

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

Application Number	16718189
Filing Date	2019-12-18
First Named Inventor	Schifano,Troy
Art Unit	
Examiner Name	
Attorney Docket Number	13709.02.USU06

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)	2020-04-09
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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Electronic Patent Application Fee Transmittal				
Application Number:		16718189		
Filing Date:		18-Dec-2019		
Title of Invention:		METHOD AND IMPLANT SYSTEM FOR SACROILIAC JOINT FIXATION AND FUSION		
First Named Inventor/Applicant Name:		Troy Schifano		
Filer:		William Kenneth Nelson		
Attorney Docket Number:		13079.02.USU06		
Filed as Small Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
SUBMISSION- INFORMATION DISCLOSURE STMT	2806	1	120	120
Total in USD (\$)				120

Electronic Acknowledgement Receipt

EFS ID:	39119431
Application Number:	16718189
International Application Number:	
Confirmation Number:	1038
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.USU06
Receipt Date:	10-APR-2020
Filing Date:	18-DEC-2019
Time Stamp:	02:37:06
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	\$ 120
RAM confirmation Number	E202040337295212
Deposit Account	
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

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)	20200409_IDS_4.pdf	612107	no	4
			901628c9069f4c06859575d50503ed0baf016757		
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30354	no	2
			269af29eaa4d299e1aece7578dd629ebb78a7129		
Warnings:					
Information:					
Total Files Size (in bytes):			642461		
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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
16/718,189	12/18/2019	Troy Schifano	13079.02.USU06

CONFIRMATION NO. 1038

13442
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P.O. Box 5637
Fresno, CA 93755-5637

PUBLICATION NOTICE



OC000000116469483

Title:METHOD AND IMPLANT SYSTEM FOR SACROILIAC JOINT FIXATION AND FUSION

Publication No.US-2020-0121375-A1

Publication Date:04/23/2020

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 16/718,189	Filing Date 12/18/2019	☐ To be Mailed
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ENTITY: ☐ LARGE ☒ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) 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), (l), 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)	RATE (\$)	ADDITIONAL FEE (\$)
AMENDMENT	04/30/2020		CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	
	Total (37 CFR 1.16(i))	* 26	Minus	** 24	= 2	x \$50 = 100
	Independent (37 CFR 1.16(h))	* 3	Minus	*** 3	= 0	x \$230 = 0
	☐ Application Size Fee (37 CFR 1.16(s))					
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					
TOTAL ADD'L FEE						100
AMENDMENT			CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	
	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".						/JAMES ELLIOTT/
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".						
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.						

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

For: METHOD AND IMPLANT SYSTEM
FOR SACROILIAC JOINT FIXATION
AND FUSION

Inventor(s): Schifano, Troy et al.

S/N: 16/718,189

Conf. No.: 1038

Filed: December 18, 2019

Examiner: MATTHEWS, TESSA M

Art Unit: 3733

Certificate of Transmission

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being transmitted to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on April 30, 2020 via the USPTO EFS-Web filing system.

Signed: /William K. Nelson/
William K. Nelson

AMENDMENT AND REQUEST FOR RECONSIDERATION

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

Dear Sir:

This paper is being submitted in response to the Office Action dated January 30, 2020 (hereinafter, the "Office Action"). Applicant respectfully requests reconsideration of the above-identified application in view of the following amendments and remarks.

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.

Listing of Claims:

1-31. (Canceled)

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

- a. creating a first incision proximal to the patient's sacroiliac joint;
- b. inserting a working channel into said first incision, said working channel having a hollow barrel with an interior guidance slot therein in the interior diameter of the hollow barrel for controlling the advancement of surgical tools passed through said working channel and having at least one tang on a distal end thereof;
- c. creating a void in said sacroiliac joint; and
- d. inserting a fusion implant into said void, wherein said fusion implant engages with bone tissue in an articular surface of at least one of the sacrum and the ilium of said sacroiliac joint.

33. (Canceled)

34. (Canceled)

35. (Previously Presented) The method of claim 32, further comprising driving said fusion implant into said void with an impactor, wherein said fusion implant includes at least one protrusion that engages with said bone tissue as said fusion implant is driven into said void.

36. (Previously Presented) The method of claim 32, wherein said fusion implant has a central body and at least one protrusion that extends from said central body.
37. (Canceled)
38. (Canceled)
39. (Canceled)
40. (Previously Presented) The method of claim 36, wherein said fusion implant contacts the patient's ilium and the patient's sacrum and fuses said joint, thereby securing said implant in said joint.
41. (Previously Presented) The method of claim 40, wherein said fusion implant is configured to substantially fix and fuse the patient's ilium to the patient's sacrum, thereby substantially immobilizing the patient's sacroiliac joint.
42. (Canceled)
43. (Previously Presented) The method of claim 36, wherein said fusion implant comprises a cavity for holding a fusion-promoting material and having at least one hole therein for allowing the growth of bone tissue into said cavity.
44. (Canceled)

45. (Canceled)

46. (Canceled)

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 plurality of implant engagement arms at a distal end of said inserter by engaging said implant engagement arms with slots on a proximal end of said fusion implant, said inserter further having a slot-engagement protrusion for engaging with said interior guidance slot; and
- b. inserting said inserter into ~~a~~the hollow barrel of said working channel with said slot-engagement protrusion aligned with said interior guidance slot within the interior diameter of said hollow barrel and advancing said inserter until said interior guidance slot arrests the penetration of said inserter and said fusion implant into said sacroiliac joint at a pre-determined depth.

48. (Canceled)

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

- a. creating a first incision 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, said surgical channel tool having at least one tang on a distal end thereof that is inserted between the articular surfaces of an ilium and a sacrum of said sacroiliac joint;

- c. creating a void in said sacroiliac joint;
 - d. inserting a fusion implant into said void through a hollow barrel of said surgical channel tool using an inserter having a plurality of implant engagement arms at its distal end engaged with slots on a proximal end of said fusion implant, said fusion implant having 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; and
 - e. driving said fusion implant into said void such that said at least one protrusion engages with said bone tissue, and said fusion implant fixes relative positions of said sacrum and said ilium.
50. (Canceled)
51. (Previously Presented) The method of claim 49, wherein said at least one protrusion comprises 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.
52. (Canceled)
53. (Canceled)
54. (Canceled)
55. (Canceled)

56. (Canceled)

57. (Canceled)

58. (Canceled)

59. (Currently Amended) The method of claim 49, wherein said fusion implant comprises a body having a cavity therein and perforations on an exterior thereof that expose said cavity to ~~an~~the exterior of said body, and a hole in a proximal end of said body for accessing ~~the~~an interior of said cavity.

60. (Previously Presented) The method of claim 49, 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)

63. (Canceled)

64. (Canceled)

65. (Canceled)

66. (Canceled)

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

- a. inserting the inserter tool into said hollow barrel of said surgical channel tool, attaching said fusion implant to an inserter tool, wherein said inserter tool has an insertion control protrusion; and
- b. inserting the inserter tool into a hollow barrel of said working channel and engaging said insertion control protrusion with an ~~insertion control mechanism~~ interior guidance slot in the interior diameter of the hollow barrel for controlling the advancement of surgical tools into said ~~working surgical channel tool~~ and preventing rotation of said surgical tools; and
- ~~b.c.~~ advancing the inserter tool until said insertion control protrusion is arrested by the interior guidance slot ~~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.

68. (Canceled)

69. (Previously Presented) 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 protrusion contacts said bone tissue.

70. (Canceled)

71. (Canceled)

72. (Canceled)

73. (Canceled)

74. (Canceled)

75. (Canceled)

76. (Canceled)

77. (Currently Amended) The method of claim 32, wherein the step of creating a ~~the~~ void in said sacroiliac joint comprises inserting a rasp having a slot-engagement protrusion into ~~a~~ the hollow barrel of said working channel with said slot-engagement protrusion ~~aligned with~~ nested in an interior guidance slot in the interior diameter of guidance slot within said hollow barrel, wherein engagement of said slot-engagement protrusion with said interior guidance slot controls the depth of advancement of said rasp through said hollow barrel and maintains said rasp in proper orientation for insertion in the void.

78. (Currently Amended) The method of claim 32, wherein said ~~working channel includes a~~ interior guidance slot is operable to engage and align for guiding for alignment and engagement with a slot-engagement protrusion of one or more surgical tools to be inserted into said hollow barrel, wherein engagement of said slot-engagement protrusion with said guidance slot controls the depth of advancement of

surgical tools through said hollow barrel and maintains said one or more surgical tools in proper orientation for insertion into said incision.

79. (Currently Amended) The method of claim 49, wherein step of creating ~~a~~the void in said sacroiliac joint comprises inserting a rasp having a slot-engagement protrusion into ~~a~~said hollow barrel of said ~~working surgical channel tool~~ with said slot-engagement protrusion aligned with an interior guidance slot in an in interior diameter of ~~insertion control mechanism within~~ said hollow barrel, wherein engagement of said slot-engagement element with said interior guidance slot ~~insertion control mechanism~~ controls the depth of advancement of said rasp through said hollow barrel and maintains said rasp in proper orientation for insertion into said void.
80. (Currently Amended) The method of claim 49, wherein said working channel includes an interior guidance slot in an in interior diameter of said working channel ~~insertion control mechanism~~ for alignment and engagement with a slot-engagement protrusion of one or more surgical tools to be inserted into said hollow barrel, wherein engagement of said slot-engagement protrusion with said interior guidance slot controls the depth of advancement of surgical tools through said hollow barrel and ~~insertion control mechanism~~ maintains said one or more surgical tools in proper orientation for insertion into said incision.
81. (Currently Amended) A method for repairing a sacroiliac joint of a patient, comprising:
- a. creating an incision 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 having a plurality of tangs

on a distal end thereof that is inserted between the articular surfaces of an ilium and a sacrum of said sacroiliac joint, said working channel including a hollow barrel having an interior guidance slot in an interior diameter of said hollow barrel ~~insertion control mechanism~~ for controlling the depth of advancement of surgical tools into said working channel and maintaining said surgical tools in proper orientation for insertion into said incision;

- c. ~~using an inserter tool to inserting~~ a fusion implant through said hollow barrel into said sacroiliac joint using an inserter having a plurality of implant engagement arms at its distal end engaged with slots on a proximal end of said fusion implant, wherein said fusion implant is inserted on a path that is substantially parallel to articular surfaces of the sacroiliac joint, said inserter tool having an insertion control protrusion for engagement with said ~~insertion control mechanism~~ interior guidance slot;
- d. advancing the inserter tool until said insertion control protrusion ~~to is arrested~~ by said interior guidance slot at a pre-determined point in the hollow barrel and placing said fusion implant into said sacroiliac joint, wherein said inserter tool is prevented from moving the fusion implant beyond ~~said a~~ pre-determined point in said sacroiliac joint; and
- e. driving said fusion implant into said sacroiliac joint such that said fusion implant engages with said bone tissue.

82. (Previously Presented) The method of claim 81, 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.

83. (Previously Presented) The method of claim 82, wherein said engagement of said fusion implant with said bone tissue fixes the relative position of said sacrum and the ilium of said sacroiliac joint.

84. (Previously Presented) The method of claim 82, 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.
85. (Previously Presented) The method of claim 81, wherein no further fusion implants are introduced into said sacroiliac joint and said fusion implant is sufficient to fuse the sacroiliac joint.
86. (Currently Amended) The method of Claim 81, further comprising creating a void in the sacroiliac joint having a complementary shape to said fusion implant, wherein said fusion implant is inserted into said void.
87. (Currently Amended) The method of Claim 81, wherein engagement of said insertion control protrusion with said interior guidance slot ~~insertion control mechanism~~ maintains said inserter tool and said fusion implant in proper orientation for insertion of the fusion implant into said sacroiliac joint.
88. (New) The method of claim 32, wherein said working channel has a plurality of tangs on a distal end thereof that are inserted between the articular surfaces of an ilium and a sacrum of said sacroiliac joint.
89. (New) The method of claim 49, wherein said surgical channel tool has a plurality of tangs on a distal end thereof that are inserted between the articular surfaces of an ilium and a sacrum of said sacroiliac joint.

REMARKS

Applicant thanks Examiner Matthews for the thorough examination of the present application, and the detailed explanations in the Office Action. The amendments and remarks herein address and overcome all of the rejections of the claims, and the present claims are considered allowable over the cited references.

Claims 32, 47, 49, 59, 67, 77-81, and 86-87 have been amended. New Claims 88-99 have been added. Claims 32, 35-36, 40-41, 43, 47, 49, 51, 59-60, 67, 69, and 77-89 are pending in the present application. No new matter is added by the amendments to claims.

Election of Species

Applicant elects Species A, Figures 49-51, and Species I, Figures 27-32B, without traverse. Claims 32, 36, 40-41, 43, 47, 49, 51, 59-60, 67, 69, and 77-89 correspond to the elected species.

Claim Objections

The objections to Claims 47, 59, 77-79, and 86 have been addressed by appropriate amendment.

The Interpretation of Claims 67 and 79-81 under 35 U.S.C. 112(f)

The Office Action asserts that the term “an insertion control mechanism” in Claims 67 and 79-81 must be interpreted under 35 U.S.C. 112(f). This rejection has been obviated by appropriate amendment. Applicant has amended the rejected claims to recite an internal

guidance slot, which provides sufficient structural description to inform one of ordinary skill in the art of the structure and function of the “internal guidance slot”. Furthermore, the “internal guidance slot” does not include the term “means”, and thus there is a presumption that the claim limitation is not to be interpreted under 35 U.S.C. 112(f). As a result, the application of 35 U.S.C. 112(f) to Claims 67 and 79-81 should be withdrawn.

