

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: MOSKOWITZ, et al.
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Title: BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY
SCREWS AND POSTERIOR CERVICAL AND LUMBAR
INTERARTICULATING JOINT CALIBRATED STAPLING
DEVICES FOR SPINAL FUSION

Mail Stop Amendment
Commissioner for Patents
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PRELIMINARY AMENDMENT

Dear Sir:

Prior to examination on the merits and calculation of the filing fee, please amend the above-identified application as follows:

Amendments to the Specification begin on page 2 of this paper;

Amendments to the Claims, as reflected in the listing of claims, begin on page 3 of this paper; and

Remarks begin on page 16 of this paper.

AMENDMENTS TO THE SPECIFICATION:

This Amendment is accompanied by a Substitute Specification (clean version and marked-up version showing changes). No new matter is added.

IN THE CLAIMS:

Please amend the claims as follows. This listing of the claims will replace all prior versions, and listings, of claims in the application:

1-25. (Canceled)

26. (New) A universal, intervertebral combination bone fusion spacer and self-drilling screw apparatus for insertion into a disc space between a first vertebral body and a second vertebral body and fusion of the first vertebral body to the second vertebral body via biological bone fusion and screw fusion, the apparatus comprising:

an intervertebral cage including:

a first integral screw guide having a first predetermined angle;

a second integral screw guide having a second predetermined angle; and

a first screw member disposed in the first integral screw guide at the first predetermined angle and at least partially within the intervertebral cage;

a second screw member disposed in the second integral screw guide at the second predetermined angle and at least partially within the intervertebral cage,

wherein a surface of each longitudinal end of the intervertebral cage includes a tool mating feature for engaging a distal end of a prong of an implantation tool.

27. (New) The apparatus of claim 26, wherein the tool mating feature is formed adjacent to an edge of an upper surface of the intervertebral cage.

28. (New) The apparatus of claim 27, wherein the tool mating feature includes one of a slot and an indentation formed adjacent to the edge of the upper surface of the intervertebral cage for receiving the distal end of the prong of the implantation tool.

29. (New) The apparatus of claim 26, wherein each of the first internal screw guide and the second internal screw guide is angled to orient the first screw member and the second screw bi-directionally in opposite directions.

30. (New) The apparatus of claim 29, wherein the first screw member is oriented rostrally (superiorly) and the second screw member is oriented caudally (inferiorly).

31. (New) The apparatus of claim 26, wherein the first internal screw guide and the second internal screw guide are aligned along a longitudinal axis of the intervertebral cage.

32. (New) The apparatus of claim 26, wherein the first internal screw guide and the second internal screw guide are symmetrically disposed on each side of a center point of the intervertebral cage along a longitudinal axis of the intervertebral cage.

33. (New) The apparatus of claim 26, wherein each of the first internal screw guide and the second internal screw guide includes a tunnel that permits only a predetermined angled trajectory of the first screw member and the second screw member.

34. (New) The apparatus of claim 26, wherein a predetermined angled trajectory of the first internal screw guide is different than a predetermined angled trajectory of the second internal screw guide.

35. (New) The apparatus of claim 26, wherein each of the first internal screw guide and the second internal screw guide includes a tunnel that permits only a 25 degree angulation of the first screw member and the second screw member.

36. (New) The apparatus of claim 26, wherein the first screw member is a self-tapping and self-drilling screw member having a tapered end and a threaded body, and
wherein the second screw member is a self-tapping and self-drilling screw member having a tapered end and a threaded body.

37. (New) The apparatus of claim 26, further comprising:
a bone graft cavity for receiving bone packing material for bone fusion between the first vertebral body and the second vertebral body.

38. (New) The apparatus of claim 37, wherein the bone graft cavity extends through the intervertebral cage for receiving bone packing material for bone fusion between the first vertebral body and the second vertebral body and across the intervertebral space.

39. (New) The apparatus of claim 26, further comprising:
a plurality of bone graft cavities extending through the intervertebral cage for receiving bone packing material for bone fusion between the first vertebral body and the second vertebral body and across the intervertebral space.

40. (New) The apparatus of claim 26, wherein each of the first internal screw guide and the second internal screw guide has a 25 degree angulation.

41. (New) The apparatus of claim 26, wherein the intervertebral cage includes an exit for one of the first integral screw guide and the second integral screw guide, the exit being adjacent to or formed in an edge of the bone graft cavity.

42. (New) The apparatus of claim 41, wherein the exit is a hemi-circular indentation on the edge of the bone graft cavity.

43. (New) The apparatus of claim 26, wherein the intervertebral cage is a cervical intervertebral cage adapted to fit into a bi-concave cervical disc space.

44. (New) The apparatus of claim 26, wherein the intervertebral cage is a lumbar intervertebral cage adapted to fit into a bi-concave lumbar disc space.

45. (New) The apparatus of claim 26, wherein the intervertebral cage is a posterior lumbar intervertebral cage adapted to fit into a bi-concave lumbar disc space.

46. (New) The apparatus of claim 26, wherein the intervertebral cage is configured for one of posterior lumbar intervertebral placement, anterior lumbar intervertebral placement, antero-lateral lumbar and thoracic intervertebral placement, and anterior cervical intervertebral placement.

47. (New) The apparatus of claim 26, wherein the intervertebral cage includes a side having a plurality of ridges.

48. (New) The apparatus of claim 47, wherein the plurality of ridges are disposed on a superior surface and/or an inferior surface of the intervertebral cage.

49. (New) The apparatus of claim 26, where the intervertebral cage includes a screw insert for securing a second universal, intervertebral combination bone fusion spacer and self-drilling screw apparatus to the universal, intervertebral combination bone fusion spacer and self-drilling screw apparatus via a plate.

50. (New) The apparatus of claim 26, wherein a wall of the intervertebral cage having the first integral screw guide and the second integral screw guide has a thickness that is greater than a thickness of sidewalls and longitudinal ends of the intervertebral cage.

51. (New) The apparatus of claim 26, wherein a wall of the intervertebral cage having the first integral screw guide and the second integral screw guide has a height that is greater than a height of sidewalls and longitudinal ends of the intervertebral cage.

52. (New) The apparatus of claim 26, wherein a height and width of sidewalls and longitudinal ends of the intervertebral cage are tapered in a direction extending away from a wall of the intervertebral cage having the first integral screw guide and the second integral screw guide.

53. (New) The apparatus of claim 26, wherein a wall of the intervertebral cage having the first integral screw guide and the second integral screw guide is parallel to an opposing wall, and

wherein a length of the wall is greater than a length of the opposing wall.

54. (New) The apparatus of claim 26, wherein inner walls of the bone graft cavity are convergent.

55. (New) The apparatus of claim 26, wherein an intersection of sidewalls and longitudinal ends of the intervertebral cage form a straight edge.

56. (New) The apparatus of claim 26, wherein an intersection of sidewalls and longitudinal ends of the intervertebral cage form an arcuate edge.

57. (New) The apparatus of claim 26, wherein the first integral screw guide and the second integral screw guide are adjacent to each other and at an angulation with respect to a wall having the first integral screw guide and the second integral screw guide.

58. (New) The apparatus of claim 56, wherein a first angulation of the first integral screw guide is opposed to a second angulation of the second integral screw guide.

59. (New) The apparatus of claim 26, wherein the first integral screw guide and the second integral screw guide are adjacent to each other along a longitudinal extent of a wall having the first integral screw guide and the second integral screw guide, and

wherein the first integral screw guide and the second integral screw guide are offset in opposite directions with respect to a center line of the longitudinal extent.

60. (New) The apparatus of claim 59, wherein a part of the first integral screw guide overlaps a part of the second integral screw guide along the longitudinal extent of the wall having the first integral screw guide and the second integral screw guide.

61. (New) The apparatus of claim 59, wherein the first integral screw guide and the second integral screw guide are at an angulation with respect to the wall having the first integral screw guide and the second integral screw guide.

62. (New) The apparatus of claim 60, wherein a first angulation of the first integral screw guide extends in a first direction from the wall having the first integral screw guide and the second integral screw guide toward a first side of the intervertebral cage,

wherein a second angulation of the second integral screw guide extends in a second direction from the wall having the first integral screw guide and the second integral screw guide toward a second side of the intervertebral cage, and

wherein the first side is opposed to the second side.

63. (New) The apparatus of claim 26, wherein the intervertebral cage includes a wall having an entry opening of the first integral screw guide and an entry opening of the second integral screw guide,

wherein the wall has four quadrants delineated by a first axis and a second axis each lying in a plane of the wall, and the first axis is at a right angle with respect to the second axis,

wherein the four quadrants include a first quadrant, a second quadrant, a third quadrant, and a fourth quadrant,

wherein the first quadrant and the fourth quadrant are opposed to the second quadrant and the third quadrant with respect to the first axis, and the first quadrant and the second quadrant are opposed to the third quadrant and the fourth quadrant with respect to the second axis,

wherein the first quadrant is diagonally opposed to the third quadrant, and the second quadrant is diagonally opposed to the fourth quadrant, and

wherein one of:

a majority of an area of the entry opening of the first integral screw guide is in the first quadrant and a majority of an area of the entry opening of the second integral screw guide is in the third quadrant; and

the majority of the area of the entry opening of the first integral screw guide is in the second quadrant and the majority of the area of the entry opening of the second integral screw guide is in the fourth quadrant.

64. (New) The apparatus of claim 26, wherein the intervertebral cage includes a wall having an entry opening of the first integral screw guide and an entry opening of the second integral screw guide,

wherein the wall has four quadrants delineated by a first axis and a second axis each lying in a plane of the wall, and the first axis is at a right angle with respect to the second axis,

wherein the four quadrants include a first quadrant, a second quadrant, a third quadrant, and a fourth quadrant,

wherein the first quadrant and the fourth quadrant are opposed to the second quadrant and the third quadrant with respect to the first axis, and the first quadrant and the second quadrant are opposed to the third quadrant and the fourth quadrant with respect to the second axis,

wherein the first quadrant is diagonally opposed to the third quadrant, and the second quadrant is diagonally opposed to the fourth quadrant, and

wherein one of:

a center of the entry opening of the first integral screw guide is in the first quadrant and a center of the entry opening of the second integral screw guide is in the third quadrant; and

the center of the entry opening of the first integral screw guide is in the second quadrant and the center of the entry opening of the second integral screw guide is in the fourth quadrant.

65. (New) The apparatus of claim 26, wherein the intervertebral cage includes a wall having an entry opening of the first integral screw guide and an entry opening of the second integral screw guide, the wall including a first corner and a second corner, the first corner being arranged at an opposite side of the wall and an opposite end of the wall with respect to the second corner,

wherein the first integral screw guide and the second integral screw guide are diagonally arranged along a direction extending from the first corner of the wall to the second corner of the wall.

66. (New) The apparatus of claim 26, wherein the intervertebral cage includes a wall having an entry opening of the first integral screw guide and an entry opening of the second integral screw guide, the wall including a first corner and a second corner, the first corner being arranged at an opposite side of the wall and an opposite end of the wall with respect to the second corner,

wherein the first integral screw guide and the second integral screw guide are adjacent to each other along a longitudinal extent of the wall and are diagonally arranged along a direction extending from the first corner of the wall to the second corner of the wall.

