

In the Drawings:

The specific changes in the replacement sheet are as follows:

5 **New Drawing Sheet 1:** New Drawing Sheet 1 provides drawings that were present
in the ‘227 Application, to which the present application claims priority and which
is incorporated into the present application by reference. See FIGS. 33-35 of the
‘227 Application. New Drawing Sheet 1 incorporates FIGS. 33-35 of the ‘227
Application as new FIGS. 126-128, and thus new FIGS. 126-128 are fully
supported by the ‘227 Application. New Drawing Sheet 1 complies with the
10 requirements of 37 C.F.R. § 1.84, and does **not** add any new matter to the present
application.

REMARKS

The present amendments are fully supported by the '227 Application, which is incorporated by reference into the originally filed application. Under 37 C.F.R. § 1.57, if a portion of the specification or drawing(s) is inadvertently omitted from an application, but
5 the application contains a claim under 37 C.F.R. § 1.78 for priority of a prior-filed non-provisional application omitted portion of the specification is completely contained in the prior-filed application, the claim under 37 C.F.R. § 1.78 shall also be considered an incorporation by reference of the prior-filed application as to the omitted portion of the specification or drawing(s) (see also M.P.E.P. § 217). The '227 Application is incorporated
10 into the present by reference by the priority claim to the '227 Application under 37 C.F.R. § 1.78 and 35 U.S.C. § 119 made in the Application Data Sheet filed with the present application. Additionally, original FIG. 39 and paragraph [0187] of the present application shows a view of the fusion implant featured in new FIGS. 126-128 and described in new paragraph [0229] (see reference number 151), and thus the present application as originally
15 filed provides support for the added drawings and description.

CONCLUSION

The office is authorized to charge any fees or credit any refunds associated with this paper to deposit account 600741. Prompt processing of the within application is requested.

5

Dated: May 18, 2021.

Respectfully Submitted,

10

By /William Nelson/
William K. Nelson
Registration No. 63,501
Customer No. 13442

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		16689073
	Filing Date		2019-11-19
	First Named Inventor	Schifano, Troy	
	Art Unit		
	Examiner Name		
	Attorney Docket Number	13709.02.USU05	

U.S.PATENTS						Remove
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	6652533		2003-11-25	O'Neil	
	2	8157865		2012-04-17	Hochschuler et al.	
	3	10682150		2020-06-16	Stark	
	4	8945224		2015-02-03	Trieu	
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Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	20050080422		2005-04-14	Otte et al.	
	2	20150073552		2015-03-12	Ouroboros Medical, Inc.	

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Attorney Docket Number	13709.02.USU05

3	20150230937	2015-08-20	Medos International Sarl
4	20160030191	2016-02-04	Neuropro Technologies, Inc.
5	20180303624	2018-10-25	Life Spine, Inc.

If you wish to add additional U.S. Published Application citation information please click the Add button.

FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ²	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T ⁵
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If you wish to add additional Foreign Patent Document citation information please click the Add button.

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
	1		

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EXAMINER SIGNATURE

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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

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Attorney Docket Number	13709.02.USU05

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/William K. Nelson/	Date (YYYY-MM-DD)	2021-05-19
Name/Print	William K. Nelson	Registration Number	63501

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
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5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Acknowledgement Receipt

EFS ID:	42770025
Application Number:	16689073
International Application Number:	
Confirmation Number:	8990
Title of Invention:	METHOD AND IMPLANT SYSTEM FOR SACROILIAC JOINT FIXATION AND FUSION
First Named Inventor/Applicant Name:	Troy Schifano
Customer Number:	13442
Filer:	William Kenneth Nelson
Filer Authorized By:	
Attorney Docket Number:	13079.02.USU05
Receipt Date:	19-MAY-2021
Filing Date:	19-NOV-2019
Time Stamp:	19:50:14
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	20210519_IDS.pdf	612298	no	5
			b7ccb46199431727fb50d300b908069c16f49238		

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Petitioner's Ex. 1013

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Total Files Size (in bytes):	612298
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.	

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875				Application or Docket Number 16/689,073		Filing Date 11/19/2019		☐ To be Mailed	
ENTITY: ☐ LARGE ☒ SMALL ☐ MICRO									
APPLICATION AS FILED - PART I									
		(Column 1)			(Column 2)				
FOR		NUMBER FILED			NUMBER EXTRA	RATE (\$)	FEE (\$)		
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))		N/A			N/A	N/A			
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))		N/A			N/A	N/A			
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))		N/A			N/A	N/A			
TOTAL CLAIMS (37 CFR 1.16(i))		minus 20 =	*			x \$50 =			
INDEPENDENT CLAIMS (37 CFR 1.16(h))		minus 3 =	*			x \$230 =			
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))		If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).							
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))									
* If the difference in column 1 is less than zero, enter "0" in column 2.						TOTAL			
APPLICATION AS AMENDED - PART II									
		(Column 1)			(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)		
	Total (37 CFR 1.16(i))	*	Minus	**	=	x \$0 =			
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x \$0 =			
	☐ Application Size Fee (37 CFR 1.16(s))								
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))								
						TOTAL ADD'L FEE			
		(Column 1)			(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)		
	Total (37 CFR 1.16(i))	*	Minus	**	=	x \$0 =			
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x \$0 =			
	☐ Application Size Fee (37 CFR 1.16(s))								
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))								
						TOTAL ADD'L FEE			
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.						LIE			
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".						/GLORIA J NORRIS/			
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	Filing Date		2019-11-19
	First Named Inventor	Schifano, Troy	
	Art Unit		
	Examiner Name		
	Attorney Docket Number	13709.02.USU05	

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Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	10456175		2019-10-29	Carver et al.	
	2	10806823		2020-10-20	Altschuler	
	3	8764729		2014-07-01	Muni et al.	
	4	9333090		2016-05-10	Donner et al.	
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	1	20190125371		2019-05-02	Asfora et al.	
	2	20180092748		2018-04-05	Donner et al.	

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3	20160184105	2016-06-30	Donner et al.
4	20070123995	2007-05-31	Hawkins et al.
5	20030220646	2003-11-27	Hawkins et al.

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	1	2018522678	JP		2018-08-16	Berthelme et al.		
	2	108175460	CN		2018-06-19	Wang		
	3	356207	MX		2018-05-18	Swensgard et al.		
	4	6259513	JP		2018-01-10	Frey et al.		
	5	102248576	KR		2021-05-06	Altschuler et al.		
	6	353031	MX		2017-12-18	Shelton et al.		

