

36. The method of claim 32, wherein said fusion implant has a central body and said at least one fixation element extends laterally from said central body, and said working channel has a hollow barrel having a shape for receiving said joint fusion implant including said at least one lateral fixation element.

5 37. The method of claim 36, wherein said hollow barrel has an oblong shape for accommodating said fusion implant and allowing said at least one fixation element to pass through said hollow barrel without obstruction, wherein said hollow barrel has a substantially uniform transverse cross section having a
10 substantially elliptical shape and the elongate portions of the elliptical cross-section function as channels for receiving said at least one lateral fixation element.

38. The method of claim 36, wherein said hollow barrel has at least one lateral slot running longitudinally along the hollow barrel to allow said at least one lateral
15 fixation element to pass through the interior passage without obstruction.

39. The method of claim 32, wherein creating said void comprises inserting a drill into said working channel and drilling said void through the connective tissues in said joint.

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

25 41. The method of claim 40, wherein said fusion implant is configured to substantially compress, fix, and fuse the patient's ilium to the patient's sacrum, thereby substantially immobilizing the patient's sacroiliac joint.

42. The method of claim 41, wherein said at least one fixation element is operable to
30 engage said bone tissue in said articular surfaces of said sacrum and ilium to

compress said sacroiliac joint and fix said sacrum and ilium in position relative to each other.

5 43. The method of claim 41, wherein said fusion implant comprises a cavity for holding a fusion-promoting material.

44. The method of claim 43, wherein said cavity comprises at least one hole therein for allowing the growth of bone tissue into said cavity.

10 45. The method of claim 32, further comprising inserting a guide wire into said sacroiliac joint of the patient, slotting a joint cutting tool over said guide wire, and placing said working channel over said guide wire and said joint cutting tool, such that said guide wire and joint cutting tool are within a hollow barrel of said working channel and an end of said working channel is within said sacroiliac joint.
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46. The method of claim 32, further comprising securing said working channel in said first incision by inserting at least one pin through a slot on exterior of said working channel and into the patient.

20 47. The method of claim 32, wherein the inserting said fusion implant comprises:
a. attaching said fusion implant to an inserter, wherein the inserter has a proximal end configured to attach to said fusion implant; and
b. inserting said inserter into a hollow barrel of said working channel until a
25 stop slot within said hollow barrel and engaged with said inserter prevents said inserter from moving further into said sacroiliac joint.

48. The method of claim 32, further comprising forming a second void in said sacroiliac joint and inserting a second fusion implant into said second void through said second barrel.

5 49. A method for repairing a sacroiliac joint of a patient using an intra-articular joint fusion device for connecting the sacrum and ilium, comprising:

- a. creating a first incision in the patient's skin proximal to the patient's sacroiliac joint;
- b. inserting a working channel of a surgical channel tool into said incision
10 from the posterior of the patient;
- c. creating a void in said sacroiliac joint;
- d. inserting an fusion implant into said void, said fusion implant having at least one fixation element for engagement with bone tissue in an articular surface of at least one of the sacrum and the ilium of said sacroiliac joint;
15 and
- e. driving said fusion implant into said void such that said at least one fixation element engages with said bone tissue, and said fusion implant fixes relative positions of said sacrum and said ilium.

20 50. The method of claim 49, wherein said at least one fixation element comprises two lateral plates positioned at an oblique angle relative to a body of said implant and a plane between interfacing articular surfaces of said sacrum and said ilium when said joint implant is inserted into said joint, said two lateral plates being angled to engage with and pierce bone tissue of said interfacing articular surfaces.

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51. The method of claim 49, wherein said at least one fixation element 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.
- 5 52. The method of claim 49, wherein said at least one fixation element comprises a screw inserted through a posterior portion of said fusion implant at an oblique angle relative to a plane between interfacing articular surfaces of said sacrum and said ilium, the screw being angled to engage with and pierce said bone tissue in said at least one of said articular surfaces of said sacrum and said ilium in said joint.
- 10
53. The method of claim 49, wherein said at least one fixation element comprises a fluke having a sharp portion for piercing said bone tissue in said articular surface of said at least one of said sacrum and said ilium.
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54. The method of claim 53, wherein said fluke is attached to a rotatable member of said fusion implant, said rotatable member having a recess for engagement with a driving tool.
- 20
55. The method of claim 55, wherein said rotatable member of said fusion implant is configured to be rotated by said driving tool to insert said fluke into said bone tissue.
- 25
56. The method of claim 49, wherein a proximal end of an elongate body of said fusion implant includes at least one receiving surface for engagement with a driving tool for driving said fusion implant into said void.

57. The method of claim 49, wherein said fusion implant comprises a body having two helical anchors for engaging with said bone tissue, and a cavity is formed between said two helical anchors.
- 5 58. The method of claim 57, wherein said two helical anchors are arranged in an interwoven double helix pattern, and each helical anchor has a sharp end for piercing said bone tissue.
59. The method of claim 49, wherein said fusion implant comprises a body having a
10 cavity therein and perforations on an exterior thereof that expose said cavity to an exterior of said body, two flukes on said exterior of said body, and a hole in a proximal end of said body for accessing the interior of said cavity.
60. The method of claim 49, wherein said fusion implant is operable to connect
15 said sacrum to said ilium and compress the sacroiliac joint.
61. The method of claim 49, further comprising forming a second incision in the patient's skin over an iliac wing of the patient.
- 20 62. The method of claim 61, wherein said surgical channel tool further comprises a second working channel that is inserted into said second incision when said working channel is inserted into said incision proximal to the patient's sacroiliac joint.
- 25 63. The method of claim 62, wherein said first and second working channels are at an acute angle relative to each other.
64. The method of claim 63, wherein said first and second working channels are connected by a connecting bar having a bend therein.

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65. The method of claim 64, wherein said acute angle allows said working channel to be engaged with a posterior side of the sacroiliac joint and said second working channel to be engaged with a posterior portion of the iliac wing simultaneously.
- 5 66. The method of claim 62, further comprising inserting a drill into said second working channel and drilling a hole through the iliac wing and into said sacrum, wherein said joint fixation device is inserted in said iliac wing and said sacrum of the patient without said joint fixation device traversing said sacroiliac joint.
- 10 67. The method of claim 62, wherein the inserting the fusion implant comprises:
- a. attaching said fusion implant to an inserter, wherein the inserter has a proximal end configured to attach to the implant; and
 - b. inserting the inserter into a hollow barrel of said working channel until a stop slot within said hollow barrel and engaged with said inserter prevents
- 15 the inserter from moving further into said sacroiliac joint.
68. The method of claim 49, wherein driving said fusion implant into said void comprises rotating said fusion implant or a portion thereof having said at least one fixation element thereon.
- 20 69. 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 fixation element is driven into said bone tissue.
- 25 70. A method for repairing a sacroiliac joint of a patient, comprising:
- a. creating a first incision in the patient's skin proximal to the patient's sacroiliac joint;

- b. inserting a first working channel into said first incision and spreading said sacroiliac joint with an inserted end of said first working channel;
- c. creating a void in said sacroiliac joint;
- d. inserting a fusion implant into said void, said fusion implant having at least one fixation element for engagement with bone tissue in an articular surface of at least one of the sacrum and the ilium of said sacroiliac joint;
- e. creating a second incision in the patient's skin over an iliac wing of the patient adjacent to said sacroiliac joint;
- f. inserting a second working channel into said second incision wherein a longitudinal axis of said second working channel does not intersect said sacroiliac joint; and
- g. inserting a joint fixation device into said ilium and said sacrum through said second working channel, wherein said joint fixation device does not traverse said sacroiliac joint.
71. The method of claim 70, further comprising rotating or driving said fusion implant after it is inserted into said void to engage said at least one fixation element with said bone tissue in said articular surfaces of the sacrum and the ilium in said sacroiliac joint.
72. The method of claim 70, wherein said first and second working channels are at an acute angle relative to each other.
73. The method of claim 72, wherein said first and second working channels are connected by a connecting bar having a bend therein.

74. The method of claim 73, wherein said acute angle allows said working channel to be engaged with a posterior side of the sacroiliac joint and said second working channel to be engaged with a posterior portion of the iliac wing simultaneously.

- 5 75. The method of claim 70, wherein the inserting the fusion implant comprises:
- a. attaching said fusion implant to an inserter, wherein the inserter has a proximal end configured to attach to the implant; and
 - b. inserting the inserter into a hollow barrel of said working channel until a stop slot within said hollow barrel and engaged with said inserter prevents
10 the inserter from moving further into said sacroiliac joint.

76. (Original) The method of claim 74, wherein said acute angle allows said working channel to be engaged with a posterior side of the sacroiliac joint and said second working channel to be engaged with a posterior portion of the iliac wing simultaneously.

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875				Application or Docket Number 16/689,073		Filing Date 11/19/2019		☐ To be Mailed			
ENTITY: ☐ LARGE ☒ SMALL ☐ MICRO											
APPLICATION AS FILED - PART I											
		(Column 1)		(Column 2)							
FOR		NUMBER FILED		NUMBER EXTRA		RATE (\$)		FEE (\$)			
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))		N/A		N/A		N/A					
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))		N/A		N/A		N/A					
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))		N/A		N/A		N/A					
TOTAL CLAIMS (37 CFR 1.16(i))		minus 20 = *				x \$50 =					
INDEPENDENT CLAIMS (37 CFR 1.16(h))		minus 3 = *				x \$230 =					
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))		If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).									
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))											
* If the difference in column 1 is less than zero, enter "0" in column 2.						TOTAL					
APPLICATION AS AMENDED - PART II											
		(Column 1)		(Column 2)		(Column 3)					
AMENDMENT	12/05/2019	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR		PRESENT EXTRA		RATE (\$)		ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(i))	* 25	Minus	** 25	= 0			x \$50 =		0	
	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		0	
		(Column 1)		(Column 2)		(Column 3)					
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR		PRESENT EXTRA		RATE (\$)		ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(i))	*	Minus	**	=			x \$0 =			
	Independent (37 CFR 1.16(h))	*	Minus	***	=			x \$0 =			
	☐ Application Size Fee (37 CFR 1.16(s))										
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))										
								TOTAL ADD'L FEE			
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.								LIE			
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".								/RENEE D HAWKINS/			
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No. _____)
Confirmation No. _____)
Applicant: Orthocision Inc.)
Examiner: unknown)
TC/Art Unit: unknown)
For: METHOD AND IMPLANT SYSTEM)
FOR SACROILIAC JOINT FIXATION)
AND FUSION)
Filed: herewith)

Certificate of Transmission

I hereby certify that this paper, together with any documents referred to as being attached, enclosed or submitted herewith, is being transmitted to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 via the USPTO EFS-Web filing system on November 19, 2019.

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

PRELIMINARY AMENDMENT

Honorable Commissioner for Patents
Alexandria, VA 22313

Dear Sir:

This preliminary amendment is submitted with the present application which is a continuation of Application No. 14/668,976 to submit replacement claims.

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

Remarks begin on **page 10** of this paper.

Listing of Claims:

1-31. (Canceled)

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

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

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

c. creating a void in said sacroiliac joint; and

15 d. inserting a fusion implant into said void, said fusion implant having at least one ~~fixation element~~ protrusion for engagement with bone tissue in an articular surface of at least one of the sacrum and the ilium of said sacroiliac joint.

33. (Canceled)

20 34. (Canceled)

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

25 36. (Currently Amended) The method of claim 32, wherein said fusion implant has a central body and said at least one ~~fixation element~~ protrusion extends laterally

from said central body, ~~and said working channel has a hollow barrel having a shape for receiving said joint fusion implant including said at least one lateral fixation element.~~

5 37. (Canceled)

38. (Canceled)

39. (Canceled)

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

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

42. (Canceled)

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43. (Original) The method of claim 41, wherein said fusion implant comprises a cavity for holding a fusion-promoting material.

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44. (Original) The method of claim 43, wherein said cavity comprises at least one hole therein for allowing the growth of bone tissue into said cavity.

45. (Canceled)

46. (Canceled)

30

47. (Currently Amended) The method of claim 32, wherein the inserting said fusion implant comprises:

- 5 a. attaching said fusion implant to an inserter having a slot-engagement protrusion, ~~wherein the inserter has a proximal end configured to attach to said fusion implant~~; and
- 10 b. inserting said inserter into a hollow barrel of said working channel with said slot-engagement protrusion aligned with ~~until a stop guidance slot~~ within said hollow barrel and advancing engaged with ~~said inserter prevents until said guidance slot arrests~~ limits the penetration of said inserter and said fusion implant from moving further into said sacroiliac joint ~~to a pre-determined depth~~.

48. (Canceled)

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

- 20 a. creating a first incision in the patient's skin proximal to the patient's sacroiliac joint;
- b. inserting a working channel of a surgical channel tool into said incision from the posterior of the patient, wherein said working channel includes an insertion control mechanism for controlling the advancement of surgical tools into said working channel;
- 25 c. creating a void in said sacroiliac joint;
- d. inserting a[[n]] fusion implant into said void using an inserter tool, said fusion implant having at least one ~~fixation element~~ 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 ~~fixation element~~protrusion engages with said bone tissue, ~~and said fusion implant fixes relative positions of said sacrum and said ilium.~~

50. (Canceled)

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

54. (Canceled)

55. (Canceled)

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 exterior of said body, ~~two flukes on said exterior of said body~~, and a hole in a proximal end of said body for accessing the interior of said cavity.

