

ICMJE DISCLOSURE FORM

Date: 8/31/2021
 Your Name: NIKHIL N VERMA
 Manuscript Title: A multi-center, single-blinded randomized controlled trial to assess the efficacy and safety of the InSpace Implant vs Partial Repair
 Manuscript number (if known): JBJS-D-21-00667R1

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.

The author's relationships/activities/interests should be defined broadly. For example, if your manuscript pertains to the epidemiology of hypertension, you should declare all relationships with manufacturers of antihypertensive medication, even if that medication is not mentioned in the manuscript.

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.	<u>None</u>	
		<u>STRYKER</u>	<u>CONSULTANT</u>
		<u>ONTHOSPACE</u>	<u>CONSULTANT</u>
		<u>ONTHOSPACE</u>	<u>STUDY FUNDING</u>
Time frame: past 36 months			
2	Grants or contracts from any entity (if not indicated in item #1 above).	<u>X</u> None	
3	Royalties or licenses	<u>X</u> None	
4	Consulting fees	<u>None</u>	
		<u>STRYKER</u>	
		<u>ONTHOSPACE</u>	

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	
8	Patents planned, issued or pending	<input checked="" type="checkbox"/> None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	<input checked="" type="checkbox"/> None	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	<input checked="" type="checkbox"/> None	
11	Stock or stock options	<input checked="" type="checkbox"/> None	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	<input checked="" type="checkbox"/> None	
13	Other financial or non-financial interests	<input checked="" type="checkbox"/> None	

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.

ICMJE DISCLOSURE FORM

Date: _____ September 8, 2021 _____

Your Name: _____ Colleen Roden _____

Manuscript Title: A multi-center, single-blinded randomized controlled trial to assess the efficacy and safety of the InSpace™ Implant vs Partial Repair for treatment of full thickness massive rotator cuff tears

Manuscript number (if known): _____ JBJS-D-21-00667R1 _____

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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.	Employee of Sponsor Company (OrthoSpace/Stryker)	
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	X_None	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	X_None	
6	Payment for expert testimony	_X_None	
7	Support for attending meetings and/or travel	_X_None	
8	Patents planned, issued or pending	_X_None	
9	Participation on a Data Safety Monitoring Board or Advisory Board	__X_None	
10	Leadership or fiduciary role in other board, society, committee or advocacy group, paid or unpaid	__X_None	
11	Stock or stock options	Stock in Sponsor Company (OrthoSpace/Stryker)	
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	_X_None	
13	Other financial or non-financial interests	_X_None	

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: September 8, 2021
Your Name: Heather Neill
Manuscript Title: A multi-center, single-blinded randomized controlled trial to assess the efficacy and safety of the InSpace™ Implant vs Partial Repair for treatment of full thickness massive rotator cuff tears
Manuscript number (if known): JBJS-D-21-00667R1

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- 1 All support for the present manuscript (e.g., funding, provision of study materials, medical writing, article processing charges, etc.)
Employee of Sponsor Company (OrthoSpace/Stryker)
No time limit for this item.

Time frame: past 36 months

- 2 Grants or contracts from ☒ None
any entity (if not indicated in item #1 above).

- 3 Royalties or licenses ☒ None

4 Consulting fees ☒ None

5 Payment or honoraria for ☒ None
lectures, presentations,
speakers bureaus,
manuscript writing or
educational events

6 Payment for expert
testimony ☒ None

7 Support for attending
meetings and/or travel ☒ None

8 Patents planned, issued or ☒ None
pending

9 Participation on a Data ☒ None
Safety Monitoring Board
or Advisory Board

10 Leadership or fiduciary ☒ None
role in other board,
society, committee or
advocacy group, paid or
unpaid

11 Stock or stock options Stock in Sponsor
Company (OrthoSpace)

12 Receipt of equipment, ☒ None
materials, drugs, medical
writing, gifts or other
services

13 Other financial or non- ☒ None
financial interests

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.