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7	20110106413	KR		2011-09-28	Muni et al.		
8	2013056121	WO		2013-04-18	Brogna et al.		
9	2010077359	WO		2010-07-08	Hardenbrook et al.		
10	2009038781	WO		2009-02-19	Khamis et al.		
11	60020851	DE		2005-07-21	Branch et al.		
12	69726491	DE		2004-01-15	Kogasaka et al.		
13	2203568	CA		1996-05-02	Grinberg		

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NON-PATENT LITERATURE DOCUMENTS

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	1	World Congress on Osteoporosis, Osteoarthritis and Musculoskeletal Diseases (WCO-IOF-ESCEO 2020): Poster Abstracts, from "Osteoporosis International, suppl. 1 31 : 133-621. Springer Nature B.V. (Dec 2020)"	
	2	Deutscher Wirbelsaulenkongress, from "European Spine Journal 29.11: 2853-2939. Springer Nature B.V. (Nov 2020)"	

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3	SCIENTIFIC ABSTRACTS, from "Journal of General Internal Medicine, suppl. Supplement 33.2: 83-840. Springer Nature B.V. (Apr 2018)"
4	World Congress on Osteoporosis, Osteoarthritis and Musculoskeletal Diseases (WCO-IOF-ESCEO 2018): Poster Abstracts, from "Osteoporosis International, suppl. Supplement 29.1: 149-565. Springer Nature B.V. (Apr 2018)"
5	2017 TERMIS - Americas Conference & Exhibition Charlotte, NC December 3-6, 2017, from "Tissue Engineering Part A 23.S1: S-1-S-159. Mary Ann Liebert, Inc. (Dec 2017)"
6	Abstracts from the 37th Congress of the Societe Internationale d'Urologie, Centro de Congresses de Lisboa, October 19-22, 2017, from "World Journal of Urology, suppl. Supplement 35.1: 1-360. Springer Nature B.V. (Oct 2017)"
7	CIRSE 2017, from "Cardiovascular and Interventional Radiology, suppl. Supplement 40 : 25-412. Springer Nature B.V. (Aug 2017)"
8	2016 TERMIS - Americas Conference and Exhibition San Diego, CA December 11-14, 2016, from "Tissue Engineering Part A 22.S1: S-1-S-156. Mary Ann Liebert, Inc. (Dec 2016)"
9	Abstract SIU 2016 Buenos Aires, Argentina book, from "World Journal of Urology, suppl. Supplement 34 : 1-248. Springer Nature B.V. (Oct 2016)"
10	IPR 2016, from "Pediatric Radiology, suppl. Supplement 46 : 1-372. Springer Nature B.V. (May 2016)"
11	Abstracts from the 38th Annual Meeting of the Society of General Internal Medicine, from "Journal of General Internal Medicine, suppl. Supplement 30 : 45-551. Springer Nature B.V. (Apr 2015)"
12	The 48th Congress of the European Society for Surgical Research, May 29 - June 1, 2013, Istanbul, Turkey, from "European Surgical Research, suppl. S1 50 : 1-161. S. Karger AG. (May 2013)"
13	Proceedings of the 2010 World Molecular Imaging Congress, Kyoto, Japan, September 8-11, 2010, from "Molecular Imaging and Biology : MIB, suppl. Supplement 12 : 495-1636. Springer Nature B.V. (Dec 2010)"

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14	CIRSE 2009: Lisbon, Portugal, September 19-23, from "Cardiovascular and Interventional Radiology, suppl. Supplement 32 : 29-346. Springer Nature B.V. (Sep 2009)"
15	International Surgical Week ISW 2009: Adelaide, September 6-10, 2009, from "World Journal of Surgery, suppl. Supplement 33 : 1-268. Springer Nature B.V. (Sep 2009)"
16	Scientific Abstracts, from "Journal of General Internal Medicine, suppl. Supplement 24 : 1-380. Springer Nature B.V. (Apr 2009)"
17	21st National Congress of the Italian Polyspecialist Society of Young Surgeons (IPSYS). June 15-18, 2008, Perugia, from "European Surgical Research 41.2: 59-196. S. Karger AG. (Aug 2008)"
18	20th National Congress of the Italian Polyspecialist Society of Young Surgeons (IPSYS): November 8-10, 2007, Naples, from "European Surgical Research 40.2: 61-183. S. Karger AG. (Feb 2008)"
19	Society of general internal medicine 23rd annual meeting Boston, Massachusetts May 4-6, 2000 abstracts, from "Journal of General Internal Medicine, suppl. Supplement 15 : 1-13. Springer Nature B.V. (Jan 2000)"

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Examiner Signature		Date Considered	
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¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

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Signature	/William K. Nelson/	Date (YYYY-MM-DD)	2021-06-21
Name/Print	William K. Nelson	Registration Number	63501

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Electronic Acknowledgement Receipt

EFS ID:	43047779
Application Number:	16689073
International Application Number:	
Confirmation Number:	8990
Title of Invention:	METHOD AND IMPLANT SYSTEM FOR SACROILIAC JOINT FIXATION AND FUSION
First Named Inventor/Applicant Name:	Troy Schifano
Customer Number:	13442
Filer:	William Kenneth Nelson
Filer Authorized By:	
Attorney Docket Number:	13079.02.USU05
Receipt Date:	22-JUN-2021
Filing Date:	19-NOV-2019
Time Stamp:	03:21:54
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.					

Electronic Acknowledgement Receipt

EFS ID:	43047841
Application Number:	16689073
International Application Number:	
Confirmation Number:	8990
Title of Invention:	METHOD AND IMPLANT SYSTEM FOR SACROILIAC JOINT FIXATION AND FUSION
First Named Inventor/Applicant Name:	Troy Schifano
Customer Number:	13442
Filer:	William Kenneth Nelson
Filer Authorized By:	
Attorney Docket Number:	13079.02.USU05
Receipt Date:	22-JUN-2021
Filing Date:	19-NOV-2019
Time Stamp:	04:06:43
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.					

Electronic Acknowledgement Receipt

EFS ID:	43053760
Application Number:	16689073
International Application Number:	
Confirmation Number:	8990
Title of Invention:	METHOD AND IMPLANT SYSTEM FOR SACROILIAC JOINT FIXATION AND FUSION
First Named Inventor/Applicant Name:	Troy Schifano
Customer Number:	13442
Filer:	William Kenneth Nelson
Filer Authorized By:	
Attorney Docket Number:	13079.02.USU05
Receipt Date:	22-JUN-2021
Filing Date:	19-NOV-2019
Time Stamp:	14:18:07
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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Total Files Size (in bytes):			882851448		
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.					