The Rejections of Claim 78 and 81-84 under 35 U.S.C. 112(b) – Indefiniteness

The rejection of Claims 78 and 81-84 under 35 U.S.C. 112 as being indefinite has been obviated by appropriate amendment.

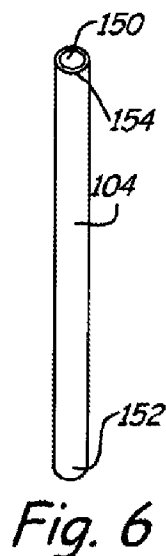
The Rejections of Claims 49, 51, 60 and 69 under 35 U.S.C. 102(a)(1)

Claims 49, 51, 60 and 69 have been rejected under 35 U.S.C. 102(a)(1) as being anticipated by Stark (US 2010/0131011). This rejection is respectfully traversed.

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). See also MPEP § 2131. “The identical invention must be shown in as complete detail as is contained in the ... claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). See also MPEP § 2131. “[U]nless a reference discloses within the four corners of the document not only all of the limitations claimed but also all of the limitations arranged or combined in the same way as recited in the claim, it

cannot be said to prove prior invention of the thing claimed and, thus, cannot anticipate under 35 U.S.C. § 102.” *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1371 (Fed. Cir. 2008).

Stark discloses tools and procedures for immobilizing the sacroiliac (SI) joint to reduce pain (see the Abstract). The disclosed kits and procedures utilize an immobilization element that may be one of a number of tapering structures that can be inserted between the sacrum and ilium in the SI joint, such as “pins, nails, screws, darts, wedges, shims, [and] cages/connector elements” (see, e.g., the Abstract and paragraph [0054] of Stark). Stark discloses a very basic, pipe-shaped cannula 124 for passing instruments and implants, without illustration or description of any specialized features of the cannula (see below FIG. 6 of Stark, showing cannula 104). It is described essential as a metal tube.



Stark makes no disclosure or suggest of a method utilizing a cannula or other channel having at least one tang on a distal end thereof, as recited in Claim 49. As a result, Stark fails to anticipate Claim 49 for at least this reason.

Additionally, FIGS. 3 and 12-18B of Stark show examples of implants for immobilizing the SI joint, which feature centrally located driver receivers for standard driver heads, such as a Phillips head receiver, a hexagonal Allen-style receiver, or a simple flat nail head driven by a hammer. Stark provides very little written discussion of the receivers in the head of the implant (see paragraph [0056]). Stark does not disclose or suggest using a fusion implant inserter having a plurality of implant engagement arms at its distal end that engage with slots on a proximal end of a fusion implant, as recited in Claim 49. Stark only discloses flat headed pins, nails, shims and the like, and rotatable implant that utilize Phillips head or Allen-type receives. As a result, Stark fails to anticipate Claim 49 for at least this additional reason.

In view of the deficiencies discussed above, Stark fails to disclose or suggest a method for repairing a sacroiliac joint, comprising inserting a surgical channel tool into an incision from the posterior of the patient having (1) at least one tang on a distal end thereof that is inserted between the articular surfaces of an ilium and a sacrum of the sacroiliac joint, or (2) using a fusion implant inserter having a plurality of implant engagement arms at its distal end that engage with slots on a proximal end of a fusion implant. Therefore, the rejection of Claim 49 and its dependent Claims 51, 60 and 69 under 35 U.S.C. § 102(b) should be withdrawn.

***The Rejection of Claims 32, 36, 40, 41, 43, 47, 67 and 77 - 87
under 35 U.S.C. 103***

Claims 32, 36, 40, 41, 43, 47, 67 and 77 - 87 have been rejected under 35 U.S.C. § 103 as being obvious in view of Stark and Walsh et al. (US 2013/0006368, “Walsh”). This rejection is respectfully traversed.

As explained above, Stark fails to disclose or suggest a method for repairing a sacroiliac joint, comprising inserting a surgical channel tool into an incision from the posterior of the patient having (1) at least one tang on a distal end thereof that is inserted between the articular surfaces of an ilium and a sacrum of the sacroiliac joint, or (2) using a fusion implant inserter having a plurality of implant engagement arms at its distal end that engage with slots on a proximal end of a fusion implant, as recited in Claim 49 of the present Application. Claims 32 and 81 have similar limitations.

The Office Action acknowledges that Stark is silent with regard to a hollow barrel having a guidance slot for controlling the advancement of surgical tools (see the first paragraph on page 14 of the Office Action). The Office Action cites Walsh to allegedly cure this deficiency (see the second paragraph on page 14 of the Office Action). It is submitted that Walsh fails to cure the deficiencies of Stark explained above, and therefore Claims 32, 49, and 81, the claims dependent therefrom, are patentable over Stark in view of Walsh for at least the reasons provided above. Thus, the arguments provided above are sufficient to overcome this rejection.

Additionally, Walsh fails to disclose an interior guidance slot in an interior diameter of a hollow barrel, as recited in Claims 32 and 81. Walsh discloses a method of inserting a compressible hydrogel implant to replace cartilage in a joint (see, e.g., paragraphs [0007]-

[0010]). Walsh discloses the use of a levered device that pushes a plunger (e.g., 820) to squeeze the hydrogel implant through a narrowing passage in a specially made tapering introducer tube (see, e.g., reference numbers 610 and 810 in FIGS. 15A-15C and 17B). The delivery tool 800 includes a lever-like clamp 840 that is swung down by the user on a pivot joint to applied pressure to the plunger 820, which in turn squeezes the hydrogel implant through the tapering introducer tube 810 to deposit the hydrogel implant in a void (see, e.g., paragraphs [0080], [0087], and [0120]). The introducer tube 810 may include a depth stop feature. However, this is a slot running through the entire sidewall of the introducer tube on two diametric sides of the introducer tube 810 in order to allow the clamp 840 to advance through the introducer tube 810 and move the plunger to the distal end of the introducer tube 810 (see, e.g., FIGS. 16A and 16D). Thus, Walsh fails to disclose or suggest an interior guidance slot *in an interior diameter of a hollow barrel*, as recited in Claims 32 and 81. The slot in the introducer tube 810 does not and cannot be limited to the interior of the introducer tube 810.

Furthermore, the system and method of Walsh are quite distinct from those of Stark. The system of Walsh does not provide a cannula system for moving multiple surgical tools (e.g., a rasp, a drill, etc.) into an interarticular space. Rather, Walsh discloses a highly specialized insertion tool for squeezing a compressible hydrogel implant into a void having a small opening and an outwardly angled, expanding volume within the joint. The implant of Walsh has to be compressible in order to both access and fill the void. The delivery tool 800 is specialized to this purpose, having a narrowing delivery tube, vacuum suction applied to the distal end of the introducer tube 810 in order facilitate advancement of the implant (see, e.g., paragraph [0120]), and “lubricious” layers within the introducer tube 810 to maintain moisture in the implant and reduce friction therein (see, e.g., paragraph [0124]). It would not be

obvious to one of ordinary skill in the art to alter the method disclosed by Stark to include any of the features of Walsh because the device and method of Walsh are directed toward a very distinct purpose and technique from that of Stark. The lever-like clamp 840 for driving the deposition of the hydrogel implant, which requires slots running through the entire thickness of the introducer tube 810 wall, would not be practicable to use for a screw implant or an implant to be hammered into place. Also, the narrowing cannula would not be practical for use with the tool set disclosed by Stark. The delivery tool 800 of Walsh and its components are clearly directed toward depositing a compressible material that must be squeezed into a void, and are not obviously adaptable to a system for implanting a screw or similar implant. Therefore, the assertion in the Office Action that it would be obvious to one of ordinary skill in the art to modify Stark in view of Walsh is improper, and the rejection under 35 U.S.C. § 103(a) should be withdrawn for this additional reason.

The Rejection of Claim 59 under 35 U.S.C. 103

Claim 59 had been rejected under 35 U.S.C. § 103(a) as being obvious in view of Stark and Sweeney (US 7,575,572). This rejection is respectfully traversed.

As explained above, Stark fails to disclose or suggest a method for repairing a sacroiliac joint, comprising inserting a surgical channel tool into an incision from the posterior of the patient having (1) at least one tang on a distal end thereof that is inserted between the articular surfaces of an ilium and a sacrum of the sacroiliac joint, or (2) using a fusion implant inserter having a plurality of implant engagement arms at its distal end that engage with slots on a proximal end of a fusion implant, as recited in Claim 49 of the present Application.

The Office Action cites Sweeney as disclosing an implant having perforations that may be used the delivery of a substance. (see the first paragraph on page 24 of the Office Action). It is submitted that Walsh fails to cure the deficiencies of Stark explained above, and therefore Claim 49, and the claims dependent therefrom, are patentable over Stark in view of Sweeney for at least the reasons provided above. Thus, the arguments provided above are sufficient to overcome this rejection, and no additional arguments or amendments are submitted at this time. However, the applicant reserves the right to do so in response to any future rejection(s).

Conclusion

In view of the above remarks, all rejections in the Office Action have been addressed. Fees for two additional claims in excess of twenty are submitted herewith. The office is authorized to charge any additional fees required by this paper, or credit any overpayments, to deposit account 600741.

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.

Dated: April 30, 2020.

Respectfully Submitted,

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Electronic Patent Application Fee Transmittal				
Application Number:		16718189		
Filing Date:		18-Dec-2019		
Title of Invention:		METHOD AND IMPLANT SYSTEM FOR SACROILIAC JOINT FIXATION AND FUSION		
First Named Inventor/Applicant Name:		Troy Schifano		
Filer:		William Kenneth Nelson		
Attorney Docket Number:		13079.02.USU06		
Filed as Small Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
CLAIMS IN EXCESS OF 20	2202	2	50	100
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				100

Electronic Acknowledgement Receipt

EFS ID:	39322687
Application Number:	16718189
International Application Number:	
Confirmation Number:	1038
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.USU06
Receipt Date:	30-APR-2020
Filing Date:	18-DEC-2019
Time Stamp:	23:36:20
Application Type:	Utility under 35 USC 111(a)

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Submitted with Payment	yes
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Payment was successfully received in RAM	\$ 100
RAM confirmation Number	E20204TN36457290
Deposit Account	
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File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		20200430_amendment_response.pdf	343788	yes	20
			8b5e8aecaef5f2515cf5db5a2d4a2a3430d38212		
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Amendment/Req. Reconsideration-After Non-Final Reject		1	1	
	Claims		2	11	
	Applicant Arguments/Remarks Made in an Amendment		12	20	
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30240	no	2
			719fc7d0c0af4f5419a7991ca1462a2fdd3045af		
Warnings:					
Information:					
Total Files Size (in bytes):			374028		

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New Applications Under 35 U.S.C. 111

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.

National Stage of an International Application under 35 U.S.C. 371

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.

New International Application Filed with the USPTO as a Receiving Office

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.
16/718,189	12/18/2019	Troy Schifano	13079.02.USU06	1038
13442	7590	07/17/2020		
Sierra IP Law, PC P.O. Box 5637 Fresno, CA 93755-5637			EXAMINER MATTHEWS, TESSA M	
			ART UNIT	PAPER NUMBER
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			07/17/2020	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.

Priority

2. This application discloses and claims only subject matter disclosed in prior application no 14/668,976, filed 3/25/2015 and application 14/668,982 filed 3/26/2015, and names the inventor or at least one joint inventor named in the prior application. Accordingly, this application may constitute a continuation or division. Should applicant desire to claim the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120, 37 CFR 1.78, and MPEP § 211 *et seq.*

The current effective filing date for the claims is 12/18/2019.

Election/Restrictions

3. It is noted that claim 35 is withdrawn because it is directed to a non-elected species as confirmed by the applicant in the Remarks of 04/30/2020. Please see the Non-Final Rejection of 01/30/2020 under the Election/Restrictions. Also note that it is claim 35, not 34 under discussion.

Claim Objections

4. Claims 32, 35, 77 and 79 are objected to because of the following informalities:
Claim 32, line 5, "in the interior" should read "in an interior".

Claim 35, “(Previously Presented)” should be changed to “Withdrawn” because the claims is directed toward a non-elected embodiment.

Claim 77, line 4, “in an interior” should read “in the interior”

Claim 79, line 4, “in an in interior” should read “in an interior”

Claim 79, line 6, “slot-engagement element” should read “slot-engagement protrusion”

Appropriate correction is required.

Examiner’s Note

5. Claims 88 and 89 each recite a plurality of tangs on the distal end of the working channel/surgical channel tool. The plurality of tangs are taken to be part of the at least one tang as disclosed in claims 32 and 49.

Claim Rejections - 35 USC § 103

6. In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

7. The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject

matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims **32, 36, 40, 41, 43, 77, 78 and 88** is/are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Stark (US 2008/0009861 A1) in view of Walsh et al. (US 2013/0006368 A1) and in view of Michelson (US 6,436,098 B1).

Regarding claim 32, Stark discloses a method for repairing a sacroiliac joint of a patient (Abstract), comprising:

- a. creating a first incision proximal to the patient's sacroiliac joint (paragraphs [0035, 66]);
- b. inserting a working channel into said first incision, said working channel having a hollow barrel for controlling the advancement of surgical tools passed through said working channel (paragraphs [0034, 36, 41, 47 - 48] discloses a cannulated device to facilitate and guide the procedure, thus controlling the advancement of surgical tools such as drills, taps, etc.);
- c. creating a void in said sacroiliac joint (paragraph [0048] discloses that the cannula provides a passageway and paragraphs [0050, 67] discloses the step of preparing the joint/surgical site, thus creating a void); and
- d. inserting a fusion implant into said void (paragraph [0068] discloses inserting an immobilization element/fusion implant into the joint space/void), wherein said fusion implant engages with bone tissue in an articular surface of at least one of the sacrum and the ilium of said sacroiliac joint (Fig. 3).

