

ICMJE DISCLOSURE FORM

Date: 25th Feb 2022

Your Name: Celina Fritz

Manuscript Title: A Multi-Center Trial on efficacy and safety of the LifeTech CeraFlex™ ASD Occluder for Transcatheter Closure in Patients with Secundum Atrial Septal Defects

Manuscript number (if known): CDT-21-798

In the interest of transparency, we ask you to disclose all relationships/activities/interests listed below that are related to the content of your manuscript. “Related” means any relation with for-profit or not-for-profit third parties whose interests may be affected by the content of the manuscript. Disclosure represents a commitment to transparency and does not necessarily indicate a bias. If you are in doubt about whether to list a relationship/activity/interest, it is preferable that you do so.

The following questions apply to the author’s relationships/activities/interests as they relate to the current manuscript only.

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In item #1 below, report all support for the work reported in this manuscript without time limit. For all other items, the time frame for disclosure is the past 36 months.

		Name all entities with whom you have this relationship or indicate none (add rows as needed)	Specifications/Comments (e.g., if payments were made to you or to your institution)
Time frame: Since the initial planning of the work			
1	All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for this item.	None	
Time frame: past 36 months			
2	Grants or contracts from any entity (if not indicated in item #1 above).	None	
3	Royalties or licenses	None	
4	Consulting fees	None	

5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	___ None	
6	Payment for expert testimony	___ None	
7	Support for attending meetings and/or travel	___ None	
8	Patents planned, issued or pending	___ None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	___ None	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	___ None	
11	Stock or stock options	___ None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	___ None	
13	Other financial or non-financial interests	___ None	

Please summarize the above conflict of interest in the following box:

/

Please place an "X" next to the following statement to indicate your agreement:

I certify that I have answered every question and have not altered the wording of any of the questions on this form.

C. Fife

ICMJE DISCLOSURE FORM

Date: 25th Feb 2022

Your Name: Andrea Engelhardt

Manuscript Title: A Multi-Center Trial on efficacy and safety of the LifeTech CeraFlex™ ASD Occluder for Transcatheter Closure in Patients with Secundum Atrial Septal Defects

Manuscript number (if known): CDT-21-798

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Time frame: Since the initial planning of the work			
1	All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for this item.	___None	Institutional grant (DHM) for study conduct by Medtronic / LifeTech
Time frame: past 36 months			
2	Grants or contracts from any entity (if not indicated in item #1 above).	_X_ None	
3	Royalties or licenses	_X_ None	
4	Consulting fees	_X_ None	

5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	<input checked="" type="checkbox"/> None	
6	Payment for expert testimony	<input checked="" type="checkbox"/> None	
7	Support for attending meetings and/or travel	<input checked="" type="checkbox"/> None	
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13	Other financial or non-financial interests	<input checked="" type="checkbox"/> None	

Please summarize the above conflict of interest in the following box:

This study was supported financially by grants from Medtronic and LifeTech

28-Feb-2022 *A. Engelheerdt*
Andrew Engelheerdt

Please place an "X" next to the following statement to indicate your agreement:

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ICMJE DISCLOSURE FORM

Date: 25th Feb 2022

Your Name: Jochen Grohmann

Manuscript Title: A Multi-Center Trial on efficacy and safety of the LifeTech CeraFlex™ ASD Occluder for Transcatheter Closure in Patients with Secundum Atrial Septal Defects

Manuscript number (if known): CDT-21-798

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Time frame: past 36 months			
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3	Royalties or licenses	<input checked="" type="checkbox"/> None	
4	Consulting fees	<input checked="" type="checkbox"/> None	

5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	<input checked="" type="checkbox"/> X <input type="checkbox"/> None	
6	Payment for expert testimony	<input checked="" type="checkbox"/> X <input type="checkbox"/> None	
7	Support for attending meetings and/or travel	<input checked="" type="checkbox"/> X <input type="checkbox"/> None	
8	Patents planned, issued or pending	<input checked="" type="checkbox"/> X <input type="checkbox"/> None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	<input checked="" type="checkbox"/> X <input type="checkbox"/> None	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	<input checked="" type="checkbox"/> X <input type="checkbox"/> None	
11	Stock or stock options	<input checked="" type="checkbox"/> X <input type="checkbox"/> None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	<input checked="" type="checkbox"/> X <input type="checkbox"/> None	
13	Other financial or non-financial interests	<input checked="" type="checkbox"/> X <input type="checkbox"/> None	

Please summarize the above conflict of interest in the following box:

<p>Nothing to disclose.</p>  <p>PD Dr. med. Jochen Grohmann 28.02.2022</p>

Please place an "X" next to the following statement to indicate your agreement:

X I certify that I have answered every question and have not altered the wording of any of the questions on this form.