Electronic Acknowledgement Receipt

EFS ID:	43061028
Application Number:	16689073
International Application Number:	
Confirmation Number:	8990
Title of Invention:	METHOD AND IMPLANT SYSTEM FOR SACROILIAC JOINT FIXATION AND FUSION
First Named Inventor/Applicant Name:	Troy Schifano
Customer Number:	13442
Filer:	William Kenneth Nelson
Filer Authorized By:	
Attorney Docket Number:	13079.02.USU05
Receipt Date:	23-JUN-2021
Filing Date:	19-NOV-2019
Time Stamp:	02:55:51
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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Information:					

58	Non Patent Literature	NPL_17D_Calzolari.pdf	15488981	no	30
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Electronic Acknowledgement Receipt

EFS ID:	43072064
Application Number:	16689073
International Application Number:	
Confirmation Number:	8990
Title of Invention:	METHOD AND IMPLANT SYSTEM FOR SACROILIAC JOINT FIXATION AND FUSION
First Named Inventor/Applicant Name:	Troy Schifano
Customer Number:	13442
Filer:	William Kenneth Nelson
Filer Authorized By:	
Attorney Docket Number:	13079.02.USU05
Receipt Date:	23-JUN-2021
Filing Date:	19-NOV-2019
Time Stamp:	18:23:01
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Non Patent Literature	NPL_18B_Bassi.pdf	16683699	no	31
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Petitioner's Ex. 1013

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14	Non Patent Literature	NPL_19J_Aagaard.pdf	17387353	no	14
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/689,073	11/19/2019	Troy Schifano	13079.02.USU05	8990
13442	7590	08/31/2021	EXAMINER	
Sierra IP Law, PC P.O. Box 5637 Fresno, CA 93755-5637			MATTHEWS, TESSA M	
			ART UNIT	PAPER NUMBER
			3773	
			MAIL DATE	DELIVERY MODE
			08/31/2021	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of Pre-AIA or AIA Status

1. The present application is being examined under the pre-AIA first to invent provisions.

Election/Restrictions

2. This application contains claims directed to the following patentably distinct species

Implant Species

Species A, Figures 49 - 51, dual helical anchor

Species B, Figures 52-54, one helical anchor

Species C, Figures 56-57, implant with lateral flukes

Species D, Figures 59-61, box-like body with holes for screws

Species E, Figures 63-64, box-like body with non-detachable blades

Species F, Figures 65-66, box-like body with detachable blades

Species G, Figures 68-70, box-like body with two flukes

Surgical Tool Species

Species H, Figures 27 - 32B, single hollow barrel

Species I, Figures 33-37, dual hollow barrels

3. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, or a single grouping of patentably indistinct species, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 32, 49, and 77 are generic.

There is a search and/or examination burden for the patentably distinct species as set forth above because at least the following reason(s) apply: The mutually exclusive aspects of the device would require individualized search strategies and performing these individualizes search strategies would be overly burdensome on the examiner.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species or grouping of patentably indistinct species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species or grouping of patentably indistinct species.

Should applicant traverse on the ground that the species, or groupings of patentably indistinct species from which election is required, are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing them to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 or pre-AIA 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Conclusion

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to TESSA M MATTHEWS whose telephone number is (571)272-8817. The examiner can normally be reached on M - F 8am - 1pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <https://ppair-my.uspto.gov/pair/PrivatePair>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/TESSA M MATTHEWS/
Examiner, Art Unit 3773

<i>Index of Claims</i> 	Application/Control No. 16/689,073	Applicant(s)/Patent Under Reexamination Schifano et al.
	Examiner TESSA M MATTHEWS	Art Unit 3773

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS										
☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47										
CLAIM		DATE								
Final	Original	08/28/2021								
	32	÷								
	33	-								
	34	-								
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	36	÷								
	37	-								
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<i>Index of Claims</i> 	Application/Control No. 16/689,073	Applicant(s)/Patent Under Reexamination Schifano et al.
	Examiner TESSA M MATTHEWS	Art Unit 3773

CLAIM		DATE								
Final	Original	08/28/2021								
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	75	-								
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	86	÷								

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		16689073
	Filing Date		2019-11-19
	First Named Inventor	Troy Schifano	
	Art Unit		
	Examiner Name		
	Attorney Docket Number		13079.02.USU05

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Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	D835787		2018-12-11	Radocy et al.	
	2	D816469		2018-05-01	Toomey	
	3	9757119		2017-09-12	Norton et al.	
	4	D765855		2016-09-06	Ben-Yehuda et al.	
	5	D728892		2015-05-12	Rogers et al.	
	6	D653344		2012-01-31	Bar-Shalom	
	7	D628292		2010-11-30	Berberich	
	8	D588700		2009-03-17	Aldecoa	

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	16689073
Filing Date	2019-11-19
First Named Inventor	Troy Schifano
Art Unit	
Examiner Name	
Attorney Docket Number	13079.02.USU05

9	6689153	2004-02-10	Skiba
10	5891146	1999-04-06	Simon et al.
11	5443509	1995-08-22	Boucher et al.
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		16689073
	Filing Date		2019-11-19
	First Named Inventor	Troy Schifano	
	Art Unit		
	Examiner Name		
	Attorney Docket Number	13079.02.USU05	

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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	16689073
Filing Date	2019-11-19
First Named Inventor	Troy Schifano
Art Unit	
Examiner Name	
Attorney Docket Number	13079.02.USU05

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/William K. Nelson/	Date (YYYY-MM-DD)	2021-09-28
Name/Print	William K. Nelson	Registration Number	63501

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

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7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
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Electronic Acknowledgement Receipt

EFS ID:	43893805
Application Number:	16689073
International Application Number:	
Confirmation Number:	8990
Title of Invention:	METHOD AND IMPLANT SYSTEM FOR SACROILIAC JOINT FIXATION AND FUSION
First Named Inventor/Applicant Name:	Troy Schifano
Customer Number:	13442
Filer:	William Kenneth Nelson
Filer Authorized By:	
Attorney Docket Number:	13079.02.USU05
Receipt Date:	28-SEP-2021
Filing Date:	19-NOV-2019
Time Stamp:	21:20:52
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	20210928_IDS.pdf	612582	no	5
			4136241c4ad86eab2a8e4b1fe2262af07d4a4602		

Warnings:

Petitioner's Ex. 1013

Information:	
Total Files Size (in bytes):	612582
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.	