60. (Currently Amended) The method of claim ~~49~~51, wherein said fusion implant is operable to connect said sacrum to said ilium ~~and compress 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 ~~62~~49, wherein the inserting the fusion implant comprises:

- a. attaching said fusion implant to ~~an~~ said inserter tool, wherein said inserter tool has an insertion control protrusion, wherein the inserter has a proximal end configured to attach to the implant; and
- b. inserting the inserter tool into a hollow barrel of said working channel and engaging said insertion control protrusion with said insertion control mechanism and advancing the inserter tool until a stop slot ~~said insertion~~

control protrusion is arrested by the insertion control mechanism at a pre-determined point in the hollow barrel, ~~within said hollow barrel and engaged with said inserter tool is prevents-prevented the inserter from~~ moving the fusion implant further into said sacroiliac joint.

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68. (Canceled)

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

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70. (Canceled)

15 71. (Canceled)

72. (Canceled)

73. (Canceled)

20

74. (Canceled)

75. (Canceled)

25 76. (Canceled)

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

- a. creating an incision in the patient's skin in a position proximal to the patient's sacroiliac joint to allow access to the posterior portion of the sacroiliac joint;
- b. inserting a working channel of a surgical channel tool into said incision from the posterior of the patient, said working channel including at least one tang protruding from a distal end of the working channel and an insertion control mechanism for controlling the advancement of surgical tools into said working channel;
- c. creating a void in said sacroiliac joint;
- d. inserting a fusion implant using an inserter into said void on a path that is substantially parallel to articular surfaces of the sacroiliac joint, said inserter having an insertion control protrusion for engagement with said insertion control mechanism;
- e. advancing the inserter tool until said insertion control protrusion to a pre-determined point in the hollow barrel and placing said fusion implant into said sacroiliac joint, and said inserter tool is prevented from moving the fusion implant further into said sacroiliac joint; and
- f. driving said fusion implant into said void such that said fusion implant engages with said bone tissue.

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

79. (New) The method of claim 78, wherein said at least one protrusion comprises a helical anchor having a sharp end for piercing said bone tissue, and said helical anchor first penetrates said articular surface of said at least one of said sacrum and said ilium.
- 5 80. (New) The method of claim 77, wherein said fusion implant comprises a cavity for holding a fusion-promoting material.
81. (New) The method of claim 80, wherein said cavity comprises at least one hole
10 therein for allowing the growth of bone tissue into said cavity.
82. (New) The method of claim 80, wherein no further fusion implants are introduced into said sacroiliac joint and said fusion implant is sufficient to fuse the sacroiliac joint.
- 15 83. (New) The method of Claim 77, wherein said at least one tang secures a position of said working channel in said sacroiliac joint to avoid movement of said working channel during insertion of said fusion implant.
- 20 84. (New) The method of Claim 77, wherein engagement of said insertion control protrusion with said insertion control mechanism maintains said inserter and said fusion implant in proper orientation for insertion of the fusion implant into said sacroiliac joint.
- 25 85. (New) The method of claim 32, wherein the inserting said fusion implant comprises:
- a. attaching said fusion implant to an inserter having a slot-engagement protrusion; and

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

86. (New) The method of claim 49, wherein the inserting said fusion implant
comprises:

10 a. attaching said fusion implant to an inserter having a slot-engagement
element; and

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

REMARKS

The present specification is identical to that of predecessor patent application No. 14/668,982. Claims 1-31, 33-34, 37-39, 42, 45-46, 48, 50, 52, 54-58, 61-66, 68, and 70-76 have been canceled and claims 32, 35-36, 41, 47, 49, 51, 53, 59-60, 67, and 69 have been amended. New Claims 77-86 have been added. A total of 25 claims are pending, of which 3 are independent. Thus, additional claim fees for 5 claims in excess of 20 (\$250) are submitted along with the present application.

The office is authorized to charge any fees or credit any refunds associated with this paper to deposit account 600741.

Prompt processing of the within application is requested.

Dated: November 19, 2019.

Respectfully Submitted,

By /William K. Nelson/
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13079.02.USU05.preliminary amendment

Electronic Acknowledgement Receipt

EFS ID:	37943986
Application Number:	16689073
International Application Number:	
Confirmation Number:	8990
Title of Invention:	METHOD AND IMPLANT SYSTEM FOR SACROILIAC JOINT FIXATION AND FUSION
First Named Inventor/Applicant Name:	Troy Schifano
Customer Number:	13442
Filer:	William Kenneth Nelson
Filer Authorized By:	
Attorney Docket Number:	13079.02.USU05
Receipt Date:	05-DEC-2019
Filing Date:	19-NOV-2019
Time Stamp:	16:22:15
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		Prelim_amend_USU05.pdf	242024	yes	11
			c5e6a392fb9f320a9739dc48be5e82621e9c06a3		

Multipart Description/PDF files in .zip description			
Document Description	Start	End	
Preliminary Amendment	1	1	
Claims	2	10	
Applicant Arguments/Remarks Made in an Amendment	11	11	
Warnings:			
Information:			
Total Files Size (in bytes):		242024	
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875						Application or Docket Number 16/689,073			
APPLICATION AS FILED - PART I									
(Column 1)		(Column 2)		SMALL ENTITY		OTHER THAN SMALL ENTITY			
FOR	NUMBER FILED	NUMBER EXTRA	RATE(\$)	FEE(\$)		RATE(\$)	FEE(\$)		
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	75		N/A			
SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A	330		N/A			
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	380		N/A			
TOTAL CLAIMS (37 CFR 1.16(j))	25	minus 20 = * 5	x 50 =	250	OR				
INDEPENDENT CLAIMS (37 CFR 1.16(h))	3	minus 3 = *	x 230 =	0.00					
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).			200					
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				0.00					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL		TOTAL			
				1235					
APPLICATION AS AMENDED - PART II									
(Column 1)		(Column 2)		(Column 3)		SMALL ENTITY		OTHER THAN SMALL ENTITY	
AMENDMENT A	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)		RATE(\$)	ADDITIONAL FEE(\$)	
	Total (37 CFR 1.16(i))	*	Minus **	=	x =	OR	x =		
	Independent (37 CFR 1.16(h))	*	Minus ***	=	x =	OR	x =		
	Application Size Fee (37 CFR 1.16(s))					OR			
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					OR			
				TOTAL ADD'L FEE		TOTAL ADD'L FEE			
AMENDMENT B	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)		RATE(\$)	ADDITIONAL FEE(\$)	
	Total (37 CFR 1.16(i))	*	Minus **	=	x =	OR	x =		
	Independent (37 CFR 1.16(h))	*	Minus ***	=	x =	OR	x =		
	Application Size Fee (37 CFR 1.16(s))					OR			
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					OR			
				TOTAL ADD'L FEE		TOTAL ADD'L FEE			
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3. ** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20". *** 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 found in the appropriate box in column 1.									



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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	TOT CLAIMS	IND CLAIMS
16/689,073	11/19/2019		1235	13079.02.USU05	25	3

CONFIRMATION NO. 8990

FILING RECEIPT



0000000113173653

13442
Sierra IP Law, PC
P.O. Box 5637
Fresno, CA 93755-5637

Date Mailed: 12/09/2019

Receipt is acknowledged of this non-provisional utility patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF FIRST INVENTOR, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection.

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Inventor(s)

Troy Schifano, Morgantown, WV;
Steve Anderson, Folsom, CA;
Teck-Mun Soo, Southfield, MI;
Gowriharan Thaiyananthan, Irvine, CA;

Applicant(s)

Orthocision Inc., Folsom, CA;

Power of Attorney: None

Domestic Priority data as claimed by applicant

This application is a CON of 14/668,976 03/25/2015
which is a CIP of 13/842,227 03/15/2013 PAT 9119732

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see <http://www.uspto.gov> for more information.) - None.

Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

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The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 16/689,073**

Projected Publication Date: 03/19/2020

Non-Publication Request: No

Early Publication Request: No

**** SMALL ENTITY ****

Title

METHOD AND IMPLANT SYSTEM FOR SACROILIAC JOINT FIXATION AND FUSION

Preliminary Class

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

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

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Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

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

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15	Alphatec Spine, Inc., Description of Alphatec Solus® Anterior Lumbar Interbody Fusion, accessed on March 27th, 2015 from "http://www.alphatecspine.com/products/thoracolumbar/solus.asp"
16	MULLER et al., Bone screw, English Abstract of European Patent Publication of EP0374088, June 20, 1990, European Patent Organization, accessed from "http://www.epo.org/searching/free/espacenet.html."
17	ROSENMAN, D., Spiral surgical tack, English Abstract of European Patent Publication EP0663184, July 19, 1995 European Patent Organization, access from "http://www.epo.org/searching/free/espacenet.html"
18	LDR Holding Corporation, Description of the ALIF cage surgical implants, available on March 27th, 2015 from "http://us.ldr.com/portals/1/PDF/Products/ROI-A/Patienteducationobliqueiraopf1reva09.pdf"
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22	USPTO Non-patent literature Database Search 2, US Patent Application No. 13/842,227, March 30, 2015

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CERTIFICATION STATEMENT

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See attached certification statement.

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

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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)	2020-01-06
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:	38218089
Application Number:	16689073
International Application Number:	
Confirmation Number:	8990
Title of Invention:	METHOD AND IMPLANT SYSTEM FOR SACROILIAC JOINT FIXATION AND FUSION
First Named Inventor/Applicant Name:	Troy Schifano
Customer Number:	13442
Filer:	William Kenneth Nelson
Filer Authorized By:	
Attorney Docket Number:	13079.02.USU05
Receipt Date:	06-JAN-2020
Filing Date:	19-NOV-2019
Time Stamp:	20:00:22
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		16689073
	Filing Date		2019-11-19
	First Named Inventor	Schifano, Troy	
	Art Unit		
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6	20140135927	2014-05-00	Pavlov
7	20080009861	2008-01-00	Stark

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Signature	/William K. Nelson/	Date (YYYY-MM-DD)	2020-02-03
Name/Print	William K. Nelson	Registration Number	63501

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

Electronic Acknowledgement Receipt

EFS ID:	38475275
Application Number:	16689073
International Application Number:	
Confirmation Number:	8990
Title of Invention:	METHOD AND IMPLANT SYSTEM FOR SACROILIAC JOINT FIXATION AND FUSION
First Named Inventor/Applicant Name:	Troy Schifano
Customer Number:	13442
Filer:	William Kenneth Nelson
Filer Authorized By:	
Attorney Docket Number:	13079.02.USU05
Receipt Date:	03-FEB-2020
Filing Date:	19-NOV-2019
Time Stamp:	15:10:47
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)	20200203_IDS_2.pdf	612246	no	4
			9be0aa9d1293f304f0ddafe831d052402dbb2992		

Warnings:

Petitioner's Ex. 1013

Information:	
Total Files Size (in bytes):	612246
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.	

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

Certificate of Transmission

I hereby certify that this paper, together with any documents referred to as being attached, enclosed or submitted herewith, is being transmitted to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 via the USPTO EFS-Web filing system on February 3, 2020.

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

PRELIMINARY AMENDMENT

Honorable Commissioner for Patents
Alexandria, VA 22313

Dear Sir:

This preliminary amendment is submitted to amend the specification and drawings of the present application to include drawings and description provided in prior US Patent Application No. 13/842,227 (the “227 Application”, filed March 15, 2013, and issued as US Pat. No. 9,119,732), to which the present application claims priority and incorporates by reference. The present amendments are proper under 37 CFR § 1.57 (see also MPEP § 217).

Amendments to the **Drawings** are found on **page 2** of this paper.

Amendments to the **Specification** are found on **page 3** of this paper.

In the Drawings:

The specific changes in the replacement sheet are as follows:

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

In the Specification:

The specification is herein amended such that paragraphs referring to new FIGS. 126-128 in the Brief Description of the Drawings and in the Detailed Description of the Specification have been added. The specific changes to the specification are provided
5 below.

1. Please add new paragraphs [0149]-[0151] after original paragraph [0148] as follows:

10 [0149] FIG. 126 shows a perspective view of a fusion implant, according to an embodiment of the present invention.

[0150] FIG. 127 shows a side view of a fusion implant, according to an embodiment of the present invention.

15 [0151] FIG. 128 shows a cross-sectional view of a fusion implant, according to an embodiment of the present invention.

2. Please renumber subsequent paragraphs beginning with [0152].

3. Please add new paragraph [0229] after original paragraph [0225] as follows:

20 [0229] In some embodiments, and without limitation, the fusion implant may have a shape and features like the implant 151 shown in FIGS. 39 and 126-129. As an example, and without limiting the invention, the implant may be a bone graft as shown in FIGS. 126-129. The implant 151 may be substantially rectangular, having ribbing 153 on opposing sides to create a surface for catching or gripping with the SI joint when it is inserted. The implant 151 may also have a tapered proximal end
25 to be inserted into the SI joint to act as a wedge, facilitating insertion. The implant 151 may also have slots 152 for receiving forceps of an inserter, and transverse holes to allow bone tissue to grow through the implant and incorporate the implant into the native bone tissue, thereby fusing the SI joint.

30 4. Please renumber subsequent paragraphs beginning with [0230].

