

ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name) Andrianna	2. Surname (Last Name) Ayiotis	3. Date 26-September-2019
4. Are you the corresponding author? ☐ Yes ☒ No		Corresponding Author's Name Charles C. Della Santina
5. Manuscript Title Continuous Vestibular Implant Stimulation Partially Restores Eye-Stabilizing Reflexes		
6. Manuscript Identifying Number (if you know it) 128397-INS-CMED-RV-3		

Section 2. The Work Under Consideration for Publication

Did you or your institution **at any time** receive payment or services from a third party (government, commercial, private foundation, etc.) for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc.)?

Are there any relevant conflicts of interest? ☒ Yes ☐ No

If yes, please fill out the appropriate information below. If you have more than one entity press the "ADD" button to add a row. Excess rows can be removed by pressing the "X" button.

Name of Institution/Company	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
NIH/NIDCD	☒	☐	☐	☐	
Labyrinth Devices, LLC	☐	☐	☒	☒	Devices and equipment were produced and provided by Labyrinth Devices, LLC, to Johns Hopkins University (JHU) School of Medicine under a sponsored research agreement in accordance with JHU policies.
MedEl GmbH	☐	☐	☒	☒	Components of devices and equipment provided by Labyrinth Devices, LLC, to Johns Hopkins University (JHU) School of Medicine under a sponsored research agreement in accordance with JHU policies were produced and provided by MedEl GmbH to Labyrinth Devices, LLC.

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Section 3. Relevant financial activities outside the submitted work.

Place a check in the appropriate boxes in the table to indicate whether you have financial relationships (regardless of amount of compensation) with entities as described in the instructions. Use one line for each entity; add as many lines as you need by clicking the "Add +" box. You should report relationships that were **present during the 36 months prior to publication**.

Are there any relevant conflicts of interest? ☐ Yes ☒ No

Section 4. Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work? ☐ Yes ☒ No

Section 5. Relationships not covered above

Are there other relationships or activities that readers could perceive to have influenced, or that give the appearance of potentially influencing, what you wrote in the submitted work?

- ☐ Yes, the following relationships/conditions/circumstances are present (explain below):
- ☒ No other relationships/conditions/circumstances that present a potential conflict of interest

At the time of manuscript acceptance, journals will ask authors to confirm and, if necessary, update their disclosure statements. On occasion, journals may ask authors to disclose further information about reported relationships.

Section 6. Disclosure Statement

Based on the above disclosures, this form will automatically generate a disclosure statement, which will appear in the box below.

Andrianna Ayiotis reports that this research was supported by grants from NIH/NIDCD awarded to Johns Hopkins University (JHU) and that Labyrinth Devices, LLC, provided JHU with devices and equipment, components of which were produced and provided to Labyrinth Devices by Med-El GmbH.

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Section 1. Identifying Information

1. Given Name (First Name) Peter J	2. Surname (Last Name) Boutros	3. Date 26-September-2019
4. Are you the corresponding author? ☐ Yes ☒ No		Corresponding Author's Name Charles C. Della Santina
5. Manuscript Title Continuous Vestibular Implant Stimulation Partially Restores Eye-Stabilizing Reflexes		
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Are there any relevant conflicts of interest? ☒ Yes ☐ No

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Labyrinth Devices, LLC	☐	☐	☒	☒	Devices and equipment were produced and provided by Labyrinth Devices, LLC, to Johns Hopkins University (JHU) School of Medicine under a sponsored research agreement in accordance with JHU policies.
MedEl GmbH	☐	☐	☒	☒	Components of devices and equipment provided by Labyrinth Devices, LLC, to Johns Hopkins University (JHU) School of Medicine under a sponsored research agreement in accordance with JHU policies were produced and provided by MedEl GmbH to Labyrinth Devices, LLC.

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name) Stephen	2. Surname (Last Name) Bowditch	3. Date 26-September-2019
4. Are you the corresponding author? ☐ Yes ☒ No		Corresponding Author's Name Charles C. Della Santina
5. Manuscript Title Continuous Vestibular Implant Stimulation Partially Restores Eye-Stabilizing Reflexes		
6. Manuscript Identifying Number (if you know it) 128397-INS-CMED-RV-3		

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Are there any relevant conflicts of interest? ☒ Yes ☐ No

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Stephen Bowditch reports that this research was supported by grants from NIH/NIDCD awarded to Johns Hopkins University (JHU) and that Labyrinth Devices, LLC, provided JHU with devices and equipment, components of which were produced and provided to Labyrinth Devices by Med-El GmbH.

ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name) John	2. Surname (Last Name) Carey	3. Date 26-September-2019
4. Are you the corresponding author? ☐ Yes ☒ No		Corresponding Author's Name Charles C. Della Santina
5. Manuscript Title Continuous Vestibular Implant Stimulation Partially Restores Eye-Stabilizing Reflexes		
6. Manuscript Identifying Number (if you know it) 128397-INS-CMED-RV-3		

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Are there any relevant conflicts of interest? ☒ Yes ☐ No

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Are there any relevant conflicts of interest? ☐ Yes ☒ No

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Dr. Carey reports that this research was supported by grants from NIH/NIDCD awarded to Johns Hopkins University (JHU) and that Labyrinth Devices, LLC, provided JHU with devices and equipment, components of which were produced and provided to Labyrinth Devices by Med-El GmbH.

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Section 1. Identifying Information

1. Given Name (First Name) Margaret	2. Surname (Last Name) Chow	3. Date 26-September-2019
4. Are you the corresponding author? ☐ Yes ☒ No		Corresponding Author's Name Charles C. Della Santina
5. Manuscript Title Continuous Vestibular Implant Stimulation Partially Restores Eye-Stabilizing Reflexes		
6. Manuscript Identifying Number (if you know it) 128397-INS-CMED-RV-3		

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Are there any relevant conflicts of interest? ☒ Yes ☐ No

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Labyrinth Devices, LLC	☐	☐	☒	☒	Devices and equipment were produced and provided by Labyrinth Devices, LLC, to Johns Hopkins University (JHU) School of Medicine under a sponsored research agreement in accordance with JHU policies.
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Are there any relevant conflicts of interest? ☐ Yes ☒ No

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Margaret Chow reports that this research was supported by grants from NIH/NIDCD awarded to Johns Hopkins University (JHU) and that Labyrinth Devices, LLC, provided JHU with devices and equipment, components of which were produced and provided to Labyrinth Devices by Med-El GmbH.

ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name) Natan	2. Surname (Last Name) Davidovics	3. Date 26-September-2019
4. Are you the corresponding author? ☐ Yes ☒ No		Corresponding Author's Name Charles C. Della Santina
5. Manuscript Title Continuous Vestibular Implant Stimulation Partially Restores Eye-Stabilizing Reflexes		
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Are there any relevant conflicts of interest? ☐ Yes ☒ No

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Natan Davidovics has nothing to disclose.

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Section 1. Identifying Information

1. Given Name (First Name) Ross	2. Surname (Last Name) Deas	3. Date 26-September-2019
4. Are you the corresponding author? ☐ Yes ☒ No		Corresponding Author's Name Charles C. Della Santina
5. Manuscript Title Continuous Vestibular Implant Stimulation Partially Restores Eye-Stabilizing Reflexes		
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Dr. Deas has nothing to disclose.

Evaluation and Feedback

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)
Charles

2. Surname (Last Name)
Della Santina

3. Date
01-October-2019

4. Are you the corresponding author? ☒ Yes ☐ No

5. Manuscript Title
Continuous Vestibular Implant Stimulation Partially Restores Eye-Stabilizing Reflexes

6. Manuscript Identifying Number (if you know it)
128397-INS-CMED-RV-3

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Name of Institution/Company	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
NIH	☒	☐	☐	☐	grant to Johns Hopkins School of Medicine
Labyrinth Devices, LLC	☐	☐	☒	☒	implant systems and loan of equipment; study participant travel funds; pursuant to research contract between Labyrinth Devices, LLC and Johns Hopkins School of Medicine
MedEl GmbH	☐	☐	☒	☒	implant system components and loan of equipment (provided to Labyrinth Devices, LLC, and then to Johns Hopkins School of Medicine via agreement between Labyrinth Devices, LLC and Johns Hopkins School of Medicine)

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Name of Entity	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
Labyrinth Devices, LLC	☐	☐	☐	☒	equity
MedEl GmbH	☐	☐	☐	☒	travel support for investigator meeting

Section 4.

Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work? ☒ Yes ☐ No

If yes, please fill out the appropriate information below. If you have more than one entity press the "ADD" button to add a row. Excess rows can be removed by pressing the "X" button.

