Official Title: **Retrospective post-market hearing performance outcome in a cohort of CI532 recipients**

NCT Number: **NCT03039283**

Document Date: **16 January 2018**

Retrospective Study Plan (RSP)

Retrospective post-market hearing performance outcome in a cohort of CI532 recipients

Retrospective CI532 Hearing Performance

CEL5661

Date: 16 January 2018

version number: 3

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Signature Page

By signing this page the Sponsor, Coordinating Investigator and Principal Investigator agree to conduct this investigation in accordance with the current investigational plan. No changes to this clinical investigation plan will be permitted without the written approval of both parties. If substantial amendments to this plan become necessary, written approval by the Ethics Committee will be obtained before the changes are clinically implemented, except under emergency circumstances to protect the rights, safety and well-being of the subjects.

Sponsor Signature

[redacted]

PRINT NAME | DATE

[redacted]

SIGNATURE | TITLE

Coordinating Investigator Signature

PRINT NAME | DATE

Coordinating Investigator

SIGNATURE | TITLE

Principal Investigator Signature

PRINT NAME | DATE

Principal Investigator

SIGNATURE | TITLE

1 Clinical Investigation Synopsis

Name of device	Commercially available Cochlear™ Nucleus® Profile with Slim Modiolar Electrode (CI532)
Short study title and study number:	CEL5661: Retrospective CI532 Hearing Performance
Principal Investigator (s)	Please refer to Appendix I
Coordinating Investigator	[redacted]
Start date	March 2017
End date	November 2018
Total expected duration of the retrospective study:	21 months
Study design:	Multicenter retrospective data collection of already available routine clinical data.
Number of datasets:	≥ 150 datasets
Inclusion criteria:	1. Ability to conduct adult hearing performance test material 2. Good German language skills to assess clinical hearing performance 3. All CI532 recipients assessed via routine clinical measurements at pre implant, and post implant intervals with available data records in hospital files. 4. Patients that have read understood and signed the PIC.
Exclusion criteria:	1. Recipients that have participated in the CLTD5446 study.
Primary objectives:	1. To assess available speech understanding in quiet and in noise pre-operative (daily listening condition) and at 6 months post CI532 implantation (best aided conditions)
Secondary objectives:	1. To compare available aided (daily listening condition) and unaided pure tone audiometric thresholds obtained before surgery and at 6 months after CI532 surgery 2. To get insight for available CI532 device characteristics (electrode impedances, NRT, MAP T and C levels) and patient characteristics (datalogging) (cdx files) 3. To assess subjective surgeon's opinion and clinical experience with CI532 via a questionnaire

Primary endpoints:	1. Change from pre-op (daily listening condition) baseline speech understanding in quiet and in noise at 6 months post-op (best aided conditions) 2. The proportion of the recipient cohort in percent examined showing post-operative improvement per test and listening condition.
Secondary endpoints:	1. Change from pre-op baseline aided (daily listening condition) and unaided thresholds at 6 months post-operative 2. Defined normative CI532 device characteristics (electrode impedances, NRT, MAP T and C levels) and patient characteristics (datalogging) 3. Combined subjective clinical experience and opinion about CI532 from surgeons

2 Terms and Abbreviations

Abbreviation	Definition
CI532	Cochlear™ Nucleus® Profile with Slim Modiolar Electrode
RSP	Retrospective Study Plan
NRT	Neural Response Telemetry
MAP T&C levels	Subjective threshold (T) or comfortable (C) level for an electrode measured in current level units.
cdx	computer record files
CRF	Case Report Form
PIC	Patient Informed Consent
CI	Cochlear implants
PMS	Post-market Surveillance
ENT	Ear Nose Throat
OLSA	Oldenburger Sentence Test
HSM	Hochmayer Schulz Moser Sentence Test
SNR	Signal to Noise Ratio
SRT	Speech Reception Threshold
EC	Ethic committee
NCA	National Competent Authority
CE	Conformité Européene = European Conformity
ID	Identification

3 Introduction

Cochlear implants (CI) restore auditory sensitivity in the case of moderate to profound levels of sensorineural hearing loss. Typically patients implanted with cochlear implants can achieve a relatively high level of speech understanding in quiet and to a lesser degree in background noise. In general performance is sufficiently high that currently for cochlear implantation in many countries the criterion is for pre-operative speech recognition scores, measured in quiet, to be inferior or equal to 50% correct using well fitted acoustic hearing aids.