REMARKS

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

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

20 Dated: February 3, 2020.

Respectfully Submitted,

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

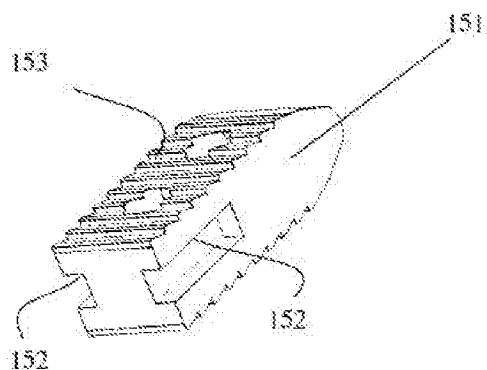


FIG. 126

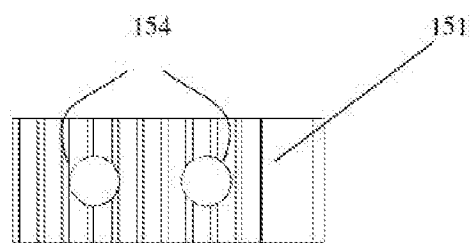


FIG. 127

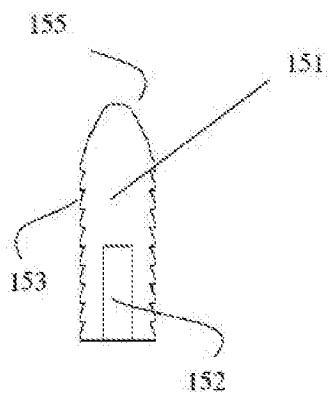


FIG. 128

Electronic Acknowledgement Receipt

EFS ID:	38481671
Application Number:	16689073
International Application Number:	
Confirmation Number:	8990
Title of Invention:	METHOD AND IMPLANT SYSTEM FOR SACROILIAC JOINT FIXATION AND FUSION
First Named Inventor/Applicant Name:	Troy Schifano
Customer Number:	13442
Filer:	William Kenneth Nelson
Filer Authorized By:	
Attorney Docket Number:	13079.02.USU05
Receipt Date:	04-FEB-2020
Filing Date:	19-NOV-2019
Time Stamp:	01:06:07
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		20200203_Prelim_amend_USU05.pdf	184844 aa6554ab4c28845842214227a4a7459967b11b16	yes	4

Multipart Description/PDF files in .zip description					
Document Description			Start	End	
Preliminary Amendment			1	1	
Drawings-only black and white line drawings			2	2	
Specification			3	3	
Applicant Arguments/Remarks Made in an Amendment			4	4	
Warnings:					
Information:					
2	Drawings-only black and white line drawings	FIGS_126_128.pdf	72758	no	1
			8e8e0c29e210cc9b05c1244ee43960f71af0dadd		
Warnings:					
Information:					
Total Files Size (in bytes):			257602		
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TRANSMITTAL FOR POWER OF ATTORNEY TO ONE OR MORE REGISTERED PRACTITIONERS

NOTE: This form is to be submitted with the Power of Attorney by Applicant form (PTO/AIA/82B) to identify the application to which the Power of Attorney is directed, in accordance with 37 CFR 1.5, unless the application number and filing date are identified in the Power of Attorney by Applicant form. If neither form PTO/AIA/82A nor form PTO/AIA82B identifies the application to which the Power of Attorney is directed, the Power of Attorney will not be recognized in the application.

Application Number	16689073
Filing Date	Nov. 19, 2019
First Named Inventor	Troy Schifano
Title	METHOD AND IMPLANT SYSTEM FOR SACROILIAC JOINT FIXATION AND FUSION
Art Unit	
Examiner Name	
Attorney Docket Number	13079.02.USU05

SIGNATURE of Applicant or Patent Practitioner

Signature	/William K. Nelson/	Date (Optional)	
Name	William K. Nelson	Registration Number	63501
Title (if Applicant is a juristic entity)			
Applicant Name (if Applicant is a juristic entity)			

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. If more than one applicant, use multiple forms.

☐

*Total of _____ forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. 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 3 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.**

POWER OF ATTORNEY BY APPLICANT

I hereby revoke all previous powers of attorney given in the application identified in either the attached transmittal letter or the boxes below.

Application Number	Filing Date
16/689,073	11-19-2019

(Note: The boxes above may be left blank if information is provided on form PTO/AIA/82A.)

☒ I hereby appoint the Patent Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above:

13442

OR

☐ I hereby appoint Practitioner(s) named in the attached list (form PTO/AIA/82C) as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the patent application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above. (Note: Complete form PTO/AIA/82C.)

Please recognize or change the correspondence address for the application identified in the attached transmittal letter or the boxes above to:

☒ The address associated with the above-mentioned Customer Number

OR

☐ The address associated with Customer Number:

OR

Firm or Individual Name				
Address				
City	State	Zip		
Country				
Telephone	Email			

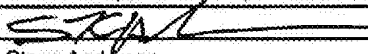
I am the Applicant (if the Applicant is a juristic entity, list the Applicant name in the box):

Orthocision, Inc.

- ☐ Inventor or Joint Inventor (title not required below)
- ☐ Legal Representative of a Deceased or Legally Incapacitated Inventor (title not required below)
- ☒ Assignee or Person to Whom the Inventor is Under an Obligation to Assign (provide signer's title if applicant is a juristic entity)
- ☐ Person Who Otherwise Shows Sufficient Proprietary Interest (e.g., a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document) (provide signer's title if applicant is a juristic entity)

SIGNATURE of Applicant for Patent

The undersigned (whose title is supplied below) is authorized to act on behalf of the applicant (e.g., where the applicant is a juristic entity).

Signature		Date (Optional)	3-1-20
Name	Steve Anderson		
Title	President		

NOTE: Signature - This form must be signed by the applicant in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. If more than one applicant, use multiple forms.

☐ Total of forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. 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 3 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.

Electronic Acknowledgement Receipt

EFS ID:	38733977
Application Number:	16689073
International Application Number:	
Confirmation Number:	8990
Title of Invention:	METHOD AND IMPLANT SYSTEM FOR SACROILIAC JOINT FIXATION AND FUSION
First Named Inventor/Applicant Name:	Troy Schifano
Customer Number:	13442
Filer:	William Kenneth Nelson
Filer Authorized By:	
Attorney Docket Number:	13079.02.USU05
Receipt Date:	02-MAR-2020
Filing Date:	19-NOV-2019
Time Stamp:	03:34:27
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	Assignee showing of ownership per 37 CFR 3.73	373_signed.pdf	454661	no	2
			33640ffec5220e8fab38fa127afc31a4e9e87259		

Warnings:

Petitioner's Ex. 1013

Information:					
2	Power of Attorney	POA.pdf	990116	no	2
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Warnings:					
Information:					
Total Files Size (in bytes):				1444777	
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.

STATEMENT UNDER 37 CFR 3.73(c)Applicant/Patent Owner: Schifano, et al.Application No./Patent No.: 16/689,073 Filed/Issue Date: 11-19-2019Titled: Method and Implant System for Sacroiliac Joint Fixation and Fusion

Orthocision, Inc. _____, a corporation

(Name of Assignee)

(Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that, for the patent application/patent identified above, it is (choose **one** of options 1, 2, 3 or 4 below):

1. ☒ The assignee of the entire right, title, and interest.
2. ☐ An assignee of less than the entire right, title, and interest (check applicable box):
- ☐ The extent (by percentage) of its ownership interest is _____%. Additional Statement(s) by the owners holding the balance of the interest must be submitted to account for 100% of the ownership interest.
- ☐ There are unspecified percentages of ownership. The other parties, including inventors, who together own the entire right, title and interest are:

Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

3. ☐ The assignee of an undivided interest in the entirety (a complete assignment from one of the joint inventors was made). The other parties, including inventors, who together own the entire right, title, and interest are:

Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

4. ☐ The recipient, via a court proceeding or the like (e.g., bankruptcy, probate), of an undivided interest in the entirety (a complete transfer of ownership interest was made). The certified document(s) showing the transfer is attached.

The interest identified in option 1, 2 or 3 above (not option 4) is evidenced by either (choose **one** of options A or B below):

- A. ☒ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel 051311, Frame 0266, or for which a copy thereof is attached.
- B. ☐ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as follows:
1. From: _____ To: _____
- The document was recorded in the United States Patent and Trademark Office at
- Reel _____, Frame _____, or for which a copy thereof is attached.
2. From: _____ To: _____
- The document was recorded in the United States Patent and Trademark Office at
- Reel _____, Frame _____, or for which a copy thereof is attached.

[Page 1 of 2]

This collection of information is required by 37 CFR 3.73(b). 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. 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.

Petitioner's Ex. 1013

STATEMENT UNDER 37 CFR 3.73(c)

3. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at
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The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

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6. From: _____ To: _____

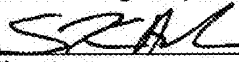
The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

☐ Additional documents in the chain of title are listed on a supplemental sheet(s).

☒ As required by 37 CFR 3.73(c)(1)(i), the documentary evidence of the chain of title from the original owner to the assignee was, or concurrently is being, submitted for recordation pursuant to 37 CFR 3.11.

[NOTE: A separate copy (i.e., a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, to record the assignment in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.



Signature

Steve Anderson

Printed or Typed Name


3-1, ~~2000~~ 2020
Date

President

Title or Registration Number

[Page 2 of 2]



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
16/689,073	11/19/2019	Troy Schifano	13079.02.USU05

CONFIRMATION NO. 8990

POA ACCEPTANCE LETTER

13442
Sierra IP Law, PC
P.O. Box 5637
Fresno, CA 93755-5637



Date Mailed: 03/03/2020

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 03/02/2020.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at (571) 272-4000 or (571) 272-4200 or 1-888-786-0101.

/sleutchit/



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
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www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
16/689,073	11/19/2019	Troy Schifano	13079.02.USU05

CONFIRMATION NO. 8990

13442
Sierra IP Law, PC
P.O. Box 5637
Fresno, CA 93755-5637

PUBLICATION NOTICE



OC000000115557823

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

Publication No.US-2020-0085480-A1

Publication Date:03/19/2020

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.

The publication may be accessed through the USPTO's publically available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently <http://www.uspto.gov/patft/>.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Public Records Division. The Public Records Division can be reached by telephone at (571) 272-3150 or (800) 972-6382, by facsimile at (571) 273-3250, by mail addressed to the United States Patent and Trademark Office, Public Records Division, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently <https://portal.uspto.gov/pair/PublicPair>. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 1-866-217-9197.

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

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

U.S.PATENTS						Remove
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	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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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		16689073
Filing Date		2019-11-19
First Named Inventor	Schifano,Troy	
Art Unit		
Examiner Name		
Attorney Docket Number	13709.02.USU05	

1	20120095560	2012-04-19	Donner
2	20100268228	2010-10-21	Petersen
3	20130172736	2012-01-03	Abdou
4	20160310197	2016-10-27	Black et al.
5	20156215184	2015-04-23	Black et al.
6	20160175113	2016-06-23	Lins
7	20146209512	2014-12-22	Lins
8	20140277165	2014-09-18	Katzman et al.

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FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ²	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T ⁵
	1							

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

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
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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**
(Not for submission under 37 CFR 1.99)

Application Number	16689073
Filing Date	2019-11-19
First Named Inventor	Schifano,Troy
Art Unit	
Examiner Name	
Attorney Docket Number	13709.02.USU05

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

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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.
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:	38971760
Application Number:	16689073
International Application Number:	
Confirmation Number:	8990
Title of Invention:	METHOD AND IMPLANT SYSTEM FOR SACROILIAC JOINT FIXATION AND FUSION
First Named Inventor/Applicant Name:	Troy Schifano
Customer Number:	13442
Filer:	William Kenneth Nelson
Filer Authorized By:	
Attorney Docket Number:	13079.02.USU05
Receipt Date:	26-MAR-2020
Filing Date:	19-NOV-2019
Time Stamp:	03:59:12
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)	20200326_IDS_3.pdf	612535	no	5
			561bc426a9ee8ffbf622dabb2dd617a9c5e3fcab		

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Total Files Size (in bytes):	612535
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	16689073
	Filing Date	2019-11-19
	First Named Inventor	Schifano,Troy
	Art Unit	
	Examiner Name	
	Attorney Docket Number	13709.02.USU05

U.S.PATENTS						Remove
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	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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Application Number	16689073
Filing Date	2019-11-19
First Named Inventor	Schifano,Troy
Art Unit	
Examiner Name	
Attorney Docket Number	13709.02.USU05

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NON-PATENT LITERATURE DOCUMENTS

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Application Number	16689073
Filing Date	2019-11-19
First Named Inventor	Schifano,Troy
Art Unit	
Examiner Name	
Attorney Docket Number	13709.02.USU05

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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)	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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EFS ID:	39119412
Application Number:	16689073
International Application Number:	
Confirmation Number:	8990
Title of Invention:	METHOD AND IMPLANT SYSTEM FOR SACROILIAC JOINT FIXATION AND FUSION
First Named Inventor/Applicant Name:	Troy Schifano
Customer Number:	13442
Filer:	William Kenneth Nelson
Filer Authorized By:	
Attorney Docket Number:	13079.02.USU05
Receipt Date:	10-APR-2020
Filing Date:	19-NOV-2019
Time Stamp:	02:18:38
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)	20200409_IDS_4.pdf	612119	no	4
			478289497f03b4385429dda6f0a385b5009ebdcc		

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

20 Certificate of Transmission

I hereby certify that this paper, together with any documents referred to as being attached,
enclosed or submitted herewith, is being transmitted to the Commissioner for Patents, P.O. Box
25 1450, Alexandria, VA 22313-1450 via the USPTO EFS-Web filing system on May 5, 2020.