67. (New) The apparatus of claim 26, wherein the intervertebral cage includes an arcuate wall.

68. (New) The apparatus of claim 26, wherein the first integral screw guide and the second integral screw guide are at an angulation with respect to a wall having the first integral screw guide and the second integral screw guide.

69. (New) The apparatus of claim 26, wherein the first integral screw guide and the second integral screw guide diverge from each other.

70. (New) The apparatus of claim 26, wherein the first integral screw guide and the second integral screw guide diverge from each other and at an angulation with respect to a wall having the first integral screw guide and the second integral screw guide.

71. (New) The apparatus of claim 26, wherein the intervertebral cage further comprises:

a third integral screw guide having a third predetermined angle;

a fourth integral screw guide having a fourth predetermined angle; and

wherein the apparatus further comprises:

a third screw member disposed in the third integral screw guide at the third predetermined angle and at least partially within the intervertebral cage; and

a fourth screw member disposed in the fourth integral screw guide at the fourth predetermined angle and at least partially within the intervertebral cage.

72. (New) The apparatus of claim 71, wherein the first screw member and the fourth screw member are oriented rostrally (superiorly) and the second screw member and the third screw member are oriented caudally (inferiorly).

73. (New) The apparatus of claim 72, wherein the second screw member and the third screw member are disposed between the first screw member and the fourth screw member along a longitudinal length of the intervertebral cage.

74. (New) The apparatus of claim 71, wherein each of the first internal screw guide, the second internal screw guide, the third internal screw guide, and the fourth internal screw guide has a 25 degree angulation.

75. (New) The apparatus of claim 71, wherein the first internal screw guide and the fourth internal screw guide are disposed adjacent to longitudinal ends of the intervertebral cage and the second internal screw guide and the third internal screw guide are disposed between the first internal screw guide and the fourth internal screw guide, and

wherein the first internal screw guide, the second internal screw guide, the third internal screw guide, and the fourth internal screw guide angled to orient the first screw member and the fourth screw member in opposite directions from the second screw member and the third screw member.

76. (New) The apparatus of claim 71, wherein the first internal screw guide, the second internal screw guide, the third internal screw guide, and/or the fourth internal screw guide are aligned along a longitudinal axis of the intervertebral cage.

77. (New) The apparatus of claim 71, wherein the first internal screw guide, the second internal screw guide, the third internal screw guide, and the fourth internal screw guide

are symmetrically disposed on each side of a center point of the intervertebral cage along a longitudinal axis of the intervertebral cage.

78. (New) The apparatus of claim 71, wherein the second screw member and the third screw member are disposed between the first screw member and the fourth screw member along a longitudinal axis of the intervertebral cage.

79. (New) The apparatus of claim 71, where the intervertebral cage includes a screw insert for securing a second universal, intervertebral combination bone fusion spacer and self-drilling screw apparatus to the universal, intervertebral combination bone fusion spacer and self-drilling screw apparatus via a plate.

80. (New) The apparatus of claim 71, wherein a wall of the intervertebral cage having the first integral screw guide, the second integral screw guide, the third integral screw guide, and the fourth integral screw guide has a thickness that is greater than a thickness of sidewalls and longitudinal ends of the intervertebral cage.

81. (New) The apparatus of claim 71, wherein a wall of the intervertebral cage having the first integral screw guide, the second integral screw guide, the third integral screw guide, and the fourth integral screw guide has a height that is greater than a height of sidewalls and longitudinal ends of the intervertebral cage.

82. (New) The apparatus of claim 71, wherein a height and width of sidewalls and longitudinal ends of the intervertebral cage are tapered in a direction extending away from a wall of the intervertebral cage having the first integral screw guide, the second integral screw guide, the third integral screw guide, and the fourth integral screw guide.

83. (New) The apparatus of claim 71, wherein a wall of the intervertebral cage having the first integral screw guide, the second integral screw guide, the third integral screw guide, and the fourth integral screw guide is parallel to an opposing wall, and
wherein a length of the wall is greater than a length of the opposing wall.

84. A method of inserting a universal, intervertebral combination bone fusion spacer and self-drilling screw apparatus into a disc space between a first vertebral body and a second vertebral body and fusing the first vertebral body to the second vertebral body via biological bone fusion and screw fusion, the method comprising:

measuring a dimension of the disc space between the first vertebral body and the second vertebral body;

determining that the disc space is a posterior lumbar disc space, an anterior lumbar disc space, or an anterior cervical disc space;

selecting the universal, intervertebral combination bone fusion spacer and self-drilling screw apparatus based on the measured dimension of the disc space and based on the determination of the disc space being the posterior lumbar disc space, the anterior lumbar disc space, or the anterior cervical disc space;

inserting the selected universal, intervertebral combination bone fusion spacer and self-drilling screw apparatus into a midline of the disc space until the selected universal, intervertebral combination bone fusion spacer and self-drilling screw apparatus is flush or countersunk relative to the first vertebral body and the second vertebral body;

inserting a first screw member into a first internal screw guide of the selected universal, intervertebral combination bone fusion spacer and self-drilling screw apparatus;

inserting a second screw member into a second internal screw guide of the selected universal, intervertebral combination bone fusion spacer and self-drilling screw apparatus;

screwing the first screw member and the second screw member into the first vertebral body and the second vertebral body respectively;

confirming a position and placement of the universal, intervertebral combination bone fusion spacer and self-drilling screw apparatus relative to the first vertebral body and the second vertebral body.

85. (New) A universal, intervertebral combination bone fusion spacer and self-drilling screw apparatus for insertion into a disc space between a first vertebral body and a second vertebral body and fusion of the first vertebral body to the second vertebral body via biological bone fusion and screw fusion, the apparatus comprising:

an intervertebral cage including:

- a first integral screw guide having a first predetermined angle;
- a second integral screw guide having a second predetermined angle; and
- a bone graft cavity for receiving bone packing material for bone fusion

between the first vertebral body and the second vertebral body;

a first screw member disposed in the first integral screw guide at the first predetermined angle and at least partially within the intervertebral cage; and

a second screw member disposed in the second integral screw guide at the second predetermined angle and at least partially within the intervertebral cage,

wherein the bone graft cavity extends through the intervertebral cage for receiving bone packing material for bone fusion between the first vertebral body and the second vertebral body and across the intervertebral space,

wherein each of the first internal screw guide and the second internal screw guide is angled to orient the first screw member and the second screw bi-directionally in opposite directions,

wherein each of the first internal screw guide and the second internal screw guide includes a tunnel that permits only a predetermined angled trajectory of the first screw member and the second screw member, and the predetermined angled trajectory of the first internal screw guide is different than the predetermined angled trajectory of the second internal screw guide,

wherein the intervertebral cage includes an exit for one of the first integral screw guide and the second integral screw guide, the exit being adjacent to or formed in an edge of the bone graft cavity,

wherein the first screw member is a self-tapping and self-drilling screw member having a tapered end and a threaded body, and wherein the second screw member is a self-tapping and self-drilling screw member having a tapered end and a threaded body,

wherein the intervertebral cage includes a side having a plurality of ridges,

wherein a surface of each longitudinal end of the intervertebral cage includes a slot or indentation formed adjacent to an edge of an upper surface of the intervertebral cage for receiving a distal end of a prong of an implantation tool,

wherein the intervertebral cage includes a wall having an entry opening of the first integral screw guide and an entry opening of the second integral screw guide,

wherein the wall has four quadrants delineated by a first axis and a second axis each lying in a plane of the wall, and the first axis is at a right angle with respect to the second axis,

wherein the four quadrants include a first quadrant, a second quadrant, a third quadrant, and a fourth quadrant,

wherein the first quadrant and the fourth quadrant are opposed to the second quadrant and the third quadrant with respect to the first axis, and the first quadrant and the second quadrant are opposed to the third quadrant and the fourth quadrant with respect to the second axis,

wherein the first quadrant is diagonally opposed to the third quadrant, and the second quadrant is diagonally opposed to the fourth quadrant, and

wherein one of:

a majority of an area of the entry opening of the first integral screw guide is in the first quadrant and a majority of an area of the entry opening of the second integral screw guide is in the third quadrant; and

the majority of the area of the entry opening of the first integral screw guide is in the second quadrant and the majority of the area of the entry opening of the second integral screw guide is in the fourth quadrant.

REMARKS

Claims 1-25 were previously pending in the application.

This Amendment cancels claims 1-25 and adds new claims 26-85. Claims 26, 84, and 85 are independent.

This Amendment does not add new matter. See, e.g., Figures 2A-5I; see also specification at paragraphs [0006] - [0031], [0065] - [0072].

This Amendment is accompanied by a Substitute Specification (clean version and marked-up version showing changes). No new matter is added.

Early and favorable prosecution on the merits is respectfully requested.

With respect to the prior copending application Serial No. 13,084,543, filed on April 11, 2011, and copending application Serial No. 13,108,982, filed on May 16, 2011, which are a Divisional and Continuation, respectively, of application Serial No. 11/842,855, filed on August 21, 2007, now U.S. Patent No. 7,942,903 issued on May 17, 2011, which is a Continuation-In-Part Application of application Serial No. 11/536,815, filed on September, 29, 2006, now U.S. Patent No. 7,846,188 issued on December 7, 2010, which is a Continuation-In-Part Application of application Serial No. 11/208,644, filed on August 23, 2005, now U.S. Patent No. 7,704,279 issued on April 27, 2010, for which priority is claimed under 35 U.S.C. §120, Applicant hereby incorporates the claim of priority under 35 U.S.C. § 119(e) of U.S. provisional application No. 60/670,231, filed on April 12, 2005.

Early and favorable prosecution on the merits is respectfully requested.

CONCLUSION

In view of the above, entry of the present Amendment and allowance of Claims 26-83 are respectfully requested. If the Examiner has any questions regarding this amendment, the Examiner is requested to contact the undersigned.

Respectfully Submitted,

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SUBSTITUTE SPECIFICATION - CLEAN VERSION

Attorney Docket No. 3003/0105PUS7

BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a Continuation Application of application Serial No. 13,084,543, filed on April 11, 2011, which is a Divisional Application of application Serial No. 11/842,855, filed on August 21, 2007, now U.S. Patent No. 7,942,903 issued on May 17, 2011, and a Continuation Application of application Serial No. 13,108,982, filed on May 16, 2011, which also is a Continuation Application of application Serial No. 11/842,855, filed on August 21, 2007, now U.S. Patent No. 7,942,903 issued on May 17, 2011, which is a Continuation-In-Part Application of application Serial No. 11/536,815, filed on September, 29, 2006, now U.S. Patent No. 7,846,188 issued on December 7, 2010, which is a Continuation-In-Part Application of application Serial No. 11/208,644, filed on August 23, 2005, now U.S. Patent No. 7,704,279 issued on April 27, 2010, for which priority is claimed under 35 U.S.C. §120; and this application also claims priority under 35 U.S.C. § 119(e) of U.S. provisional application No. 60/670,231, filed on April 12, 2005; the entire contents of all the above identified patent applications are hereby incorporated by reference.

