 2011).

Scores on both speech tests will be obtained at pre-implant (hearing aid), at the 6-month postactivation interval and at the annual follow-ups until study completion (36 months). In an attempt to standardize speech assessment methods across commercial implanting centers, the following metrics were chosen based on the Minimum Speech Test Battery (MSTB) published in 2011 as a joint effort of the cochlear implant industry and the audiologic/otologic professional community. These test materials are provided free of charge to any cochlear implanting center and include calibration and instructions for use.

The primary endpoints will be that mean performance with each of these measures will show significant benefit with use of the Hybrid device (Hybrid mode and Everyday Listening condition) at the end of the 36 months study period compared to the preoperative Everyday Listening (one or more hearing aids) condition.

**Data Analysis**

- **Analysis of Safety**

- Adverse Events and Serious Adverse Events will be expressed as events per patient – time.
- All adverse event rates will be reported as the number and frequency of events with corresponding 95% exact binomial confidence limits and the number of events per patient-time (e.g., events per 10 patient years), and compared to the adverse events from G07019 (Hybrid L24 pivotal study).
- Time to first adverse event (including total losses of residual hearing) will be summarized using Kaplan Meier plots. Exploratory proportional hazards regression models will be used to determine whether baseline factors are associated with risk for adverse events over follow-up. Hazard ratios and 95% confidence intervals for these analyses will be cited.

- **Analysis of Efficacy**

  The significance of the mean differences in speech recognition scores between preoperative and the 36-month post-implant interval will be analyzed using paired t-tests. If there was significant evidence that the assumptions of the t-tests did not hold (i.e., $p < 0.05$ from a Shapiro-Wilk test of normality), then Wilcoxon signed rank tests will be used.

**Adverse Events**

For purposes of this protocol, adverse events will be consistent with complaint reporting for similar approved technologies under 21 CFR 820.198. The sponsor expects an increase in the percent AEs reported per the installed base given the required reporting under this protocol.

As for loss of hearing sensitivity at the implant ear, this data will be trended in a similar fashion to the pivotal protocol (G070191) but will not be considered an adverse event unless the loss reaches a profound level (PTA average of 90 dB or greater for frequencies 125-1000Hz), total loss and/or explantation. Should an explantation occur, the sponsor will treat this as a serious injury with reporting occurring under the Medical Device Reporting regulations (21 CFR Part 803) in addition to inclusion in the annual update report on the PAS.

**Length of Follow-up**

Subjects will be followed for three (3) years post-activation.

## DATA COLLECTION PROCEDURES

As most cochlear implant patients routinely return for annual follow-up/programming visits, the yearly data collection is not anticipated to place a burden on sites or subjects. Conservatively, it is anticipated that there could be a 30% lost-to-follow-up rate[3]. Therefore recruitment will be sufficient to account for this potential attrition.

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[3] Based on sponsor experience with previous post-market studies

**Data Collection Forms**

Study subjects will be required to sign an Informed Consent.

The Post Approval Study will require IRB approval. Study initiation will not begin before IRB approval is received at the respective institutions.

**Reporting Requirements for Interim/Final Reports**

The sponsor will submit annual interim reports beginning one year from the date of the Post Approval Study protocol. These interim reports will contain the following information:

- Study enrollment by site
- Data collected relative to the primary and secondary endpoints
- Adverse events related to the device/procedure

**Test Metrics and Procedures-**

The following data will be gathered for each study subject following study enrollment and is summarized in Table 1:

<u>Pre-implant</u>

- Otologic/medical questionnaire (health history);
- Unaided audiometric threshold measures, for each ear;
- Aided soundfield thresholds;
- Aided CNC Words presented in quiet at 60 dBA;
- Aided AzBio sentences presented at 60 dBA with +10dB SNR;
    - Each speech perception metric will be administered in the following two conditions:
        - Unilateral hearing aid at implant ear, only;
        - Everyday Listening condition (bilateral hearing aids or one aid and acoustic 'unaided' from contralateral ear);
- Modified device use questionnaire;
- Health Utility Index (HUI);

<u>Activation</u>

- Otologic/medical questionnaire (health history);
- Unaided audiometric threshold measures, for each ear;
- CNC Words presented in quiet at 60 dBA,
- AzBio sentences presented at 60 dBA with +10dB SNR;