ICMJE DISCLOSURE FORM

Date: 28th Feb 2022

Your Name: *Ingo Dählmann*

Manuscript Title: A Multi-Center Trial on efficacy and safety of the LifeTech CeraFlex™ ASD Occluder for Transcatheter Closure in Patients with Secundum Atrial Septal Defects

Manuscript number (if known): CDT-21-798

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1	All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.) No time limit for this item.	<input type="checkbox"/> None <i>Reimbursement (study fees)</i> <i>5400 EURO paid by German Heart Center Munich</i>	
Time frame: past 36 months			
2	Grants or contracts from any entity (if not indicated in item #1 above).	<input checked="" type="checkbox"/> None	
3	Royalties or licenses	<input checked="" type="checkbox"/> None	
4	Consulting fees	<input checked="" type="checkbox"/> None	

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28.FEB 2022

Prof. Dr. med. Ingo Dähnert
 FA für Kinder- u. Jugendmedizin
 SP Kinderkardiologie
 Erwachsene mit angeborenen Herzfehlern (EMAH)
 Pädiatrische Intensivmedizin

Herzzentrum Leipzig
 Universitätsklinik für Kinderkardiologie
 Direktor: Prof. Dr. med. Ingo Dähnert
 Strümpellstraße 39
 04289 Leipzig
 Tel.: 0341 865-1036 | Fax: 0341 865-1143

ICMJE DISCLOSURE FORM

Date: 25th Feb 2022

Your Name: Johanna Hummel

Manuscript Title: A Multi-Center Trial on efficacy and safety of the LifeTech CeraFlex™ ASD Occluder for Transcatheter Closure in Patients with Secundum Atrial Septal Defects

Manuscript number (if known): CDT-21-798

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3	Royalties or licenses	__X__ None	
4	Consulting fees	__X__ None	

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13	Other financial or non-financial interests	<input checked="" type="checkbox"/> None	

Please summarize the above conflict of interest in the following box:

28.02.2022



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ICMJE DISCLOSURE FORM

Date: 25th Feb 2022

Your Name: Daniel Tanase

Manuscript Title: A Multi-Center Trial on efficacy and safety of the LifeTech CeraFlex™ ASD Occluder for Transcatheter Closure in Patients with Secundum Atrial Septal Defects

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no conflict of interest

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Donnel Tomox

ICMJE DISCLOSURE FORM

Date: 25th Feb 2022

Your Name: *Peter Ewert*

Manuscript Title: A Multi-Center Trial on efficacy and safety of the LifeTech CeraFlex™ ASD Occluder for Transcatheter Closure in Patients with Secundum Atrial Septal Defects

Manuscript number (if known): CDT-21-798

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Please place an "X" next to the following statement to indicate your agreement:

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München, 14.3.2022 P. [Signature]

Prof. Dr. P. Eberhart
 Klinik für angeborene Herzfehler und
 Kinderkardiologie
 Deutsches Herzzentrum
 des Freistaates Bayern
 - Klinik an der Technischen Universität
 Lazarusstr. 36 - 80336 München

ICMJE DISCLOSURE FORM

Date: 14th Feb. 2022

Your Name: Andreas Eicken MD

Manuscript Title: A Multi-Center Trial on efficacy and safety of the LifeTech CeraFlex™ ASD Occluder for Transcatheter Closure in Patients with Secundum

Manuscript number (if known): CDT-21-798

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3	Royalties or licenses	___ None	
4	Consulting fees	1500 Euro ___	Proctor Lifetech ASD-Occlusion

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Prof. Dr. med. A. Eicken
 Leitender Oberarzt
 Klinik für angeborene Herzfehler und
 Kinderkardiologie
 Deutsches Herzzentrum München
 des Freistaates Bayern
 - Klinik an der Technischen Universität München -
 Lazarettstr. 36 - 80636 München