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

30 PRELIMINARY AMENDMENT

Honorable Commissioner for Patents
Alexandria, VA 22313

Dear Sir:

35 This preliminary amendment is submitted to amend the specification and drawings
of the present application to include drawings and description provided in prior US Patent
Application No. 13/842,227 (the “227 Application”, filed March 15, 2013, and issued as
US Pat. No. 9,119,732), to which the present application claims priority and incorporates by
reference. The present amendments are proper under 37 CFR § 1.57 (see also MPEP § 217).

40 Amendments to the **Drawings** are found on **page 2** of this paper.

Amendments to the **Specification** are found on **page 3** of this paper.

In the Drawings:

The specific changes in the replacement sheet are as follows:

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

In the Specification:

The specification is herein amended such that paragraphs referring to new FIGS. 126-128 in the Brief Description of the Drawings and in the Detailed Description of the Specification have been added. The specific changes to the specification are provided
5 below.

1. Please add new paragraphs [0149]-[0151] after original paragraph [0148] as follows:

10 [0149] FIG. 126 shows a perspective view of a fusion implant, according to an embodiment of the present invention.

[0150] FIG. 127 shows a side view of a fusion implant, according to an embodiment of the present invention.

15 [0151] FIG. 128 shows a cross-sectional view of a fusion implant, according to an embodiment of the present invention.

2. Please renumber subsequent paragraphs beginning with [0152].

3. Please add new paragraph [0229] after original paragraph [0225] as follows:

20 [0229] In some embodiments, and without limitation, the fusion implant may have a shape and features like the implant 151 shown in FIGS. 39 and 126-129. As an example and without limiting the invention, the implant may be a bone graft as shown in FIGS. 126-129. The implant 151 may be substantially rectangular, having ribbing 153 on opposing sides to create a surface for catching or gripping with the SI joint when it is inserted. The implant 151 may also have a tapered proximal end
25 to be inserted into the SI joint to act as a wedge, facilitating insertion. The implant 151 may also have slots 152 for receiving forceps of an inserter, and transverse holes to allow bone tissue to grow through the implant and incorporate the implant into the native bone tissue, thereby fusing the SI joint.

30 4. Please renumber subsequent paragraphs beginning with [0230].

REMARKS

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

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

20 Dated: May 5, 2020.

Respectfully Submitted,

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

Serial No. 16/689,073

4

Preliminary Amendment

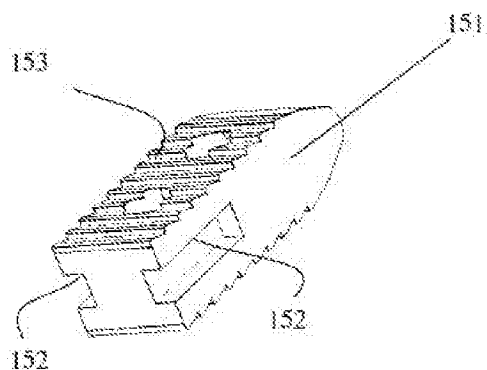


FIG. 126

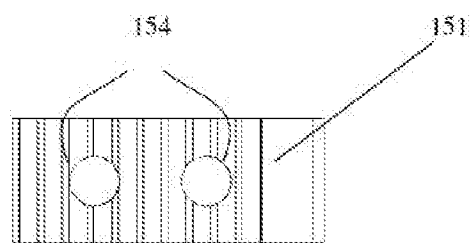


FIG. 127

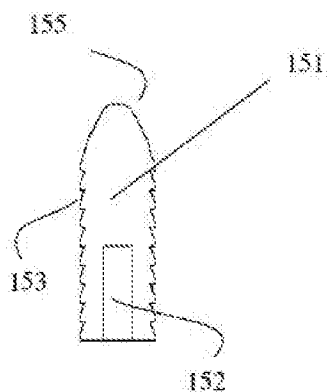


FIG. 128

Electronic Acknowledgement Receipt

EFS ID:	39361628
Application Number:	16689073
International Application Number:	
Confirmation Number:	8990
Title of Invention:	METHOD AND IMPLANT SYSTEM FOR SACROILIAC JOINT FIXATION AND FUSION
First Named Inventor/Applicant Name:	Troy Schifano
Customer Number:	13442
Filer:	William Kenneth Nelson
Filer Authorized By:	
Attorney Docket Number:	13079.02.USU05
Receipt Date:	06-MAY-2020
Filing Date:	19-NOV-2019
Time Stamp:	02:47:31
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		20200505_Prelim_amend_USU05.pdf	184752	yes	4
			43c3a6dc760a34785c9a415fe7a1f66e78b1d061		

	Multipart Description/PDF files in .zip description		
	Document Description	Start	End
	Preliminary Amendment	1	1
	Drawings-only black and white line drawings	2	2
	Specification	3	3
	Applicant Arguments/Remarks Made in an Amendment	4	4

Warnings:

Information:

2	Drawings-only black and white line drawings	FIGS_126_128.pdf	72758	no	1
			8e8e0c29e210cc9b05c1244ee43960f71af0dadd		

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Total Files Size (in bytes):	257510
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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.

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

U.S.PATENTS						Remove
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	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	16689073
Filing Date	2019-11-19
First Named Inventor	Schifano,Troy
Art Unit	
Examiner Name	MATTHEWS, TESSA M
Attorney Docket Number	13709.02.USU05

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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NON-PATENT LITERATURE DOCUMENTS

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

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

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

Application Number	16689073
Filing Date	2019-11-19
First Named Inventor	Schifano,Troy
Art Unit	
Examiner Name	MATTHEWS, TESSA M
Attorney Docket Number	13709.02.USU05

CERTIFICATION STATEMENT

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

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

OR

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

See attached certification statement.

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

☒ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/William K. Nelson/	Date (YYYY-MM-DD)	2020-10-14
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.**

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.
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:	40846604
Application Number:	16689073
International Application Number:	
Confirmation Number:	8990
Title of Invention:	METHOD AND IMPLANT SYSTEM FOR SACROILIAC JOINT FIXATION AND FUSION
First Named Inventor/Applicant Name:	Troy Schifano
Customer Number:	13442
Filer:	William Kenneth Nelson
Filer Authorized By:	
Attorney Docket Number:	13079.02.USU05
Receipt Date:	14-OCT-2020
Filing Date:	19-NOV-2019
Time Stamp:	17:56:01
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	2020_1014_IDS.pdf	612560	no	5
			6eb4a091471ea5ad0cd661f0ecfd3049798df937		

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Petitioner's Ex. 1013

Information:	
Total Files Size (in bytes):	612560
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		16689073
	Filing Date		2019-11-19
	First Named Inventor	Schifano, Troy	
	Art Unit		
	Examiner Name		
	Attorney Docket Number		13709.02.USU05

U.S. PATENTS						Remove
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	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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Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	20100106200		2010-04-29	Stark	
	2	20110184518		2011-07-28	Trieu	

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Application Number		16689073
Filing Date		2019-11-19
First Named Inventor	Schifano,Troy	
Art Unit		
Examiner Name		
Attorney Docket Number	13709.02.USU05	

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

Application Number	16689073
Filing Date	2019-11-19
First Named Inventor	Schifano,Troy
Art Unit	
Examiner Name	
Attorney Docket Number	13709.02.USU05

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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.

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

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

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The 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.
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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)).
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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:	42095352
Application Number:	16689073
International Application Number:	
Confirmation Number:	8990
Title of Invention:	METHOD AND IMPLANT SYSTEM FOR SACROILIAC JOINT FIXATION AND FUSION
First Named Inventor/Applicant Name:	Troy Schifano
Customer Number:	13442
Filer:	William Kenneth Nelson
Filer Authorized By:	
Attorney Docket Number:	13079.02.USU05
Receipt Date:	04-MAR-2021
Filing Date:	19-NOV-2019
Time Stamp:	20:36:24
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)	20210304_IDS_5.pdf	612208	no	4
			7c85fe0f433778d18abc91a0e01c2a17ed30aba4		

Warnings:

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

Certificate of Transmission

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

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

PRELIMINARY AMENDMENT

Honorable Commissioner for Patents
Alexandria, VA 22313

Dear Sir:

This preliminary amendment is submitted to amend the specification and drawings of the present application to include drawings and description provided in prior US Patent Application No. 13/842,227 (the “227 Application”, filed March 15, 2013, and issued as US Pat. No. 9,119,732), to which the present application claims priority and incorporates by reference. The present amendments are proper under 37 CFR § 1.57 (see also MPEP § 217), 37 CFR § 1.121, and MPEP § 714(I).

Amendments to the **Drawings** are found on **page 2** of this paper.

Amendments to the **Specification** are found on **page 3** of this paper.

5

10

UNITED STATES PATENT APPLICATION FOR

15

20

METHOD AND IMPLANT SYSTEM FOR SACROILIAC JOINT FIXATION AND
FUSION

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FIELD OF THE INVENTION

[0001] The present invention relates generally to medical devices and medical
5 methods. More particularly, the present invention relates to musculoskeletal surgical
methods and associated surgical tools for treatment of the sacroiliac joint.

DISCUSSION OF THE BACKGROUND

[0002] Lower back pain is a common ailment among the population and results in
10 both pain and suffering as well as loss of work time. Thus, approaches for the treatment
of back pain can both relieve suffering as well as reduce employee down time. Thus,
effective treatments for lower back pain have both economic benefits as well as the
benefit of alleviating considerable suffering.

[0003] The sacroiliac joint is located in the lower back at the juncture of the
15 ilium, the upper bone of the pelvis, and the sacrum at the base of the spine. While the
sacroiliac joint has a limited range of motion, dysfunction of the joint has been identified.
The joint is supported by a range of ligaments including, for example, the sacroiliac
ligament at the base of the joint and the anterior sacroiliac ligament at the top of the joint.

[0004] The sacroiliac joint (SI joint) is increasingly being diagnosed as a common
20 pain generator. That is, SI joint degenerative disease and instability are being diagnosed
and treated more commonly. Sacroiliac pain may be caused by a disruption in the joint
itself, a biomechanical problem like a muscle imbalance, trauma, an inflammatory
condition like ankylosing spondylitis, or a degenerative problem as seen with post-lumbar

fusion adjacent segment disorder. Other contributing factors include post pregnancy pain/instability, longer life span, and/or more active lifestyles. In addition, complex spine surgeries, such as for correction of sagittal plane deformity, often require iliac fixation to maintain correction in patients with a high pelvic incidence or high risk of lumbo-sacral hardware failure.

[0005] High energy pelvic ring injuries that involve disruption of the SI joint and/or displaced fractures of the sacrum present unique challenges to the orthopedic traumatologist. Some sacral fractures require solid posterior stabilization, which may be difficult to achieve with typical treatment methods. Furthermore, vertically unstable sacral fractures/SI joint disruptions have a relatively high incidence of neurovascular injury and may require unique stabilization. Typically, a spinal surgeon will be involved to perform lumbo-pelvic stabilization of these injuries to provide vertical stability of the injury. However, there may be significant soft tissue trauma associated with these injuries, making extensive surgical approaches of elevated risk in terms of infection and wound complications.

[0006] Immobilization of the SI joint can result in significant relief of lower back pain. Current techniques and instrumentation systems may require extensive surgical exposure and dissection. Moreover, such instrumentation systems are typically designed for other applications, and not to connect and stabilize the lumbar spine and pelvis. As a result, this can make the surgical times longer and more frustrating for surgeons and surgical staff. For example, traditional posterior iliac screws are often prominent because the posterior iliac crest is relatively subcutaneous. Yet, this sometimes makes hardware

painful for the patient and at risk for pressure soreness following surgery.

[0007] Furthermore, the current techniques and instruments do not allow for a secure and consistent fusion construct. They may provide one or the other many times, but not both issues. This may lead to further SI joint instability and a failed surgery.

5 **[0008]** It is therefore desirable to provide new surgical methods and tools for treating damaged sacroiliac joints that securely and consistently fuse the joint.

SUMMARY OF THE INVENTION

[0009] The present invention is an improved methods and devices for the
10 immobilization or fusion of the Sacroiliac joint and apparatuses for facilitating the procedure. Immobilization may refer to mechanical holding or surgical fusion.

[0010] The present invention provides a system and surgical tools for introducing fusion implants that may perform the functions of mechanical fixation and stability, compression, and bony fusion. The present invention also relates to improved implant
15 devices that may perform the functions of mechanical fixation and stability, compression, and bony fusion. The present invention also relates to methods of introducing fusion implants into a targeted joint through a novel exposure device. Specifically, with respect to some embodiments, an approach is described to address the SI joint through a posterior access approach while delivering fusion device that includes both a cavity or channel for
20 graft or fusion-promoting material and fixation elements which can be in the form of helical anchors, claw or fluke anchors, blades, screws, and/or other fixation elements, which provide for compression across the sacroiliac joint. In some embodiments, a

double barreled exposure device may be utilized to address the SI joint through a posterior approach while delivering both a fusion device to the SI joint and a separate fixation device for fixing the sacrum and ilium together, which can be in the form of a screw, or the like.