BACKGROUND OF THE INVENTION

FIELD OF INVENTION

[0002] The present invention relates to a unique universal bidirectional screw (BDS) system, and in particular its application to the spine, also referred to as bi-directional fixating transvertebral (BDFT) screws which can be used as a stand-alone intervertebral device which combines the dual functions of an intervertebral spacer which can be filled with bone fusion material(s), as well as a transvertebral bone fusion screw apparatus. In the posterior lumbosacral and thoracic spine, BDFT screw/box constructs can be used independently or supplemented with a novel horizontal mini-plate which prevents upward bone graft intrusion into the thecal sac and nerves. In the anterior lumbosacral spine BDFT screw box constructs can be inserted into and supplemented by a circumferential cage. These posteriorly and anteriorly placed stand-alone intervertebral body fusion constructs may obviate the need for supplemental pedicle screw fixation.

[0003] The present invention also relates to stand-alone or supplemental posterior cervical and lumbar calibrated inter-articular joint stapling devices which may obviate and/or lessen the need for supplemental pedicle screw fixation.

DESCRIPTION OF THE RELEVANT ART

[0004] The history and evolution of instrumented spinal fusion in the entire human spine has been reviewed in our two prior copending applications Ser. No. 11/536,815, filed on Sep. 29, 2006, and Ser. No. 11/208,644, filed on Aug. 23, 2005, the related contents of which are hereby incorporated by reference. Currently the majority of posterior cervical and almost all anterior and posterior lumbosacral and thoracic fusion techniques are typically supplemented with pedicle screw placement. Complications of pedicle screw placement in cervical, thoracic and lumbar

spine include duration of procedure, significant tissue dissection and muscle retraction, misplaced screws with neural and/or vascular injury, excessive blood loss, need for transfusions, prolonged recovery, incomplete return to work, and excess rigidity leading to adjacent segmental disease requiring further fusions and re-operations. Recent advances in pedicle screw fixation including minimally invasive and image-guided technology, and the development of flexible rods, imperfectly address some but not all of these issues.

[0005] Complications of all current spinal interbody fusion devices is their lack of coverage of the majority of the cross-sectional area of the vertebral endplates, and their lack of adequate, if any capacity to penetrate bone, and hence the heightened risk of implant extrusion. Furthermore the bone and biological bone fusion agents which are packed into the intervertebral space can easily blossom and grow upward into the thecal sac causing neural compression, in the absence of a physical barrier between the fusing growing bone, and the thecal sac.

SUMMARY

[0006] Herein we describe multiple device embodiments which combine in a single construct the dual functions of an intervertebral spacer maintaining disc space height, and transvertebral body fusion screws.

[0007] We also introduce an entirely novel horizontal mini-plate capping off the intervertebral space capable of functioning as a physical barrier preventing upward bone intrusion and/or compression of the ventral thecal sac, and traversing and exciting nerve roots.

[0008] Furthermore, we present an advanced mechanism in calibrated posterior facet joint stapling compared to our previous designs illustrated in our co-pending patents. We also

introduce the entirely novel concept of posterior cervical facet staples to obviate and/or diminish the need for posterior cervical pedicle screw instrumented fusion. Using combinations and permutations of different embodiments of cervical facet staples in a modular manner advances the concept of flexible fusion in the cervical spine.

[0009] To achieve safe, effective and minimally invasive segmental spinal fusion, applicants propose the use of novel bi-directional fixating transvertebral (BDFT) screws which can be strategically inserted via anterior or posterior surgical spinal approaches into the anterior and middle columns of the intervertebral disc space. In our previous applications these bi-directional screws employed turning a wormed driving screw which turns a spur gear which in turn simultaneously turns a rostral oriented screw into the cephalad vertebral body, and a caudal directed screw into the caudal vertebral body. The vertebral bodies above and below the disc space by virtue of their engagement and penetration by the BDFT screws are thus linked, interlocked, and eventually biologically fused with placement of intervertebral bone agents.

[0010] In this current application one or more of the described embodiments may eliminate the intervening wormed driving screws and gears required by previous designs, e.g., a gearless screw box is achieved. We have designed a screw box to be placed inter-vertebrally, either unilaterally or bilaterally, in particular, posteriorly between vertebral bodies. The housing screw box incorporates built-in screw and/or drill guides which allow the direct placement and insertion of two self drilling screws which are driven in two opposing directions into superior and inferior vertebral bodies, respectively. One screw within the screw box is angled superiorly, and the other screw in the screw box is angled inferiorly.

[0011] In yet another embodiment, in addition to these features we designed an expanding screw box with sliding triangular bases to house two screws driven in two opposing directions which can be expanded in two simultaneous directions, height and depth, by turning a built-in screw adjuster. This is accomplished by a combined positioning tool/screw guide/cage expander to further enhance trajectory precision and to simultaneously expand the screw box in height and depth to custom-fit the individual disc space height. This embodiment has two sub-embodiments; one has two laterally oriented BDFT screws, and the other has a lateral and a medial oriented BDFT screw. These innovations represent a continued evolution of our concept of expandable fusion cages described in our previous co-pending patents.

[0012] In yet another embodiment we designed a screw box which houses only one, instead of two screws. Each box allows the placement of one superior or inferior directed screw on one side (left or right), and the contra lateral screw box device allows placement of an inferior or superior oriented screw which goes in the opposite direction of the contra lateral device. In totality these two separate single screw boxes fuse the superior and inferior vertebrae. The potential advantage of this embodiment is that it diminishes the width of the screw box in cases where it might be favorable to have less nerve root retraction with a smaller width device.

[0013] In all screw-box embodiments, a rostral-directed screw is passed through one built-in screw guide of the device which then is inserted and screwed into the superior vertebral body. Then a caudal directed screw is passed through an adjacent built-in screw guide which then is inserted and screwed into the inferior vertebral body. The novelty of this design is the built-in prescribed angles of the integral screw guides which allow the posterior transvertebral penetration into the vertebral bodies. This is a truly amazing feat accomplished in the posterior

lumbar spine considering the small anatomically restricted work zone within which to work, which is very narrowly prescribed by obtuse angulations between screw and intervertebral bone surfaces, and by nerve root, facet joint and pedicle. We have also designed a positioning tool for the placement of the non-expandable screw boxes which has a screwdriver with a flexible shaft specifically designed to fit these devices if a straight screw driver impedes screw placement. Hence these external tools provide the means in any circumstance to accomplish precision screw trajectory. The embodiments described herein compared to our previous co-pending patent designs, streamline and ease production of bi-directionally oriented transvertebral screws, and allows placement of longer and wider screws with greater bone penetration to provide yet a sturdier fusion construct. The designs are also easily modifiable for anterior placement into the cervical spine. The expandable embodiment of the screw box can also be enlarged and modified to be suitable for cervical, thoracic and lumbar vertebral body replacements.

[0014] The box casings have multiple perforations to allow both screw traversal and horizontal bone packing preventing upward vertical migration of bone. The boxes prevent subsidence. Both the inside of the denuded intervertebral space, and the screw boxes can be packed with autologous or allograft bone, BMP, DBX or similar osteoconductive material. Posteriorly or anteriorly in the lumbar spine, these screws can be capped with a horizontal mini-plate which will prevent bony growth into the thecal sac and nerves. We refer to this as a two-in-one device, i.e. two screw boxes/BDFT screws combined with one horizontal mini-plate. This is an entirely novel concept in posterior lumbar spinal surgery. In yet another embodiment two BDFT screw boxes can be combined with a circumferential cage (also 2 in 1) to be placed anteriorly into the lumbar spine.

[0015] It is believed that BDFT-screw constructs provide as strong or stronger segmental fusion as pedicle screws without the complications arising from pedicle screw placement which include screw misplacement with potential nerve and/or vascular injury, violation of healthy facets, possible pedicle destruction, blood loss, and overly rigid fusions. By placing screws across the intervertebral space from vertebral body to vertebral body, engaging anterior and middle spinal columns, and not the vertebral bodies via the transpedicular route, the healthy facet joints, if they exist, are preserved. Because this technique accomplishes both anterior and middle column fusion, without rigidly fixating the posterior column, it in essence creates a flexible fusion. This device therefore is a flexible fusion device because the preserved posterior facet joints retain their function achieving at least a modicum of mobility and hence a less rigid (i.e. a flexible) fusion.

[0016] The very advantage of transpedicular screws which facilitate a strong solid fusion by rigidly engaging all three spinal columns is the same mechanical mechanism whereby complete inflexibility of all columns is incurred thereby leading to increasing rostral and caudal segmental stress which leads to an increased rate of re-operation.

[0017] Transvertebral fusion also leads to far less muscle retraction, blood loss, and significant reduction in O.R. time. Thus the complication of pedicular screw pull-out and hence high re-operation rate associated with the current embodiment of flexible fusion pedicle screws/rods is obviated. The lumbosacral screw box embodiments and BDFT screws can be introduced via posterior lateral, transforaminal or anterior interbody fusion approaches/techniques. Although one can opt to supplement these screws with transpedicular

screws there would be no absolute need for supplemental pedicle screw fixation with these operative techniques.

[0018] BDFT screw constructs outlined here can also be combined with novel zero-profile horizontal cervical and, lumbar/thoracic mini-plates. Likewise one or two of these devices can be inserted anteriorly with or without circumferential cage supplementation.

[0019] Because the BDFT screws engage a small percentage of the rostral and caudal vertebral body surface area, multi-level fusions can be performed with these devices.

[0020] Previous improvements included a novel calibrated lumbar/thoracic facet stapling device which staples the inferior articulating facet of the superior segment to the superior articulating facet of the caudal vertebral segment unilaterally or bilaterally, which may minimize motion until interbody fusion occurs. In the present patent application we introduce a new design of the staple enhancing its calibrating capability.

[0021] In this patent application we also introduce a novel posterior cervical facet stapling device which staples the inferior articulating facet of the superior cervical segment with the superior articulating facet of the caudal vertebral segment unilaterally or bilaterally.

[0022] The advantage of cervical facet staples is speed and safety. The risks of cervical facet pedicle screw fixation which include nerve root and vertebral artery injuries are completely obviated. Thus they thereby achieve the same function of pedicle screws without the risks.

[0023] Placement of different embodiments of the cervical facet staples along unilateral and/or bilateral facet joints in a modular manner, lead to differing degrees of calibrated motion joint motion hence introducing for the first time the concept of calibrated cervical fusion.

[0024] Currently failed anterior lumbar arthroplasties are salvaged by combined anterior and posterior fusions. BDFT screw constructs could be utilized as a one-step salvage operation for failed/extruded anteriorly placed lumbar artificial discs obviating the above salvage procedure which has far greater morbidity.

[0025] For example, in one general aspect, a self-drilling bone fusion screw apparatus includes a first sliding box, a second sliding box, positioned relative to the first sliding box, a first screw member having a tapered end and a threaded body disposed within the first sliding box, a second screw member having a tapered end and a threaded body disposed within the second sliding box, and an adjuster for adjusting the height of the sliding boxes.