The CE marked Cochlear™ Nucleus® Profile with Slim Modiolar Electrode (CI532) has a perimodiolar (pre-curved) design and is designed to bring electrode contacts closer to the medial wall of the cochlea and so therefore closer to the spiral ganglion. This could potentially improve the hearing performance.

This investigation aims to retrospectively collect hearing performance data that have been measured by five clinics in Germany as part of their clinical routine in CI532 recipients. This will allow the combination of post market follow-up hearing performance data within the same language group to be used as bench mark data.

4 Identification and description of the commercially available CI532

The **CE marked CI532** is manufactured at Cochlear Limited in Australia. The CI532 is commercially available as a state of the art treatment for moderately severe to profound levels of sensorineural hearing loss within the clinical routine.

Please refer to the commercially available brochures; manuals and labelling in German language for identification and description of the commercially available CI532:

- Nucleus® Cochlea-Implantate - Wichtige Informationen für Cochlea-Implantatträger
- Nucleus® CI532 Cochlea-Implantat mit Slim-Modiolar-Elektrode - Handbuch für Ärzte
- Nucleus® CI532 Cochlea-Implantat mit Slim-Modiolar-Elektrode – Dokumentation
- Cochlear™ Nucleus® Weltweit eingeschränkte Garantiebestimmungen

The unique serial numbers of the CE marked CI532 device are collected to facilitate follow-up with the clinics if required.

5 Justification for the design of the clinical investigation

An extended review of clinical performance data for CI532 device (Section 19) has identified limited hearing performance outcome data. Cochlear is already collecting post market clinical data with the ongoing CLTD5446, but is aiming to collect additional data from a wider subject population with this retrospective evaluation. Therefore the aim of this study is to establish more post-market hearing performance outcomes with CI532 to establish bench mark speech data for German hearing performance material for CI532 recipients.

6 Risks and benefits of the commercially available CI532 and clinical investigation

6.1 Anticipated clinical benefits

Within the scope of this study neither treatment nor special clinical interventions are planned. Therefore no anticipated clinical benefits for the patients are expected other than that this study will provide more insight in the benefits of CI treatment with CI532 as post-market follow-up. The CI532 Hazards Analysis and Routine post-market surveillance (PMS) will be updated with any new identified risks from this study.

6.2 Anticipated adverse device effects and risks related to the commercially available CI532, risks associated with participation in the clinical investigation and risk mitigation

Not applicable, because of this retrospective nature of this study. Patients are not exposed to any additional clinical investigational measurements beyond the clinical routine measures.

6.3 Risks associated with data protection

As precaution to avoid any risks associated with data protection the patient's identity and all information collected during the investigation will be kept strictly confidential and in accordance with EU data protection laws. Each participant's data will be given a unique code and the list of codes will be kept by the investigator as described in the data privacy section.

6.4 Risk-to-benefit rationale

In conclusion taking part in the study does not incur any risks for the participating patients.

The study aims to give insight in speech perception benefit at 6 months after switch on of CI532 and this will help clinicians in their routine clinical practice.

Given the above the potential benefits will outweigh the risks.

7 Objectives, hypothesis and Endpoints

7.1 Objectives

7.1.1 Primary Objective

To assess available speech understanding in quiet and in noise pre-operative (daily listening condition) and at 6 months post CI532 implantation (best aided conditions).