[0011] It is therefore an object of the present invention to provide an improved approach for both mechanical holding and surgical fusion through novel exposure devices described herein. The implants described herein may be introduced through a posterior approach to address the SI joint and the fusion device may perform the functions of fixation, compression, and bony fusion, providing a secure fixation element for mechanical stability and a bony fusion element that allows for fusion between the sacrum and the ilium.

[0012] It is also an object of the present invention to provide an improved, combined approach for both mechanical holding and surgical fusion using novel fusion devices that may be introduced through a novel exposure device through a posterior approach, while delivering a separate fixation device which can be in the form of a screw, or the like. Furthermore, the fusion device is delivered to the joint, placed between the sacrum and ilium, while the fixation device is delivered through the iliac wing, closest to the iliac crest, into the sacrum while not entering or going across the SI joint.

[0013] It is also an object of the present invention to provide novel fusion implants that are capable of performing perform the functions of fixation, compression, and bony fusion, allowing for stable fusion of the SI joint through a single posterior approach. However, such fusion implants may be used in combination with other devices to mechanically fix and stabilize the joint.

[0014] In some embodiments, the present invention relates to a fusion implant, comprising an elongate body adapted for placement in an intra-articular space between articular surfaces of a joint in general longitudinal alignment with a plane between the articular surfaces of the joint; at least one fixation element for engagement with bone tissue in at least one of the articular surfaces of the joint; and a cavity in the implant for holding a fusion-promoting material.

[0015] In some embodiments, the present invention relates to a medical instrument kit, including a joint fusion implant having a central body and at least one lateral fixation element for engagement with bone tissue in articular surfaces of a joint, and a surgical tool having a working channel for insertion into an incision (e.g., over a sacroiliac joint) in a human or animal, the working channel having a hollow barrel having a shape for receiving the joint fusion implant including the at least one lateral fixation element. The surgical tool may include at least one tang at the distal end thereof for insertion in a joint exposed by the incision, where the tang is operable to secure maintain a position of the working channel in the joint. In some implementations, and without limitation, the hollow barrel may have an oblong cross-sectional shape for accommodating the joint fusion implant and allowing the at least one fixation element to pass through the hollow barrel without obstruction, where the hollow barrel has a substantially uniform transverse cross section having a substantially elliptical shape and the elongate portions of the elliptical cross-section function as channels for receiving the at least one lateral fixation element. In some implementations, and without limitation, the hollow barrel may have at least one lateral slot running longitudinally along the hollow barrel to allow the at least

one fixation element to pass through the interior passage without obstruction. In some embodiments, and without limitation, the surgical tool may further include a second working channel that is inserted into a second incision over an iliac wing of the human patient adjacent to the sacroiliac joint when the working channel is inserted into the sacroiliac joint. In some implementations, and without limitation, the working channel and the second working channel are connected by a connecting bar having a bend therein, and are connected at an acute angle that allows the working channel to be engaged with a posterior side of the sacroiliac joint and the second working channel to be engaged with a posterior portion of the iliac wing simultaneously. The kit may further include additional instruments to establish the working channels in the first and second incisions, and for introducing the fusion implant into the SI joint and a joint fixation device (e.g., a surgical screw) into the ilium and sacrum without traversing the SI joint, including a drill operable to be passed through the working channel into the incision and drilling a void through the connective tissues in the SI joint, as well as drill bits; an inserter having a proximal end configured to attach to the fusion implant, the inserter being operable to pass the fusion implant through the hollow barrel and into the joint; an impactor for driving the fusion implant into the joint, wherein driving the fusion implant engages the at least one fixation element with articular surfaces in the joint; joint cutting instruments; dilators; guide wires; guide pins; guide pin assemblies; a rasp; a box chisel; a driver for inserting surgical screws (e.g., a flex-shaft driver); adjustable arms for stabilizing the working channels; and other tools that may be utilized in establishing incisions and access to a joint or bone tissue.

[0016] In some embodiments, the present invention relates to a method including creating an incision proximal to the patient's SI joint, dilating the incision, engaging an exposure device with the incision, creating a void in the SI joint, and inserting and securing a joint fusing device in the void between the ilium and sacrum.

5 **[0017]** In some embodiments, the present invention relates to a method including creating an incision proximal to the patient's SI joint, creating an incision over iliac wing, dilating the incisions, engaging the exposure device with both incisions, creating a void in the SI joint, inserting a graft into the void, drilling a hole through the ilium and the S1 vertebra of the sacrum, and inserting a joint fusing device in the ilium and sacrum.

10 **[0018]** In some embodiments, the present invention relates to a method for repairing a sacroiliac joint of a patient that includes creating a first incision in the patient's skin proximal to the patient's sacroiliac joint; inserting a first working channel into the first incision and spreading the sacroiliac joint with an inserted end of the first working channel; creating a void in the sacroiliac joint; inserting a fusion implant into the
15 void, the fusion implant having at least one fixation element for engagement with bone tissue in the articular surfaces of the sacrum and the ilium in the sacroiliac joint; creating a second incision in the patient's skin over an iliac wing of the patient adjacent to the sacroiliac joint; inserting a second working channel into the second incision wherein a longitudinal axis of the second working channel does not intersect the sacroiliac joint;
20 and inserting a joint fixation device into the ilium and the sacrum through the second working channel, wherein the joint fixation device does not traverse the sacroiliac joint.

[0019] In some embodiments, the present invention relates to a method including

preparing the patient for surgery (e.g., positioning the patient in a prone position to provide the surgeon access to the SI joint, general or local anesthesia, and the like), locating the SI joint and an incision point for access to the SI joint (e.g., by blunt finger palpation), insertion of a pin or wire to create an incision, insertion of a dilator over the pin and impacting the dilator to dilate the incision to a width through which instruments may be passed, inserting a working channel of an exposure device over the dilator, securing the working channel in position with fixing pins, removing the dilator, inserting a drill bit apparatus through the work channel, using the drill bit apparatus in the working channel to displace bone in the SI joint thereby creating a void, removing the drill bit apparatus, loading a joint fusion device into the first working channel until the joint fusion device is positioned proximal to the void in the patient's SI joint, inserting an impactor into the working channel and applying force to displace the graft into the void in the patient's SI joint, inserting a driver into the working channel, engaging the joint fusion device with the driver, and rotating the driver to rotate the joint fusion device such that anchoring devices on said joint fusion device engage with bone tissue of at least one of the sacrum and the ilium, removing all instruments, and closing the incision.

[0020] In some embodiments, the present invention relates to a joint fixation method including preparing the patient for surgery (e.g., positioning the patient in a prone position to provide the surgeon access to the SI joint, general or local anesthesia, and the like), locating the SI joint and an incision point for access to the SI joint (e.g., by blunt finger palpation), insertion of a pin or wire to create an incision, insertion of a dilator over the pin and impacting the dilator to dilate the incision to a width through which

instruments may be passed, inserting a working channel of an exposure device over the dilator, securing the working channel in position with fixing pins, removing the dilator, inserting a drill bit apparatus through the work channel, using the drill bit apparatus in the working channel to displace bone in the SI joint thereby creating a void, removing the
5 drill bit apparatus, excavating cortical bone tissue from articular surfaces within the joint, loading a joint fusion device into the first working channel until the joint fusion device is positioned proximal to the void in the patient's SI joint, inserting an impactor into the working channel and applying force to displace the joint fusion device into the void in the patient's SI joint, removing all instruments, and closing the incision.

10 **[0021]** In some embodiments, the present invention relates to a method of implanting a fusion device into a sacroiliac joint of a patient, including creating an incision in the patient's skin proximal to the patient's sacroiliac joint; using a joint probe to identify the sacroiliac joint; inserting a guide wire through a canal in the joint probe and into the sacroiliac joint; slotting a surgical channel device over the guide wire, the
15 surgical channel device having a working channel; creating a void in the sacroiliac joint, wherein creating the void comprises displacing a portion of the patient's ilium and a portion of the patient's sacrum with an inserted end of the working channel, inserting a drill bit into the working channel, and drilling the void into the sacroiliac joint; inserting a fusion implant into the void, wherein the fusion implant includes a plurality of fixation
20 elements and is configured to substantially compress, fix, and fuse the patient's ilium to the patient's sacrum; and engaging the fixation elements of the fusion implant with bone tissue in the articular surfaces of the patient's ilium and sacrum.

[0022] In some embodiments, the present invention relates to a method including preparing the patient for surgery (e.g., positioning the patient in a prone position to provide the surgeon access to the SI joint, general or local anesthesia, and the like), making a small incision over the top of the iliac wing from a posterior approach, locating
5 the SI joint and an incision point for access to the SI joint (e.g., by blunt finger palpation), insertion of a pin or wire to create an incision, insertion of a dilator over the pin and impacting the dilator to dilate the incision to a width through which instruments may be passed, inserting a first working channel of a double-barreled, double-angled exposure device over the dilator and inserting a second working channel of said exposure
10 device in the incision over the iliac wing, securing the first and second working channels in position with fixing pins, removing the dilator, inserting a drill bit apparatus through each of the first and second work channels, using the drill bit apparatus in the first working channel to displace bone in the SI joint thereby creating a void, using the drill bit apparatus (or a second drill bit apparatus) in the second working channel to drill a hole in
15 the iliac crest and the S1 vertebra of the sacrum, removing the drill bit apparatus, loading a graft onto an inserter and inserting the graft and inserter into the first working channel until the graft is positioned proximal to the void in the patient's SI joint, inserting an impactor into the first working channel and applying force to displace the graft into the void in the patient's SI joint, inserting a joint fusion device coupled to a fusion device
20 inserter into the second working channel and implanting said joint fusion device in the hole in the iliac crest and the sacrum, removing all instruments, and closing the incisions.

[0023] Additional objects of the invention will be apparent from the detailed

descriptions and the claims herein.

BRIEF DESCRIPTION OF THE DRAWINGS

- [0024] FIG. 1 is an anterior view of the bony anatomy of the pelvis and sacrum.
- 5 [0025] FIG. 2 is a posterior view of the bony anatomy of the pelvis and sacrum.
- [0026] FIG. 3 is a right lateral view of the bony anatomy of the pelvis and sacrum.
- [0027] FIG. 4 is a left lateral view of the bony anatomy of the pelvis and sacrum.
- [0028] FIG. 5 is a superior view of the bony anatomy of the pelvis and sacrum.
- [0029] FIG. 6 is an inferior view of the bony anatomy of the pelvis and sacrum.
- 10 [0030] FIG. 7 is an oblique view of the right sacroiliac joint.
- [0031] FIG. 8 is a perspective view of a joint probe.
- [0032] FIG. 9 is an enlarged view of the joint probe in FIG. 8.
- [0033] FIG. 10 is an end view of the joint probe in FIG. 8.
- [0034] FIG. 11 is a perspective view of a guide pin.
- 15 [0035] FIG. 12 is an end view of the guide pin in FIG. 11.
- [0036] FIG. 13 is a perspective view of a joint cutting instrument.
- [0037] FIG. 14 is an enlarged view of the joint cutting instrument in FIG. 13.
- [0038] FIG. 15 is an end view of the joint cutting instrument in FIG. 13.
- [0039] FIG. 16 is a perspective view of a t-handle addition for a joint cutting
20 instrument.
- [0040] FIG. 17 is an end view of the t-handle addition in FIG. 16.
- [0041] FIG. 18 is a perspective view of a joint cutting assembly.

[0042] FIG. 19 is an exploded, perspective view of the joint cutting assembly in FIG. 18.

[0043] FIG. 20 is a perspective view of a drill bit.

[0044] FIG. 21 is an end view of the drill bit in FIG. 20.

5 **[0045]** FIG. 22 is a perspective view of a fixation pin insertion assembly.

[0046] FIG. 23 is an exploded, perspective view of the fixation pin insertion assembly in FIG. 22.

[0047] FIG. 24 is a side view of a box chisel.

[0048] FIG. 25 is a side view of a rasp.

10 **[0049]** FIG. 26 is a perspective view of a bone graft impactor.

[0050] FIG. 27 is a perspective view of a surgical tool according to an embodiment of the present invention.

[0051] FIG. 28 is a side view of a surgical tool according to an embodiment of the present invention.

15 **[0052]** FIG 29 is a top view of a surgical tool according to an embodiment of the present invention.

[0053] FIG. 30 is a perspective view of a surgical tool according to an embodiment of the present invention.

20 **[0054]** FIG. 31 is a perspective view of a surgical tool according to an embodiment of the present invention.

[0055] FIG. 32A is a close-up perspective view of the distal end of a surgical tool according to an embodiment of the present invention, where the surgical includes tangs at a

distal end thereof.

[0056] FIG. 32B is a close-up perspective view of the distal end of a surgical tool according to an embodiment of the present invention, where the surgical includes tangs at a distal end thereof.

5 **[0057]** FIG. 33 is a perspective view of a surgical tool according to an embodiment of the present invention.

[0058] FIG. 34 is a side view of a surgical tool according to an embodiment of the present invention.

[0059] FIG. 35 is a top view of a surgical tool according to an embodiment of the present invention.
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[0060] FIG. 36 is a bottom view of a surgical tool according to an embodiment of the present invention.

[0061] FIG. 37 is an isolated, top view of a surgical tool according to an embodiment of the present invention.

15 **[0062]** FIG. 38 is a perspective view of a fusion implant inserter for use with a surgical tool according to an embodiment of the present invention.