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/689,073	11/19/2019	Troy Schifano	13079.02.USU05	8990
13442	7590	10/14/2021	EXAMINER	
Sierra IP Law, PC P.O. Box 5637 Fresno, CA 93755-5637			MATTHEWS, TESSA M	
			ART UNIT	PAPER NUMBER
			3773	
			MAIL DATE	DELIVERY MODE
			10/14/2021	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<i>Applicant-Initiated Interview Summary</i>	Application No. 16/689,073	Applicant(s) Schifano et al.		
	Examiner TESSA M MATTHEWS	Art Unit 3773	AIA (First Inventor to File) Status No	Page 1 of 1

All Participants (applicant, applicants representative, PTO personnel)	Title	Type
TESSA M MATTHEWS	Primary Examiner	Telephonic
WILLIAM NELSON	Attorney of Record	

Date of Interview: 12 October 2021

Issues Discussed:

Election/Restriction

Discussed election of box-like implant species from original parent disclosure. The examiner noted that so long as the species was supported in the previous application it would appropriate to elect the implant species.

/TESSA M MATTHEWS/ Examiner, Art Unit 3773	
Applicant is reminded that a complete written statement as to the substance of the interview must be made of record in the application file. It is the applicants responsibility to provide the written statement, unless the interview was initiated by the Examiner and the Examiner has indicated that a written summary will be provided. See MPEP 713.04 Please further see: MPEP 713.04 Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews, paragraph (b) 37 CFR § 1.2 Business to be transacted in writing	

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview.

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No. 16/689,073)
)
5 Confirmation No. 8990)
)
Applicant: Orthocision Inc.)
)
Examiner: MATTHEWS, TESSA M.)
10)
TC/Art Unit: 3773)
)
For: METHOD AND IMPLANT SYSTEM)
FOR SACROILIAC JOINT FIXATION)
15 AND FUSION)
)
Filed: November 19, 2019)
_____)

20 Certificate of Transmission

I hereby certify that this paper, together with any documents referred to as being attached,
enclosed or submitted herewith, is being transmitted to the Commissioner for Patents, P.O. Box
25 1450, Alexandria, VA 22313-1450 via the USPTO EFS-Web filing system on October 18, 2021.

Signed: _____
William K. Nelson

30 **AMENDMENT AND RESPONSE TO ELECTION OF SPECIES REQUIREMENT**

Honorable Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

35 Dear Sir:

This paper is being submitted in response to the communication from the Office dated
August 31, 2021 (hereinafter, the "Office Action"), in which the Office has included an
Election of Species requirement.

40 Amendments to the claim are found in the **listing of claims** which begins on **page 2** of
this paper.

Remarks begin on **page 12** of this paper.

In the Claims:

1-31. (Canceled)

5 32. (Currently Amended) A method for repairing a sacroiliac joint of a patient, comprising:

a. creating a first incision in the patient's skin proximal to the patient's sacroiliac joint;

10 b. inserting a working channel having at least one tang on a distal end thereof into said first incision and spreading said sacroiliac joint with an inserted end of said first working channel;

c. creating a void in said sacroiliac joint; and

d. inserting a fusion implant into said void, said fusion implant having:

15 i. a tapered distal end configured to be inserted between an ilium and a sacrum of said sacroiliac joint, and

ii. a central body comprising

20 1. first two opposite lateral sides, each opposite side comprising a groove beginning at the proximal end of the body and continuing along each of the two opposite sides for at least part of the length, the distance between the two sides defining a width of the body, and

25 2. a second two opposite sides located between the first two opposite sides, each of said two opposite sides having a plurality of ~~at least one~~ protrusions for engagement with bone tissue in an articular surface of at least one of the sacrum and the ilium of said sacroiliac joint to prevent pullout of said fusion implant.

33. (Canceled)

34. (Canceled)

5

35. (Currently Amended) The method of claim 32, further comprising driving said fusion implant into said void with an impactor, wherein driving said fusion implant engages said ~~at least one~~ pluralities of protrusions with said bone tissue.

10

36. (Canceled) ~~The method of claim 32, wherein said fusion implant has a central body and said at least one protrusion extends laterally from said central body.~~

37. (Canceled)

15

38. (Canceled)

39. (Canceled)

20

40. (Canceled) ~~The method of claim 32, wherein said fusion implant contacts the patient's ilium and the patient's sacrum and compresses said joint, thereby securing said implant in said joint.~~

25

41. (Currently Amended) The method of claim ~~40~~ 32, wherein said fusion implant is ~~configured to substantially fix~~ es and fuses the patient's ilium to the patient's sacrum, thereby substantially ~~immobilizing~~ immobilizes the patient's sacroiliac joint.

42. (Canceled)

43. (Currently Amended) The method of claim 41, wherein said fusion implant comprises at least one passage therethrough for a cavity for holding a fusion-promoting material and allowing growth of bone through the said at least one passage.
- 5 44. (Currently Amended) The method of claim 43, wherein said ~~cavity comprises at least one hole therein~~passage comprises a plurality of passages for allowing the growth of bone tissue into said cavity through said fusion implant.
- 10 45. (Canceled)
46. (Canceled)
- 15 47. (Currently Amended) The method of claim 32, wherein the inserting said fusion implant comprises:
- a. attaching said fusion implant to an inserter having ~~a slot~~groove-engagement protrusion~~arms that nest in said grooves~~; and
- b. inserting said inserter into a hollow barrel of said working channel with said slot-engagement ~~protrusion~~arms aligned with a guidance slot within said hollow barrel and advancing said inserter until said guidance slot arrests the penetration of said inserter and said fusion implant into said sacroiliac joint at a pre-determined depth.
- 20
48. (Canceled)
- 25 49. (Currently Amended) A method for repairing a sacroiliac joint of a patient using an intra-articular joint fusion device for connecting the sacrum and ilium, comprising:

- 5
- a. creating a first incision in the patient's skin proximal to the patient's sacroiliac joint;
 - b. inserting a working channel of a surgical channel tool into said incision from the posterior of the patient, wherein said working channel includes an insertion control mechanism for controlling the advancement of surgical tools into said working channel;
 - c. creating a void in said sacroiliac joint;
 - d. inserting a fusion implant into said void using an inserter tool, said fusion implant having ~~at least one~~ a plurality of protrusions for engagement with bone tissue in an articular surface of at least one of the sacrum and the ilium of said sacroiliac joint to prevent pullout of said fusion implant; and
 - e. driving said fusion implant into said void such that said ~~at least one~~ plurality of protrusions engages with said bone tissue.
- 10