Stark discloses a cannula with a hollow barrel to be used to form a working channel into said first incision, but is silent regarding the limitation that the hollow barrel has an interior guidance slot in the interior diameter of the hollow barrel for controlling the advancement of surgical tools and having at least one tang on a distal end thereof.

Walsh teaches a method in the related field of joint repair (Abstract). Walsh teaches a tube (Fig. 17A, ref. 810) with an interior guidance slot in the interior diameter of the hollow barrel (ref. 818 is considered an interior slot because it extends through the interior or inner wall of the barrel) for controlling the advancement of surgical tool (ref. 828, Fig. 16E). The surgical tool has a motion limiter or depth stop (ref. 828) which is configured to slide within the slot of the tube (paragraph [0130]). The engagement of the slot and stop can help prevent or otherwise limit distal movement of the surgical tool within the tube and can help limit rotation during use (paragraph [0130]). Walsh teaches that the engagement can advantageously help limit the depth to which an implant can be delivered relative to an implant site of a patient and thus improve the safety and efficacy of the implant, related tools and implant procedure (paragraph [0130]). It would have been obvious to one having ordinary skill in the art before the effective filing date of the claimed invention to modify the cannula and other related surgical tools configured to be placed within the cannula (screwdriver, rasp, drill, tap, mallet, etc.) of Stark with the interior guidance slot and stop as taught by Walsh for the purpose of limiting the depth of the fusion implant into the void in the SI joint to improve the safety and efficacy of the implant and method.

Michelson teaches methods and tools for spinal surgeries (Abstract). Michelson teaches the use of a working channel having a hollow barrel (ref. 140), wherein the hollow barrel has at least one tang on a distal end thereof (Michelson teaches a plurality of embodiments for the distal end, comprising a sharp toothed end with a plurality of tangs ref. 142, Fig. 5 or a plurality of sharp prongs ref. 342, Figs. 7A-8). Michelson teaches that both embodiments affix the hollow barrel to the vertebra of interest while also being limited in depth so as not to damage the vertebrae (Cols. 19 & 28). It would have been obvious to one having ordinary skill in the art before the effective filing date of the claimed invention to modify the cannula of Stark to include the at least one tang on the distal end, as taught by Michelson, for the purpose of anchoring the hollow barrel to the surgical site to prevent unwanted movement while also preventing damage to the tissue.

Regarding claim 36, Stark in view of Walsh and in view of Michelson discloses the method of claim 32, wherein said fusion implant has a central body and at least one protrusion that extends from said central body (Stark discloses a screw, wherein the threads are the at least one protrusion and extend from a core/body of the screw).

Regarding claim 40, Stark in view of Walsh and in view of Michelson discloses the method of claim 36, wherein said fusion implant contacts the patient's ilium and the patient's sacrum and fuses said joint, thereby securing said implant in said joint (Stark discloses immobilization of the joint, thus fusing).

Regarding claim 41, Stark in view of Walsh and in view of Michelson discloses the method of claim 40, wherein said fusion implant is configured to substantially fix and fuse the patient's ilium to the patient's sacrum, thereby substantially immobilizing the patient's sacroiliac joint (via the implant, the sacrum and ilium are fixed to one another and immobilized).

Regarding claim 43, Stark in view of Walsh and in view of Michelson discloses the method claim 36, wherein said fusion implant comprises a cavity for holding a fusion-promoting material and having at least one hole therein for allowing the growth of bone tissue into said cavity (Stark, paragraphs [0038, 57] discloses that the implant may be hollow, thus having a cavity fully capable of holding a fusion-promoting material and wherein the open ends of the implant are hole fully capable of allowing the growth of bone tissue into the cavity).

Regarding claim 77, Stark in view of Walsh and in view of Michelson discloses the method of claim 32, wherein the step of creating the void in said sacroiliac joint comprises inserting a rasp having a slot-engagement protrusion into the hollow barrel of said working channel with said slot-engagement protrusion nested in an interior guidance slot in the interior diameter of said hollow barrel, wherein engagement of said slot-engagement protrusion with said interior guidance slot controls the depth of advancement of said rasp through said hollow barrel and maintains said rasp in proper orientation for insertion in the void (Stark teaches the use of a rasp to create the void in the SI joint in paragraph [0050] and Stark as modified by Walsh results in the raps or

cutters and mallets to be equipped with a slot-engagemepent protrusion to be aligned with the guidance slot within the hollow barrel to maintain the rasp in proper orientation, including depth control).

Regarding claim 78, Stark in view of Walsh and in view of Michelson discloses the method of claim 32, wherein sad interior guidance slot is operable to engage and align a slot-engagement protrusion of one or more surgical tools to be inserted into said hollow barrel, wherein engagement of said slot-engagement protrusion with said guidance slot controls the depth of advancement of surgical tools through said hollow barrel and maintains said one or more surgical tools in proper orientation for insertion into said incision (Stark as modified by Walsh results in the working channel including a guidance slot for alignment and engagement with a protrusion of the one or more surgical tools, wherein the engagement of the slot and protrusion maintains the tools in proper orientation for insertion and controls the depth since the slot does not extend along the entire length of the hollow barrel. Please see the rejection of claim 32 above).

Regarding claim 88, Stark in view of Walsh and in view of Michelson discloses the method of claim 32, wherein said working channel has a plurality of tangs on a distal end thereof that are inserted between the articular surfaces of an ilium and a sacrum of the said sacroiliac joint (Stark teaches the approach and method to the SI joint in which the distal end of the working channel engages the ilium and sacrum and Michelson teaches the plurality of tangs on the distal end, as detailed above in claim 32).

9. Claims **49, 51, 60, 69** and **89** is/are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Stark (US 2008/0009861 A1) in view of view of Michelson (US 6,436,098 B1) and in view of Bagby (US 2004/0193174 A1).

Regarding claim 49, Stark discloses a method for repairing a sacroiliac joint of a patient (Abstract), comprising:

a. creating a first incision proximal to the patient's sacroiliac joint (paragraphs [0035, 66]);

b. inserting a surgical channel tool into said incision from the posterior of the patient (paragraphs [0034, 36, 41, 47 - 48] discloses a cannulated device to facilitate and guide the procedure, and Figure 3 shows a posterior oriented implant. Furthermore paragraph [0036] incorporates by reference U.S. Pat. No. 5,741,261 which discloses posterior approaches in Figures 1 - 4);

c. creating a void in said sacroiliac joint (paragraph [0048] discloses that the cannula provides a passageway and paragraphs [0050, 67] discloses the step of preparing the joint/surgical site, thus creating a void);

d. inserting a fusion implant into said void through a hollow barrel of said surgical channel tool (paragraph [0068] discloses inserting an immobilization element/fusion implant into the joint space/void) using an inserter (paragraph [0059]), said fusion implant having 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 (paragraph [0038] discloses that the implant may be a screw, either hollow or solid. The threads of

the screw are considered to be the protrusion and Fig. 3 shows the screw/implant placed posterior such that the threads engage with the bone tissue of both the sacrum and ilium); and

e. driving said fusion implant into said void such that said at least one protrusion engages with said bone tissue (paragraphs [0038, 68]), and said fusion implant fixes relative positions of said sacrum and said ilium (paragraph [0007] discloses immobilization of the SI joint, thus fixing the relative positions of the sacrum and ilium via the implant/screw).

Stark is silent regarding the limitations that said surgical channel tool having at least one tang on a distal end thereof that is inserted between the articular surfaces of an ilium and a sacrum of said sacroiliac joint and that said inserter has a plurality of implant engagement arms at its distal end engaged with slots on a proximal end of said fusion implant

Michelson teaches methods and tools for spinal surgeries (Abstract). Michelson teaches the use of a working channel having a hollow barrel (ref. 140), wherein the hollow barrel has at least one tang on a distal end thereof (Michelson teaches a plurality of embodiments for the distal end, comprising a sharp toothed end with a plurality of tangs ref. 142, Fig. 5 or a plurality of sharp prongs ref. 342, Figs. 7A-8). Michelson teaches that both embodiments affix the hollow barrel to the vertebra of interest while also being limited in depth so as not to damage the vertebrae (Cols. 19 & 28). It would have been obvious to one having ordinary skill in the art before the effective filing

date of the claimed invention to modify the cannula/surgical channel tool of Stark to include the at least one tang on the distal end, as taught by Michelson, for the purpose of anchoring the hollow barrel to the surgical site to prevent unwanted movement while also preventing damage to the tissue.

Bagby teaches methods in the related field of spinal implants (Abstract) comprising an inserter (paragraph [0029], ref. 12, Fig. 1) configured to engage with an implant (paragraph [0029], ref. 14, Fig. 1). The inserter has a plurality of engagement arms at a distal end (paragraph [0030], ref. 32, Fig. 1) configured to engage with slots on the implant (paragraph [0031], ref. 36, Fig. 1). Bagby teaches that the plurality and shape of the arms and slots help to stabilize the implant onto the inserter and prevent rocking or unwanted slippage (paragraph [0035]). It would have been obvious to one having ordinary skill in the art before the effective filing date of the claimed invention to modify the inserter and implant of Stark, to include the plurality of arms at the distal end of the inserter and slots at the proximal end of the implant, for the purpose of stabilizing the implant during insertion.

Regarding claim 51, Stark in view of Michelson and Bagby discloses the method of claim 49, wherein said at least one protrusion comprises 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 (Stark, Fig. 14 shows a screw with a helical thread which is taken to be the helical anchor and having a sharp end refs. 268 fully capable of piercing bone tissue).

Regarding claim 60, Stark in view of Michelson and Bagby discloses the method of claim 49, wherein said fusion implant is operable to connect said sacrum to said ilium in fixed relative positions in the sacroiliac joint (Stark, Fig. 3 and paragraph [0002]).

Regarding claim 69, Stark in view of Michelson and Bagby discloses 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 protrusion contacts said bone tissue (Stark, Fig. 3 shows the implant contacting the bone tissue of the joint).

Regarding claim 89, Stark in view of Michelson and Bagby discloses the method of claim 49, wherein said surgical channel tool has a plurality of tangs on a distal end thereof that are inserted between the articular surfaces of an ilium and a sacrum of said sacroiliac joint (Stark teaches the approach and method to the SI joint in which the distal end of the working channel engages the ilium and sacrum and Michelson teaches the plurality of tangs on the distal end, as detailed above in claim 32).

10. Claims **47, 67, 79** and **80 - 87** is/are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Stark (US 2008/0009861 A1) in view of Michelson (US 6,436,098 B1) and in view of Bagby (US 2004/0193174 A1) and further in view of Walsh et al. (US 2013/0006368 A1)

Regarding claim 47, Stark in view of Walsh and in view of Michelson discloses 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 (Stark as modified by Walsh results in an inserter, such as the driver as disclosed in paragraph [0059] of Stark, with a slot-engagement protrusion which is taught by Walsh), and

b. inserting said inserter into the hollow barrel of said working channel with said slot-engagement protrusion aligned with said interior guidance slot within the interior diameter of said hollow barrel and advancing said inserter until said interior guidance slot arrests the penetration of said inserter and said fusion implant into said sacroiliac joint to a pre-determined depth (Stark teaches the steps of using the inserter in the hollow barrel of the working channel/cannula and Stark as modified by Walsh results in the protrusion aligned with the interior guidance slot to limit or arrest the penetration of the inserter and implant into the SI joint).

However Stark in view of Walsh and Michelson does not disclose that the inserter has a plurality of implant engagement arms at a distal end of said inserter and the step of attaching comprises engaging said implant engagement arms with slots on a proximal end of said fusion implant.

Bagby teaches methods in the related field of spinal implants (Abstract) comprising an inserter (paragraph [0029], ref. 12, Fig. 1) configured to engage with an implant (paragraph [0029], ref. 14, Fig. 1). The inserter has a plurality of engagement arms at a distal end (paragraph [0030], ref. 32, Fig. 1) configured to engage with slots

on the implant (paragraph [0031], ref. 36, Fig. 1). Bagby teaches that the plurality and shape of the arms and slots help to stabilize the implant onto the inserter and prevent rocking or unwanted slippage (paragraph [0035]). It would have been obvious to one having ordinary skill in the art before the effective filing date of the claimed invention to modify the inserter and implant of Stark, to include the plurality of arms at the distal end of the inserter and slots at the proximal end of the implant, for the purpose of stabilizing the implant during insertion.

Regarding claim 67, Stark in view of Michelson and Bagby discloses the method of claim 49, wherein the inserting the fusion implant comprises:

a. inserting the inserter tool into said hollow barrel of said surgical channel tool (Stark, paragraph [0059]),

Stark is silent regarding the limitation that the inserter tool has an insertion control protrusion and engaging said insertion control protrusion with an interior guidance slot in the interior diameter of the hollow barrel for controlling the advancement of surgical tools into said surgical channel tool and preventing rotation of said surgical tools and advancing the inserter tool until said insertion control protrusion is arrested by the interior guidance slot 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.