[0026] Implementations of this aspect may include one or more of the following features. For example, the first and second screw members may be medially aligned. At least one of the first and second screw members may be laterally aligned. The first and second screw members are laterally aligned. One of the first and second screw members is laterally aligned and the other screw member is laterally aligned. The first and second sliding boxes may be substantially triangularly shaped. The triangularly shaped first and second sliding boxes may include a sliding rail and ridged surfaces. The triangularly shaped first and second sliding boxes may include holes for bone grafts. The adjuster may include a screw.

[0027] In another general aspect, a self-drilling bone fusion screw apparatus includes a box, a first screw member having a tapered end and a threaded body disposed at least partially within the box and laterally aligned with the box, a second screw member having a tapered end and a threaded body disposed at least partially within the box and laterally aligned with the box, and a plurality of ridges disposed on along the sides of the box.

[0028] Implementations of this aspect may include one or more of the following features. For example, the apparatus may include bone graft holes. The apparatus may be attachable to a second self-drilling fusion screw apparatus via a plate.

[0029] In another general aspect, a self-drilling bone fusion screw apparatus may include a first box, a first screw member having a tapered end and a threaded body disposed at least partially within the first box and laterally aligned with the first box, a second box, a second screw member having a tapered end and a threaded body disposed at least partially within the second box and laterally aligned with the second box, and an attachment member for engaging the first and second boxes.

[0030] Implementations of this aspect may include one or more of the following features. For example, the self-drilling bone fusion screw apparatus may include bone graft holes. The plate may be directly joined to the first and second boxes by a plurality of screws. The attachment member for engaging the first and second boxes may include a plate or the attachment member may include a circumferential cage defining at least one recess. The first and the second boxes may be positioned within or securely held within the recess of the circumferential cage, e.g., with an interference fit.

[0031] In another general aspect, a tool assembly for manipulating a self-drilling bone fusion screw apparatus includes a handle, a gripper cooperating with the handle and having a plurality of prongs, a screw guide, held in place the plurality of prongs, for controlling the direction of self-drilling screws that are screwed into a vertebral body.

[0032] Implementations of this aspect may include one or more of the following features. For example, the tool assembly for manipulating a self-drilling bone fusion screw apparatus may

include a key for controlling an adjustment device which controls the height of the self-drilling bone fusion screw apparatus. The tool assembly according to claim may include a driver assembly. The driver assembly may include a handle, a drive bit portion, and a flexible drive shaft extending between the handle and the drive bit portion for manipulating a screw of an expandable or non-expandable screw box. The assembly may include one or more of an expandable screw box and/or a non-expandable screw box. The boxes may include one or more screws. The screw boxes may be joined by or include an attachment member, such as a plate and/or a circumferential cage.

[0033] In another general aspect, a cervical facet staple includes a curved staple base, at least two prongs attached to the bottom surface of the curved staple base, and an insertion member disposed on the top surface of the curved staple base.

[0034] Implementations of this aspect may include one or more of the following features. For example, the staple may include at least four prongs attached to the bottom surface of the curved staple base. The insertion member may include a threaded insert.

[0035] In another general aspect, an impaction tool for a cervical facet staple includes a handle, a stem attached to the handle, a plurality of wings for contacting the cervical facet staple, and an insertion member for coupling the cervical facet staple to the impaction tool.

[0036] Implementations of this aspect may include one or more of the following features. For example, the handle may include a flattened portion that can be struck by a mallet.

[0037] In another general aspect, a lumbar facet staple includes a pair of rotating arms, at least two prongs attached to the inner surfaces of the rotating arms, a plurality of spurs attached

to one of the rotating arms, and a ratchet attached to one of the rotating arms. The rotating arms and prongs are rotated to a closed position to staple a lumbar facet joint.

BRIEF DESCRIPTION OF DRAWINGS

[0038] FIGS. 1A-D illustrate the Lumbar intervertebral screw box with one lateral oriented BDFT screw and one medially oriented BDFT screw (Embodiment IA) in sagittal-oblique (FIG. 1A), superior perspective (FIG. 1 B), inferior perspective (FIG. 1C) and exploded (FIG. 1 D) views.

[0039] FIG. 1E illustrates the lumbar intervertebral expandable screw box with two lateral oriented BDFT screws (Embodiment IB; sagittal-oblique view).

[0040] FIGS. 2A-C illustrate the Lumbar intervertebral non-expandable screw box with two BDFT screws (Embodiment II) in lateral (FIG. 2A), oblique (FIG. 2B), and superior perspective (FIG. 2C) views.

[0041] FIG. 3 illustrates a superior oblique perspective view of left and right lumbar intervertebral non-expandable screw boxes with one BDFT screw (Embodiment III).

[0042] FIGS. 4A-B illustrate the horizontal intervertebral zero-profile mini-plate prior to insertion (FIG. 4A), and after insertion (FIG. 4B) into two non-expandable lumbar intervertebral screw boxes with two BDFT screws.

[0043] FIG. 4C illustrates two non-expandable lumbar intervertebral screw boxes with two screws within a large circumferential cage for anterior placement into the lumbar spine

[0044] FIGS. 5A-C illustrate t positioning tool/screw guide/box expander in oblique perspective (FIG. 5A), lateral (FIG. 5B), and exploded (FIG. 5C) views.

[0045] FIG. 5D illustrates a superior oblique perspective view of the positioning tool/drill guide/box expander component.

[0046] Figures E-G illustrate the sequential steps (I-III) of the positioning tool/screw guide/box expander assembly. Step I (FIG. 5E), step II (FIG. 5F), and step III (FIG. 5G).

[0047] FIGS. 5H-I illustrate the positioning tool for impaction and placement of the non-expandable screw box with two transvertebral screws. Embodiment I has a rectangular positioning handle (FIG. 5H), and embodiment II has a circular positioning handle (FIG. 5I)

[0048] FIGS. 6A-B illustrate the insertion of expandable Lumbar bi-directional screw box with two BDFT screws into the Lumbar spine in oblique (FIG. 6A) and lateral (FIG. 6B) views.

[0049] FIGS. 7A-B illustrate the cervical facet staple (Embodiment I) in lateral (FIG. 7A) and oblique (FIG. 7B) views.

[0050] FIG. 8A-C illustrate the cervical facet staple (Embodiment II) in oblique (FIG. 8A), superior perspective (FIG. 8B) and inferior-oblique (FIG. 8C) views.

[0051] FIG. 9A illustrates the two-pronged cervical facet staple inserter/impactor (Embodiment I).

[0052] FIG. 9B illustrates the two-pronged cervical facet staple inserter/impactor inserted into the staple (Embodiment I).

[0053] FIG. 10A illustrates the four pronged cervical facet staple impactor (Embodiment II).

[0054] FIG. 10B illustrates the four pronged cervical facet staple impactor inserted into the cervical facet staple (Embodiment II).

[0055] FIG. 10C illustrates an inferior-oblique perspective view of the four-pronged cervical facet staple impactor (Embodiment II).

[0056] FIG. 11A illustrates placement of two-pronged cervical facet staples in a three-dimensional cervical spine.

[0057] FIG. 11B illustrates placement of four-pronged cervical facet staples in a three-dimensional cervical spine.

[0058] FIG. 11C illustrates modular placement of two and four pronged cervical facet staples in a three-dimensional cervical spine to achieve differing calibrated degrees of flexibility.

[0059] FIGS. 12 A-B illustrate the Lumbar facet joint staple with a calibrated ratcheting mechanism in opened (Figure A) and closed (Figure B) positions.

DETAILED DESCRIPTION OF THE INVENTION

[0060] 1. The Medical Device

[0061] Referring to FIGS. 1-6, the above described problem can be solved in the thoracic and lumbar spine by insertion into the denuded intervertebral disc space multiple embodiments of screw box constructs with BDFT screws.

[0062] FIGS. 1A-D illustrate three-dimensional views of the Lumbar intervertebral expandable screw box 100 with two BDFT screws 101, 102; one lateral and one medially oriented (Embodiment IA). FIG. 1E illustrates a sagittal-oblique view of the lumbar intervertebral expandable screw box 120 with two lateral oriented BDFT screws 121, 122 (Embodiment IB).

[0063] The expandable box 100 consists of top and bottom triangular sliding bases 103, 104 (FIG. 1-D). The superior and inferior segments of the height/depth adjusting screw 105 are integrated and connected to the two separate top and bottom triangular bases 103, 104, respectively. By turning this adjusting screw 105 back and forth i.e. clock-wise, and counter clockwise, the sliding rails 106 of the top triangular base 103 (FIG. 1D) slide up and down the rail inserts 107 on the bottom triangular base 104 (FIG. 1D). This action will simultaneously alter the intervertebral height and depth of the screw box 100 allowing individualized custom fitting of the screw box 100 conforming to the dimensions of the disc space.

[0064] Transvertebral screw 101 penetrates the top base 103, and transvertebral screw 102 traverses the bottom base 104 of the screw box 100. The two screws 101, 102 traverse the screw box 100 in opposing directions, bi-directionally (whether they are lateral or medially oriented). The external edges of the triangular bases 103, 104 in contact with vertebral body surfaces include ridges 107. This facilitates the screw box's 100 incorporation into and fusion with the superior and inferior vertebral bodies (FIGS. 1A-E). Both top and bottom screw box bases 103, 104 are perforated with holes 108 to allow bone placement for fusion. The entire construct, furthermore, is hollow to allow bone filling. Hence this device functions as both an intervertebral bone fusion spacer and bi-directional transvertebral screw fusion device.

[0065] FIGS. 2A-C illustrate three-dimensional views of the Lumbar intervertebral non-expandable screw box 200 with two BDFT screws 201, 202 (Embodiment II). Screws 201 and 202 perforate and orient in opposing, superior and inferior directions. There are holes 208 and hollow spaces allowing packaging with bone. There are also holes which allow the traversal of screws. The superior and inferior edges include ridges 207 to facilitate integration and fusion

with superior and inferior vertebral bodies. The expandable screw box 200 may include a screw insert 209 to attach a horizontal mini-plate (not shown). The self-contained internalized drill guides are at a 25 degree angle. The screw boxes can be designed with the internalized drill guides with different angles and/or different positions within the box.

[0066] FIG. 3 illustrates a three-dimensional view of left and right lumbar intervertebral non-expandable screw boxes 300a, 300b with one BDFT screw 301 or 302 (Embodiment III). It is roughly half the width of Embodiments I and II. Screw 301 is inserted into screw box 300a (left) and screw 302 is inserted into screw box 300b (right). There are holes 308 and hollow spaces allowing packing of bone to achieve biological fusion. The combined effect of one superior oriented and one inferior oriented screw fuses the superior and inferior vertebral bodies with small constructs. This also enables placement of larger dimension screws compared to embodiments I and II.