[0063] FIG. 39 is a perspective view of a fusion implant inserter engaged with a fusion implant for use with a surgical tool according to an embodiment of the present invention

20 **[0064]** FIG. 40 is a cross sectional view of one barrel of a surgical tool according to an embodiment of the present invention.

[0065] FIG. 41 is a cross sectional, side view of one barrel a surgical tool according

to an embodiment of the present invention engaged with a fusion implant inserter.

[0066] FIG. 42 is a cross sectional, side view of one barrel a surgical tool according to an embodiment of the present invention engaged with a fusion implant inserter .

[0067] FIG. 43 is a cross sectional, side view of one barrel a surgical tool according
5 to an embodiment of the present invention fully engaged with a fusion implant inserter.

[0068] FIG. 44 is a perspective view of a fixation implant assembly.

[0069] FIG. 45 is an exploded, perspective view of a fixation implant assembly.

[0070] FIG. 46 is a perspective view of a fixation implant insertion assembly.

[0071] FIG. 47 is an exploded, perspective view of a fixation implant insertion
10 assembly.

[0072] FIG. 48 is a perspective view of an adjustable rack for attaching working channels according to an embodiment of the present invention.

[0073] FIG. 49 is a perspective view of a fusion implant having helical fixation elements according to an embodiment of the present invention.

15 **[0074]** FIG. 50 is a side perspective view of a fusion implant having helical fixation elements according to an embodiment of the present invention.

[0075] FIG. 51 is a distal view of a fusion implant having helical fixation elements according to an embodiment of the present invention.

[0076] FIG. 52 is a perspective view of a fusion implant having a helical fixation
20 element according to an embodiment of the present invention.

[0077] FIG. 53 is a side view of a fusion implant having a helical fixation element according to an embodiment of the present invention.

[0078] FIG. 54 is a distal view of a fusion implant having a helical fixation element according to an embodiment of the present invention.

[0079] FIG. 55 is an oblique, posterior view of the sacroiliac joint with a fusion implant having helical fixation elements placed in the sacroiliac joint through a posterior approach according to an embodiment of the present invention.

[0080] FIG. 56 is a perspective view of a fenestrated sacroiliac fusion implant having lateral flukes according to an embodiment of the present invention.

[0081] FIG. 57 is a side perspective view of a fenestrated sacroiliac fusion implant having lateral flukes according to an embodiment of the present invention.

[0082] FIG. 58 is an oblique, posterior view of the sacroiliac joint with a fenestrated fusion implant having lateral flukes placed in the sacroiliac joint through a posterior approach according to an embodiment of the present invention.

[0083] FIG. 59 is a perspective view of an open-body, compression screw sacroiliac fusion implant according to an embodiment of the present invention.

[0084] FIG. 60 is a superior view of an open-body, compression screw sacroiliac fusion implant according to an embodiment of the present invention.

[0085] FIG. 61 is a side view of an open-body, compression screw sacroiliac fusion implant according to an embodiment of the present invention.

[0086] FIG. 62 is an oblique, posterior view of the sacroiliac joint with an open-body, compression screw sacroiliac fusion implant placed in the sacroiliac joint through a posterior approach according to an embodiment of the present invention.

[0087] FIG. 63 is a perspective view of an open-body sacroiliac fusion implant

having lateral blades according to an embodiment of the present invention.

[0088] FIG. 64 is a superior view of an open-body sacroiliac fusion implant having lateral blades according to an embodiment of the present invention.

[0089] FIG. 65 is a perspective view of an open-body sacroiliac fusion implant
5 having detachable lateral blades according to an embodiment of the present invention.

[0090] FIG. 66 is a perspective view of a detached lateral blade for an open-body sacroiliac fusion implant according to an embodiment of the present invention.

[0091] FIG. 67 is an oblique, posterior view of the sacroiliac joint with an open-body sacroiliac fusion implant having lateral blades placed in the sacroiliac joint through a
10 posterior approach according to an embodiment of the present invention .

[0092] FIG. 68 is a perspective view of an open-body sacroiliac fusion implant having a rotatable member with lateral flukes according to an embodiment of the present invention.

[0093] FIG. 69 is a proximal view of an open-body sacroiliac fusion implant having
15 a rotatable member with lateral flukes according to an embodiment of the present invention.

[0094] FIG. 70 is a side view of an open-body sacroiliac fusion implant having a rotatable member with lateral flukes according to an embodiment of the present invention.

[0095] FIG. 71 is an oblique posterior view of the sacroiliac joint.

[0096] FIG. 72 is an oblique posterior view of the sacroiliac joint and a joint probe.

20 **[0097]** FIG. 73 is an oblique posterior view of the sacroiliac joint and a joint probe with the joint probe identifying the SI joint.

[0098] FIG. 74 is an enlarged oblique posterior view of the sacroiliac joint and a

joint probe with the joint probe identifying the SI joint.

[0099] FIG. 75 is an oblique posterior view of the SI joint and a joint probe with a guide pin marking the SI joint.

[00100] FIG. 76 is an oblique posterior view of an SI joint with a joint cutting
5 instrument entering the joint.

[0100] FIG. 77 is an enlarged oblique posterior view of an SI joint with a joint cutting instrument entering the joint.

[0101] FIG. 78 is an oblique posterior view of a surgical tool according to an embodiment of the present invention inserted into an SI joint.

10 **[0102]** FIG. 79 is an oblique posterior view of a joint cutting assembly and a surgical tool according to an embodiment of the present invention inserted into an SI joint.

[0103] FIG. 80 is an oblique posterior view of an SI joint with a surgical tool according to an embodiment of the present invention and a fixation pin assembly.

[0104] FIG. 81 is an enlarged oblique posterior view displaying a fixation pin
15 assembly and a surgical tool according to an embodiment of the present invention.

[0105] FIG. 82 is an oblique posterior view of a surgical tool according to an embodiment of the present invention inserted into an SI joint with the guide pins marking implant placements.

[0106] FIG. 83 is an enlarged, superior view of a surgical tool according to an
20 embodiment of the present invention inserted into an SI joint with the guide pins marking implant placements.

[0107] FIG. 84 is an oblique posterior view of a surgical tool according to an

embodiment of the present invention inserted into an SI joint with drill bits present in working channel of the surgical tool.

[0108] FIG. 85 is an enlarged oblique posterior view of a surgical tool according to an embodiment of the present invention inserted into an SI joint with drill bits present in working channel of the surgical tool.

[0109] FIG. 86 is an oblique posterior view of a surgical tool according to an embodiment of the present invention inserted into an SI joint with a box chisel inserted into a working channel of the surgical tool.

[0110] FIG. 87 is an enlarged oblique posterior view of a box chisel inserted into an SI joint, with a working channel removed from view for clarity.

[0111] FIG. 88 is an oblique posterior view of a surgical tool according to an embodiment of the present invention inserted into an SI joint with a rasp inserted into a working channel of the surgical tool.

[0112] FIG. 89 is an enlarged oblique posterior view of a rasp inserted into an SI joint, with a working channel removed from view for clarity.

[0113] FIG. 90 is an oblique posterior view of a surgical tool according to an embodiment of the present invention inserted into an SI joint with a fusion implant inserter inserted into a working channel of the surgical tool.

[0114] FIG. 91 is an oblique posterior view of a surgical tool according to an embodiment of the present invention inserted into an SI joint with an impactor inserted into a working channel of the surgical tool.

[0115] FIG. 92 is an oblique posterior view of an SI joint with a joint cutting

instrument entering the joint.

[0116] FIG. 93 is an enlarged oblique posterior view of an SI joint with a joint cutting instrument entering the joint.

[0117] FIG. 94 is an oblique posterior view of a surgical tool engaged with the
5 sacroiliac joint and the iliac wing according to an embodiment of the present invention inserted into an SI joint.

[0118] FIG. 95 is an oblique posterior view of a joint cutting assembly and a surgical tool engaged with the sacroiliac joint and the iliac wing according to an embodiment of the present invention inserted into an SI joint.

10 **[0119]** FIG. 96 is an oblique posterior view of an SI joint with a surgical tool and a fixation pin assembly engaged with the sacroiliac joint and the iliac wing according to an embodiment of the present invention.

[0120] FIG. 97 is an enlarged oblique posterior view displaying a fixation pin assembly and a surgical tool engaged with the sacroiliac joint and the iliac wing according
15 to an embodiment of the present invention.

[0121] FIG. 98 is an oblique posterior view of a surgical tool with the guide pins engaged with the sacroiliac joint and the iliac wing according to an embodiment of the present invention inserted into an SI joint.

[0122] FIG. 99 is an enlarged, superior view of a surgical tool with the guide pins
20 engaged with the sacroiliac joint and the iliac wing according to an embodiment of the present invention.

[0123] FIG. 100 is a superior view of guide pin placements according to an

embodiment of the present invention.

[0124] FIG. 101 is an enlarged superior view of guide pin placements according to an embodiment of the present invention.

5 **[0125]** FIG. 102 is an enlarged, posterior view of guide pin placements according to an embodiment of the present invention.

[0126] FIG. 103 is an anterior view of a surgical tool according to an embodiment of the present invention inserted into an SI joint with guide pins for guiding fusion implant placement.

10 **[0127]** FIG. 104 is a superior view of a surgical tool according to an embodiment of the present invention engaged into an SI joint with guide pins for guiding fusion implant placement.

[0128] FIG. 105 is an oblique posterior view of a surgical tool according to an embodiment of the present invention engaged with an SI joint and the iliac wing with drill bits present in working channels of the surgical tool.

15 **[0129]** FIG. 106 is an enlarged oblique posterior view of a surgical tool according to an embodiment of the present invention engaged with an SI joint and the iliac wing with drill bits present in working channels of the surgical tool.

[0130] FIG. 107 is an oblique posterior view of a surgical tool according to an embodiment of the present invention engaged with an SI joint and the iliac wing with a box chisel inserted into a working channel of the surgical tool.

20 **[0131]** FIG. 108 is an enlarged oblique posterior view of a box chisel inserted into an SI joint, with a working channel removed from view for clarity.

[0132] FIG. 109 is an oblique posterior view of a surgical tool according to an embodiment of the present invention engaged with an SI joint and the iliac wing with a rasp inserted into a working channel of the surgical tool.

[0133] FIG. 110 is an enlarged oblique posterior view of a rasp inserted into an SI joint, with a working channel removed from view for clarity.

[0134] FIG. 111 is an oblique posterior view of a surgical tool according to an embodiment of the present invention engaged with an SI joint and the iliac wing with an impactor inserted into a working channel of the surgical tool.

[0135] FIG. 112 is an enlarged oblique posterior view of an impactor inserted into an SI joint, with a working channel removed from view for clarity.

[0136] FIG. 113 is an oblique posterior view of a surgical tool according to an embodiment of the present invention inserted into an SI joint with a fusion implant inserter placed in a working channel of the surgical tool.

[0137] FIG. 114 is an oblique posterior view of a surgical tool according to an embodiment of the present invention inserted into an SI joint with an impactor inserted into a working channel of the surgical tool.

[0138] FIG. 115 is an enlarged, oblique view of a fusion implant and a fixation implant in place in the sacroiliac joint and the iliac wing and sacrum, respectively, where the fixation implant does not pass through the sacroiliac joint.

[0139] FIG. 116 is an enlarged, superior view of a fusion implant and a fixation implant in place in the sacroiliac joint and the iliac wing and sacrum, respectively.

[0140] FIG. 117 is a posterior view of a pelvis with a surgical tool according to an

embodiment of the present invention inserted into an SI joint.

[0141] FIG. 118 is a posterior view of a pelvis with a surgical tool according to an embodiment of the present invention with two independent working channels, one inserted into an SI joint and one positioned over an iliac crest.

5 **[0142]** FIG. 119 is a posterior view of a pelvis with a surgical tool according to an embodiment of the present invention with two independent working channels attached by an adjustable rack.

[0143] FIG. 120 is a posterior view of a pelvis with a surgical tool according to an embodiment of the present invention with two parallel barrels.

10 **[0144]** FIG. 121 is an enlarged posterior view showing two fusion implants inserted in an SI joint.

[0145] FIG. 122 is a posterior view of a pelvis with a surgical tool according to an embodiment of the present invention with two independent working channels, one inserted into an SI joint and one inserted over an iliac crest. The working channel inserted into the SI
15 joint may have two barrels for the placement of two fusion devices in the SI joint.

[0146] FIG. 123 is an enlarged posterior view showing two fusion devices inserted in an SI joint and one fixation device in the ilium.

[0147] FIG. 124 is a superior view showing two fusion devices inserted in an SI joint and one fixation device in the ilium.

20 **[0148]** FIG. 125 is a posterior view of a pelvis with two surgical tools according to an embodiment of the present invention with a bilateral placement of the two surgical tools for the placement of bilateral implants.

[0149] FIG. 126 shows a perspective view of a fusion implant, according to an embodiment of the present invention.

[0150] FIG. 127 shows a side view of a fusion implant, according to an embodiment of the present invention.

5 **[0151]** FIG. 128 shows a cross-sectional view of a fusion implant, according to an embodiment of the present invention.