Walsh teaches a method in the related field of joint repair (Abstract). Walsh teaches a tube (Fig. 17A, ref. 810) with interior guidance slot in the interior diameter of the tube/hollow barrel (ref. 818 is shown extending through the inner surface of the tube and thus the interior diameter) for controlling the advancement of an inserter tool (ref. 820). Said inserter tool having an insertion control protrusion (ref. 828) for engagement with said slot (Fig. 16D, paragraph [0130]). The engagement of the insertion control mechanism and protrusion can help prevent or otherwise limit distal movement of the inserter tool within the tube and can help limit rotation during use (paragraph [0130]). Walsh teaches that the engagement can advantageously help limit the depth to which an implant can be delivered relative to an implant site of a patient and thus improve the safety and efficacy of the implant, related tools and implant procedure (paragraph [0130]). It would have been obvious to one having ordinary skill in the art before the effective filing date of the claimed invention to modify the cannula/working channel and inserter tool of Stark with the insertion control protrusion and interior guidance slot as taught by Walsh for the purpose of limiting the depth of the fusion implant into the void in the SI joint to improve the safety and efficacy of the implant and method. Please note that Stark as modified by Walsh results in the step of 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, wherein said inserter tool is prevented from moving the fusion implant beyond said pre-determined point into said sacroiliac joint.

Regarding claim 79, Stark in view of Michelson and in view of Bagby discloses the method of claim 49, except wherein step of creating the void in said sacroiliac joint comprises inserting a rasp having a slot-engagement protrusion into the hollow barrel of said surgical channel tool with said slot-engagement protrusion aligned with an interior guidance slot in an interior diameter of said hollow barrel, wherein engagement of said slot-engagement element with said interior guidance slot controls the depth of advancement of said rasp through said hollow barrel and maintains said rasp in proper orientation for insertion into said void. However Stark does disclose the use of a rasp or other cutting tools to prepare the joint space (paragraphs [0041, 50]).

Regarding claim 80, Stark in view of Michelson and in view of Bagby discloses the method of claim 49, except wherein said working channel includes an interior guidance slot in an interior of said working channel for alignment and engagement with a slot- engagement protrusion of one or more surgical tools to be inserted into said hollow barrel, wherein engagement of said slot-engagement protrusion with said interior guidance slot controls the depth of advancement of said rasp through said hollow barrel and maintains said one or more surgical tools in proper orientation for insertion into said incision.

Walsh teaches a method in the related field of joint repair (Abstract). Walsh teaches a tube (Fig. 17A, ref. 810) with an interior guidance slot in an interior of a working channel (ref. 818, the slot is shown extending through the interior of the working channel, thus is considered an interior guidance slot) for controlling the advancement of

surgical tool (ref. 828, Fig. 16E). The surgical tool has a motion limiter or depth stop/protrusion (ref. 828) which is configured to slide within the slot of the tube (paragraph [0130]). The engagement of the slot and stop can help prevent or otherwise limit distal movement of the surgical tool within the tube and can help limit rotation during use (paragraph [0130]). Walsh teaches that the engagement can advantageously help limit the depth to which an implant can be delivered relative to an implant site of a patient and thus improve the safety and efficacy of the implant, related tools and implant procedure (paragraph [0130]). Regarding claims 79 and 80, it would have been obvious to one having ordinary skill in the art before the effective filing date of the claimed invention to modify the cannula and other related surgical tools configured to be placed within the cannula (screwdriver, rasp, drill, tap, mallet, etc.) of Stark with the slot and protrusion as taught by Walsh for the purpose of limiting the depth of the fusion implant into the void in the SI joint to improve the safety and efficacy of the implant and method.

Regarding claim 81, Stark discloses a method for repairing a sacroiliac joint of a patient (Abstract), comprising:

- a. creating an incision proximal to the patient's sacroiliac joint to allow access to the posterior portion of the sacroiliac joint (paragraphs [0035, 66]);
 - b. inserting a working channel of a surgical channel tool into said incision from the posterior of the patient wherein the tool is inserted between the articular surfaces of an ilium and a sacrum of said sacroiliac joint (paragraphs [0034, 36, 41, 47 - 48])
- discloses a cannulated device to facilitate and guide the procedure, and Figure 3 shows a posterior oriented implant such that the tool would be inserted between the articular

surfaces of the ilium and sacrum. Furthermore paragraph [0036] incorporates by reference U.S. Pat. No. 5,741,261 which discloses posterior approaches in Figures 1 - 4);

c. inserting a fusion implant through said hollow barrel into said sacroiliac joint using an inserter, wherein said fusion implant is inserted on a path that is substantially parallel to articular surfaces of the sacroiliac joint (paragraph [0049] discloses various insertion tools which may be used, e.g. driver, mallet, tap, hammer, etc.),

d. advancing the inserter tool through the hollow barrel and placing said fusion implant into said sacroiliac joint (paragraphs [0038, 68]),

e. driving said fusion implant into said sacroiliac joint such that said fusion implant engages with said bone tissue (paragraphs [0038, 68]).

Stark discloses a cannula with a hollow barrel to be used to form a working channel into said first incision and an inserter tool, but is silent regarding the limitations

1) said working channel having a plurality of tangs on a distal end thereof;

2) wherein the hollow barrel has an interior guidance slot in an interior diameter of said hollow barrel for controlling the depth of advancement of surgical tools into said working channel and maintaining said surgical tools in proper orientation for insertion into said incision; said inserter having an insertion control protrusion for engagement with said interior guidance slot and advancing the inserter tool until said insertion control protrusion is arrested by said interior guidance slot in the hollow barrel and wherein said inserter tool is prevented from moving the fusion implant beyond said pre-determined point into said sacroiliac joint

3) said inserter having a plurality of implant engagement arms at its distal end engaged with slots on a proximal end of said fusion implant;

Regarding point 1) above, Michelson teaches methods and tools for spinal surgeries (Abstract). Michelson teaches the use of a working channel having a hollow barrel (ref. 140), wherein the hollow barrel has at least one tang on a distal end thereof (Michelson teaches a plurality of embodiments for the distal end, comprising a sharp toothed end with a plurality of tangs ref. 142, Fig. 5 or a plurality of sharp prongs ref. 342, Figs. 7A-8). Michelson teaches that both embodiments affix the hollow barrel to the vertebra of interest while also being limited in depth so as not to damage the vertebrae (Cols. 19 & 28).]. It would have been obvious to one having ordinary skill in the art before the effective filing date of the claimed invention to modify the working channel of Stark to include the at least one tang on the distal end, as taught by Michelson, for the purpose of anchoring the hollow barrel to the surgical site to prevent unwanted movement while also preventing damage to the tissue.

Regarding point 2) above Walsh teaches a method in the related field of joint repair (Abstract). Walsh teaches a tube (Fig. 17A, ref. 810) with an insertion control mechanism (ref. 818) for controlling the advancement of an inserter tool (ref. 820). Said inserter tool having an insertion control protrusion (ref. 828) for engagement with said insertion control mechanism (Fig. 16D, paragraph [0130]). The engagement of the insertion control mechanism and protrusion can help prevent or otherwise limit distal movement of the inserter tool within the tube and can help limit rotation during use

(paragraph [0130]). Walsh teaches that the engagement can advantageously help limit the depth to which an implant can be delivered relative to an implant site of a patient and thus improve the safety and efficacy of the implant, related tools and implant procedure (paragraph [0130]). It would have been obvious to one having ordinary skill in the art before the effective filing date of the claimed invention to modify the hollow barrel and inserter tool of Stark with the interior guidance slot and protrusion as taught by Walsh for the purpose of limiting the depth of the fusion implant into the void in the SI joint to improve the safety and efficacy of the implant and method. Please note that Stark as modified by Walsh results in the steps of controlling the depth of advancement of the inserter tool into said working channel and maintaining said tool in proper orientation for insertion into said incision; and advancing the inserter tool until said insertion control protrusion is arrested by said interior guidance slot in the hollow barrel and wherein said inserter tool is prevented from moving the fusion implant beyond said pre-determined point into said sacroiliac joint.

Regarding point 3) above, Bagby teaches methods in the related field of spinal implants (Abstract) comprising an inserter (paragraph [0029], ref. 12, Fig. 1) configured to engage with an implant (paragraph [0029], ref. 14, Fig. 1). The inserter has a plurality of engagement arms at a distal end (paragraph [0030], ref. 32, Fig. 1) configured to engage with slots on the implant (paragraph [0031], ref. 36, Fig. 1). Bagby teaches that the plurality and shape of the arms and slots help to stabilize the implant onto the inserter and prevent rocking or unwanted slippage (paragraph [0035]). It would have been obvious to one having ordinary skill in the art before the effective

filing date of the claimed invention to modify the inserter and implant of Stark such that the inserter has a plurality of implant engagement arms at its distal end to engage with slots on a proximal end of the fusion implant, for the purpose of stabilizing the implant during insertion.

Regarding claim 82, Stark in view of Walsh and in view of Michelson and in view of Bagby discloses the method of claim 81, 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 (Stark, paragraph [0034] discloses that the implant may be a screw, wherein the helical threads of the screw are considered to be the protrusion).

Regarding claim 83, Stark in view of Walsh and in view of Michelson and in view of Bagby discloses the method of claim 82, wherein said engagement of said fusion implant with said bone tissue fixes the relative position of said sacrum and the ilium of said sacroiliac joint (Stark, Fig. 3 and paragraph [0002]).

Regarding claim 84, Stark in view of Walsh and in view of Michelson and in view of Bagby discloses the method of claim 82, 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 (Stark, Fig. 14 shows a screw with a helical thread which is taken to be the helical anchor and having a sharp end refs. 268 fully capable of piercing bone tissue

and Fig. 3 shows the implant being placed substantially parallel to the articular surfaces of the joint, thus first penetrating the surfaces).

Regarding claim 85, Stark in view of Walsh and in view of Michelson and in view of Bagby discloses the method of claim 81, wherein no further fusion implants are introduced into said sacroiliac joint and said fusion implant is sufficient to fuse the sacroiliac joint (Stark, Fig. 3).

Regarding claim 86, Stark in view of Walsh and in view of Michelson and in view of Bagby discloses the method of Claim 81, further comprising creating a void in the sacroiliac joint having a complementary shape to said fusion implant, wherein said fusion implant is inserted into said void (Stark, paragraph [0050-51] disclose creating a void with a size slightly smaller than the size of the implant, thus having a complementary shape).

Regarding claim 87, Stark in view of Walsh and in view of Michelson and in view of Bagby discloses the method of Claim 81, wherein engagement of said insertion control protrusion with said interior guidance slot maintains said inserter tool and said fusion implant in proper orientation for insertion of the fusion implant into said sacroiliac joint (Walsh, paragraph [0130]).

11. Claim **59** is/are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Stark (US 2008/0009861 A1) in view of view of Michelson (US 6,436,098 B1) and

in view of Bagby (US 2004/0193174 A1) and further in view of Sweeney (US 7,575,572 B2).

Regarding claim 59, Stark discloses the method of claim 49, wherein said fusion implant comprises a body having a cavity therein (paragraph [0057] discloses that the fusion implant may be hollow, thus having a cavity), and a hole in a proximal end of said body for accessing the interior of said cavity (the hollow screw is adapted to be placed over a guide pin, thus having a hole in both the proximal and distal ends of the body), but is silent regarding that the body of the implant has perforations on an exterior thereof that expose said cavity to an exterior of said body. However Stark does disclose the use of various biological active agents to be used in combination with the implant, but is silent regarding the use of perforations on the screw body.

Sweeney teaches a bone screw (Abstract) with perforations/fenestrations on an exterior thereof that exposes an internal cavity to the exterior (Fig. 1, ref. 130). Sweeney teaches that the perforations may be used for the delivery of a desired substance to the bone (Col. 1, lines 55 - 65). It would have been obvious to one having ordinary skill in the art before the effective filing date of the claimed invention to modify the screw of Stark in view of Michelson and in view of Bagby to include the perforations, as taught by Sweeney, for the purpose of better applying and using biological active agents in combination with the screw.