15 50. (Canceled)

51. (Currently Amended) The method of claim 49, wherein said ~~at least one~~ plurality of protrusions comprises two sets of pluralities of protrusions, a first plurality of protrusions on a first lateral face of said fusion implant and a second plurality of protrusions on a second lateral face of said fusion implant ~~a helical anchor having a sharp end for piercing said bone tissue in an articular surface of at least one of said sacrum and said ilium.~~

20

52. (Canceled)

25 53. (Canceled) ~~The method of claim 49, wherein said at least one protrusion comprises a fluke having a sharp portion for piercing said bone tissue in said articular surface of said at least one of said sacrum and said ilium.~~

54. (Canceled)

55. (Canceled)

5

56. (Canceled)

57. (Canceled)

10

58. (Canceled)

15

20

59. (Currently Amended) The method of claim 49, wherein said fusion implant comprises a body having a ~~cavity therein~~passage therethrough for holding a fusion-promoting material and allowing growth of bone through the said passage and a second two opposite lateral sides, each opposite side comprising a groove beginning at the proximal end of the body and continuing along each of the two opposite sides for at least part of the length, the distance between the second two opposite sides defining a width of the first lateral face and the second lateral face~~and perforations on an exterior thereof that expose said cavity to an exterior of said body, and a hole in a proximal end of said body for accessing the interior of said cavity.~~

25

60. (Previously Presented) The method of claim 51, wherein said fusion implant is operable to connect said sacrum to said ilium in fixed relative positions in the sacroiliac joint.

61. (Canceled)

62. (Canceled)

30

63. (Canceled)

Serial No. 16/689,073

6

64. (Canceled)

65. (Canceled)

5

66. (Canceled)

67. (Currently Amended) The method of claim 49~~59~~, wherein the inserting the fusion implant comprises:

10

a. attaching said fusion implant to said inserter tool to said grooves of said fusion implant, wherein said inserter tool has a groove-engagement arms that nest in said grooves~~an insertion control protrusion~~; and

15

b. inserting the inserter tool into a hollow barrel of said working channel and engaging said insertion control protrusion with said insertion control mechanism and advancing the inserter tool until said insertion control protrusion is arrested by the insertion control mechanism at a pre-determined point in the hollow barrel, and said inserter tool is prevented from moving the fusion implant further into said sacroiliac joint.

20

68. (Canceled)

69. (Currently Amended) The method of claim 49, wherein driving said fusion implant into said void comprises pushing said fusion implant into said void such that the ~~at least one~~plurality of protrusions contacts said bone tissue.

25

70. (Canceled)

71. (Canceled)

72. (Canceled)

73. (Canceled)

5

74. (Canceled)

75. (Canceled)

10 76. (Canceled)

77. (Currently Amended) A method for repairing a sacroiliac joint of a patient using an intra-articular joint fusion device for connecting the sacrum and ilium, comprising:

- 15 a. creating an incision in the patient's skin in a position proximal to the patient's sacroiliac joint to allow access to the posterior portion of the sacroiliac joint;
- b. inserting a working channel of a surgical channel tool into said incision from the posterior of the patient, said working channel including at least
- 20 one tang protruding from a distal end of the working channel and an insertion control mechanism for controlling the advancement of surgical tools into said working channel;
- c. creating a void in said sacroiliac joint;
- d. inserting a fusion implant using an inserter into said void on a path that is
- 25 substantially parallel to articular surfaces of the sacroiliac joint, wherein said fusion implant includes two opposing articular engagement faces, each of said faces having a plurality of protrusions for engagement with

bone tissue in articular surfaces of each of said sacroiliac joint to prevent pullout of said fusion implant from said sacroiliac joint—said inserter having an insertion control protrusion for engagement with said insertion control mechanism;

- 5 e. advancing the inserter tool until said insertion control protrusion to a pre-determined point in the hollow barrel and placing said fusion implant into said sacroiliac joint, ~~and said inserter tool is prevented from moving the fusion implant further into said sacroiliac joint;~~ and
- 10 f. driving said fusion implant into said void such that said fusion implant engages with said bone tissue.

78. (Canceled) ~~The method of claim 77, wherein said fusion implant includes at least one protrusion for engagement with bone tissue in an articular surface of at least one of the sacrum and the ilium of said sacroiliac joint.~~

79. (Canceled) ~~The method of claim 78, wherein said at least one protrusion comprises a helical anchor having a sharp end for piercing said bone tissue, and said helical anchor first penetrates said articular surface of said at least one of said sacrum and said ilium.~~

80. (Currently Amended) The method of claim 77, wherein said fusion implant comprises ~~a cavity~~at least one passage through said two opposing articular engagement faces for holding a fusion-promoting material.

81. (Currently Amended) The method of claim 80, wherein said ~~cavity~~comprises at least one hole therein for allowing passage allows for the growth of bone tissue into said cavity through said at least one passage.

82. (Previously Presented) The method of claim 80, wherein no further fusion implants are introduced into said sacroiliac joint and said fusion implant is sufficient to fuse the sacroiliac joint.
- 5 83. (Previously Presented) The method of Claim 77, wherein said at least one tang secures a position of said working channel in said sacroiliac joint to avoid movement of said working channel during insertion of said fusion implant.
- 10 84. (Currently Amended) The method of Claim 77, wherein said inserter has an insertion control protrusion for engagement with said insertion control mechanism and engagement of said insertion control protrusion with said insertion control mechanism maintains said inserter and said fusion implant in proper orientation for insertion of the fusion implant into said sacroiliac joint.
- 15 85. (Previously Presented) The method of claim 32, wherein the inserting said fusion implant comprises:
- a. attaching said fusion implant to an inserter having a slot-engagement protrusion; and
- 20 b. inserting said inserter into a hollow barrel of said working channel with said slot-engagement protrusion aligned with a guidance slot within said hollow barrel, wherein engagement of said slot-engagement protrusion with said guidance slot maintains said inserter and said fusion implant in proper orientation for insertion of the fusion implant into said sacroiliac joint.
- 25 86. (Previously Presented) The method of claim 49, wherein the inserting said fusion implant comprises:
- a. attaching said fusion implant to an inserter having a slot-engagement element; and

- b. inserting said inserter into a hollow barrel of said working channel with said slot-engagement protrusion aligned with said insertion control mechanism within said hollow barrel, wherein engagement of said slot-engagement element with said insertion control mechanism maintains said inserter and said fusion implant in proper orientation for insertion of the fusion implant into said sacroiliac joint.