7.1.2 Secondary Objective

1. To compare available aided (daily listening condition) and unaided pure tone audiometric thresholds obtained before surgery and at 6 months after CI532 surgery
2. To get insight for available CI532 device characteristics (electrode impedances, NRT, MAP T and C levels) and patient characteristics (datalogging) (cdx files)
3. To assess subjective surgeon's opinion and clinical experience with CI532 via a questionnaire

7.2 Endpoints

7.2.1 Primary Endpoint

1. Change from pre-op (daily listening condition) baseline speech understanding in quiet and in noise at 6 months post-op (best aided conditions).
2. The proportion of the recipient cohort in percent examined showing post-operative improvement per test and listening condition.

7.2.2 Secondary Endpoint

1. Change from pre-op baseline aided (daily listening condition) and unaided thresholds at 6 months post-operative
2. Defined normative CI532 device characteristics (electrode impedances, NRT, MAP T and C levels) and patient characteristics (datalogging)
3. Combined subjective clinical experience and opinion about CI532 from surgeons

7.3 Hypotheses

7.3.1 Primary hypotheses of retrospective study

1. H_0: Speech understanding in quiet and in noise at the 6 months post-operative visit are equal with speech understanding in quiet and noise at the pre-operative evaluation visit
   H_1: Speech understanding in quiet and in noise at the 6 months post-operative visit is better than speech understanding in quiet and noise at the pre-operative evaluation visit
2. H_0: The proportion of the recipient's cohort examined showing post-operative improvement per test and listening condition is below 80% for the 6 months post-operative visit.
   H_1: The proportion of the recipient's cohort examined showing post-operative improvement per test and listening condition is ≥ 80% (Dowell, Hollow & Winton, 2004) for the 6 months post-operative visit.

8 Design of the clinical investigation

8.1 General

The aim of this study is to assess hearing performance based on clinically available routine hearing measures to demonstrate changes from pre- to post-CI treatment for patients implanted with the CI532 cochlear implant in a German speaking cohort.

The study is multi-centric including five centres in Germany (Kiel, Erlangen, Frankfurt am Main, Freiburg, Hannover) to retrospectively gather bench mark hearing performance data of CI532 recipients. The centres have been chosen due to their experience with CI532 and the availability of hearing performance data with CI532.

The hearing performance data located in patient's hospital file will be pseudo-anonymized by the clinician and entered into the study database. Therefore no bias is expected and no corrective action on a potential bias is required.

The hearing performance data has been gathered as part of the routine clinical measurements pre-operatively and at 3 and 6 months post-operatively for speech understanding in quiet and in noise and for unaided and aided thresholds. In addition medical history, anomalies in terms of electrode placement and recipient's device characteristics will be collected. Surgeons with CI532 experience will be asked to retrospectively evaluate the handling and usability of CI532 during conducted surgeries.

A first data export will be conducted after 50 datasets have been entered to informally view the datasets per centre. Over the study period clinicians are asked to gradually enrol the CI532 recipient's based on available datasets. It is expected to enrol ≥ 150 datasets until end of the study.

8.2 Datasets for the commercially available CI532

The pre-operative datasets are dependent on the recipient's daily device use. This is dependent on the advice of the recipient's ENT practitioner or clinical routine and could consist of either: a) an unaided condition, b) hearing aid unilateral/bilateral, or c) unilateral CI. Preoperative device use and hearing performance will be collected and considered for analysis as the comparator to the postoperative hearing performance.

The post-operative best aided conditions are dependent on the clinical routine advice and could consist of: a) a contralateral hearing aid, b) unaided contralateral ear, or c) contralateral

CI. Evaluation of electrode placement and location in the scala, by e.g. imaging data, will be considered during postoperative hearing performance analysis.

8.3 Subjects

8.3.1 Inclusion Criteria

1. Ability to conduct adult hearing performance test material
2. Good German language skills to assess clinical hearing performance
3. All CI532 recipients assessed via routine clinical measurements at pre implant, and post implant intervals with available data records in hospital files.
4. Patients that have read understood and signed the PIC.