Response to Arguments

12. Applicant's arguments with respect to claims 32, 36, 40, 41, 43, 47, 49, 51, 59, 60, 67, 69, 77 - 89 have been considered but are moot because the arguments do not apply to any of the combination of references being used in the current rejection.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Please see PTO-892.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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>Notice of References Cited</i>	Application/Control No. 16/718,189		Applicant(s)/Patent Under Reexamination Schifano et al.	
	Examiner TESSA M MATTHEWS		Art Unit 3773	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-6436098-B1	08-2002	Michelson; Gary Karlin	A61B17/025	606/86A
*	B	US-20040193174-A1	09-2004	Bagby, George W.	A61F2/446	606/99
*	C	US-20130006368-A1	01-2013	Walsh; Steven P.	A61F2/30756	623/18.11
	D					
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*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

<i>Search Notes</i> 	Application/Control No. 16/718,189	Applicant(s)/Patent Under Reexamination Schifano et al.
	Examiner TESSA M MATTHEWS	Art Unit 3773

CPC - Searched*		
Symbol	Date	Examiner
A61F2002/4627	01/28/2020	T. Matthews
A61B17/8872,1757,7055,8605,869,1671	01/28/2020	T. Matthews
Updated Search	07/16/2020	T. Matthews

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
Search consult with Jacqueline Johanas	01/28/2020	T. Matthews
Inventor and applicant name search in EAST	01/28/2020	T. Matthews
Please see attached EAST search history	01/28/2020	T. Matthews
Please see attached updated EAST search history	07/16/2020	T. Matthews

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

/TESSA M MATTHEWS/ Examiner, Art Unit 3773	
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<i>Index of Claims</i> 	Application/Control No. 16/718,189	Applicant(s)/Patent Under Reexamination Schifano et al.
	Examiner TESSA M MATTHEWS	Art Unit 3773

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
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CLAIMS										
☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47										
CLAIM		DATE								
Final	Original	01/28/2020	07/16/2020							
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	41	✓	✓							
	42	-	-							

<i>Index of Claims</i> 	Application/Control No. 16/718,189	Applicant(s)/Patent Under Reexamination Schifano et al.
	Examiner TESSA M MATTHEWS	Art Unit 3773

CLAIM		DATE								
Final	Original	01/28/2020	07/16/2020							
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)

Application Number	16718189
Filing Date	2019-12-18
First Named Inventor	Schifano, Troy
Art Unit	
Examiner Name	
Attorney Docket Number	13709.02.USU06

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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	10219841		2019-03-05	Compton et al.	
	2	D704334		2014-05-06	Walthall	
	3	9186155		2015-11-17	Katzman et al.	
	4	8882818		2014-11-11	Vestgaarden	
	5	9375243		2016-06-28	Vestgaarden	
	6	9895176		2018-02-20	Vestgaarden	
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Application Number		16718189
Filing Date		2019-12-18
First Named Inventor	Schifano,Troy	
Art Unit		
Examiner Name		
Attorney Docket Number	13709.02.USU06	

1	20120095560	2012-04-19	Donner
2	20100268228	2010-10-21	Petersen
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4	20160310197	2016-10-27	Black et al.
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6	20160175113	2016-06-23	Lins
7	20146209512	2014-12-22	Lins
8	20140277165	2014-09-18	Katzman et al.

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Art Unit	
Examiner Name	
Attorney Docket Number	13709.02.USU06

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
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(Not for submission under 37 CFR 1.99)

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Filing Date	2019-12-18		
First Named Inventor	Schifano,Troy		
Art Unit			
Examiner Name			
Attorney Docket Number	13709.02.USU06		

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)	2020-03-26
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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Doc code: IDS

PTO/SB/08a (01-10)

Doc description: Information Disclosure Statement (IDS) Filed

Approved for use through 07/31/2012. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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

Application Number	16718189
Filing Date	2019-12-18
First Named Inventor	Schifano,Troy
Art Unit	
Examiner Name	
Attorney Docket Number	13709.02.USU06

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	4481020		1984-11-06	Lee et al.	
	2	D847994		2019-05-07	Asfora et al.	
	3	D857897		2019-08-27	Loftus	
	4	D3579830		1971-05-25	Morel	

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Art Unit	
Examiner Name	
Attorney Docket Number	13709.02.USU06

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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	/TESSA M MATTHEWS/	Date Considered	05/28/2020
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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.

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
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Art Unit			
Examiner Name			
Attorney Docket Number	13709.02.USU06		

CERTIFICATION STATEMENT

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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.

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Signature	/William K. Nelson/	Date (YYYY-MM-DD)	2020-04-09
Name/Print	William K. Nelson	Registration Number	63501

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Application Number	16718189
Filing Date	2019-12-18
First Named Inventor	Schifano, Troy
Art Unit	
Examiner Name	MATTHEWS, TESSA M
Attorney Docket Number	13079.02.USU06

U.S.PATENTS

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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	7575572		2009-08-00	Sweeney	

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	1	20190343640	A1	2019-11-00	Donner	
	2	20190209011		2019-07-00	Donner	
	3	20020055737		2002-05-00	Lieberman	
	4	20130006368		2013-01-00	Walsh	
	5	20130172736		2013-07-00	Abdou	

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Attorney Docket Number	13079.02.USU06

6	20140135927	2014-05-00	Pavlov
7	20080009861	2008-01-00	Stark

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Examiner Signature	/TESSA M MATTHEWS/	Date Considered	05/28/2020
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EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
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S4	9	((("Schifano") near3 ("Troy"))).INV.	US- PGPUB; USPAT; USOCR	OR	OFF	2020/01/22 12:40
S5	159	((("Anderson") near3 ("Steve"))).INV.	US- PGPUB; USPAT; USOCR	OR	OFF	2020/01/22 12:40
S6	3	((("Soo") near3 ("Teck-Mun"))).INV.	US- PGPUB; USPAT; USOCR	OR	OFF	2020/01/22 12:42
S7	9	((("Thaiyananthan") near3 ("Gowriharan"))).INV.	US- PGPUB; USPAT; USOCR	OR	OFF	2020/01/22 12:42
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S9	543	S8 and (((sacrum sacral)adj3(ilic ilium)) sacroiliac)	US- PGPUB; USPAT	OR	OFF	2020/01/23 12:01
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S21	18	("2014/0207240").URPN.	USPAT	OR	OFF	2020/01/24 14:46
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S25	658	S24 and (surgical surgery)	US-PGPUB; USPAT	OR	OFF	2020/01/24 15:20
S26	1	("20080009861").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/01/27 13:23
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S30	56,008	(cannula tube trocar retractor)same((limit\$4 control\$4 prevent\$4 stop\$4)with(depth insertion distance))	US-PGPUB; USPAT	OR	OFF	2020/01/28 14:51
S31	6,472	S30 and ((slot recess groove keyway channel)with(protrusion tab key raised))	US-PGPUB; USPAT	OR	OFF	2020/01/28 14:52
S32	2,640	S31 and (surgical surgery)	US-PGPUB; USPAT	OR	OFF	2020/01/28 14:53
S33	23,821	(cannula tube trocar retractor)same((limit control prevent)with(depth insertion distance))	US-PGPUB; USPAT	OR	OFF	2020/01/28 14:53

S34	1,591	S33 and ((slot recess)with(protrusion tab key))	US-PGPUB; USPAT	OR	OFF	2020/01/28 14:53
S35	658	S34 and (surgical surgery)	US-PGPUB; USPAT	OR	OFF	2020/01/28 14:53
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S37	633	S32 and ((stop partial)with(recess channel keyway groove slot))	US-PGPUB; USPAT	OR	OFF	2020/01/28 14:55
S38	0	("2018/0235643").URPN.	USPAT	OR	OFF	2020/01/28 15:03
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S43	4,239	A61F2002/4627.cpc.	US-PGPUB; USPAT	OR	OFF	2020/01/28 15:39
S44	1,450,697	S43 ((limit\$4 stop\$4 prevent\$4)with(groove key slot channel recess))	US-PGPUB; USPAT	OR	ON	2020/01/28 15:40
S45	3	"20130006368"	US-PGPUB; USPAT	OR	OFF	2020/01/28 15:40
S46	35,122	((screw)with(cavities perforation\$2 hole bore))and(medical surgical surgery)	US-PGPUB; USPAT	OR	OFF	2020/01/28 16:26

S47	26,594	((screw)with(cavities perforation\$2 hole bore))and(bone)	US-PGPUB; USPAT	OR	OFF	2020/01/28 16:26
S48	996	((screw)with(cavities perforation\$2))and(bone)	US-PGPUB; USPAT	OR	OFF	2020/01/28 16:27
S49	484	S48 and (spine)	US-PGPUB; USPAT	OR	OFF	2020/01/28 16:29
S50	2	"20080009861"	US-PGPUB; USPAT	OR	OFF	2020/05/28 10:14
S51	3	"20130006368"	US-PGPUB; USPAT	OR	OFF	2020/05/28 10:22
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S61	75	("2009/0149857").URPN.	USPAT	OR	OFF	2020/05/28 11:00
S62	2,072	(cannula)same((align\$4 limit\$4)with(groov\$3 slot\$3))	US- PGPUB; USPAT	OR	OFF	2020/05/28 11:01
S63	1,464	S62 and (surgical surgery spine spinal)	US- PGPUB; USPAT	OR	OFF	2020/05/28 11:02
S64	723	S63 and ((groove\$3 slot\$3)with(interior inner))	US- PGPUB; USPAT	OR	OFF	2020/05/28 11:02
S65	1	("20080009861").PN.	US- PGPUB; USPAT; USOCR	OR	OFF	2020/06/03 09:59
S66	1	("20130006368").PN.	US- PGPUB; USPAT; USOCR	OR	OFF	2020/06/03 10:00
S67	1	("20040193174").PN.	US- PGPUB; USPAT; USOCR	OR	OFF	2020/06/03 10:01
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S71	0	("20080009861").PN.	USPAT; USOCR	OR	OFF	2020/07/08 09:23
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EAST Search History (Interference)

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C:\Users\tmatthews1\Documents\EAST\Workspaces\16718189.wsp

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875				Application or Docket Number 16/718,189		Filing Date 12/18/2019		☐ 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), (l), 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 \$100 =						
INDEPENDENT CLAIMS (37 CFR 1.16(h))		minus 3 =	*	x \$460 =						
☐ 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	11/17/2020	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)		ADDITIONAL FEE (\$)		
	Total (37 CFR 1.16(i))	* 25	Minus	** 26	= 0	x \$100 =		0		
	Independent (37 CFR 1.16(h))	* 3	Minus	*** 3	= 0	x \$480 =		0		
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))									
						TOTAL ADD'L FEE		0		
		(Column 1)	(Column 2)	(Column 3)						
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)		ADDITIONAL FEE (\$)		
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	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".						/THUY T TA/				
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".										
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.										

This collection of information is required by 37 CFR 1.16. 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 12 minutes 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.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL **(Submitted Only via EFS-Web)**

Application Number	16/718,189	Filing Date	2019-12-18	Docket Number (if applicable)	13079.02.USU06	Art Unit	3773
First Named Inventor	Schifano			Examiner Name	MATTHEWS, TESSA M		

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.

Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. The Instruction Sheet for this form is located at WWW.USPTO.GOV

SUBMISSION REQUIRED UNDER 37 CFR 1.114

Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____

☐ Other _____

☒ Enclosed

☒ Amendment/Reply

☐ Information Disclosure Statement (IDS)

☐ Affidavit(s)/ Declaration(s)

☐ Other _____

MISCELLANEOUS

☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of months _____
 (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

☐ Other _____

FEES

☒ The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.
 The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to
 Deposit Account No 600741

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

☒ Patent Practitioner Signature
 Applicant Signature

Signature of Registered U.S. Patent Practitioner			
Signature	William K. Nelson/	Date (YYYY-MM-DD)	2020-11-17
Name	William K. Nelson	Registration Number	63501

This collection of information is required by 37 CFR 1.114. 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 1.11 and 1.14. This collection is estimated to take 12 minutes 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.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Privacy Act Statement

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.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
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.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
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.
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Electronic Patent Application Fee Transmittal

Application Number:	16718189			
Filing Date:	18-Dec-2019			
Title of Invention:	METHOD AND IMPLANT SYSTEM FOR SACROILIAC JOINT FIXATION AND FUSION			
First Named Inventor/Applicant Name:	Troy Schifano			
Filer:	William Kenneth Nelson			
Attorney Docket Number:	13079.02.USU06			
Filed as Small Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension - 1 month with \$0 paid	2251	1	110	110
Miscellaneous:				
RCE- 1ST REQUEST	2801	1	680	680
Total in USD (\$)				790

Electronic Acknowledgement Receipt

EFS ID:	41151746
Application Number:	16718189
International Application Number:	
Confirmation Number:	1038
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.USU06
Receipt Date:	17-NOV-2020
Filing Date:	18-DEC-2019
Time Stamp:	23:29:26
Application Type:	Utility under 35 USC 111(a)

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RAM confirmation Number	E2020AGN29391862
Deposit Account	
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		20201117_amendment_RCE.pdf	344275	yes	22
			a124198a38672c4a3724cf7e591ff4bbc6a419f5		
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Applicant Arguments/Remarks Made in an Amendment		14	22	
	Claims		2	13	
	Amendment Submitted/Entered with Filing of CPA/RCE		1	1	
Warnings:					
Information:					
2	Extension of Time	sb0022.pdf	184289	no	2
			ea15a8cd728884fda8464cc9d66d17b33ee65f97		
Warnings:					
Information:					
3	Request for Continued Examination (RCE)	sb0030e_fill.pdf	697615	no	3
			e546496db6c19a388f30856ae0ac5aa6f83d8002		
Warnings:					
Information:					
4	Fee Worksheet (SB06)	fee-info.pdf	32511	no	2
			0bee1ec8a209a19bad3a5e569fb247534b979dc5		
Warnings:					
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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.

National Stage of an International Application under 35 U.S.C. 371

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.

New International Application Filed with the USPTO as a Receiving Office

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.

REMARKS

Applicant thanks Examiner Matthews for the thorough examination of the present application, and the detailed explanations in the Office Action. The amendments and remarks herein address and overcome all of the rejections of the claims, and the present claims are considered allowable over the cited references.

Claims 32, 36, 40-41, 49, 77, 79, 81, 83-84, and 88 have been amended. Claims 35, 82, and 89 have been canceled. New Claims 90-91 have been added. Claims 32, 36, 40-41, 43, 47, 49, 51, 59-60, 67, 69, 77-81, 83-88, and 90-91 are pending in the present application. No new matter is added by the amendments to claims.

Claim Objections

The objections to Claims 32, 35, 77, and 79 have been addressed by appropriate amendment.

The Rejections of Claims 32, 36, 40, 41, 43, 77-78, and 88 under 35 U.S.C. 103(a)

Claims 32, 36, 40, 41, 43, 77-78, and 88 have been rejected under 35 U.S.C. 103(a) as being obvious over Stark (US 2010/0131011) in view of Walsh et al. (US 2013/0006368, “Walsh”) and Michelson (US 6,436,098, “Michelson”). This rejection is respectfully traversed.