REMARKS

Amendments to the Claims:

This paper includes amendments to Claims 32, 35, 41, 43-44, 47, 49, 51, 59, 67, 69, 77, 80-81, and 84. Claims 36, 40, 53, and 78-79 have been canceled. Claims 32, 35, 41,
5 43-44, 47, 49, 51, 59-60, 67, 69, 77, and 80-86 are presently pending. No additional fees are believed to be due at this time. The present amendment adds no new matter.

Election of species requirement:

10 The Office Action includes two different categories of species and requires the Applicant to select one species from each category. The Office Action asserts that the present application contains claims directed to multiple implant species and requires Applicant to select one of the following identified implant species:

Species A, Figures 49 - 51, dual helical anchor;
15 Species B, Figures 52-54, one helical anchor;
Species C, Figures 56-57, anchor with lateral flukes;
Species E, Figures 59-61, box-like body with holes for screws;
Species F, Figures 65-66, box-like body with detachable blades;
Species G, Figures 68-70, box-like body with two flukes; and
20 Species XX, Figures 123-125, a box-like implant.

Species XX was not identified in the Office Action, but was discussed by Applicant and Examiner during an interview on October 12, 2021, and it was agreed that the embodiment shown particularly FIGS. 126-128 and shown below would be available as an
25 electable species.

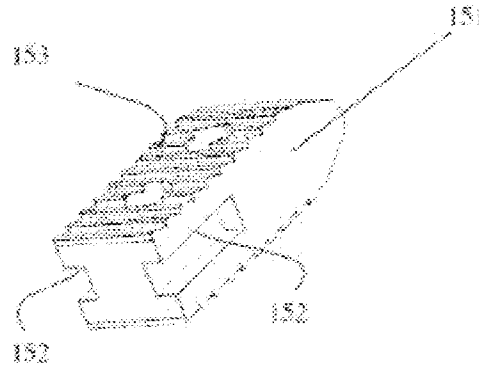


FIG. 126

The Office Action also asserts that the present application contains claims directed to multiple surgical tool species and requires Applicant to select one of the following identified surgical tool species:

5

Species H, Figures 27 – 32B, single hollow barrel; and

Species I, Figures 33 - 37, dual hollow barrels.

However, the Office Action does not sufficiently explain why the species are independent and distinct¹, which is required for a proper restriction or election of species requirement. The Office Action simply lists the alleged species and offers the following conclusory statement:

10

“The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these

¹ Applicant notes 35 U.S.C. § 121 states that if “two or more independent *and* distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions” (emphasis added). See also 37 C.F.R. § 1.142; M.P.E.P § 802. The plain meaning of a statute should be followed in the absence of evidence of contrary legislative intent. See *Caminetti v. United States*, 242 U.S. 470, 485, 37 S.Ct. 192, 61 L.Ed. 442 (1917); *Train v. Colorado Public Interest Research Group, Inc.*, 426 U.S. 1, 10, 96 S.Ct. 1938, 48 L.Ed.2d 434 (1976). Because the statutory language is clear, an election of species should only be required when there are embodiments or versions of an invention that are both independent and distinct.

species are not obvious variants of each other based on the current record” (see the first paragraph on page 3 of the Office Action).

The above excerpt neither provides (1) any explanation as to why the alleged species are distinct, nor (2) any discussion as to the features of the species to support the assertion that they are independent and distinct.

The mere identification of alleged species in combination with a statement that concludes that the species are “independent or distinct” is inadequate to support an election of species requirement. As stated in M.P.E.P. § 808, “[e]very requirement to restrict has two aspects: (A) the reasons (as distinguished from the mere statement of conclusion) why each invention as claimed is either independent or distinct from the other(s); and (B) the reasons why there would be a serious burden on the examiner if restriction is not required, i.e., the reasons for insisting upon restriction therebetween...” (emphasis added). Additionally, the “particular reasons relied on by the examiner for holding that the inventions as claimed are either independent or distinct should be concisely stated... [a] mere statement of conclusion is inadequate.” See M.P.E.P. § 808.01 (emphasis added). “The reasons upon which the conclusion is based should be given.” See *Ibid.* “For example, relative to a combination and a subcombination thereof, the examiner *should point out the reasons why he or she considers the subcombination to have utility by itself or in other combinations, and why he or she considers that the combination as claimed does not require the particulars of the subcombination as claimed.*” See *Ibid.*

Concluding that the alleged species are “independent or distinct” (1) fails to meet the statutory standard set forth in 35 U.S.C. § 121 (see footnote 1), which is required for a proper restriction of any species, and (2) does not provide the reasons why the species are considered independent and distinct. For example, there is no discussion as to why a surgical implant having one helical anchor is independent and distinct from a surgical implant having two helical anchors. Because there is no discussion of the differences in features or characteristics of the alleged species whatsoever, the Office Action cannot logically include a particularized discussion of the reasons why alleged species are

considered independent or distinct. Therefore, for at least this reason, the Election of Species requirement is improper.

Applicant elects to Species XX and H, which correspond to Claims 32, 35, 41, 43-44, 47, 49, 51, 59-60, 67, 69, 77, and 80-86, with traverse.

Applicant traverses the requirement of an Election of Species firstly based on the fact that the Office Action fails to provide any explanation as to why the alleged species are independent and distinct, as explained above. Secondly, Applicant traverses the Election of Species requirement because the Office Action fails to meet the burden on the Office to explain the reasons for the requiring the election. MPEP § 803 states that “[i]f the search and examination of all the claims in an application can be made without serious burden, the examiner must examine them on the merits, even though they include claims to independent or distinct inventions.” “[T]he examiner, in order to establish reasons for insisting upon restriction, *must explain why there would be a serious burden on the examiner if restriction is not required.*” See MPEP § 808.02 (emphasis added). “Thus the examiner must show by appropriate explanation one of the following:

(A) Separate classification thereof: This shows that each invention has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search. Patents need not be cited to show separate classification.

(B) A separate status in the art when they are classifiable together: Even though they are classified together, each invention can be shown to have formed a separate subject for inventive effort when the examiner can show a recognition of separate inventive effort by inventors. Separate status in the art may be shown by citing patents which are evidence of such separate status, and also of a separate field of search.

(C) A different field of search: Where it is necessary to search for one of the inventions in a manner that is not likely to result in finding art pertinent to the other invention(s) (e.g., searching different classes/subclasses or electronic resources, or

employing different search queries[]], a different field of search is shown, even though the two are classified together. The indicated different field of search must in fact be pertinent to the type of subject matter covered by the claims. Patents need not be cited to show different fields of search.” See *Ibid*.