Patent?	Pending?	Issued?	Licensed?	Royalties?	Licensee?	Comments
Multiple patents related to vestibular implant technology (US7225028B2; US7647120B2; US8529463B2; US9211407B2; US8868202B2; US8768484B2; US9289598B2; EP2720750B1; US8751012B2)	☒	☒	☒	☒	Labyrinth Devices, LLC	Owned by Johns Hopkins University

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Dr. Della Santina (CCDS) and The Johns Hopkins University (JHU) hold royalty interests in pending and awarded patents related to technologies discussed in this manuscript. CCDS holds an equity interest in and is CEO/CSO of Labyrinth Devices, LLC. CCDS's spouse is employed part-time by Labyrinth Devices, LLC. The terms of these arrangements are managed in accordance with JHU policies on conflict of interest.

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Dr. Della Santina reports grants from NIH, non-financial support and other from Labyrinth Devices, LLC, non-financial support and other from MedEl GmbH, during the conduct of the study; other from Labyrinth Devices, LLC, other from MedEl GmbH, outside the submitted work; In addition, Dr. Della Santina has a patent Multiple patents related to vestibular implant technology (US7225028B2; US7647120B2; US8529463B2; US9211407B2; US8868202B2; US8768484B2; US9289598B2; EP2720750B1; US8751012B2) with royalties paid to Labyrinth Devices, LLC and Dr. Della Santina (CCDS) and The Johns Hopkins University (JHU) hold royalty interests in pending and awarded patents related to technologies discussed in this manuscript. CCDS holds an equity interest in and is CEO/CSO of Labyrinth Devices, LLC. CCDS's spouse is employed part-time by Labyrinth Devices, LLC. The terms of these arrangements are managed in accordance with JHU policies on conflict of interest.

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1. Given Name (First Name) Gene	2. Surname (Last Name) Fridman	3. Date 01-October-2019
4. Are you the corresponding author? ☐ Yes ☒ No		Corresponding Author's Name Charles C. Della Santina
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Are there any relevant conflicts of interest? ☒ Yes ☐ No

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NIH	☒	☐	☐	☐	grant to Johns Hopkins School of Medicine

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MedEl GmbH	☒	☐	☐	☐	

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Patent?	Pending?	Issued?	Licensed?	Royalties?	Licensee?	Comments
US20120277835	☐	☒	☒	☐	Labyrinth Devices, LLC	Owned by Johns Hopkins University
US8768484B2	☐	☒	☒	☐	Labyrinth Devices, LLC	Owned by Johns Hopkins University
US20130253286	☒	☐	☐	☐		

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Dr. Fridman reports grants from NIH, during the conduct of the study; grants from MedEl GmbH, outside the submitted work. In addition, Dr. Fridman has a patent US20120277835 licensed to Labyrinth Devices, LLC, a patent US8768484B2 licensed to Labyrinth Devices, LLC, and a patent US20130253286 pending.

ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name) Yoav	2. Surname (Last Name) Gimmon	3. Date 26-September-2019
4. Are you the corresponding author? ☐ Yes ☒ No		Corresponding Author's Name Charles C. Della Santina
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Labyrinth Devices, LLC	☐	☐	☒	☒	Devices and equipment were produced and provided by Labyrinth Devices, LLC, to Johns Hopkins University (JHU) School of Medicine under a sponsored research agreement in accordance with JHU policies.
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Are there any relevant conflicts of interest? ☐ Yes ☒ No

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Do you have any patents, whether planned, pending or issued, broadly relevant to the work? ☐ Yes ☒ No

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Section 1. Identifying Information

1. Given Name (First Name) Andreas	2. Surname (Last Name) Hofner	3. Date 26-September-2019
4. Are you the corresponding author? ☐ Yes ☒ No		Corresponding Author's Name Charles C. Della Santina
5. Manuscript Title Continuous Vestibular Implant Stimulation Partially Restores Eye-Stabilizing Reflexes		
6. Manuscript Identifying Number (if you know it) 128397-INS-CMED-RV-3		

Section 2. The Work Under Consideration for Publication

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Are there any relevant conflicts of interest? ☐ Yes ☒ No

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Andreas Hofner has nothing to disclose.

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1. Given Name (First Name) Andreas	2. Surname (Last Name) Jaeger	3. Date 26-September-2019
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5. Manuscript Title Continuous Vestibular Implant Stimulation Partially Restores Eye-Stabilizing Reflexes		
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Are there any relevant conflicts of interest? ☐ Yes ☒ No

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Dr. Jaeger has nothing to disclose.