Stark discloses tools and procedures for immobilizing the sacroiliac (SI) joint to reduce pain (see the Abstract). The disclosed kits and procedures utilize an immobilization element that may be one of a number of tapering structures that can be inserted between the sacrum and

ilium in the SI joint, such as “pins, nails, screws, darts, wedges, shims, [and] cages/connector elements” (see, e.g., the Abstract and paragraph [0054] of Stark). The Office has previously acknowledged that Stark is silent with regard to a hollow barrel having a guidance slot for controlling the advancement of surgical tools (see the second paragraph on page 14 of the Office Action dated January 30, 2020), and the Office Action cites Walsh to allegedly cure this deficiency.

However, Walsh fails to disclose an interior guidance slot in an interior diameter of a hollow barrel that does not traverse the outer diameter of the hollow barrel, as recited in Claims 32 and 81. Walsh discloses a method of inserting a compressible hydrogel implant to replace cartilage in a joint (see, e.g., paragraphs [0007]-[0010]). Walsh discloses the use of a levered device that pushes a plunger (e.g., 820) to squeeze the hydrogel implant through a narrowing passage in a specially made tapering introducer tube (see, e.g., reference numbers 610 and 810 in FIGS. 15A-15C and 17B). The delivery tool 800 includes a lever-like clamp 840 that is swung down by the user on a pivot joint to applied pressure to the plunger 820, which in turn squeezes the hydrogel implant through the tapering introducer tube 810 to deposit the hydrogel implant in a void (see, e.g., paragraphs [0080], [0087], and [0120]). This is a slot running through the entire sidewall of the introducer tube on two diametric sides of the introducer tube 810 in order *to allow the clamp 840 to advance through the introducer tube 810 and move the plunger to the distal end of the introducer tube 810* (see, e.g., FIGS. 16A and 16D). Walsh does not suggest an interior slot withing a working channel.

The design of Walsh requires a slot the traverses the entire wall of the cannula in order to allow the lever mechanism to depress the hydrogel through the cannula. The lever and slot combination of Walsh operates like a hydraulic jack mechanism, applying pressure as the lever

is depressed. The mechanism cannot operate if the path of the lever is removed, e.g., by making the slot of the introducer tube such that the slot does not pass through the entire wall of the introducer tube. Thus, Walsh fails to disclose or suggest an interior guidance slot *in an interior diameter of a hollow barrel that does not traverse the outer diameter of said hollow barrel*, as recited in Claims 32 (Claim 81 has similar limitations). The slot in the introducer tube 810 does not and cannot be limited to the interior of the introducer tube 810. Also, redesigning the slot of Walsh such that it does not pass entirely through the wall of the tube would eliminate the functionality of the design of Walsh. It is not obvious to modify a prior art invention in a way that would destroy its advantageous property. *Eisai Co. Ltd. v. Dr. Reddy's Labs., Ltd.*, 533 F.3d 1353, 87 USPQ2d 1452 (Fed. Cir. 2008). Thus, it is not obvious to modify Stark in view of Walsh in the manner suggested in the office action.

Furthermore, the system and method of Walsh are quite distinct from those of Stark. The system of Walsh does not provide a cannula system for moving multiple surgical tools (e.g., a rasp, a drill, etc.) into an interarticular space. Rather, Walsh discloses a highly specialized insertion tool for squeezing a compressible hydrogel implant into a void having a small opening and an outwardly angled, expanding volume within the joint. The implant of Walsh has to be compressible in order to both access and fill the void. The delivery tool 800 is specialized to this purpose, having a narrowing delivery tube, vacuum suction applied to the distal end of the introducer tube 810 in order facilitate advancement of the implant (see, e.g., paragraph [0120]), and “lubricious” layers within the introducer tube 810 to maintain moisture in the implant and reduce friction in therein (see, e.g., paragraph [0124]). It would not be obvious to one of ordinary skill in the art to alter the method disclosed by Stark to include any of the features of Walsh because the device and method of Walsh are directed toward a very

distinct purpose and technique from that of Stark. The lever-like clamp 840 for driving the deposition of the hydrogel implant, which requires slots running through the entire thickness of the introducer tube 810 wall, would not be practicable to use for a screw implant or an implant to be hammered into place. Also, the narrowing cannula would not be practical for use with the tool set disclosed by Stark. The delivery tool 800 of Walsh and its components are clearly directed toward depositing a compressible material that must be squeezed into a void, and are not obviously adaptable to a system for implanting a screw or similar implant. Therefore, the assertion in the Office Action that it would be obvious to one of ordinary skill in the art to modify Stark in view of Walsh is improper, and the combination of Stark and Walsh fails to disclose or suggest the method of Claim 32 for at least the foregoing reasons.

It is submitted that Michelson fails to cure the deficiencies of Stark and Walsh explained above, and therefore Claim 32 and the claims dependent therefrom, are patentable over Stark in view of Walsh and Michelson for at least the reasons provided above. Thus, the rejection under 35 U.S.C. § 103(a) should be withdrawn.

The Rejection of Claims 49, 51, 60, 69, and 89 under 35 U.S.C. 103

Claims 49, 51, 60, 69, and 89 have been rejected under 35 U.S.C. § 103 as being obvious over Stark in view of Michelson (US 6,436,098) and Bagby (US 2004/0193174). This rejection is respectfully traversed.

Stark discloses tools and procedures for immobilizing the sacroiliac (SI) joint to reduce pain (see the Abstract). The disclosed kits and procedures utilize an immobilization element that may be one of a number of tapering structures that can be inserted between the

sacrum and ilium in the SI joint, such as “pins, nails, screws, darts, wedges, shims, [and] cages/connector elements” (see, e.g., the Abstract and paragraph [0054] of Stark). Stark discloses a very basic, pipe-shaped cannula 124 for passing instruments and implants, as it is described essential as a metal tube. As acknowledged in the Office Action, Stark makes no disclosure or suggest of a method utilizing a cannula or other channel having at least one tang on a distal end thereof, as recited in Claims 49 (see the 3rd ¶ on page 10 of the Office Action).

The Office Action cites Michelson for the purpose of curing the acknowledged deficiency of Stark. The Office Action asserts that Michelson discloses a “sharp toothed end with a plurality of tangs... [that] affix the hollow barrel to the vertebra of interest while also being limited in depth so as not to damage the vertebrae” (see the ¶ bridging pages 10-11 of the Office Action). The tangs disclosed by Michelson pierce vertebral bone, and are not inserted between the sacrum and ilium of a sacroiliac joint. Furthermore, the tangs disclosed by Michelson are clearly sharp for purposes of penetrating bone. Thus, Michelson fails to disclose or suggest surgical channel tool having two bilateral **blunt** tangs on a distal end thereof that **are inserted between the articular surfaces of an ilium and a sacrum of said sacroiliac joint**, as recited in Claim 49.

The Office Action cites Bagby as disclosing an implant having slots and an inserter that engages with the slots (see the 2nd ¶ on page 11 of the Office Action). It is submitted that Bagby fails to cure the deficiencies of Stark in view of Michelson explained above, and therefore Claim 49, and the claims dependent therefrom, are patentable over Stark in view of Michelson and Bagby for at least the reasons provided above. Thus, the arguments provided above are sufficient to overcome this rejection, and no additional arguments or amendments are

submitted at this time. However, the applicant reserves the right to do so in response to any future rejection(s).

In view of the deficiencies discussed above, Stark in view of Michelson and Bagby fails to disclose or suggest the method of Claim 49. Therefore, the rejection of Claim 49 and its dependent Claims 51, 60, 69, and 89 under 35 U.S.C. § 102(b) should be withdrawn.

The Rejection of Claims 47, 67, 79, and 80-87 under 35 U.S.C. 103

Claims 47, 67, 79, and 80-87 have been rejected under 35 U.S.C. § 103(a) as being obvious over Stark in view of Michelson, Bagby, and Walsh et al. (US 2013/0006368, “Walsh”). This rejection is respectfully traversed.

As explained above, the combined teachings of Stark, Walsh, and Michelson fail to disclose or suggest an interior guidance slot in an interior diameter of a hollow barrel that does not traverse the outer diameter of said hollow barrel, as recited in Claims 32, 49, and 81. It is submitted that Bagby fails to cure the deficiencies of Stark, Walsh, and Michelson explained above, and therefore Claims 32, 49, and 81 and the claims dependent therefrom, are patentable over Stark in view of Walsh, Michelson, and Bagby for at least this reason.

Also as explained above, the combined teachings of Stark, Michelson, and Bagby fail to disclose or suggest blunt tangs on a distal end thereof that are inserted between the articular surfaces of an ilium and a sacrum of said sacroiliac joint, as recited in Claims 49 and 81. It is submitted that Walsh fails to cure the deficiencies of Stark, Michelson, and Bagby explained above, and therefore Claims 49 and 81 and the claims dependent therefrom, are patentable over Stark in view of Walsh, Michelson, and Bagby for at least this reason.

Finally, none of the cited references disclose or suggest a working channel or cannula that includes a cut out between a plurality of tangs on one side of the working channel to accommodate bony protrusions of an ilium, as recited in Claim 81.

The Rejection of Claim 59 under 35 U.S.C. 103

Claim 59 had been rejected under 35 U.S.C. § 103(a) as being obvious over Stark in view of Michelson, Bagby, Walsh and Sweeney (US 7,575,572). This rejection is respectfully traversed.

As explained above, the combined teachings of Stark, Michelson, Bagby, and Walsh fails to disclose or suggest a method for repairing a sacroiliac joint, comprising inserting a surgical channel tool into an incision from the posterior of the patient having (1) an interior guidance slot in an interior diameter of a hollow barrel that does not traverse the outer diameter of the hollow barrel, or (2) blunt tangs on a distal end of a surgical channel that are inserted between the articular surfaces of an ilium and a sacrum of said sacroiliac joint (see Claim 49).

The Office Action cites Sweeney as disclosing an implant having perforations that may be used the delivery of a substance. It is submitted that Sweeney fails to cure the deficiencies of Stark, Michelson, Bagby, and Walsh explained above, and therefore Claim 49, and the claims dependent therefrom, are patentable over Stark in view of Michelson, Bagby, Walsh, and Sweeney for at least the reasons provided above. Thus, the arguments provided above are sufficient to overcome this rejection, and no additional arguments or amendments are submitted at this time. However, the applicant reserves the right to do so in response to any future

rejection(s).

Conclusion

In view of the above remarks, all rejections in the Office Action have been addressed. Fees for Request for Continued Examination are submitted herewith. No excess claim fees are believed to be due. The office is authorized to charge any additional fees required by this paper, or credit any overpayments, to deposit account 600741.

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.

Dated: November 17, 2020.

Respectfully Submitted,

By: /William K. Nelson/

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Listing of Claims:

1-31. (Canceled)

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

- a. creating a first incision proximal to the patient's sacroiliac joint;
- b. inserting a working channel into said first incision, said working channel having a hollow barrel with an interior guidance slot in ~~the~~an interior diameter of the hollow barrel that does not traverse the outer diameter of said hollow barrel for controlling the depth to which advancement of surgical tools passed through said working channel, and having at least one tang on a distal end thereof;
- c. creating a void in said sacroiliac joint; and
- d. inserting a fusion implant into said void, wherein said fusion implant includes at least one protrusion that engages with bone tissue in an articular surface of at least one of the sacrum and the ilium of said sacroiliac joint thereby preventing pullout of the fusion implant.

33. (Canceled)

34. (Canceled)

35. (Canceled) ~~The method of claim 32, further comprising driving said fusion implant into said void with an impactor, wherein said fusion implant includes at least one~~

~~protrusion that engages with said bone tissue as said fusion implant is driven into said void.~~

36. (Currently Amended) The method of claim 32, wherein said fusion implant has a central body and said at least one protrusion that extends from said central body and fixes relative positions of said ilium and sacrum with engagement of said at least one protrusion with said ilium and sacrum.

37. (Canceled)

38. (Canceled)

39. (Canceled)

40. (Currently Amended) The method of claim 36, wherein said ~~fusion implant~~ contacts at least one protrusion is an anchor that penetrates at least one of the patient's ilium and the patient's sacrum and fuses thereby fixes relative positions of said joint ilium and sacrum, thereby securing said implant in said joint.

41. (Currently Amended) The method of claim 40, wherein said ~~fusion implant~~ at least one protrusion is a helical anchor is configured operable to substantially fix ~~and fuse~~ the patient's ilium to the patient's sacrum, thereby substantially immobilizing the patient's sacroiliac joint.