5

The Office Action fails to meet the Examiner’s burden as set forth in the above-mentioned sections of the M.P.E.P. More particularly, the Office Action discuss the examination burden in a conclusory fashion lacking any apparent connection to the claims or specification of the present application, providing no explanation as to: (1) separate
10 classification of the Species; (2) separate status in the art when they are classifiable together; or (3) a different field of search, as required by the M.P.E.P. The Office Action merely concludes that:

“The mutually exclusive aspects of the device would require individualized search strategies and performing these individualized search strategies would be
15 overly burdensome on the examiner” (see the second paragraph on page 3 of the Office Action).

The foregoing conclusory statements offer no explanation as to why examining the alleged Species A-I together would place a *serious burden* on the Examiner. There is no
20 connection between these conclusory statements and any comparison of the limitations of the alleged species. Therefore, the Office Action fails to explain reasons why there would be a serious burden on the Examiner if the Election of Species is not required.

In conclusion, the Office Action (1) fails to provide any explanation as to why the
25 alleged species are independent and distinct, and (2) fails to meet the Examiner’s burden as set forth in the above-mentioned sections of the M.P.E.P. Accordingly, it is respectfully submitted that the Election of Species requirement set forth in the Office Action is improper and it is respectfully requested that the Election of Species requirement be withdrawn.

30

CONCLUSION

The application is believed to be in condition for formal action by the Office. Such action is respectfully solicited. The office is authorized to charge any additional fees required by this paper, or credit any overpayments, to deposit account 600741.

5 If it is deemed helpful or beneficial to the efficient prosecution of the present application, the Examiner is invited to contact Applicant's undersigned representative by telephone.

10 Dated: October 18, 2021.

Respectfully Submitted,

By /William Nelson/
William K. Nelson
Registration No. 63,501
15 Customer No. 13442

Electronic Acknowledgement Receipt

EFS ID:	44060344
Application Number:	16689073
International Application Number:	
Confirmation Number:	8990
Title of Invention:	METHOD AND IMPLANT SYSTEM FOR SACROILIAC JOINT FIXATION AND FUSION
First Named Inventor/Applicant Name:	Troy Schifano
Customer Number:	13442
Filer:	William Kenneth Nelson
Filer Authorized By:	
Attorney Docket Number:	13079.02.USU05
Receipt Date:	19-OCT-2021
Filing Date:	19-NOV-2019
Time Stamp:	02:38:21
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		20211018_resposne_restriction_USU05.pdf	202049 33c145d7401863228ccbad7022bc2029cc980b23	yes	17

	Multipart Description/PDF files in .zip description		
	Document Description	Start	End
	Response to Election / Restriction Filed	1	1
	Claims	2	11
	Applicant Arguments/Remarks Made in an Amendment	12	17
Warnings:			
Information:			
Total Files Size (in bytes):		202049	
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.			

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	16689073
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	Art Unit	
	Examiner Name	
	Attorney Docket Number	13079.02.USU05

U.S.PATENTS						
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	6436098		2002-08-20	Michelson	
	2	6770074		2004-08-03	Michelson	
	3	6652533		2003-11-25	O'Neil	
	4	6648917		2003-11-18	Gerbec et al.	
	5	6846327		2005-01-25	Khandkar et al.	
	6	7018416		2006-03-28	Hanson et al.	
	7	7125425		2006-10-24	Foley et al.	
	8	7229477		2007-06-12	Biscup	

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9	7648509		2010-01-19	Stark	
10	8740912		2014-06-03	Stark	
11	9668781		2017-06-06	Stark	
12	9808346		2017-11-07	Stark	
13	10149764		2018-12-11	Stark	
14	10682150		2020-06-16	Stark	
15	8021392		2011-09-20	Petersen	
16	9241798		2016-01-26	Petersen	
17	10245044		2019-04-02	Petersen	
18	8025684		2011-09-27	Garcia-Bengochea et al.	
19	8128700		2012-03-06	Delurio et al.	

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	20	8157865		2012-04-17	Hochschuler et al.	
	21	8162981		2012-04-24	Vestgaarden	
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	23	8882818		2014-11-11	Vestgaarden	
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31	8403991		2013-03-26	Ullrich, Jr. et al.	
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33	8579912		2013-11-12	Isaza et al.	
34	8945224		2015-02-03	Trieu	
35	8961571		2015-02-24	Lee et al.	
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	42	10265176		2019-04-23	Donner et al.	
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	45	10492802		2019-12-03	Donner et al.	
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53	9247943		2016-02-02	Kleiner	
54	9451986		2016-09-27	Stoffman	
55	9492284		2016-11-15	Ginn et al.	
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58	10004547		2018-06-26	Reiley	
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60	9801732		2017-10-31	Chin et al.	
61	9833321		2017-12-05	Rindal	
62	10070970		2018-09-11	Lynn et al.	
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65	10201427		2019-02-12	Mauldin	
66	10363140		2019-07-30	Mauldin et al.	
67	10206739		2019-02-19	Godara et al.	
68	10219841		2019-03-05	Compton	
69	10219912		2019-03-05	Suh et al.	
70	10245158		2019-04-02	Song	
71	10357368		2019-07-23	Aksu	
72	10555818		2020-02-11	McConnell et al.	
73	10744003		2020-08-18	Ryan et al.	
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75	10779958		2020-09-22	Lins	
76	10820917		2020-11-03	Sharifi-Mehr et al.	
77	D905232		2020-12-15	Schifano et al.	
78	10492802		2019-12-03	Donner et al.	
79	10646258		2020-05-12	Donner et al.	
80	9498349		2016-11-22	Patterson et al.	
81	10254044		2019-04-09	Schindler et al.	
82	10660763		2020-05-26	Wilson et al.	
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86	6371988		2002-04-16	Pafford et al.	
87	10682150		2020-06-16	Stark	
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	1	20010031967		2001-10-18	Nicholson et al.	
	2	20020143400		2007-06-12	Biscup	
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6	20060089633		2011-04-05	Bleich et al.	
7	20060178673		2006-08-10	Curran	
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9	20090259261		2017-05-30	Reiley	
10	20190133613		2019-05-09	Reiley et al.	
11	20080009861		2008-01-10	Stark	
12	20090024174		2009-01-22	Stark	
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17	20090099610		2009-04-16	Johnson et al.	
18	20090312763		2009-12-17	McCormack	
19	20110098817		2011-04-28	Eckhardt	
20	20110184518		2011-07-28	Trieu	
21	20110238181		2011-09-29	Trieu	
22	20110264229		2011-10-27	Donner	
23	20140031935		2014-01-30	Donner et al.	
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31	20120259365		2012-10-11	Richelsoph	
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33	20130006368		2013-01-03	Walsh et al.	
34	20130173004		2013-07-04	Greenhalgh et al.	
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39	20150012097		2015-01-08	Ibarra	
40	20150025534		2015-01-22	Gordon et al.	
41	20150073552		2015-03-12	To	
42	20150112444		2015-04-23	Aksu	
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44	20150230937		2015-08-20	Voellmicke	
45	20150250611		2015-09-10	Schifano et al.	
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49	20160175113		2016-06-23	Lins	
50	20160310197		2016-10-27	Black et al	
51	20180303624		2018-10-25	Shoshtaev	
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53	20190090888		2019-03-28	Sand et al.	
54	20190262010		2019-08-29	Cerundolo et al.	
55	20200093612		2020-03-26	Blain	
56	20200138452		2020-05-07	Gatrell et al.	
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	60	20200315811		2020-10-08	Cryder	
	61	20200390566		2020-12-17	Murray	
	62	20210015502		2021-01-21	Sharifi-Mehr	
	63	20200029979		2020-01-30	Donner et al.	
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	71	20050165420		2005-07-28	Cha	
	72	20140277460		2014-09-18	Schifano	