[0067] FIGS. 4A and B illustrate three-dimensional views of the horizontal intervertebral zero profile mini-plate 400 with two non-expandable lumbar intervertebral screw boxes 300a, 300b housing two BDFT screws 301, 302. FIG. 4A illustrates the perforations 401 within the plate 400 through which small plate securing screws 310 will be inserted to connect it to the built-in screw holes of the screw box 300a, 300b (FIG. 4B). The horizontal mini-plate 400 together with the top surfaces of left and right screw boxes 300a, 300b provide a physical barrier between the underlying bone placed beneath it (not illustrated), and the thecal sac and nerve roots above it (not illustrated).

[0068] FIG. 4C illustrates two screw boxes 300c, 300d within a circumferential cage 420 (2 in 1) construct which is designed for anterior placement into the lumbar spine. There are slots

308a, 308b for bone graft placement, both outside and inside the boxes. The circumferential cage 420 has perforations 401a for the placement of transvertebral screws (not shown).

[0069] FIGS. 5A-C illustrate three-dimensional views of the external drill/screw guide-box expander 500 which assists in screw trajectory and box expansion (embodiments IA-B). For embodiments II and III, the same instrument is utilized; however, an expanding Allen key component is not used.

[0070] The key components of this device include an Allen key 501, a spring 502, a handle 503, a griper 504 and a screw guide 505. The Allen key 501 when inserted in the insertion 514 and turned, turns the screw adjuster (FIG. 5C) which in turn regulates top and bottom triangular screw box base sliding, and hence box 200 width and depth. The griper 504 has griper prongs 506 which insert into grooves of the screw guide 505 and the screw box 200 (FIGS. 5A-D) thus perfectly aligning them.

[0071] FIG. 5D illustrates a superior oblique view of the screw guide 505 demonstrating insertions 509 for griper prong 506, built-in trajectory guides 511, 512 for insertions of screws 101 and 102, and the Allen key 501.

[0072] FIGS. 5E-G illustrate three-dimensional views of the sequential steps necessary for the external guide assembly. FIG. 5E illustrates the insertion of the Allen key 501 into the handle 503. FIG. 5F illustrates the insertion of the handle 503 through the spring 502 and griper 504. FIG. 5G illustrates insertion of the griper 504 into the screw guide 505.

[0073] FIGS. 5H-I illustrate three-dimensional views of a positioning tool 500a for impaction and placement of two transvertebral screws 201, 202 in the non-expandable screw box 200. The driver assembly 550 consists of a screw driver 551, a flexible shaft 552 and a square

recess bit 553. This facilitates turning the screws 201, 202 into the bone. The flexible shaft 552 facilitates the avoidance of spinous processes which might hinder the screw driving if the shaft 552 were straight. The positioning tool 500a can have a rectangular handle, Embodiment I (FIG. 5H), or a circular handle, Embodiment II (FIG. 5I). This serves to position the screw box within the intervertebral space, and screws 201, 202 within the screw box. Once positioned, the screw box can be impacted by tapping the handle with a mallet (not shown). The positioning tool's 500a griper handle inserts into the screw guide and the box, which maintains alignment.

[0074] FIG. 6A illustrates a three-dimensional view of insertion of the construct (Embodiment I) into the lumbar intervertebral disc space.

[0075] FIG. 6B illustrates a three dimensional lateral view of insertion of the construct (Embodiment I) into the disc space with short screws. Placement with longer screws would capture more bone.

[0076] FIGS. 7A and B illustrate three-dimensional views of the two-pronged cervical facet staple 700 (Embodiment I). There is a staple base 701 which is contoured to align with the curved surface of the cervical facet joints. There is a superior impactor threaded insert 702. An impactor can be screwed into this insert 702 and then impacted with a mallet. The two spikes 703, 704 perforate the inferior and superior facets of the superior and inferior vertebral bodies hence leading to cervical facet joint fusion. The spikes can be designed with ridges and/or fishhooks to facilitate irreversible extraction.

[0077] FIGS. 8A-C illustrate three-dimensional views of the four-pronged cervical facet staple 800 (Embodiment II). Likewise it has a staple base 805 contoured specifically for the surface of the facet joint. It also has an impactor insert 806. The insertion of a device with four

prongs 801-804 instead of two prongs further limits the degrees of motion of the joint hence making the fusion more rigid.

[0078] FIGS. 9 A-B illustrate a three-dimensional view of the two-pronged cervical staple impactor 900. It has a handle 901, a stem 902, and a screw insert 903 which can be screwed into the threaded staple insert. The impactor has two wings 904 which keep the staple base edges in place facilitating staple impaction. The handle 901 of the impactor 900 is broad in order to allow impaction by a mallet.

[0079] FIGS. 10A-C illustrate three-dimensional views of the four-pronged cervical staple impactor 1000 (Embodiment II). It has the same features as the two-pronged impactor 900, except its wings 1004 are broader accommodating the broader staple base. The impactor 1000 also includes a handle 1001, a stem 1002, and an impact screw 1003.

[0080] FIG. 11A illustrates a three-dimensional view of placement of the two pronged cervical facet staple 700 into a cervical spine model having vertebral body 1103 and lamina 1104. One staple 700 is perched on the joint 1101 prior to impaction. The other staple 700 is impacted.

[0081] FIG. 11B illustrates a three-dimensional view of placement of the four pronged cervical facet staple 800 into a cervical spine pre and post impaction.

[0082] FIG. 11C illustrates the concept of modularity and incremental diminution of movement of the joint by the modular placement of different combinations and permutations of varying numbers of two and four pronged cervical facet staples 700, 800. If one wishes to have the most flexible (least rigid) fusion, one would place a unilateral two pronged staple 700. One can increase i.e. calibrate increasing degrees of rigidity by increasing the number of prongs

penetrating the facet joints bilaterally. In FIG. 11C each facet joint is fused using a total number of six prongs. One side this is accomplished by using three two pronged staples 700, and on the other side using one four pronged staple 800 and one two pronged staple 700. These two embodiments can be mixed and matched unilaterally or bilaterally to vary the degree of rigidity and conversely flexibility of fusion. The most flexible fusion at one level would be accomplished by one staple 700 (2 prongs). The highest level of rigidity would be achieved by placing two four pronged staples 800 on both sides totaling sixteen prongs. Intermediate degrees of relative joint motion can be modulated by insertion into the cervical facet joints staples in two-four prong increments from 2-16. Each additional prong further limits the degree of facet joint motion hence increasing rigidity, and conversely decreasing flexibility. Thus the novel modular use of these embodiments heralds an era of flexible cervical spine fusion.

[0083] FIGS. 12 A-B illustrate a lumbar facet joint staple 1200 in open and closed positions and having staple prongs 1203. This lumbar facet staple has been thoroughly described in our previous co-pending patent application Ser. No. 11/536,815, filed on Sep. 29, 2006, and Ser. No. 11/208,644, filed on Aug. 23, 2005, the relevant portion of each of which is hereby incorporated by reference hereinafter. The new improvement of this device includes a ratchet 1201. The staple 1200 can be incrementally closed with increased ratcheting over increasing number of spurs 1202. This achieves increasing calibrated levels of lumbar facet joint fusion, and conversely diminishing joint flexibility. This new designs further enhances the capacity to achieve flexible fusions in the lumbar spine.

[0084] 2. The Surgical Method

[0085] Exemplary surgical steps for practicing one or more of the foregoing embodiments will now be described.

[0086] The posterior lumbar spine implantation of all the screw box 100, 200, 300 embodiments, with BDFT screws, and horizontal mini-plate 400 can be implanted via previously described posterior lumbar interbody fusion (PLIF) or posterior transforaminal lumbar interbody fusion (TLIF) procedures. The procedures can be performed open, microscopic, closed tubular or endoscopic. Fluoroscopic guidance can be used with any of these procedures.

[0087] After adequate induction of anesthesia, the patient is placed in the prone position. A midline incision is made for a PLIF procedure, and one or two parallel paramedian incisions or a midline incision is made for the TLIF procedure. For the PLIF, a unilateral or bilateral facet sparing hemi-laminotomy is created to introduce screw box 100, 200, 300 embodiments I-III into the disc space, after it is adequately prepared.

[0088] For the TLIF procedure, after unilateral or bilateral dissection and drilling of the inferior articulating surface and the medial superior articulating facet the far lateral disc space is entered and a circumferential discectomy is performed. The disc space is prepared and the endplates exposed.

[0089] Then one screw box 100, 200, 300 of either embodiments I-III is placed on either right, left or both sides. Then another screw box of embodiments 100, 200, 300 I-III is placed on the contralateral side. For embodiment I the external screw guide 505/box expander is attached to the screw box (FIGS. 5A-H). First the Allen key 501 is screwed until the box conforms perfectly to the height and depth of the space. Then a pilot hole can be drilled or an awl can start a pilot hole in the vertebral bodies. Then a transvertebral screw is screwed into the vertebral

body via the built-in box screw guides 505. For difficult angles, an angled screw driver can be employed.

[0090] For embodiments II-III the same method is used for placing screws, except the Allen key 501 is not utilized in the absence of plate expansion.

[0091] If bilateral constructs have been inserted, bone is packed into the intervertebral space, as well as within the device. Then the horizontal intervertebral zero profile mini-plate 400 is slid beneath the thecal sac and is secured to both left and right screw boxes with small mini-plate screws 210 (FIGS. 4A-B). This prevents bone intrusion into the thecal sac and hence possible nerve root compression.

[0092] FIGS. 6A and B illustrate the process of insertion and final placement of the construct into the lumbar spine. The mini-plates 400 can come in different horizontal lengths and widths to accommodate different intra and inter-patient disc space diameters. The BDFT screws can come in different widths, lengths and thread designs.

[0093] The anterior thoracic and lumbar spine implantation of one, two or three screw box constructs 100, 200, 300 and BDFT screws can be performed in a similar manner to the posterior application. Likewise, a horizontal mini-plate 400 can be used to cap two or three screw box constructs 100, 200, 300 (one placed midline deeply, one placed left and one placed right, forming a triangulation). Alternatively two screw box constructs may be placed into a circumferential ring for anterior placement. Anterior placement of these devices can be performed into the L4/5 and L5/S1 spaces on the supine anesthetized patient via previously described open microscopic or endoscopic techniques. Once the disc space is exposed and discectomy and space preparation are performed, placement of one, two or three screw box

embodiments 100, 200, 300 (I-III) or a 2 in I construct can be placed. The screw placement is facilitated by the internal screw guides, and different positioning tools ((FIG. 5). A right angled screw driver and/or ratchet could alternatively be employed A capping mini-plate 400 may be applied if desirable. The mechanism of screw placement and mini-plate 400 attachment are identical to what was described above.

[0094] The posterior placement of screw box constructs 100, 200, 300 alone or combined with horizontal mini-plates 400 into the thoracic spine can be performed via previously described transpedicular approaches; open or endoscopic. The anterior placement into the thoracic spine can be accomplished via a trans-thoracic approach. Once the disc space is exposed via either approach, any combination of the above mention Embodiments (I-III) can be inserted.

Engagement of the devices is identical to what was mentioned above.