42. (Canceled)

43. (Previously Presented) The method of claim 36, wherein said fusion implant comprises a cavity for holding a fusion-promoting material and having at least one hole therein for allowing the growth of bone tissue into said cavity.
44. (Canceled)
45. (Canceled)
46. (Canceled)
47. (Previously Presented) The method of claim 32, wherein the inserting said fusion implant comprises:
- a. attaching said fusion implant to an inserter having a plurality of implant engagement arms at a distal end of said inserter by engaging said implant engagement arms with slots on a proximal end of said fusion implant, said inserter further having a slot-engagement protrusion for engaging with said interior guidance slot; and
 - b. inserting said inserter into the hollow barrel of said working channel with said slot-engagement protrusion aligned with said interior guidance slot within the interior diameter of said hollow barrel and advancing said inserter until said interior guidance slot arrests the penetration of said inserter and said fusion implant into said sacroiliac joint at a pre-determined depth.
48. (Canceled)

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

- a. creating a first incision proximal to the patient's sacroiliac joint;
- b. inserting a surgical channel tool into said incision from the posterior of the patient, said surgical channel tool having ~~at least one~~having two bilateral blunt tangs on a distal end thereof that ~~is~~are inserted between the articular surfaces of an ilium and a sacrum of said sacroiliac joint to stabilize the surgical channel tool as surgical instruments are passed through the surgical channel into the sacroiliac joint, said surgical channel including a hollow barrel having an interior guidance slot in an interior diameter of said hollow barrel for controlling the depth of advancement of surgical tools into said working channel and maintaining said surgical tools in proper orientation for insertion into said incision, wherein said interior guidance slot does not traverse the outer diameter of said hollow barrel;
- c. creating a void in said sacroiliac joint;
- d. inserting a fusion implant into said void through a ~~said~~ hollow barrel of said surgical channel tool using an inserter having a plurality of implant engagement arms at its distal end engaged with slots on a proximal end of said fusion implant, said fusion implant having 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; and
- e. driving said fusion implant into said void such that said at least one protrusion engages with said bone tissue preventing pullout of the fusion implant, and said fusion implant fixes relative positions of said sacrum and said ilium.

50. (Canceled)

51. (Previously Presented) The method of claim 49, wherein said at least one protrusion comprises 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.
52. (Canceled)
53. (Canceled)
54. (Canceled)
55. (Canceled)
56. (Canceled)
57. (Canceled)
58. (Canceled)
59. (Previously Presented) The method of claim 49, wherein said fusion implant comprises a body having a cavity therein and perforations on an exterior thereof that expose said cavity to the exterior of said body, and a hole in a proximal end of said body for accessing an interior of said cavity.

60. (Previously Presented) The method of claim 49, 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)
63. (Canceled)
64. (Canceled)
65. (Canceled)
66. (Canceled)
67. (Previously Presented) The method of claim 49, wherein the inserting the fusion implant comprises:
- a. inserting the inserter tool into said hollow barrel of said surgical channel tool, wherein said inserter tool has an insertion control protrusion;
 - b. engaging said insertion control protrusion with an interior guidance slot in the interior diameter of the hollow barrel for controlling the advancement of surgical tools into said surgical channel tool and preventing rotation of said surgical tools; and

- c. advancing the inserter tool until said insertion control protrusion is arrested by the interior guidance slot 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.

68. (Canceled)

69. (Previously Presented) 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 protrusion contacts said bone tissue.

70. (Canceled)

71. (Canceled)

72. (Canceled)

73. (Canceled)

74. (Canceled)

75. (Canceled)

76. (Canceled)

77. (Currently Amended) The method of claim 32, wherein the step of creating the void in said sacroiliac joint comprises inserting a rasp having a slot-engagement protrusion into the hollow barrel of said working channel with said slot-engagement protrusion nested in ~~an~~the interior guidance slot in the interior diameter of said hollow barrel, wherein engagement of said slot-engagement protrusion with said interior guidance slot controls the depth of advancement of said rasp through said hollow barrel and maintains said rasp in proper orientation for insertion in the void.
78. (Previously Presented) The method of claim 32, wherein said interior guidance slot is operable to engage and align a slot-engagement protrusion of one or more surgical tools to be inserted into said hollow barrel, wherein engagement of said slot-engagement protrusion with said guidance slot controls the depth of advancement of surgical tools through said hollow barrel and maintains said one or more surgical tools in proper orientation for insertion into said incision.
79. (Currently Amended) The method of claim 49, wherein step of creating the void in said sacroiliac joint comprises inserting a rasp having a slot-engagement protrusion into said hollow barrel of said surgical channel tool with said slot-engagement protrusion aligned with an interior guidance slot in ~~an~~in~~the~~ interior diameter of said hollow barrel, wherein engagement of said slot-engagement ~~element~~protrusion with said interior guidance slot controls the depth of advancement of said rasp through said hollow barrel and maintains said rasp in proper orientation for insertion into said void.
80. (Previously Presented) The method of claim 49, wherein said working channel includes an interior guidance slot in an in interior diameter of said working channel for alignment and engagement with a slot-engagement protrusion of one or more

surgical tools to be inserted into said hollow barrel, wherein engagement of said slot-engagement protrusion with said interior guidance slot controls the depth of advancement of surgical tools through said hollow barrel and maintains said one or more surgical tools in proper orientation for insertion into said incision.

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

- a. creating an incision 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 having a plurality of blunt tangs on a distal end thereof that ~~is~~are inserted between ~~the~~ articular surfaces of an ilium and a sacrum of said sacroiliac joint to stabilize the surgical channel tool as surgical instruments are passed through the working channel into the sacroiliac joint, wherein said working channel has a cut out between said plurality of tangs on one side of the working channel to accommodate bony protrusions of said ilium, said working channel including a hollow barrel having an interior guidance slot in an interior diameter of said hollow barrel- for controlling the depth of advancement of surgical tools into said working channel and maintaining said surgical tools in proper orientation for insertion into said incision, wherein said interior guidance slot does not traverse the outer diameter of said hollow barrel;
- c. inserting a fusion implant having a plurality of bone-engagement protrusions through said hollow barrel into said sacroiliac joint using an inserter having a plurality of implant engagement arms at its distal end engaged with slots on a proximal end of said fusion implant, wherein said fusion implant is inserted on a path that is substantially parallel to articular surfaces of the sacroiliac

joint, said inserter tool having an insertion control protrusion for engagement with said interior guidance slot;

d. advancing the inserter tool until said insertion control protrusion is arrested by said interior guidance slot in the hollow barrel and placing said fusion implant into said sacroiliac joint, wherein said inserter tool is prevented from moving the fusion implant beyond a pre-determined point in said sacroiliac joint; and

e. driving said fusion implant into said sacroiliac joint such that said plurality of bone-engagement protrusions ~~said fusion implant engage~~[[s]] with said articular surfaces of said ilium and said sacrum ~~bone tissue~~ thereby preventing pullout of the fusion implant from said sacroiliac joint.

82. (Canceled) ~~The method of claim 81, 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.~~

83. (Currently Amended) The method of claim ~~82~~81, wherein said engagement of said fusion implant with said bone tissue fixes the relative position of said sacrum and the ilium of said sacroiliac joint.

84. (Currently Amended) The method of claim ~~82~~81, wherein said ~~at least one~~ plurality of bone-engagement protrusions comprise[[s]] 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.

85. (Previously Presented) The method of claim 81, wherein no further fusion implants are introduced into said sacroiliac joint and said fusion implant is sufficient to fuse the sacroiliac joint.
86. (Previously Presented) The method of Claim 81, further comprising creating a void in the sacroiliac joint having a complementary shape to said fusion implant, wherein said fusion implant is inserted into said void.
87. (Previously Presented) The method of Claim 81, wherein engagement of said insertion control protrusion with said interior guidance slot maintains said inserter tool and said fusion implant in proper orientation for insertion of the fusion implant into said sacroiliac joint.
88. (Currently Amended) The method of claim 32, wherein said working channel has a plurality of blunt tangs on a distal end thereof that are inserted between the articular surfaces of an ilium and a sacrum of said sacroiliac joint to stabilize the surgical channel tool as surgical instruments are passed through the working channel into the sacroiliac joint.
89. (Canceled) ~~The method of claim 49, wherein said surgical channel tool has a plurality of tangs on a distal end thereof that are inserted between the articular surfaces of an ilium and a sacrum of said sacroiliac joint.~~
90. (New) The method of claim 32, wherein said working channel has a cut out between said plurality of tangs on one side of the working channel to accommodate bony protrusions of said ilium.

91. (New) The method of claim 49, wherein said surgical channel has a cut out between said plurality of tangs on one side of the surgical channel to accommodate bony protrusions of said ilium.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

For: METHOD AND IMPLANT SYSTEM
FOR SACROILIAC JOINT FIXATION
AND FUSION

Inventor(s): Schifano, Troy et al.

S/N: 16/718,189

Conf. No.: 1038

Filed: December 18, 2019

Examiner: MATTHEWS, TESSA M

Art Unit: 3733

Certificate of Transmission

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being transmitted to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on November 17, 2020 via the USPTO EFS-Web filing system.

Signed: /William K. Nelson/
William K. Nelson

AMENDMENT AND REQUEST FOR CONTINUED EXAMINATION

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

Dear Sir:

This paper is being submitted in response to the Office Action dated July 17, 2020 (hereinafter, the "Office Action"). Applicant respectfully requests reconsideration of the above-identified application in view of the following amendments and remarks. Applicant submits herewith a request for continued examination and the corresponding fee.

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

Remarks begin on **page 14** of this paper.

PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)		Docket Number (Optional) 13079.02.USU06
Application Number 16/718,189	Filed 12-18-2019	
For METHOD AND IMPLANT SYSTEM FOR SACROILIAC JOINT FIXATION AND FUSION		
Art Unit 3773	Examiner MATTHEWS, TESSA M	

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above-identified application.

The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):

	<u>Fee</u>	<u>Small Entity Fee</u>	<u>Micro Entity Fee</u>	
☒ One month (37 CFR 1.17(a)(1))	\$200	\$100	\$50	\$ <u>100</u>
☐ Two months (37 CFR 1.17(a)(2))	\$600	\$300	\$150	\$ _____
☐ Three months (37 CFR 1.17(a)(3))	\$1,400	\$700	\$350	\$ _____
☐ Four months (37 CFR 1.17(a)(4))	\$2,200	\$1,100	\$550	\$ _____
☐ Five months (37 CFR 1.17(a)(5))	\$3,000	\$1,500	\$750	\$ _____

☒ Applicant asserts small entity status. See 37 CFR 1.27.

☐ Applicant certifies micro entity status. See 37 CFR 1.29.
Form PTO/SB/15A or B or equivalent must either be enclosed or have been submitted previously.

☐ A check in the amount of the fee is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☐ The Director has already been authorized to charge fees in this application to a Deposit Account.

☐ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to
Deposit Account Number _____.

☒ Payment made via EFS-Web.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest. See 37 CFR 3.71. 37 CFR 3.73(b) statement is enclosed (Form PTO/SB/96).

☒ attorney or agent of record. Registration number 63501.

☐ attorney or agent acting under 37 CFR 1.34. Registration number _____.

/William K. Nelson/

11/17/2020

Signature

Date

William K. Nelson

Typed or printed name

Telephone Number

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. Submit multiple forms if more than one signature is required, see below*.

☐ * Total of _____ forms are submitted.

This collection of information is required by 37 CFR 1.136(a). 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 1.11 and 1.14. This collection is estimated to take 6 minutes 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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Privacy Act Statement

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.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
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.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
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 inspection 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.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		16718189
	Filing Date		2019-12-18
	First Named Inventor	Schifano, Troy	
	Art Unit		
	Examiner Name	MATTHEWS, TESSA M	
	Attorney Docket Number	13709.02.USU06	

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	D894381		2020-08-25	Shaw et al.	
	2	D870263		2019-12-17	Adams et al.	
	3	D840030		2019-02-05	Smith et al.	
	4	D832423		2018-10-30	Ishida	
	5	D828551		2018-09-11	Zou et al.	
	6	D827133		2018-08-28	Großer et al	
	7	D685087		2013-06-25	Voic	
	8	D673670		2013-01-01	Linnenschmidt	

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

Application Number	16718189
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First Named Inventor	Schifano,Troy
Art Unit	
Examiner Name	MATTHEWS, TESSA M
Attorney Docket Number	13709.02.USU06

9	D651309		2011-12-27	Rowe et al.	
10	D642261		2011-07-26	York et al.	
11	D625805		2010-10-19	Hereford	
12	D397217		1998-08-18	Brookfield	
13	D353456		1994-12-13	Fayngold et al.	

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	1					

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Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ² i	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							

If you wish to add additional Foreign Patent Document citation information please click the Add button

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NON-PATENT LITERATURE DOCUMENTS

Remove

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		16718189
	Filing Date		2019-12-18
	First Named Inventor	Schifano, Troy	
	Art Unit		
	Examiner Name	MATTHEWS, TESSA M	
	Attorney Docket Number	13709.02.USU06	

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		

If you wish to add additional non-patent literature document citation information please click the Add button

EXAMINER SIGNATURE

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*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	16718189
Filing Date	2019-12-18
First Named Inventor	Schifano,Troy
Art Unit	
Examiner Name	MATTHEWS, TESSA M
Attorney Docket Number	13709.02.USU06

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)	2020-11-17
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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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:	41151794
Application Number:	16718189
International Application Number:	
Confirmation Number:	1038
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.USU06
Receipt Date:	17-NOV-2020
Filing Date:	18-DEC-2019
Time Stamp:	23:50:00
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)	2020_1014_IDS.pdf	612513	no	5
			f484f335804a1f347bccac4c5ea8a629d0f68dba		

Warnings:

Petitioner's Ex. 1008

Information:	
Total Files Size (in bytes):	612513
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.	

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875				Application or Docket Number 16/718,189		Filing Date 12/18/2019		☐ 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), (l), 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	12/18/2020	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)		ADDITIONAL FEE (\$)		
	Total (37 CFR 1.16(i))	* 23	Minus	** 26	= 0	x \$50 =		0		
	Independent (37 CFR 1.16(h))	* 3	Minus	*** 3	= 0	x \$240 =		0		
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))									
						TOTAL ADD'L FEE		0		
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.						LDRC				
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".						/EVA V GILLIS/				
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".										
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.										