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Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ²	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T ⁵
	1	110123436	CN		2019-08-16	李勇 et al.		☐
	2	2727004	FR		1996-05-24	Tisserand		☐
	3	2017066443	WO		2017-04-20	Moore et al.		☐
	4	2018195406	WO		2018-10-25	Harshman et al.		☐
	5	2019137626	WO		2019-07-18	Bake et al.		☐
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	7	1290985	EP		2008-04-09	Casquero et al.		☐

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	8	2877128	EP		2018-06-27	ULLRICH et al.		☐
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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
	1	Giannikas, K. A., Khan, A. M., Karski, M. T., & Maxwell, H. A. (2004). Sacroiliac joint fusion for chronic pain: a simple technique avoiding the use of metalwork. European Spine Journal, 13(3), 253–256 accessed from "https://doi.org/10.1007/s00586-003-0620-1"	☐
	2	Captiva Spine, TransFasten Posterior Sacroiloc (SI) Joint Fusion System, accessed on November 3 from "https://transfasten.captivaspine.com/si-joint-surgeon-providers/"	☐
	3	Cohen, S. P., Chen, Y., & Neufeld, N. J. (2013), Sacroiliac joint pain: a comprehensive review of epidemiology, diagnosis and treatment, Expert Review of Neurotherapeutics, 13(1), 99–116, accessed from "https://doi.org/10.1586/ern.12.148"	☐
	4	English Abstract of CN110123436 - Retrieved from Espacenet at https://worldwide.espacenet.com/patent/search/family/067578913/publication/CN110123436A?q=pn%3DCN110123436A	☐
	5	English Abstract of FR2727004A - Retrieved from Espacenet at https://worldwide.espacenet.com/patent/search/family/009469098/publication/FR2727004A1?q=pn%3DFR2727004A1	☐

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EXAMINER SIGNATURE

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

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CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/William K. Nelson/	Date (YYYY-MM-DD)	2021-11-03
Name/Print	William K. Nelson	Registration Number	63501

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	First Named Inventor		
	Art Unit		
	Examiner Name		
	Attorney Docket Number		13079.02.USU05

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Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	6436098		2002-08-20	Michelson	
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	3	6652533		2003-11-25	O'Neil	
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	7	7125425		2006-10-24	Foley et al.	
	8	7229477		2007-06-12	Biscup	

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9	7648509		2010-01-19	Stark	
10	8740912		2014-06-03	Stark	
11	9668781		2017-06-06	Stark	
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15	8021392		2011-09-20	Petersen	
16	9241798		2016-01-26	Petersen	
17	10245044		2019-04-02	Petersen	
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19	8128700		2012-03-06	Delurio et al.	

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20	8157865		2012-04-17	Hochschuler et al.	
21	8162981		2012-04-24	Vestgaarden	
22	8623053		2014-01-07	Vestgaarden	
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29	8348950		2013-01-08	Assell et al.	
30	9101371		2015-08-11	Assell et al.	

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31	8403991		2013-03-26	Ullrich, Jr. et al.	
32	8551171		2013-10-08	Johnson et al.	
33	8579912		2013-11-12	Isaza et al.	
34	8945224		2015-02-03	Trieu	
35	8961571		2015-02-24	Lee et al.	
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37	9017407		2015-04-28	Donner	
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42	10265176		2019-04-23	Donner et al.	
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45	1049280			Donner et al./Not on google patents	
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47	9119732		2015-09-01	Schifano et al.	
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49	10426539		2019-10-01	Schifano et al.	
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54	9451986		2016-09-27	Stoffman	
55	9492284		2016-11-15	Ginn et al.	
56	9662128		2017-05-30	Reiley	
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65	10201427	2019-02-12	Mauldin
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75	10779958		2020-09-22	Lins	
76	10820917		2020-11-03	Sharifi-Mehr et al.	
77	D905232		2020-12-15	Schifano et al.	
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	1	20010031967		2001-10-18	Nicholson et al.	
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50	20160310197	2016-10-27	Black et al
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61	20200390566	2020-12-17	Murray
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71	20050165420	2005-07-28	Cha
72	20140277460	2014-09-18	Schifano

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	1	110123436	CN		2019-08-16	李勇 et al.		
	2	2727004	FR		1996-05-24	Tisserand		
	3	2017066443	WO		2017-04-20	Moore et al.		
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	6	1328216	EP		2009-09-02	White et al.		
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8	2877128	EP	2018-06-27	JLLRICH et al.
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	1	Giannikas, K. A., Khan, A. M., Karski, M. T., & Maxwell, H. A. (2004). Sacroiliac joint fusion for chronic pain: a simple technique avoiding the use of metalwork. European Spine Journal, 13(3), 253–256 accessed from "https://doi.org/10.1007/s00586-003-0620-1"	
	2	Captiva Spine, TransFasten Posterior Sacroiloc (SI) Joint Fusion System, accessed on November 3 from "https://transfasten.captivaspine.com/si-joint-surgeon-providers/"	
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See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

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Name/Print	William K. Nelson	Registration Number	63501

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5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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