DETAILED DESCRIPTION

[0152] Reference will now be made in detail to certain embodiments of the invention, examples of which are illustrated in the accompanying drawings. While the invention will be described in reference to these figures and certain implementations and examples of the embodiments, it will be understood that such implementations and examples are not intended to limit the invention. To the contrary, the invention is intended to cover alternatives, modifications, and equivalents that are included within the spirit and scope of the invention as defined by the claims. In the following disclosure, specific details are given to provide a thorough understanding of the invention. References to various features of the "present invention" throughout this document do not mean that all claimed embodiments or methods must include the referenced features. It will be apparent to one skilled in the art that the present invention may be practiced without these specific details or features.

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[0153] Reference will be made to the exemplary illustrations in the accompanying drawings, and like reference characters may be used to designate like or corresponding parts

throughout the several views of the drawings.

[0154] The present invention relates to novel fusion implants and surgical tools designed for repairing a damaged or injured sacroiliac joint in a human patient, and methods for using such fusion implants and tools in procedures for repairing the damaged or injured sacroiliac joint. More specifically, the present invention pertains to a method for compressing, fixing, and fusing a damaged sacroiliac joint using a fusion implant having fixation element(s) (e.g., integrally formed fixation elements) and a channel or cavity for holding bone growth-promoting materials that provides for mechanical stability and promotes the formation of a contiguous piece of bone from the sacrum to the ilium. The fusion implants may be applied to the SI joint through a novel surgical tool (e.g., an exposure device) without the need for additional patient positioning or secondary surgery.

[0155] With respect to some embodiments, an approach is described to address the SI joint through a posterior approach while delivering a fusion implant device that may both compress and fix the SI joint and deliver bone growth-promoting material (e.g., autologous bone, allograft, BMP, etc.). The fusion implant may be delivered to the joint, placed between the sacrum and ilium, and one or more fixation elements (e.g., integral fixation elements) of the fusion implant may be engaged with bone tissue in the articular surfaces of the sacrum and ilium of the patient to thereby compress and fix the SI joint. In some embodiments, an additional fixation device may be delivered through the iliac wing and into the sacrum to assist in mechanically fixing the ilium and sacrum together, without the fixation device entering or traversing the SI joint.

[0156] An exemplary exposure device may include a working channel for guiding

various surgical tools during a minimally invasive SI joint repair procedure. The surgical tool may allow the insertion of a fusion implant into the SI joint through the working channel in the surgical tool and guide the placement of the fusion implant into the SI joint. The tool enables a minimally invasive surgical method for repairing an SI joint that results in a secure, consistent, and reliable fusion of the SI joint. The surgical tool enables the insertion of the fusion implant into the SI joint while avoiding damage to the soft and connective tissues in and around the SI joint by closely controlling the placement of the fusion implant. The surgical tool may have a barrel or cannula through which the fusion implant is passed into the SI joint that has an interior perimeter shape that is complementary to and/or accommodative of the perimeter shape of the fusion implant. For example, and without limitation, the fusion implant may have lateral fixation elements (e.g., flukes or blades) for engaging with bone tissue in the articular surfaces of the sacrum and/or ilium within the sacroiliac joint, and the interior of the cannula or barrel may have an oblong or elliptical cross-sectional shape or lateral slots such that the lateral fixation elements of the fusion implant can be passed through the barrel or cannula without obstruction. The matching of the perimeter shapes of the interior of the barrel and the fusion implant may also allow the fusion implant to be properly oriented for placement in the SI joint. In some examples, and without limitation, the interior of the barrel may also include longitudinal notches that may be engaged with tabs or protrusions on the fusion implant in order to maintain proper orientation of the fusion implant within the barrel.

[0157] In some embodiments, the exposure device may include an additional working channel that is placed laterally to the SI working channel and over the iliac wing.

The additional working channel may allow for the insertion of a fixation device (e.g., surgical screw) into the ilium and sacrum to aid in mechanically securing the SI joint. The additional channel may enable the insertion of a joint fixation device (e.g., a screw or other stabilizing device) into the ilium and sacrum such that the additional joint fixation device
5 does not enter or traverse (pass through) the SI joint, thereby further avoiding damage to connective tissue of the SI joint.

Relevant anatomy description

[0158] Referring to the drawings, FIG. 1 displays the bony anatomy of the sacrum
10 and pelvis in a frontal, or anterior, view. The SI joint 102 is located between the ilium, or iliac wing, 100 and the sacrum 101 at the base of the pelvis 201. Additionally, the ridgeline of the articular process, the lateral ala 203 and the pedicle 104 of vertebrae S1 can be observed in this view. In FIG. 2, it can be seen that the SI joint 102 is not fully exposed for direct visualization from a rear, or posterior, viewpoint due to the angled and
15 raised iliac crest 200 of the iliac wing 100. This angle provides a landmark for the entry point of the exposure device of the present invention at the posterior iliac crest. In FIG. 3 and FIG. 4, the prominence of the iliac crest 200 is displayed, along with the large surface area of the iliac wing 100, while the SI joint is fully enclosed between the iliac wing 100 and the sacrum 101 and occluded for direct visualization by the iliac wing 100.
20 Again, the landmark of the posterior iliac crest can be seen. From a top down view, or superior view, the sacroiliac joint 102 can be fully observed between the iliac wing 100 and the sacrum 101, as shown in FIG. 5. Also shown in FIG. 5, the full sacrum 101 and

specifically the vertebral body 103 of S1. The posterior superior iliac crest and the entry point of the S1 pedicle 104 can be observed in a direct line from one another (see also FIGS. 110-111).

[0159] In FIG. 6, it can be again observed that the SI joint is occluded from direct

5 visualization due to the anatomy of the sacrum 101, the ilium 100 and the pelvis 201.

Therefore, the only direct visualization of the SI joint can be achieved through an anterior, superior or posterior-oblique view of the sacrum and pelvis. Due to major

organs being present in the pelvic-sacral cavity (colon, rectum, bladder, etc.), an anterior or superior approach to the bony anatomy and, specifically the SI joint, presents an

10 unreasonable risk. Lateral approaches can be performed as described in Published US Patent Serial Number 5,334,205 to Cain, entitled "Sacroiliac Joint Fixation Guide,"

incorporated herein by reference and Published US Patent Serial Number 8,221,428 to Trieu, entitled "Sacro-iliac joint implant system, method and instrument," incorporated

herein by reference. However, these techniques rely on non-direct confirmation methods

15 such as navigation and fluoroscopy to determine accurate landmark and sacroiliac joint locations.

[0160] The present invention provides for novel surgical techniques and novel

fusion implant and instrument designs which allow for a direct visualization of the SI joint by utilizing a posterior-oblique access method to the anatomy as displayed in the

20 oblique view of FIG. 7. In this drawing, the SI joint 102 can be clearly viewed between the right ilium 100 and sacrum 101. A corresponding joint may be exposed through the

same approach on the left hand side. Additionally, the anatomical landmark of the right

posterior iliac crest and the corresponding access to the S1 pedicle 104 can be seen through this approach.

Instruments

5 **[0161]** The present invention utilizes a novel exposure device and a surgical tool kit that may be used in a novel surgical method to introduce and secure a fusion implant in a patient's SI joint. The present invention also relates to novel fusion implants that may be implanted into the SI joint, for example, by the novel surgical tools and methods of the present invention. Exemplary tools are described herein.

10 **[0162]** The novel exposure device may be a surgical guiding tool having a working channel therein for guiding other surgical tools for use in repairing an SI joint.

[0163] FIGS. 27-32B, show exemplary exposure devices 137 and 137a for accessing a sacroiliac joint is shown, having a working channel 239 that may be engaged with a posterior side of the sacroiliac joint. The working channels of the exposure devices
15 may have a hollow barrel therein for passing various surgical tools that may have a shape corresponding to (complementary to) the hollow barrel. The working channel may provide a guide for inserting the various surgical tools into the SI joint, allowing precise surgical incisions, insertions of the fusion implant, etc. The barrel of the working channel may have an interior perimeter shape that is complementary to and/or accommodative of the perimeter
20 shape of a fusion implant may be passed into the SI joint. The matching of the perimeter shapes of the interior of the barrel and the fusion implant may allow the fusion implant to be properly oriented for placement in the SI joint. For example, and without limitation, the

exemplary exposure device 137 has a barrel having a substantially circular interior cross-section that may accommodate fusion implants that have circular cross-section (e.g., a helical implant) or a cross-section having a greatest diameter that is less than the diameter of the interior cross-section of the barrel.

5 **[0164]** In a further example, and without limitation, the barrel exposure device 137a may have an oblong or elliptical interior cross-section 190a, where the elongated portions of the barrel (e.g., the portions of the interior cross-section of the barrel that near the end of the major axis of the elliptical shape) act as channels through which lateral extensions of a fusion implant (e.g., a fusion implant having flukes or blades) may pass without obstruction.

10 The interior of the barrel may have other shapes as well. For example, and without limitation, the interior perimeter of the barrel may have two lateral slots spaced at about 180° from one another in order to accommodate two lateral flukes, hooks, or blades extending from a body of an SI fusion implant. The working channel 239 may also have one or more pin guide slots 139 on one or more sides thereof for insertion of fixing pins to
15 immobilize the exposure device 137 or 137a when it is engaged with the SI joint. In other implementations, and without limitation, a stabilizing arm (e.g., a retractor arm- not shown) may be engaged with a handle 140 and/or slot 141 in the handle in order hold the exposure device in a static and stable position.

20 **[0165]** The working channel 239 may have one or more windows 138 in the sides of the hollow barrel allowing the progress of a tool inserted therein to be observed through the one or more windows. For example, a surgical implement (e.g., a dilator) inserted into the hollow barrel of working channel 239 may have notches and/or unit markings on a side

thereof that are visible through the one or more windows 138, allowing the progress and depth of the surgical implement to be precisely known. The windows 138 may also allow access to the surgical implements inserted into the working channel. If a surgical implement becomes difficult to remove during a surgical procedure due to the presence of fluid in the hollow barrel of the working channel (e.g., creating suction), appropriate tools can be used to access the surgical instrument through the window(s) 138 to aid in the removal of the surgical implement.

[0166] Referring to FIG. 29, the hollow barrel of the working channel 239 may have a slot 146 (e.g., a timing feature) that arrests the progress of a surgical implement inserted into the hollow barrel of the channel. The slot 146 prevents the surgical implement from advance too far into the SI joint or the ilium and sacrum, thereby preventing damage to the tissue of the patient. The surgical implements used in connection with the exposure device 137 may have a protrusion that is complementary to the slot 146, such that the slot is effective in controlling a depth to which the surgical implement can be inserted. The slot 146 also may ensure that such surgical implements having a complementary protrusion are and remain properly oriented in the hollow barrel of the working channel, with no axial movement, during the surgical procedure.

[0167] The hollow barrel of the working channel may also have guiding slots therein for properly aligning instruments (e.g., a fusion implant inserter, an impactor, etc.) and/or fusion implants for passage through the hollow barrel. The guiding slots may engage notches or protrusions on the instruments or implants such that the notches or protrusions slide along the guiding slots as the instrument or fusion implant is advanced

through the hollow barrel. For example, and without limitation, guiding slots 146a are shown in the hollow barrel of exposure device 137a in FIG. 31. The guiding slots 146a are located at 180° relative to one another in the hollow barrel, but the invention is not limited to such an arrangement. Various implementations of the exposure device of the present invention may have one or more guiding slots (e.g., 1, 2, 3, etc.) and they may be arranged in various spatial arrangements within the hollow barrel.

[0168] The insertable end 142 of the working channel 239 may have a rounded circular or oblong geometry that prevents or reduces damage to the soft and connective tissues in and around the posterior side of the SI joint. Guide channels having other shapes (e.g., rectangular or square) may damage soft tissues around the SI joint when the guide channel is inserted therein. The round geometry of the insertable end 142 favorably reduces or prevents such damage. The round or circular insertable end 142 may also have a tapered or rounded profile, which may further aid in reducing or preventing damage to the soft and connective tissues around the SI joint. It is to be appreciated that the present invention is not limited to working channels having round, circular, or rounded ends. The working channels may have other perimeter shapes circular, oval, triangular, polygonal (pentagonal, hexagonal, etc.), Reuleaux shapes, and other applicable shapes.

[0169] The insertable end of the working channel may also include one or more prongs or tangs that extend beyond the end of the hollow barrel. The one or more prongs or tangs may allow the working channel to be more easily centered in the SI joint (e.g., with the tangs aligned along the plane between the articular surfaces of the SI joint), and may also serve to help stabilize the position of the working channel in the SI joint. For

example, and without limitation, FIGS. 30, 32A, and 32B show embodiments of an exposure device that includes tangs 180a and 180b extending from the distal, insertable end of exposure devices 137b and 137b. The tangs 180a and 180b are positioned 180° relative to one another on the end of the hollow barrel, but the invention is not limited to such an arrangement. In some embodiments (e.g., an embodiment exemplified by 137b shown in FIG. 32A), and without limitation, the tangs 180a and 180b may be included at the ends of the major axis of the oblong (e.g., elliptical) end of the working channel, which may be used with an implant having lateral fixation elements such as flukes that may be rotated into the bone tissue after being placed in the SI joint. In other embodiments (e.g., an embodiment exemplified by 137c shown in FIG. 32B), and without limitation, the tangs 180a and 180b may be included at the ends of the minor axis of the oblong (e.g., elliptical) end of the working channel, which may be used with an implant having lateral fixation elements such as lateral plates that may be inserted directly into the bone tissue of the SI joint.