This collection of information is required by 37 CFR 1.16. 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 12 minutes 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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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

For: METHOD AND IMPLANT SYSTEM
FOR SACROILIAC JOINT FIXATION
AND FUSION

Inventor(s): Schifano, Troy et al.

S/N: 16/718,189

Conf. No.: 1038

Filed: December 18, 2019

Examiner: MATTHEWS, TESSA M

Art Unit: 3733

Certificate of Transmission

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being transmitted to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on December 18, 2020 via the USPTO EFS-Web filing system.

Signed: /William K. Nelson/
William K. Nelson

PRELIMINARY AMENDMENT

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

Dear Sir:

This paper is a preliminary amendment after filing a Request for Continued Examination. Applicant respectfully requests entry and consideration of the following amendments.

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

Remarks begin on **page 14** of this paper.

Listing of Claims:

1-31. (Canceled)

32. (Previously Presented) A method for repairing a sacroiliac joint of a patient, comprising:

- a. creating a first incision proximal to the patient's sacroiliac joint;
- b. inserting a working channel into said first incision, said working channel having a hollow barrel with an interior guidance slot in an interior diameter of the hollow barrel that does not traverse the outer diameter of said hollow barrel for controlling the depth to which advancement of surgical tools passed through said working channel, and having at least one tang on a distal end thereof;
- c. creating a void in said sacroiliac joint; and
- d. inserting a fusion implant into said void, wherein said fusion implant includes at least one protrusion that engages with bone tissue in an articular surface of at least one of the sacrum and the ilium of said sacroiliac joint thereby preventing pullout of the fusion implant.

33. (Canceled)

34. (Canceled)

35. (Canceled)

36. (Previously Presented) The method of claim 32, wherein said fusion implant has a central body and said at least one protrusion that extends from said central body and fixes relative positions of said ilium and sacrum with engagement of said at least one protrusion with said ilium and sacrum.
37. (Canceled)
38. (Canceled)
39. (Canceled)
40. (Previously Presented) The method of claim 36, wherein said at least one protrusion is an anchor that penetrates at least one of the patient's ilium and the patient's sacrum and thereby fixes relative positions of said ilium and sacrum.
41. (Previously Presented) The method of claim 40, wherein said at least one protrusion is a helical anchor operable to substantially fix the patient's ilium to the patient's sacrum, thereby substantially immobilizing the patient's sacroiliac joint.
42. (Canceled)
43. (Previously Presented) The method of claim 36, wherein said fusion implant comprises a cavity for holding a fusion-promoting material and having at least one hole therein for allowing the growth of bone tissue into said cavity.
44. (Canceled)

45. (Canceled)
46. (Canceled)
47. (Previously Presented) The method of claim 32, wherein the inserting said fusion implant comprises:
- a. attaching said fusion implant to an inserter having a plurality of implant engagement arms at a distal end of said inserter by engaging said implant engagement arms with slots on a proximal end of said fusion implant, said inserter further having a slot-engagement protrusion for engaging with said interior guidance slot; and
 - b. inserting said inserter into the hollow barrel of said working channel with said slot-engagement protrusion aligned with said interior guidance slot within the interior diameter of said hollow barrel and advancing said inserter until said interior guidance slot arrests the penetration of said inserter and said fusion implant into said sacroiliac joint at a pre-determined depth.
48. (Canceled)
49. (Currently Amended) A method for repairing a sacroiliac joint of a patient, comprising:
- a. creating a first incision proximal to the patient's sacroiliac joint;
 - b. inserting a surgical channel tool into said incision from the posterior of the patient, said surgical channel tool having ~~having~~ two bilateral blunt tangs on a distal end thereof that are inserted between the articular surfaces of an ilium

and a sacrum of said sacroiliac joint to stabilize the surgical channel tool as surgical instruments are passed through the surgical channel into the sacroiliac joint, said surgical channel including a hollow barrel having an interior guidance slot in an interior diameter of said hollow barrel for controlling the depth of advancement of surgical tools into said working channel and maintaining said surgical tools in proper orientation for insertion into said incision, wherein said interior guidance slot does not traverse the outer diameter of said hollow barrel;

- c. creating a void in said sacroiliac joint;
- d. inserting a fusion implant into said void through said hollow barrel of said surgical channel tool using an inserter having a plurality of implant engagement arms at its distal end engaged with slots on a proximal end of said fusion implant, said fusion implant having 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; and
- e. driving said fusion implant into said void such that said at least one protrusion engages with said bone tissue preventing pullout of the fusion implant, and said fusion implant fixes relative positions of said sacrum and said ilium.

50. (Canceled)

51. (Previously Presented) The method of claim 49, wherein said at least one protrusion comprises 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.

52. (Canceled)

- 53. (Canceled)
- 54. (Canceled)
- 55. (Canceled)
- 56. (Canceled)
- 57. (Canceled)
- 58. (Canceled)
- 59. (Previously Presented) The method of claim 49, wherein said fusion implant comprises a body having a cavity therein and perforations on an exterior thereof that expose said cavity to the exterior of said body, and a hole in a proximal end of said body for accessing an interior of said cavity.
- 60. (Previously Presented) The method of claim 49, 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)

63. (Canceled)
64. (Canceled)
65. (Canceled)
66. (Canceled)
67. (Previously Presented) The method of claim 49, wherein the inserting the fusion implant comprises:
- a. inserting the inserter tool into said hollow barrel of said surgical channel tool, wherein said inserter tool has an insertion control protrusion;
 - b. engaging said insertion control protrusion with an interior guidance slot in the interior diameter of the hollow barrel for controlling the advancement of surgical tools into said surgical channel tool and preventing rotation of said surgical tools; and
 - c. advancing the inserter tool until said insertion control protrusion is arrested by the interior guidance slot 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.
68. (Canceled)
69. (Previously Presented) 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 protrusion contacts said bone tissue.

70. (Canceled)
71. (Canceled)
72. (Canceled)
73. (Canceled)
74. (Canceled)
75. (Canceled)
76. (Canceled)
77. (Previously Presented) The method of claim 32, wherein the step of creating the void in said sacroiliac joint comprises inserting a rasp having a slot-engagement protrusion into the hollow barrel of said working channel with said slot-engagement protrusion nested in the interior guidance slot in the interior diameter of said hollow barrel, wherein engagement of said slot-engagement protrusion with said interior guidance slot controls the depth of advancement of said rasp through said hollow barrel and maintains said rasp in proper orientation for insertion in the void.
78. (Previously Presented) The method of claim 32, wherein said interior guidance slot is operable to engage and align a slot-engagement protrusion of one or more surgical

tools to be inserted into said hollow barrel, wherein engagement of said slot-engagement protrusion with said guidance slot controls the depth of advancement of surgical tools through said hollow barrel and maintains said one or more surgical tools in proper orientation for insertion into said incision.

79. (Previously Presented) The method of claim 49, wherein step of creating the void in said sacroiliac joint comprises inserting a rasp having a slot-engagement protrusion into said hollow barrel of said surgical channel tool with said slot-engagement protrusion aligned with an interior guidance slot in the interior diameter of said hollow barrel, wherein engagement of said slot-engagement protrusion with said interior guidance slot controls the depth of advancement of said rasp through said hollow barrel and maintains said rasp in proper orientation for insertion into said void.
80. (Previously Presented) The method of claim 49, wherein said working channel includes an interior guidance slot in an interior diameter of said working channel for alignment and engagement with a slot-engagement protrusion of one or more surgical tools to be inserted into said hollow barrel, wherein engagement of said slot-engagement protrusion with said interior guidance slot controls the depth of advancement of surgical tools through said hollow barrel and maintains said one or more surgical tools in proper orientation for insertion into said incision.
81. (Currently Amended) A method for repairing a sacroiliac joint of a patient, comprising:
- a. creating an incision 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 having a plurality of blunt

tangs on a distal end thereof that are inserted between articular surfaces of an ilium and a sacrum of said sacroiliac joint to stabilize the surgical channel tool as surgical instruments are passed through the working channel into the sacroiliac joint, ~~wherein said working channel has a cut out between said plurality of tangs on one side of the working channel to accommodate bony protrusions of said ilium,~~ said working channel including a hollow barrel having an interior guidance slot in an interior diameter of said hollow barrel for controlling the depth of advancement of surgical tools into said working channel and maintaining said surgical tools in proper orientation for insertion into said incision, wherein said interior guidance slot does not traverse the outer diameter of said hollow barrel;

- c. inserting a fusion implant having a plurality of bone-engagement protrusions through said hollow barrel into said sacroiliac joint using an inserter having a plurality of implant engagement arms at its distal end engaged with slots on a proximal end of said fusion implant, wherein said fusion implant is inserted on a path that is substantially parallel to articular surfaces of the sacroiliac joint, said inserter tool having an insertion control protrusion for engagement with said interior guidance slot;
- d. advancing the inserter tool until said insertion control protrusion is arrested by said interior guidance slot in the hollow barrel and placing said fusion implant into said sacroiliac joint, wherein said inserter tool is prevented from moving the fusion implant beyond a pre-determined point in said sacroiliac joint; and
- e. driving said fusion implant into said sacroiliac joint such that said plurality of bone-engagement protrusions engage with said articular surfaces of said ilium and said sacrum thereby preventing pullout of the fusion implant from said sacroiliac joint.

82. (Canceled)
83. (Previously Presented) The method of claim 81, wherein said engagement of said fusion implant with said bone tissue fixes the relative position of said sacrum and the ilium of said sacroiliac joint.
84. (Previously Presented) The method of claim 81, wherein said plurality of bone-engagement protrusions comprise 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.
85. (Previously Presented) The method of claim 81, wherein no further fusion implants are introduced into said sacroiliac joint and said fusion implant is sufficient to fuse the sacroiliac joint.
86. (Previously Presented) The method of Claim 81, further comprising creating a void in the sacroiliac joint having a complementary shape to said fusion implant, wherein said fusion implant is inserted into said void.
87. (Previously Presented) The method of Claim 81, wherein engagement of said insertion control protrusion with said interior guidance slot maintains said inserter tool and said fusion implant in proper orientation for insertion of the fusion implant into said sacroiliac joint.
88. (Previously Presented) The method of claim 32, wherein said working channel has a plurality of blunt tangs on a distal end thereof that are inserted between the articular surfaces of an ilium and a sacrum of said sacroiliac joint to stabilize the surgical

channel tool as surgical instruments are passed through the working channel into the sacroiliac joint.

89. (Canceled)

90. (Canceled) ~~The method of claim 32, wherein said working channel has a cut out between said plurality of tangs on one side of the working channel to accommodate bony protrusions of said ilium.~~

91. (Canceled) ~~The method of claim 49, wherein said surgical channel has a cut out between said plurality of tangs on one side of the surgical channel to accommodate bony protrusions of said ilium.~~

REMARKS

Claims 49 and 81 have been amended. Claims 90-91 have been canceled. Claims 32, 36, 40-41, 43, 47, 49, 51, 59-60, 67, 69, 77-81, and 83-88 are pending in the present application. No new matter is added by the amendments to claims. No excess claim fees are believed to be due. The office is authorized to charge any additional fees required by this paper, or credit any overpayments, to deposit account 600741.

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.

Dated: December 18, 2020.

Respectfully Submitted,

By: /William K. Nelson/

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Electronic Acknowledgement Receipt

EFS ID:	41435091
Application Number:	16718189
International Application Number:	
Confirmation Number:	1038
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.USU06
Receipt Date:	18-DEC-2020
Filing Date:	18-DEC-2019
Time Stamp:	15:57:56
Application Type:	Utility under 35 USC 111(a)

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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		20201218_preliminary_amendment.pdf	219071	yes	13
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Multipart Description/PDF files in .zip description			
Document Description	Start	End	
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		16718189
	Filing Date		2019-12-18
	First Named Inventor	Schifano, Troy	
	Art Unit		
	Examiner Name		
	Attorney Docket Number	13709.02.USU06	

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	1	8882818		2014-11-11	Vestgaarden	
	2	8740912		2014-06-03	Stark	
	3	9451986		2016-09-27	Stoffman et al.	
	4	9381045		2016-07-05	Donner et al.	

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Application Number		16718189
Filing Date		2019-12-18
First Named Inventor	Schifano,Troy	
Art Unit		
Examiner Name		
Attorney Docket Number	13709.02.USU06	

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

Application Number	16718189
Filing Date	2019-12-18
First Named Inventor	Schifano,Troy
Art Unit	
Examiner Name	
Attorney Docket Number	13709.02.USU06

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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).

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☐ 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)	2021-04-03
Name/Print	William K. Nelson	Registration Number	63501

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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.
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EFS ID:	42095284
Application Number:	16718189
International Application Number:	
Confirmation Number:	1038
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.USU06
Receipt Date:	04-MAR-2021
Filing Date:	18-DEC-2019
Time Stamp:	20:22:21
Application Type:	Utility under 35 USC 111(a)

Payment information:

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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)	20200409_IDS_5.pdf	612128	no	4
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	Filing Date		2019-12-18
	First Named Inventor	Schifano, Troy	
	Art Unit		
	Examiner Name		
	Attorney Docket Number	13709.02.USU06	

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	8025684		2011-09-00	Garcia-Bengochea	
	2	9662128		2017-05-30	Reiley	
	3	9492284		2016-11-15	Ginn et al.	
	4	9421109		2016-08-23	Donner	
	5	8128700		2012-03-06	Delurio et al.	
	6	9375243		2016-06-28	Vestgaarden	
	7	8403991		2013-03-26	Ullrich et al.	
	8	9808346		2017-11-07	Stark	