8.3.2 Exclusion Criteria

1. Recipients that have participated in the CLTD5446 study.

8.3.3 Criteria and procedures for subject's withdrawal or discontinuation

Subjects can decide to withdraw from the investigation without indicating any reasons at any stage. Recipient's datasets will then be excluded from the CI532 retrospective evaluation.

8.3.4 Point of enrolment

Subjects are enrolled into the clinical investigation when they have signed the Informed Consent Form.

8.3.5 Total expected duration of the clinical investigation

It is expected to retrospectively collect CI532 hearing performance data between March 2017 to November 2018.

8.3.6 Expected duration of each subject's participation

Not applicable due to the retrospective data collection.

8.3.7 Number of subjects required to be included in the clinical investigation

The anticipated number of datasets is ≥ 150.

8.3.8 Estimated time needed to select this number (i.e. enrolment period)

The estimated time to collect ≥ 150 datasets are 21 months.

8.4 Procedures

No product or procedure related training is required since we will collect pseudo-anonymised clinical follow-up data hearing performance data and device characteristic data exported from clinical software provided with this CE marked product. The clinics will be trained by the Clinical Project Manager how to pseudo-anonymise the clinical data.

The clinic will recruit patients by phone and or mail. Based on their clinical database they select patients that fulfil the inclusion criteria and will provide the Patient Informed Consent to these patients by mail. Potentially a follow-up call will be conducted by the clinic to answer open

questions from the recipient. After patients have signed the Patient Informed Consent they will send it back to the clinic.

After the clinic has received the signed Informed Consent the clinician enters the available hearing performance data from the recipient's hospital file into the electronic data capturing system in a pseudo-anonymized way (See section 15.2).

The device/patient characteristics will be collected through anonymized computer record files ("cdx") produced by the CustomSound software which is routinely used to fit the CI532 recipients. The cdx files will be pseudo-anonymized with a unique patient code and sent to Cochlear.

Study subjects did follow clinical routine treatment practices and this retrospective approach does not impact routine clinical treatment at the implanting centre.

The surgeon's questionnaire will be filled by at least one surgeon per site once that surgeon has achieved a minimum experience of ten (10) CI532 surgeries. This could be in the beginning or close to the end of the study based on the surgeon's experience with CI532. Completed paper surgeon's questionnaire will be shipped to the clinical project manager by regular mail for further handling and analysis.

8.5 Monitoring Plan

Please refer to the Monitoring Plan.

9 Statistical Considerations

Please refer to the Statistical Plan.

Depending on the clinic different types of speech understanding measurements in noise will be measured. For example the OLSA is an adaptive test in which the 50% point of the discrimination function is measured. This point of the discrimination function has the maximal steepness and is most sensitive to changes in hearing function. On the other hand, HSM is a test with a fixed SNR. In this test different points along the discrimination function are being measured. The steepness changes at these different points of the discrimination function. Therefore, there is no linear relation between the test results for the OLSA and HSM sentence materials and it is not possible to calculate a linear relation like "a change of x dB SNR in OLSA corresponds to y% change in HSM". Therefore the type of speech test material in noise has to be considered as dependent variables for analysis of group performance.

10 Data Management

Data collection is performed through [redacted], a web-based system for electronic data capturing. Site personnel will be trained to use this system. Data validity has to be confirmed by the investigator through an electronic signature. An audit trail is kept by this system and data clarifications may be generated by the system and sponsor personnel after review of data.

[redacted] is a system that has been verified and validated by the vendor. Installation of the system within Cochlear has been validated as well. Study-specific implementations are validated by Data Management and consist of verification that all required items are included, validity of edit checks and appropriate functionality of conditional fields. The study-specific data in [redacted] can only be accessed by those that have been allocated their individual account, which are personnel of the investigational sites, Clinical Project Manager, Study Monitors and Data Management staff.