[0095] For posterior placement of cervical facet staple 700, 800 embodiments, after adequate induction of anesthesia the patient is flipped prone and his head and neck secured. A single midline or two para-median incisions are made for unilateral or bilateral or multilevel placement of staples. Ultimately the facet joint is exposed. Alternatively and preferably this can be performed percutaneously under fluoroscopic guidance with intravenous sedation. The staple 700, 800 (Embodiments I or II) is loaded into the impactor 900, 1000. The staple 700, 800 is placed on the two articulating cervical facets, and then impacted into the joint. To achieve modular calibrated fusion different combinations and permutations of cervical facet stales can be inserted ranging from a single unilateral two pronged staple providing a high degree of flexibility to a total of four bilaterally placed four pronged staples 800 (16 prongs) leading to the highest degree of rigidity. Additional bone may or may not be placed in its vicinity to facilitate

permanent and solid fusion. This procedure can be performed open, closed, percutaneously, tubular, endoscopically or microscopically. FIGS. 11A-C illustrates placement of the staples 700, 800 in the cervical spine.

[0096] We have previously described surgical placement of the lumbar facet joint staple in our two co-pending patents. The surgical procedure for this device is identical to that which has been previously mentioned.

[0097] The present inventions may provide effective and safe techniques that overcome the problems associated with current transpedicular based cervical, thoracic and lumbar fusion technology, and for many degenerative stable and unstable spine disease. These inventions could replace much pedicle screw-based instrumentation in many but not all degenerative spine conditions.

[0098] The speed and simplicity of placement of cervical and lumbar facet staples, and placement of Lumbar screw box-BDFT constructs far exceeds that of current pedicle screw technology. Furthermore, these devices have markedly significantly decreased risk of misguided screw placement, and hence decreased risk of neural and vascular injury, and blood loss. In the lumbar spine BDFT screw constructs and facet staples could be applied modularly in different combinations to achieve different degrees of rigidity (flexibility). Patients having these devices would have decreased recovery and back to work time. These devices most likely lead to similar if not equal fusion with significantly less morbidity, and hence overall make them a major advance in the evolution of spinal instrumented technology leading to advances in the care of the spinal patient.

[0099] Another major novelty and advance is the introduction of simple and safe modular calibrated cervical flexible fusion. To our knowledge neither a similar device nor a similar mathematical concept of modular joint flexibility/fusion calibration has been postulated for the cervical spine or for any other articulating joint.

[00100] To our knowledge there have not been any previously described similar posterior lumbar and thoracic combined spacer and screw constructs. These devices can similarly be modified to stabilize bone fractures throughout the entire body. To our knowledge the description of zero to subzero profile anterior or posterior horizontal spinal plates which traverse the diameter of the disc space has not been previously described.

BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND
POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT
CALIBRATED STAPLING DEVICES FOR SPINAL FUSION

~~[0001]~~ **[0001]** ~~This application is a Continuation-In-Part Application of copending application Serial No. 11/536,815, filed on September, 29, 2006, which is a Continuation-In-Part Application of copending application Serial No. 11/208,644, filed on August 23, 2005 for which priority is claimed under 35, U.S.C. §120; and this application also claims priority under 35 U.S.C. § 119(e) of U.S. provisional application No. 60/670,231, filed on April 12, 2005; the entire contents of all the above identified patent applications are hereby incorporated by reference. This application is a Continuation Application of application Serial No. 13,084,543, filed on April 11, 2011, which is a Divisional Application of application Serial No. 11/842,855, filed on August 21, 2007, now U.S. Patent No. 7,942,903 issued on May 17, 2011, and a Continuation Application of application Serial No. 13,108,982, filed on May 16, 2011, which also is a Continuation Application of application Serial No. 11/842,855, filed on August 21, 2007, now U.S. Patent No. 7,942,903 issued on May 17, 2011, which is a Continuation-In-Part Application of application Serial No. 11/536,815, filed on September, 29, 2006, now U.S. Patent No. 7,846,188 issued on December 7, 2010, which is a Continuation-In-Part Application of application Serial No. 11/208,644, filed on August 23, 2005, now U.S. Patent No. 7,704,279 issued on April 27, 2010, for which priority is claimed under 35 U.S.C. §120; and this application also claims priority under 35 U.S.C. § 119(e) of U.S. provisional application No. 60/670,231, filed on April 12, 2005; the entire contents of all the above identified patent applications are hereby incorporated by reference.~~

[0001] [0002].....

BACKGROUND OF THE INVENTION

FIELD OF INVENTION

Field of Invention

[0002] The present invention relates to a unique universal bidirectional screw (BDS) system, and in particular its application to the spine, also referred to as bidirectional fixating transvertebral (BDFT) screws which can be used as a standalone intervertebral device which combines the dual functions of an intervertebral spacer which can be filled with bone fusion material(s), as well as a transvertebral bone fusion screw apparatus. In the posterior lumbosacral and thoracic spine, BDFT screw/box constructs can be used independently or supplemented with a novel horizontal mini-plate which prevents upward bone graft intrusion into the thecal sac and nerves. In the anterior lumbosacral spine BDFT screw box constructs can be inserted into and supplemented by a circumferential cage. These posteriorly and anteriorly placed stand-alone intervertebral body fusion constructs may obviate the need for supplemental pedicle screw fixation.

[0003] The present invention also relates to stand-alone or supplemental posterior cervical and lumbar calibrated inter-articular joint stapling devices which may obviate and/or lessen the need for supplemental pedicle screw fixation.

DESCRIPTION OF THE RELEVANT ART

Description of the Relevant Art

[0004] The history and evolution of instrumented spinal fusion in the entire human spine has been reviewed in our two prior copending applications Serial No. 11/536,815, filed on September, 29, 2006, and

Serial No. 11/208,644, filed on August 23, 2005, the related contents of which are hereby incorporated by reference. Currently the majority of posterior cervical and almost all anterior and posterior lumbosacral and thoracic fusion techniques are typically supplemented with pedicle screw placement. Complications of pedicle screw placement in cervical, thoracic and lumbar spine include duration of procedure, significant tissue dissection and muscle retraction, misplaced screws with neural and/or vascular injury, excessive blood loss, need for transfusions, prolonged recovery, incomplete return to work, and excess rigidity leading to adjacent segmental disease requiring further fusions and re-operations. Recent advances in pedicle screw fixation including minimally invasive and image-guided technology, and the development of flexible rods, imperfectly address some but not all of these issues.

[0005] Complications of all current spinal interbody fusion devices is their lack of coverage of the majority of the cross- sectional area of the vertebral endplates, and their lack of adequate, if any capacity to penetrate bone, and hence the heightened risk of implant extrusion. Furthermore the bone and biological bone fusion agents which are packed into the intervertebral space can easily blossom and grow upward into the thecal sac causing neural compression, in the absence of a physical barrier between the fusing growing bone, and the thecal sac.

SUMMARY

Summary

[0006] Herein we describe multiple device embodiments which combine in a single construct the dual functions of an intervertebral spacer maintaining disc space height, and transvertebral body fusion screws.

[0007] We also introduce an entirely novel horizontal mini-plate capping off the intervertebral space capable of functioning as a physical barrier preventing upward bone intrusion and/or compression of the ventral thecal sac, and traversing and exciting nerve roots.

[0008] Furthermore, we present an advanced mechanism in calibrated posterior facet joint stapling compared to our previous designs illustrated in our co-pending patents. We also introduce the entirely novel concept of posterior cervical facet staples to obviate and/or diminish the need for posterior cervical pedicle screw instrumented fusion. Using combinations and permutations of different embodiments of cervical facet staples in a modular manner advances the concept of flexible fusion in the cervical spine.

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[0009] To achieve safe, effective and minimally invasive segmental spinal fusion, applicants propose the use of novel bi-directional fixating transvertebral (BDFT) screws which can be strategically inserted via anterior or posterior surgical spinal approaches into the anterior and middle columns of the intervertebral disc space. In our previous applications these bi-directional screws employed turning a wormed driving screw which turns a spur gear which in turn simultaneously turns a rostral oriented screw into the cephalad vertebral body, and a caudal directed screw into the caudal vertebral body. The vertebral bodies above and below the disc space by virtue of their engagement and penetration by the BDFT screws are thus linked, interlocked, and eventually biologically fused with placement of intervertebral bone agents.

[0010] In this current application one or more of the described embodiments may eliminate the intervening wormed driving screws and gears required by previous designs, e.g., a gearless screw box is achieved. We have designed a screw box to be placed inter-vertebrally, either unilaterally or bilaterally, in

particular, posteriorly between vertebral bodies. The housing screw box incorporates built-in screw and/or drill guides which allow the direct placement and insertion of two self drilling screws which are driven in two opposing directions into superior and inferior vertebral bodies, respectively. One screw within the screw box is angled superiorly, and the other screw in the screw box is angled inferiorly.

[0011] In yet another embodiment, in addition to these features we designed an expanding screw box with sliding triangular bases to house two screws driven in two opposing directions which can be expanded in two simultaneous directions, height and depth, by turning a built-in screw adjuster. This is accomplished by a combined positioning tool/screw guide/cage expander to further enhance trajectory precision and to simultaneously expand the screw box in height and depth to custom-fit the individual disc space height. This embodiment has two sub-embodiments; one has two laterally oriented BDFT screws, and the other has a lateral and a medial oriented BDFT screw. These innovations represent a continued evolution of our concept of expandable fusion cages described in our previous co-pending patents.

[0012] In yet another embodiment we designed a screw box which houses only one, instead of two screws. Each box allows the placement of one superior or inferior directed screw on one side (left or right), and the contra lateral screw box device allows placement of an inferior or superior oriented screw which goes in the opposite direction of the contra lateral device. In totality these two separate single screw boxes fuse the superior and inferior vertebrae. The potential advantage of this embodiment is that it diminishes the width of the screw box in cases where it might be favorable to have less nerve root retraction with a smaller width device.

[0013] In all screw-box embodiments, a rostral-directed screw is passed through one built-in screw guide of the device which then is inserted and screwed into the superior vertebral body. Then a caudal directed screw is passed through an adjacent built-in screw guide which then is inserted and screwed into the inferior vertebral body. The novelty of this design is the built-in prescribed angles of the integral screw guides which allow the

posterior transvertebral penetration into the vertebral bodies. This is a truly amazing feat accomplished in the posterior lumbar spine considering the small anatomically restricted work zone within which to work, which is very narrowly prescribed by obtuse angulations between screw and intervertebral bone surfaces, and by nerve root, facet joint and pedicle. We have also designed a positioning tool for the placement of the non-expandable screw boxes which has a screwdriver with a flexible shaft specifically designed to fit these devices if a straight screw driver impedes screw placement. Hence these external tools provide the means in any circumstance to accomplish precision screw trajectory. The embodiments described herein compared to our previous co-pending patent designs, streamline and ease production of bi-directionally oriented transvertebral screws, and allows placement of longer and wider screws with greater bone penetration to provide yet a sturdier fusion construct. The designs are also easily modifiable for anterior placement into the cervical spine. The expandable embodiment of the screw box can also be enlarged and modified to be suitable for cervical, thoracic and lumbar vertebral body replacements.