[0170] The working channel may have other additional features such as handles 140 and slots 141 therein (e.g., for inserting handle extensions, etc.), as well. Additionally, the handle 140 may also be attachable to a stabilizing structure (e.g., a table or surgical arm, retractor/stabilizing arms, etc.) to prevent movement of the exposure device or surgical implements engaged therewith during surgical procedure. It is to be appreciated that the above description of the exposure tool does not limit the present invention, and other features are contemplated in and within the scope of the present invention.

[0171] In some embodiments the invention may comprise a double-barreled

working channel having side by side (e.g., parallel) hollow barrels, each able to receive and guide surgical implements. The two barrels may have a same or different length. In reference to FIG. 120, a double-barreled working channel 295 may have first and second parallel barrels. Working channel 295 may allow multiple fusion implants to be inserted into an SI joint. In such embodiments, the additional working channel of the double-barreled working channel may have similar features as described above with respect to the working channel 239.

[0172] In some embodiments of the present invention, and without limitation, the exposure device may be a surgical guiding tool having two working channels therein for guiding other surgical tools for use in repairing an SI joint. The two working channels may be attached to one another by a connecting member, such as a bar or a rack. The bar may have a bend or angle therein that positions the two working channels at an angle (with respect to their longitudinal axes) relative to one another in a range of 0° to 180°. In some embodiments, the angle between the two working channels may be acute (e.g., about 30° to about 50°, or any angle in that range, such as about 45°). The angled positions of the two working channels allows one working channel to be positioned over the SI joint and the second working channel to be positioned over the ilium (e.g., the iliac wing) simultaneously and snugly, enabling the insertion of one more joint fusion implants into the SI joint and a joint fixation device (e.g., a bone screw) into the ilium and sacrum in a single procedure with a simple tool, without the need to reposition the surgical tool to insert either the joint fusion implants or the fixation device. In further embodiments, the relative angle of orientation of the two working channels may be a

right angle or may be obtuse, depending on the desired insertion point on the ilium. If a different entry point for a joint fusion device is desired, the relative orientation angle of the two working channels may be in a range of about 45° to about 180° (e.g., about 90° to about 180°, about 45° to about 135°, about 90° to about 120°, or any value or range of values therein). For example, if the desired entry point on the ilium is more lateral or anterior, the angle of orientation between the two working channels may be 90° or greater.

[0173] Referring to FIGS. 33-37, a dual working channel exposure device 300 is shown having a connecting bar 337 connecting a first working channel 339 and a second working channel 350. The connecting bar 337 may have a bend or angle 343 between the first and second working channels 339 and 350. In some implementations, and without limiting the invention, the bend 343 may have an obtuse angle in a range of about 110° to about 160° (e.g., about 135° or any value therein). In some implementations, and without limiting the invention, the bend 343 may result in the first and second working channels being positioned at an acute angle relative to one another that may be complementary to the obtuse angle of the bend 343. In alternative implementations, and without limitation, the connecting bar may have a lockable joint therein between the first and second working channels 339 and 350 that may be adjusted to have an angle in a of about 90° to about 180° (e.g., about 135° or any value therein). The angle of the connecting bar 343 is configured to accommodate the contour of the pelvis between the ilium and the SI joint such that the first working channel 339 can be engaged with a posterior side of the sacroiliac joint and the second working channel 350 can be engaged with a posterior portion of the ilium

simultaneously.

[0174] The connecting bar 337 may also have a second angle therein, as shown in the top perspective of FIG. 35 and the bottom perspective of FIG. 36. The first and second working channels 339 and 350 may be positioned at an angle between about 5° and about 40° (e.g., about 15°, or any angle therein). To further illustrate, the bar 343 may be angled such that the longitudinal axes of the first and second working channels 339 and 350 may run along different, but parallel planes. Thus, the working channels 339 and 350 are positioned at an acute angle relative to one another from a side perspective (e.g., FIG. 34), and on parallel planes relative to each other from top or bottom perspective (e.g., FIGS. 35 and 36). The additional angle in the connecting bar 343 may aid in positioning the second working channel 350 on the ilium when the first working channel is engaged with the SI joint, such that the second working channel 350 is positioned over the iliac wing, close to the iliac crest. The position and angle of the second working channel 350 may allow the insertion of a bone fusion device (e.g., a bone screw) through the ilium and the sacrum (e.g., the S1 vertebrae) through the hollow barrel of the second working channel 350, such that the bone fusion device does not traverse the SI joint (e.g., it is inserted anteriorly to the SI joint).

[0175] Each working channel may have a hollow barrel therein for passing various surgical tools that have a shape corresponding to (e.g., complementary to) the hollow barrel. The working channels provide a guide for inserting the various surgical tools into the SI joint and the ilium, allowing precise surgical incisions, insertions of fusion implants, bone-growth promoting material, etc. The working channel position over the SI joint may have a

hollow barrel having an oblong or elliptical internal cross-section or other shape for accommodating fusion implants having one or more lateral fixation elements, as discussed above. Each of the first and second working channels 339 and 350 may have one or more pin guide slots 349 on a side thereof for insertion of fixing pins to immobilize the exposure device 300 when it is engaged with the SI joint and the ilium. The first and second working channels may also each have one or more windows 338 in sides of the hollow barrels allowing the progress of a tool inserted therein to be observed through the one or more windows, and allow access to instruments in the working channels through the windows, similarly to window 138 described above.

10 **[0176]** Referring to FIG. 37, the hollow barrels of the first and second working channels 339 and 350 may have a slot 346 (e.g., a timing feature) that arrests the progress of a surgical implement inserted into the hollow barrel of the channel. The slot 346 may prevent the surgical implement from advance too far into the SI joint or the ilium and sacrum and may ensure that surgical tools passed through the hollow barrels remain
15 properly oriented, with no axial movement, thereby preventing damage to the tissue of the patient. The surgical implements used in connection with the dual working channel surgical tool may have a protrusion that is complementary to the slot 346, such that the slot is effective in controlling a depth to which the surgical implement can be inserted.

[0177] The insertable end 342 of the first working channel 339 may have a round or
20 circular geometry that prevents or reduces damage to the soft and connective tissues in and around the posterior side of the SI joint. The round or circular insertable end 342 may also have a tapered or rounded profile, which may aid in reducing or preventing damage to the

soft and connective tissues around the SI joint. The second working channel 350 may also have circular and/or rounded or tapered insertable end 342, as well. It is to be appreciated that the present invention is not limited to working channels having round, circular, oblong or otherwise rounded ends. The insertable end of the working channel 339 may also
5 include one or more prongs or tangs that extend beyond the end of the hollow barrel, as discussed above. The one or more prongs or tangs may allow the working channel to be more easily centered in the SI joint (e.g., with the tangs aligned along the plane between the articular surfaces of the SI joint), and may also serve to help stabilize the position of the working channel in the SI joint.

10 **[0178]** The first and second working channels may have other additional features such as handles 340 and slots 341 therein (e.g., for inserting handle extensions), as well. It is to be appreciated that the above description of the surgical tool does not limit the present invention, and other features are contemplated in the present invention.

[0179] In some embodiments the invention may comprise one or more separate
15 working channels that may be used in a similar manner to the dual working channel exposure device. In reference to FIG. 119, the invention may include first and second working channels 290, which can be individually positioned, for example, with one inserted into the posterior of the SI joint, and another positioned over the iliac wing. In such embodiments, the individual working channels may have the same features
20 described above with respect to the dual working channel exposure devices described herein, except for the connecting bar 343 and the features particular thereto.

[0180] In some embodiments, the invention may include a kit or set of surgical

implements and one or more joint fusion implants and joint fixation devices (e.g., surgical screws) that are associated with one or more of the exposure devices described above. Various tools may be included in such a set, including a joint cutting instrument (e.g., dilator), guide pins, guide pin assemblies, a drill, drill bits, a rasp, a box chisel, an inserter, and an impactor. Each of such tools may correspond to the exposure devices described herein. For example, the joint cutting instrument, the drill bits, the rasp, the box chisel, the inserter, and the impactor each may have a shape that is complementary to a hollow barrel of the exposure device, allowing each instrument to be inserted into the hollow barrel flush and in the proper orientation, without room to deviate from the path of the barrel. Thus, the working channel of the exposure device may act as precise guides for the surgical implements described above.

[0181] These surgical implements may be made of any suitable material, including medical grade plastics, metals, or alloys. In some embodiments, and without limitation, the tools are single use, in other embodiments the tools may be reused (and autoclaved, cleaned or otherwise suitably disinfected for further use). The tools may have various configurations, including those that differ from those depicted and specifically described herein.

[0182] The implements may include a joint probe capable of being used to locate an insertion point in an SI joint for a fusion implant. The joint probe may have a hollow channel therethrough for inserting a guide wire into the SI joint once the joint probe is properly positioned in the insertion point. Referring to FIGS. 8-11, the joint probe may have a rounded tip 111 for locating the insertion point, a shaft 112, and a handle 110. A

hollow channel 113 run through the length of the joint probe to allow a guide wire to be inserted therethrough and into the SI joint.

[0183] The set of tools may also include guide pins for securing the exposure device to the SI joint and the ilium. Referring to FIGS. 11-12, the guide pin 115 may have shaft that corresponds to the central channel of the joint probe and may be inserted into the SI joint through the dilator, to guide tools and implements subsequently positioned in said SI joint.

[0184] The set of surgical implements may include a dilator, which may be any device or structure capable of dilating an incision made in a human or other animal.

FIGS. 13-19 illustrate an example of a dilator system that may be included in the present invention. Dilator 116 may be made of any suitable material and may have any suitable dimensions and configuration. In the depicted example, dilator 116 has a distal end 117, a proximal end 118, and a shaft therebetween. Proximal end 118 may have any configuration suitable to dilate an opening or incision, for example an incision made by a pin or wire in the patient's flesh and dilate that incision to increase its size. The proximal end 118 may be tapered, coming to a point at its end. The distal end 117 may be faceted, allowing it to be engaged with a grooved end 120 of a T-handle 119. A dilator assembly, an example of which is shown in FIGS. 18 and 19, allows the dilator to be spun or otherwise manipulated to adjust the size of an incision. The dilator 116 (and the t-handle 119) may have a central channel 213 running down its length that may allow a guide wire or pin to be inserted therethrough into the incision.

[0185] Fixing pins 126 and a fixing pin handle 125, as shown in FIGS. 22-23,

may be included in the set of tools that correspond to the pin guide slots 139 on sides of the working channels of the exposure devices. The guide pins may also have a sharp and/or threaded end 115 for piercing bone and other tissues. The fixing pins may correspond to the pin guide holes on sides of the working channels (e.g., pin holes 139, and 349) of the exposure devices described above. The fixing pins can be used to secure the working channels in a desired position over the SI joint or the ilium.

[0186] A drill 122, as shown in FIGS. 20-21, may be included in the set to allow for bone preparation for fusion implant insertion. The drill may have a thread portion 124 with numerous designs in order to provide a hole with the desired female thread cut in the desired anatomy. The drill may also be designed to be attached to power instruments, a hand drill or a handle. Without limiting the invention, FIG. 20 an exemplary drill having a Jacob's chuck connection 123 so that it may be attached to a powered drill for quick preparation. Additionally, the drill may have a central channel 124 running down its length that may allow a guide wire or pin 114 to be inserted there through into the incision as seen in FIG. 21.

[0187] A chisel 131, as shown in FIG. 24, may be included in the set to provide an opening in the bone with desired dimensions on its distal tip 134 to better facilitate entry for the fusion implant. The distal tip 134 may have a tapered nose in order to self-distract its way in between the sacrum and ilium. The distal tip 134 may also have cutting edges to dig into the bone and remove it from the surgical site. The chisel may be used to penetrate the cortical tissue of the sacrum and ilium to allow anchoring portions of the joint fusion implants of the present invention to penetrate the bone tissue and

thereby anchor the fusion implant in the joint. The distal tip 134 may also have a containment device for removal of surgical site bone and windows may exist in the containment device to collect bone debris and remove the bone debris after removal from surgical site. The distal tip 134 may be undersized to a fusion implant to be inserted in order to ensure full bony contact on all sides of the fusion site. The chisel may have an outer diameter, as seen in FIG. 24, that matches the inner diameter of a working channel (e.g., working channels 239, 339, and 350) to keep the chisel directed in an axial plane for desired implant preparation. The chisel may have a timing feature 133 that mates with a female timing feature (e.g., timing feature 146 or 346) on the inside of a working channel to keep the chisel from plunging too far into the surgical site and to further keep the chisel in the proper orientation for desired implant site preparation.

[0188] Additionally, a rasp 132, as shown in FIG. 25, may be included in the set to provide an opening in the bone with desired dimensions on its distal tip 135 to better prepare the bone for a fusion site for the fusion implant. The distal tip 135 may have a tapered nose in order to self-distract its way in between the sacrum and ilium. The distal tip 135 may have aggressive teeth which can scrape the bone to help prepare the bone surface for receiving anchoring portions of joint fusion implants of the present invention.

The rasp may have an outer diameter as seen in FIG. 25, that matches the inner diameter of a working channel (e.g., working channels 239, 339, and 350) to keep the rasp directed in an axial plane for desired implant preparation. The rasp may have a timing feature 133 that mates with a female timing feature (e.g., timing feature 146 or 346) on the inside of a working channel to keep the instrument from traveling too far into the