11 Amendments to the RSP

No changes in the study protocol shall be effected without mutual agreement of the investigator(s) and the Sponsor. All changes must be documented by signed RSP amendment. Substantial changes will require notification to the Ethics Committee.

12 Deviations from the RSP

The expected number of deviations is anticipated to be low due to the retrospective nature of the study. Only datasets of CI532 recipients that have signed the Patient Informed Consent will be part of this evaluation. Any deviations by the clinical investigator shall be documented and reported to the Sponsor and the EC as necessary.

13 Device accountability

Not applicable because of the retrospective approach in already implanted CI532 recipients.

14 Statements of compliance

14.1 Declaration of Helsinki and compliance with standards

The clinical investigation shall be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki (2013), the EN ISO 14155:2011 and any regional or national regulations, as appropriate. This retrospective investigation will be registered on ClinicalTrials.gov.

14.2 Ethics Committee Approval

The clinical investigation shall not commence prior to the written favourable opinion or approval from the EC is obtained.

The investigator shall submit the final version of the clinical investigation plan, the informed consent and all subsequently required documents to the Ethics Committee. A copy of the Ethics Committee opinion/approval shall be provided to the sponsor.

Sponsor and investigator shall continue the communication with the EC as required by national regulations, the clinical investigational plan or the responsible EC.

Any additional requirements imposed by the EC shall be followed.

The investigator shall submit the appropriate documentation if any extension or renewal of the EC approval is required. In particular substantial amendments to the clinical investigation plan, the informed consent, or other written information provided to subjects must be approved in writing by the EC.

The investigator shall send written status summaries of the investigation to the EC regularly as per local EC requirements.

Upon completion of the clinical investigation, the investigator shall provide the EC with a brief report of the outcome of the clinical investigation as per local EC requirement.

The clinical investigation is covered by the Cochlear global cover insurance. No additional clinical trial insurance is required, because no exposure to recipients applies.

14.3 Audits and Supervision

Study sites and study documentation may be subject to Quality Assurance audits during the course of the clinical investigation. In addition, regulatory bodies at their discretion may conduct inspections, during and after study completion.

14.4 Study Records

The investigational site will receive and has to maintain an Investigator's File which does include without limitation at a minimum the signed Retrospective Study Plan, the EC approval letter, completed Informed Consent Forms, Investigator copies of all CRFs, correspondence with the Sponsor and third parties related to the study, a subject identification list, and a site delegation and signature sheet. All study records and source documents shall be archived at the investigational site, which aims to be the implanting centre for this study, for at least 15 years after the end of the study.

15 Informed consent process

15.1 Obtaining informed consent

The investigator must obtain written informed consent from the subject prior to any clinical investigation related activity, and after explaining the rationale for and the details, aims and objectives of the study and the extent of the subject's involvement. Ample time must be provided for the subject to inquire about details of the investigation and to decide whether to participate. All questions about the investigation should be answered to the satisfaction of the subject or the subject's legally acceptable representative. Subjects must not be coerced or unduly influenced to participate or to continue to participate in an investigation.

Each subject and the person who conducted the informed consent discussion must sign and date the informed consent form. Where required, a witness must sign and personally date the consent form.

A copy of the information leaflet and consent form must be given to the subject. All signed Informed Consent Forms must be archived in the Investigator's File at the investigational site, according to the requirements of the country's health regulations, but for a minimum of 15 years after completion of the clinical investigation.

The investigator shall forward any amendment made to the approved subject informed consent for review to the Sponsor or Study Monitor and any other written information to be provided to the subject, prior to submission to his EC.

15.2 Data Privacy

Subjects will be identified on CRFs or similar documents by a unique subject identification code. No personal identification of private information will be extracted. Completed CRFs or similar documents are confidential documents and will only be available to the Sponsor and their representatives, the investigator, the investigational statistician, and if requested to the Ethics Committee and national regulatory authorities.

The investigator and site staff will not include the name of any subject in any CRF or other forms, electronic files, publication, or submission to a regulatory authority; will not otherwise disclose the identity of any subject; and, in any CRF, will refer to each subject by his/her unique identification code.