[0014] The box casings have multiple perforations to allow both screw traversal and horizontal bone packing preventing upward vertical migration of bone. The boxes prevent subsidence. Both the inside of the denuded intervertebral space, and the screw boxes can be packed with autologous or allograft bone, BMP, DBX or similar osteoconductive material. Posteriorly or anteriorly in the lumbar spine, these screws can be capped with a horizontal mini-plate which will prevent bony growth into the thecal sac and nerves. We refer to this as a two-in-one device, i.e. two screw boxes/BDFT screws combined with one horizontal mini-plate. This is an entirely novel concept in posterior lumbar spinal surgery. In yet another embodiment two BDFT screw boxes can be combined with a circumferential cage (also 2 in 1) to be placed anteriorly into the lumbar spine. The box casings have multiple perforations to allow both screw traversal and horizontal bone packing preventing upward vertical migration of bone. The boxes prevent subsidence. Both the inside of the denuded

~~intervertebral space, and the screw boxes can be packed with autologous or allograft bone, BMP, DBX or similar osteoconductive material. Posteriorly or anteriorly in the lumbar~~

[0015] It is believed that BDFT- screw constructs provide as strong or stronger segmental fusion as pedicle screws without the complications arising from pedicle screw placement which include screw misplacement with potential nerve and/or vascular injury, violation of healthy facets, possible pedicle destruction, blood loss, and overly rigid fusions. By placing screws across the intervertebral space from vertebral body to vertebral body, engaging anterior and middle spinal columns, and not the vertebral bodies via the transpedicular route, the healthy facet joints, if they exist, are preserved. Because this technique accomplishes both anterior and middle column fusion, without rigidly fixating the posterior column, it in essence creates a flexible fusion. This device therefore is a flexible fusion device because the preserved posterior facet joints retain their function achieving at least a modicum of mobility and hence a less rigid (i.e. a flexible) fusion.

[0016] The very advantage of transpedicular screws which facilitate a strong solid fusion by rigidly engaging all three spinal columns is the same mechanical mechanism whereby complete inflexibility of all columns is incurred thereby leading to increasing rostral and caudal segmental stress which leads to an increased rate of re-operation.

[0017] Transvertebral fusion also leads to far less muscle retraction, blood loss, and significant reduction in O.R. time. Thus the complication of pedicular screw pull-out and hence high re-operation rate associated with the current embodiment of flexible fusion pedicle screws/rods is obviated. The lumbosacral screw box embodiments and BDFT screws can be introduced via posterior lateral, transforaminal or anterior interbody fusion approaches /techniques. Although one can opt to supplement these screws with transpedicular screws there would be no absolute need for supplemental pedicle screw fixation with these operative techniques.

[0018] BDFT screw constructs outlined here can also be combined with novel zero-profile horizontal cervical and, lumbar/thoracic mini-plates. Likewise one or two of these devices can be inserted anteriorly with or without circumferential cage supplementation.

[0019] Because the BDFT screws engage a small percentage of the rostral and caudal vertebral body surface area, multi-level fusions can be performed with these devices.

[0020] Previous improvements included a novel calibrated lumbar /thoracic facet stapling device which staples the inferior articulating facet of the superior segment to the superior articulating facet of the caudal vertebral segment unilaterally or bilaterally, which may minimize motion until interbody fusion occurs. In the present patent application we introduce a new design of the staple enhancing its calibrating capability.

[0021] In this patent application we also introduce a novel posterior cervical facet stapling device which staples the inferior articulating facet of the superior cervical segment with the superior articulating facet of the caudal vertebral segment unilaterally or bilaterally.

[0022] The advantage of cervical facet staples is speed and safety. The risks of cervical facet pedicle screw fixation which include nerve root and vertebral artery injuries are completely obviated. Thus they thereby achieve the same function of pedicle screws without the risks.

[0023] Placement of different embodiments of the cervical facet staples along unilateral and/or bilateral facet joints in a modular manner, lead to differing degrees of calibrated motion joint motion hence introducing for the first time the concept of calibrated cervical fusion.

[0024] Currently failed anterior lumbar arthroplasties are salvaged by combined anterior and posterior fusions. BDFT screw constructs could be utilized as a one- step salvage operation for failed/extruded anteriorly placed lumbar artificial discs obviating the above salvage procedure which has far greater morbidity.

[0025] For example, in one general aspect, a self-drilling bone fusion screw apparatus includes a first sliding box, a second sliding box, positioned relative to the first sliding box, a first screw member having a

tapered end and a threaded body disposed within the first sliding box, a second screw member having a tapered end and a threaded body disposed within the second sliding box, and an adjuster for adjusting the height of the sliding boxes.

[0026] Implementations of this aspect may include one or more of the following features. For example, the first and second screw members may be medially aligned. At least one of the first and second screw members may be laterally aligned. The first and second screw members are laterally aligned. One of the first and second screw members is laterally aligned and the other screw member is laterally aligned. The first and second sliding boxes may be substantially triangularly shaped. The triangularly shaped first and second sliding boxes may include a sliding rail and ridged surfaces. The triangularly shaped first and second sliding boxes may include holes for bone grafts. The adjuster may include a screw.

[0027] In another general aspect, a self-drilling bone fusion screw apparatus includes a box, a first screw member having a tapered end and a threaded body disposed at least partially within the box and laterally aligned with the box, a second screw member having a tapered end and a threaded body disposed at least partially within the box and laterally aligned with the box, and a plurality of ridges disposed on along the sides of the box.

[0028] Implementations of this aspect may include one or more of the following features. For example, the apparatus may include bone graft holes. The apparatus may be attachable to a second self-drilling fusion screw apparatus via a plate.

[0029] In another general aspect, a self-drilling bone fusion screw apparatus may include a first box, a first screw member having a tapered end and a threaded body disposed at least partially within the first box and laterally aligned with the first box, a second box, a second screw

member having a tapered end and a threaded body disposed at least partially within the second box and laterally aligned with the second box, and an attachment member for engaging the first and second boxes.

[0030] Implementations of this aspect may include one or more of the following features. For example, the self-drilling bone fusion screw apparatus may include bone graft holes. The plate may be directly joined to the first and second boxes by a plurality of screws. The attachment member for engaging the first and second boxes may include a plate or the attachment member may include a circumferential cage defining at least one recess. The first and the second boxes may be positioned within or securely held within the recess of the circumferential cage, e.g. with an interference fit.

[0031] In another general aspect, a tool assembly for manipulating a self-drilling bone fusion screw apparatus includes a handle, a gripper cooperating with the handle and having a plurality of prongs, a screw guide, held in place the plurality of prongs, for controlling the direction of self-drilling screws that are screwed into a vertebral body.

[0032] Implementations of this aspect may include one or more of the following features. For example, the tool assembly for manipulating a self-drilling bone fusion screw apparatus may include a key for controlling an adjustment device which controls the height of the self-drilling bone fusion screw apparatus. The tool assembly according to claim may include a driver assembly. The driver assembly may include a handle, a drive bit portion, and a flexible drive shaft extending between the handle and the drive bit portion for manipulating a screw of an expandable or non-expandable screw box. The assembly may include one or more of an expandable screw box and/or a non-expandable screw box. The boxes may include one or more screws. The screw boxes may be joined by or include an attachment member, such as a plate and/or a circumferential cage.

[0033] In another general aspect, a cervical facet staple includes a curved staple base, at least two prongs attached to the bottom surface of the curved staple base, and an insertion member disposed on the top surface of the curved staple base.

[0034] Implementations of this aspect may include one or more of the following features. For example, the staple may include at least four prongs attached to the bottom surface of the curved staple base. The insertion member may include a threaded insert.

[0035] In another general aspect, an impaction tool for a cervical facet staple includes a handle, a stem attached to the handle, a plurality of wings for contacting the cervical facet staple, and an insertion member for coupling the cervical facet staple to the impaction tool.

[0036] Implementations of this aspect may include one or more of the following features. For example, the handle may include a flattened portion that can be struck by a mallet.

[0037] In another general aspect, a lumbar facet staple includes a pair of rotating arms, at least two prongs attached to the inner surfaces of the rotating arms, a plurality of spurs attached to one of the rotating arms, and a ratchet attached to one of the rotating arms. The rotating arms and prongs are rotated to a closed position to staple a lumbar facet joint.

BRIEF DESCRIPTION OF DRAWINGS

[0038] FIGS. 1A-D illustrate the Lumbar intervertebral screw box with one lateral oriented BDFT screw and one medially oriented BDFT screw (Embodiment 1A) in sagittal-oblique (FIG. 1A), superior perspective (FIG. 1B), inferior perspective (FIG. 1C) and exploded (FIG. 1D) views.

~~Figures 1A-D illustrate the Lumbar intervertebral screw box with one lateral oriented BDFT screw and one medially oriented two BDFT screw (Embodiment 1A) in sagittal-oblique~~

~~(Figure 1A), superior perspective (Figure 1B), inferior perspective (Figure 1C) and exploded (Figure 1D) views.~~

[0039] Figure 1 E illustrates the lumbar intervertebral expandable screw box with two lateral oriented BDFT screws (Embodiment IB; sagittal-oblique view).

[0040] Figures 2A-C illustrate the Lumbar intervertebral non-expandable screw box with two BDFT screws (Embodiment II) in lateral (Figure 2A), oblique (Figure 2B), and superior perspective (Figure 2C) views.

[0041] Figure 3 illustrates a superior oblique perspective view of left and right lumbar intervertebral non-expandable screw boxes with one BDFT screw (Embodiment III).

[0042] Figures 4A-B illustrate the horizontal intervertebral zero-profile mini-plate prior to insertion (Figure 4A), and after insertion (Figure 4B) into two non-expandable lumbar intervertebral screw boxes with two BDFT screws.

[0043] Figure 4C illustrates two non-expandable lumbar intervertebral screw boxes with two screws within a large circumferential cage for anterior placement into the lumbar spine

[0044] Figures 5A-C illustrate the positioning tool / screw guide/box expander in oblique perspective (Figure 5A), lateral (Figure 5B), and exploded (Figure 5C) views.

[0045] Figure 5D illustrates a superior oblique perspective view of the positioning tool/drill guide/box expander component.

[0046] Figures 5E-G illustrate the sequential steps (I-III) of the positioning tool/screw guide/box expander assembly. Step I (Figure 5E), step II (Figure 5F), and step III (Figure 5G).

[0047] Figures 5H-I illustrate the positioning tool for impaction and placement of the non-expandable screw box with two transvertebral screws. Embodiment I has a rectangular positioning handle (Figure 5H), and embodiment II has a circular positioning handle (Figure 5I).

[0048] Figures 6A-B illustrate the insertion of expandable Lumbar bi-directional screw box with two BDFT screws into the Lumbar spine in oblique (Figure 6A) and lateral (Figure 6B) views.

[0049] Figures 7A-B illustrate the cervical facet staple (Embodiment I) in lateral (Figure 7A) and oblique (Figure 7B) views.