- Each speech perception metric will be administered in the following two conditions:
    - Unilateral Condition: Hybrid mode or CI alone if subject no longer utilizes the acoustic component.
    - Everyday Listening Condition: Combined, Bimodal, Hybrid or CI alone

Postactivation and Annual Follow-ups

- Otologic/medical questionnaire (health history);
- Unaided audiometric threshold measures, for each ear;
- CNC Words presented in quiet at 60 dBA,
- AzBio sentences presented at 60 dBA with +10dB SNR;
    - Each speech perception metric will be administered in the following two conditions:
        - Unilateral Condition: Hybrid mode or CI alone if subject no longer utilizes the acoustic component.
        - Everyday Listening Condition: Combined, Bimodal, Hybrid or CI alone
- Modified device use questionnaire
- Health Utility Index (HUI).

Unaided audiometric thresholds will be obtained for each ear, *with insert earphones*, using the standard audiometric technique for pure-tone air-conduction testing.

Testing, for each ear, will include the following:

- Air conduction thresholds at 125, 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, and 8000 Hz;
- Bone conduction thresholds at 250, 500, 750, 1000, 1500, 2000, and 4000 Hz;
- Tympanometry at each ear.

**External Equipment Check**

Prior to any efficacy testing (e.g. speech perception testing) an assessment of the external hardware- CP900 sound processor, CP900 accessories and the acoustic component will be made

If any clinically significant change in unaided thresholds is noted then the amplification fitting(s) will be re-evaluated and adjustments made if necessary.

Table 1- Summary of Measures

| | Baseline Evaluation | Initial Device Activation | 6 mos post | 12 mos Post | 24 mos Post | 36 mos Post |
|---|---|---|---|---|---|---|
| **Informed Consent** | X | | | | | |
| **Otologic & Medical History** | X | X | X | X | X | X |
| **Verification of Hearing Aid/Acoustic Component Function** | X | X | X | X | X | X |
| **Unaided Hearing Thresholds and Tympanometry** | X | X | X | X | X | X |
| **Aided Audiometric Thresholds** | X | | | | | |
| **Processor Hardware Performance Check** | | X | X | X | X | X |
| **CNC test (Ipsi & Everyday)** | X | X | X | X | X | X |
| **AzBio-+10 S/R (Ipsi & Everyday)** | X | X | X | X | X | X |
| **Modified device use questionnaire** | X | | X | X | X | X |
| **HUI** | X | | X | X | X | X |

**Interim Evaluation intervals**

Should a subject report a decrement in performance and should that decrement in performance not be directly related to a simple hardware problem all specified interval testing will be conducted. Additionally, an otologic/medical case history will be taken.

**Evaluation Prior to Re-implantation with a Long Electrode**

In order to ensure that accurate information is gathered for any subjects electing to undergo explantation and re-implantation with a long array due, additional data will be collected prior to re-implantation. This evaluation will include the following information and will follow the procedures as described in the annual evaluation schedule:

- Audiometric testing
- Word recognition testing
- Psychophysical and electrical impedance measurements
- Otologic /medical questionnaire

If explantation occurs, in addition to being considered a serious injury, an MDR will be filed per 21 CRF 803.

**Study Completion**

Completed Subjects

Study subjects will be considered 'complete' when all assessments through 3 years postactivation have been performed in accordance with the study protocol. For subjects explanted, they will continue to be monitored on an annual basis whether reimplanted or not.

Discontinued Subjects

Any subject may voluntarily discontinue the PAS at any time without prejudice. The Investigator may discontinue a subject from the study at any time if (s)he considers that remaining in the study compromises the subject's health or the subject is not sufficiently cooperative. In either event, reason(s) for discontinuation should be recorded on a study withdrawal form, provided as part of the CRFs for the study.

Possible reasons for study discontinuation include the following:

- AE necessitating discontinuation from the study.
- The subject is lost to follow-up.
- Voluntary decision to withdraw consent made by the subject[4].
- Investigator decision[5].

[4] Withdrawal of consent is defined as the subject's voluntary decision to revoke consent to continue participation in the study.

- Other reason.

In case of a subject lost-to-follow-up, the Investigator must document a 'good faith' effort to attempt contacting the subject (or relative/family contact) by phone, email or letter multiple times. If attempts are unsuccessful, the 'subject withdrawal' form is to be completed in the study file and reported, as appropriate, in required reports to the Sponsor, IRB and FDA.

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