An identification code (pseudo-anonym) will be used [redacted]

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

16 Incident reporting

16.1 Incident Reporting

This investigation is performed using CE marked devices thus requiring reporting of incidents under the MEDDEV 2.12-1 via Cochlear's policy & procedures for complaints- and issues handling as implemented routinely for all products under postmarket surveillance as part of our mandated postmarket vigilance. Due to the retrospective approach, any incidents may have already been reported as part of the hospital's routine via Cochlear's policy & procedures for complaint and issue handling. To close any potential gaps, we will actively ask if all complaints and incidents have been reported to Cochlear via Cochlear's policy & procedures for complaint and issues handling in the CRFs.

16.2 Definition of Incident

"Any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a subject, or user or of other persons or to a serious deterioration in their state of health."

16.3 Reporting process

As is routine, the investigator shall report all incidents without undue delay to the sponsor, EC and as applicable to the NCA:

Name of contact person of the sponsor: [redacted]

Fax: [redacted]

E-mail: [redacted]

The Sponsor shall assess all reported incidents with the investigator, co-ordinate appropriate actions, if required, and provide the NCA with a final report.

The investigator shall report all incidents to his/her EC using the applicable report form as per national requirement.

17 Suspension or premature termination

The Sponsor will withdraw from sponsorship of the clinical investigation if,

1.) major non-adherence to the RSP is occurring

2.) it is anticipated that the subject recruitment via patient informed consent signature will not be adequate to meet the objectives of the retrospective investigation

18 Publication Policy

Investigators will be able to publish and/or present their own data. The publishing investigator will provide the sponsor with a manuscript copy of the abstract and paper at least 30 days in advance of publication or presentation. If the publication contains information that the sponsor at his discretion finds worth protecting in the form of a patent or trademark etc., the sponsor has the right to delay the publication or presentation for 90 days.

After finishing the study it is planned to generate a joint publication by the clinical investigator(s) and the sponsor. The responsibility for writing the publication is with the Coordinating Investigator. In case of multi-centre investigation, the authorship will be based on contribution of complete datasets and contribution to paper preparation according to the rules of the journal chosen for publication. The joint publication must be reviewed by the sponsor at least 30 days in advance to any release of publication. If the publication contains information that the sponsor at his discretion finds worth protecting in the form of a patent or trademark etc., the sponsor has the right to delay the publication or presentation for 90 days.

19 Bibliography

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Dowell, R.C., Hollow, R., & Winton, E. (2004).Outcomes for cochlear implant users with significant residual hearing: Implications for selection criteria in children. Archives of Otolaryngology, Head and Neck Surgery, 130, 575-581.

20 Revision History

Version Number	Date	Reason for Change
2	22.06.2017	Updated study start and end date
3	16.01.2018	Updated study end date and duration of study Updated phone numbers of Coordinating Investigator and Principal Investigator Kiel and name of sponsor representative

21 Appendix I: List of Investigators

Site ID	Name and professional position of Investigator	Address	Telephone, email
[redacted]	[redacted]	Klinik für Hals-, Nasen-, Ohrenheilkunde, Kopf- und Halschirurgie [redacted] D-24105 Kiel Germany	[redacted]
[redacted]	[redacted]	Deutsches HörZentrum Hannover der HNO-Klinik der MHH [redacted] D-30625 Hannover Germany	[redacted]
[redacted]	[redacted]	Universitätsklinikum Erlangen Hals-Nasen-Ohren-Klinik [redacted] D-91054 Erlangen, Germany	[redacted]
[redacted]	[redacted]	Universitätsklinik für Hals-, Nasen- und Ohrenheilkunde [redacted] D-79106 Freiburg i. Br. Germany	[redacted]
[redacted]	[redacted]	Klinikum der J. W. Goethe-Universität Frankfurt, [redacted] D-60590 Frankfurt a. M., Germany	[redacted]