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1. Given Name (First Name)

Kelly

2. Surname (Last Name)

Lane

3. Date

26-September-2019

4. Are you the corresponding author?

☐ Yes

☒ No

Corresponding Author's Name

Charles C. Della Santina

5. Manuscript Title

Continuous Vestibular Implant Stimulation Partially Restores Eye-Stabilizing Reflexes

6. Manuscript Identifying Number (if you know it)

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Section 1. Identifying Information

1. Given Name (First Name) Andreas	2. Surname (Last Name) Marx	3. Date 26-September-2019
4. Are you the corresponding author? ☐ Yes ☒ No		Corresponding Author's Name Charles C. Della Santina
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Are there any relevant conflicts of interest? ☒ Yes ☐ No

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Are there any relevant conflicts of interest? ☐ Yes ☒ No

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1. Given Name (First Name)

Mehdi

2. Surname (Last Name)

Rahman

3. Date

26-September-2019

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Corresponding Author's Name

Charles C. Della Santina

5. Manuscript Title

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5. Manuscript Title Continuous Vestibular Implant Stimulation Partially Restores Eye-Stabilizing Reflexes		
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4. Are you the corresponding author? ☐ Yes ☒ No		Corresponding Author's Name Charles C. Della Santina
5. Manuscript Title Continuous Vestibular Implant Stimulation Partially Restores Eye-Stabilizing Reflexes		
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1. Given Name (First Name) Carolina	2. Surname (Last Name) Treviño	3. Date 26-September-2019
4. Are you the corresponding author? ☐ Yes ☒ No		Corresponding Author's Name Charles C. Della Santina
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MedEl GmbH	☐	☐	☒	☒	Components of devices and equipment provided by Labyrinth Devices, LLC, to Johns Hopkins University (JHU) School of Medicine under a sponsored research agreement in accordance with JHU policies were produced and provided by MedEl GmbH to Labyrinth Devices, LLC.

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)
Nicolas

2. Surname (Last Name)
Valentin

3. Date
26-September-2019

4. Are you the corresponding author?

☐ Yes ☒ No

Corresponding Author's Name
Charles C. Della Santina

5. Manuscript Title
Continuous Vestibular Implant Stimulation Partially Restores Eye-Stabilizing Reflexes

6. Manuscript Identifying Number (if you know it)
128397-INS-CMED-RV-3

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Nicolas Valentin has nothing to disclose.

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ICMJE Form for Disclosure of Potential Conflicts of Interest

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4. Are you the corresponding author? ☐ Yes ☒ No		Corresponding Author's Name Charles C. Della Santina
5. Manuscript Title Continuous Vestibular Implant Stimulation Partially Restores Eye-Stabilizing Reflexes		
6. Manuscript Identifying Number (if you know it) 128397-INS-CMED-RV-3		

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NIH/NIDCD	☒	☐	☐	☐	
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Dr. Ward reports that this research was supported by grants from NIH/NIDCD awarded to Johns Hopkins University (JHU) and that Labyrinth Devices, LLC, provided JHU with devices and equipment, components of which were produced and provided to Labyrinth Devices by Med-El GmbH.



CONSORT 2010 checklist of information to include when reporting a pilot or feasibility randomized trial in a journal or conference abstract

Item	Description	Reported on line number
Title	Identification of study as randomised pilot or feasibility trial	This trial is NOT randomized
Authors *	Contact details for the corresponding author	14
Trial design	Description of pilot trial design (eg, parallel, cluster)	662
Methods		661
Participants	Eligibility criteria for participants and the settings where the pilot trial was conducted	662
Interventions	Interventions intended for each group	666
Objective	Specific objectives of the pilot trial	668
Outcome	Prespecified assessment or measurement to address the pilot trial objectives**	668
Randomization	How participants were allocated to interventions	Nonrandomized
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	Nonblinded for VOR measurements
Results		198
Numbers randomized	Number of participants screened and randomised to each group for the pilot trial objectives**	Nonrandomized
Recruitment	Trial status†	N/A (not a conference abstract)
Numbers analysed	Number of participants analysed in each group for the pilot objectives**	904
Outcome	Results for the pilot objectives, including any expressions of uncertainty**	198
Harms	Important adverse events or side effects	198
Conclusions	General interpretation of the results of pilot trial and their implications for the future definitive trial	58
Trial registration	Registration number for pilot trial and name of trial register	663
Funding	Source of funding for pilot trial	1332

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.

**this item is specific to conference abstracts*

***Space permitting, list all pilot trial objectives and give the results for each. Otherwise, report those that are a priori agreed as the most important to the decision to proceed with the future definitive RCT.*

†For conference abstracts.