A. Meil

ICMJE DISCLOSURE FORM

Date: September 13, 2021

Your Name: Ed Rogusky, MD

Manuscript Title: A multi-center, single-blinded randomized controlled trial to assess the efficacy and safety of the InSpace™ Implant vs Partial Repair for treatment of full thickness massive rotator cuff tears

Manuscript number (if known): JBJS-D-21-00667R1

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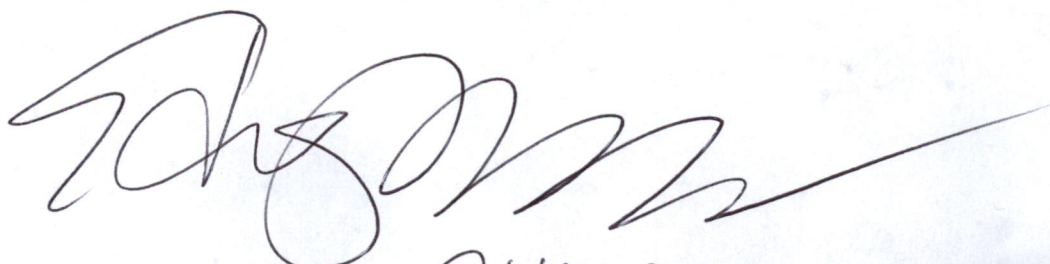
In item #1 below, report all support for the work reported in this manuscript without time limit. For all other items, the time frame for disclosure is the past 36 months.

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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.	<u>None</u>	Study was Sponsored by OrthoSpace/Stryker. Study Devices were provided for that study subjects, research support was provided.
Time frame: past 36 months			
2	Grants or contracts from any entity (if not indicated in item #1 above).	<u>X</u> None	
3	Royalties or licenses	<u>X</u> None	

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

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9/1/9/21

ICMJE DISCLOSURE FORM

Date: Sept 9, 2021
 Your Name: Peter Lapner
 Manuscript Title: A multi-center, single-blinded randomized controlled trial to assess the efficacy and safety of the InSpace™ Implant vs Partial Repair for treatment of full thickness massive rotator cuff tears
 Manuscript number (if known): JBJS-D-21-00667R1

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

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ICMJE DISCLOSURE FORM

Date: 9/8/21
 Your Name: Joseph Abboud
 Manuscript Title: A multi-center, single-blinded randomized controlled trial to assess the efficacy and safety of the InSpace™ Implant vs Partial Repair for treatment of full thickness massive rotator cuff tears
 Manuscript number (if known): JBJS-D-21-00667R1

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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.	THIS WAS an IDE. Stryker supported the research effort	
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 type="checkbox"/> None	DJO, Zimmer Biomet, Globus, Integra

			Slack Orthopaedics, OsteoCentric Technologies
			Wolters Kluwer Health-Lippincott Williams & Wilkins
4	Consulting fees	___None	Stryker, DJO, Zimmer Biomet, Globus
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	X None	
6	Payment for expert testimony	__X__None	
7	Support for attending meetings and/or travel	___None	DJO, Stryker
8	Patents planned, issued or pending	___None	Shoulder Implant Component; Glenoid Joint Spacers. US Provisional Patent 62/804800
			Provisional Patent: Machine Learning Sytems to Predict Prediseased Bone Anatomy
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	Mid Atlantic Shoulder and Elbow Society
			Shoulder JAM LLC, American Shoulder and Elbow Society
			American Shoulder and Elbow Society Foundation
11	Stock or stock options	___None	Shoulder JAM LLC, Marlin Medical Alliance, Mininvasive Aevumed, OBERD
12	Receipt of equipment, materials, drugs, medical writing, gifts or other services	__X__None	
13	Other financial or non-financial interests	___None	Research Support: Zimmer Biomet, Integra, Department Of Defense, OREF, Arthrex, Orthofix
			Scientific Advisory Board: Mininvasive, Aevumed

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: 9/10/2021
 Your Name: Uma Srikumaran MD
 Manuscript Title: A multi-center, single-blinded randomized controlled trial to assess the efficacy and safety of the InSpace™ Implant vs Partial Repair for treatment of full thickness massive rotator cuff tears
 Manuscript number (if known): JBJS-D-21-00667R1

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Time frame: past 36 months			
2	Grants or contracts from any entity (if not indicated in item #1 above).	<input type="checkbox"/> None	
		Depuy/Synthes, Arthrex, Wright, Smith & Nephew, ASES, Omega	
3	Royalties or licenses	<input checked="" type="checkbox"/> None	

4	Consulting fees	<input checked="" type="checkbox"/> X <input type="checkbox"/> None	
5	Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events	Tigon Medical, Conventus, Fx Shoulder USA, Orthofix, Heron, Pacira	
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 type="checkbox"/> None	
		Conventus, Fx Shoulder USA, Tigon Medical	
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 type="checkbox"/> None	
		Tigon Medical	
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	

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