[0050] Figures 8-C illustrate the cervical facet staple (Embodiment II) in oblique (Figure 8A), superior perspective (Figure 8B) and inferior-oblique (Figure 8C) views.

[0051] Figure 9A illustrates the two-pronged cervical facet staple inserter/impactor (Embodiment I).

[0052] Figure 9B illustrates the two-pronged cervical facet staple inserter/impactor inserted into the staple (Embodiment I).

[0053] Figure 10A illustrates the four pronged cervical facet staple impactor (Embodiment II).

[0054] Figure 10B illustrates the four pronged cervical facet staple impactor inserted into the cervical facet staple (Embodiment II).

[0055] Figure 10C illustrates an inferior-oblique perspective view of the four - pronged cervical facet staple impactor (Embodiment II).

[0056] Figure 11A illustrates placement of two-pronged cervical facet staples in a three-dimensional cervical spine.

[0057] Figure 11 B illustrates placement of four-pronged cervical facet staples in a three-dimensional cervical spine.

[0058] Figure 11C illustrates modular placement of two and four pronged cervical facet staples in a three-dimensional cervical spine to achieve differing calibrated degrees of flexibility.

[0059] Figures 12 A-B illustrate the Lumbar facet joint staple with a calibrated ratcheting mechanism in opened (Figure A) and closed (Figure B) positions.

DETAILED DESCRIPTION OF THE INVENTION

1. THE MEDICAL DEVICE

[0060] Referring to Figures 1-6, the above described problem can be solved in the thoracic and lumbar spine by insertion into the denuded intervertebral disc space multiple embodiments of screw box constructs with BDFT screws.

[0061] Figures 1A-D illustrate three-dimensional views of the Lumbar intervertebral expandable screw box 100 with two BDFT screws 101, 102; one lateral and one medially oriented (Embodiment IA). Figure 1E illustrates a sagittal-oblique view of the lumbar intervertebral expandable screw box 120 with two lateral oriented BDFT screws 121, 122 (Embodiment IB).

[0062] The expandable box 100 consists of top and bottom triangular sliding bases 103, 104 (Figures 1-D). The superior and inferior segments of the height/depth adjusting screw 105 are integrated and connected to the two separate top and bottom triangular bases 103, 104, respectively. By turning this adjusting screw 105 back and forth i.e. clock-wise, and counter clockwise, the sliding rails 106 of the top triangular base 103 (Figure 1D) slide up and down the rail inserts 107 on the bottom triangular base 104 (Figure 1D). This action will simultaneously alter the intervertebral height and depth of the screw box 100 allowing individualized custom fitting of the screw box 100 conforming to the dimensions of the disc space.

[0063] Transvertebral screw 101 penetrates the top base 103, and transvertebral screw 102 traverses the bottom base 104 of the screw box 100. The two screws 101, 102 traverse the screw box 100 in opposing directions, bi-directionally (whether they are lateral or medially oriented). The external edges of the triangular bases 103, 104 in contact with vertebral body

surfaces include ridges 107. This facilitates the screw box's 100 incorporation into and fusion with the superior and inferior vertebral bodies (Figures 1A-E). Both top and bottom screw box bases 103, 104 are perforated with holes 108 to allow bone placement for fusion. The entire construct, furthermore, is hollow to allow bone filling. Hence this device functions as both an intervertebral bone fusion spacer and bidirectional transvertebral screw fusion device.

[0064] Figures 2A-C illustrate three-dimensional views of the Lumbar intervertebral non-expandable screw box 200 with two BDFT screws 201, 202 (Embodiment II). Screws 201 and 202 perforate and orient in opposing, superior and inferior directions. There are holes 208 and hollow spaces allowing packaging with bone. There are also holes which allow the traversal of screws. The superior and inferior edges include ridges 207 to facilitate integration and fusion with superior and inferior vertebral bodies. The expandable screw box 200 may include a screw insert 209 to attach a horizontal mini-plate (not shown). The self-contained internalized drill guides are at a 25 degree angle. The screw boxes can be designed with the internalized drill guides with different angles and/or different positions within the box.

[0065] Figure 3 illustrates a three-dimensional view of left and right lumbar intervertebral non-expandable screw boxes 300a, 300b with one BDFT screw 301 or 302 (Embodiment III). It is roughly half the width of Embodiments I and II. Screw 301 is inserted into screw box 300a (left) and screw 302 is inserted into screw box 300b (right). There are holes 308 and hollow spaces allowing packing of bone to achieve biological fusion. The combined effect of one superior oriented and one inferior oriented screw fuses the superior and inferior vertebral bodies with small constructs. This also enables placement of larger dimension screws compared to embodiments I and II.

[0066] Figures 4A and B illustrate three-dimensional views of the horizontal intervertebral zero profile mini-plate 400 with two non-expandable lumbar intervertebral screw boxes 300a, 300b housing two BDFT screws 301, 302. Figure 4A illustrates the perforations 401 within the plate 400 through which small plate securing screws 310 will be inserted to connect it to the built-in screw holes of the screw box 300a, 300b (Figure 4B). The horizontal mini-plate 400 together with the top surfaces of left and right screw boxes 300a, 300b provide a physical barrier between the underlying bone placed beneath it (not illustrated), and the thecal sac and nerve roots above it (not illustrated).

[0067] Figure 4C illustrates two screw boxes 300c, 300d within a circumferential cage 420 (2 in 1) construct which is designed for anterior placement into the lumbar spine. There are slots 308a, 308b for bone graft placement, both outside and inside the boxes. The circumferential cage 420 has perforations 401 a for the placement of transvertebral screws (not shown).

[0068] Figures 5A-C illustrate three-dimensional views of the external drill /screw guide -box expander 500 which assists in screw trajectory and box expansion (embodiments IA-B). For embodiments II and III, the same instrument is utilized; however, an expanding Allen key component is not used.

[0069] The key components of this device include an Allen key 501, a spring 502, a handle 503, a griper 504 and a screw guide 505. The Allen key 501 when inserted in the insertion 514 and turned, turns the screw adjuster (Figure 5C) which in turn regulates top and bottom triangular screw box base sliding, and hence box 200 width and depth. The griper 504 has griper prongs 506 which insert into grooves of the screw guide 505 and the screw box 200 (Figures 5A-D) thus perfectly aligning them.

[0070] Figure 5D illustrates a superior oblique view of the screw guide 505 demonstrating insertions 509 for griper prong 506, built-in trajectory guides 511, 512 for insertions of screws 101 and 102, and the Allen key 501.

[0071] Figures 5E-G illustrate three—dimensional views of the sequential steps necessary for the external guide assembly. Figure 5E illustrates the insertion of the Allen key 501 into the handle 503. Figure 5F illustrates the insertion of the handle 503 through the spring 502 and griper 504. Figure 5G illustrates insertion of the griper 504 into the screw guide 505.

[0072] Figures 5H-1 illustrate three-dimensional views of a positioning tool 500a for impaction and placement of two transvertebral screws 201, 202 in the non- expandable screw box 200. The driver assembly 550 consists of a screw driver 551, a flexible shaft 552 and a square recess bit 553. This facilitates turning the screws 201, 202 into the bone. The flexible shaft 552 facilitates the avoidance of spinous processes which might hinder the screw driving if the shaft 552 were straight. The positioning tool 500a can have a rectangular handle, Embodiment I (FigureSH), or a circular handle, Embodiment II (Figure 51). This serves to position the screw box within the intervertebral space, and screws 201, 202 within the screw box. Once positioned, the screw box can be impacted by tapping the handle with a mallet (not shown). The positioning tool's 500a griper handle inserts into the screw guide and the box, which maintains alignment.

[0073] Figure 6A illustrates a three-dimensional view of insertion of the construct (Embodiment I) into the lumbar intervertebral disc space.

[0074] Figure 6B illustrates a three dimensional lateral view of insertion of the construct (Embodiment I) into the disc space with short screws. Placement with longer screws would capture more bone.

[0075] Figures 7Aand B illustrate three-dimensional views of the two-pronged cervical facet staple 700 (Embodiment I). There is a staple base 701 which is contoured to align with the curved surface of the cervical

facet joints. There is a superior impactor threaded insert 702. An impactor can be screwed into this insert 702 and then impacted with a mallet. The two spikes 703, 704 perforate the inferior and superior facets of the superior and inferior vertebral bodies hence leading to cervical facet joint fusion. The spikes can be designed with ridges and/ or fishhooks to facilitate irreversible extraction.

[0076] Figures 8A-C illustrate three-dimensional views of the four-pronged cervical facet staple 800 (Embodiment II). Likewise it has a staple base 805 contoured specifically for the surface of the facet joint. It also has an impactor insert 806. The insertion of a device with four prongs 801-804 instead of two prongs further limits the degrees of motion of the joint hence making the fusion more rigid.

[0077] Figures 9 A-B illustrate a three-dimensional view of the two-pronged cervical staple impactor 900. It has a handle 901, a stem 902, and a screw insert 903 which can be screwed into the threaded staple insert. The impactor has two wings 904 which keep the staple base edges in place facilitating staple impaction. The handle 901 of the impactor 900 is broad in order to allow impaction by a mallet.

[0078] Figures 10A -C illustrate three-dimensional views of the four-pronged cervical staple impactor 1000 (Embodiment II). It has the same features as the two-pronged impactor 900, except its wings 1004 are broader accommodating the broader staple base. The impactor 1000 also includes a handle 1001, a stem 1002, and an impact screw 1003.

[0079] Figure 11A illustrates a three-dimensional view of placement of the two pronged cervical facet staple 700 into a cervical spine model having vertebral body 1103 and lamina 1104. One staple 700 is perched on the joint 1101 prior to impaction. The other staple 700 is impacted.

[0080] Figure 11 B illustrates a three-dimensional view of placement of the four pronged cervical facet staple 800 into a cervical spine pre and post impaction.

[0081] Figure 11C illustrates the concept of modularity and incremental diminution of movement of the joint by the modular placement of different combinations and permutations of varying numbers of two and four pronged cervical facet staples 700, 800. If one wishes to have the most flexible (least rigid) fusion, one would place a unilateral two pronged staple 700. One can increase i.e. calibrate increasing degrees of rigidity by increasing the number of prongs penetrating the facet joints bilaterally. In Figure 11C each facet joint is fused using a total number of six prongs. One side this is accomplished by using three two pronged staples 700, and on the other side using one four pronged staple 800 and one two pronged staple 700. These two embodiments can be mixed and matched unilaterally or bilaterally to vary the degree of rigidity and conversely flexibility of fusion. The most flexible fusion at one level would be accomplished by one staple 700 (2 prongs). The highest level of rigidity would be achieved by placing two four pronged staples 800 on both sides totaling sixteen prongs. Intermediate degrees of relative joint motion can be modulated by insertion into the cervical facet joints staples in two-four prong increments from 216. Each additional prong further limits the degree of facet joint motion hence increasing rigidity, and conversely decreasing flexibility. Thus the novel modular use of these embodiments heralds an era of flexible cervical spine fusion.

[0082] Figures 12 A - B illustrate a lumbar facet joint staple 1200 in open and closed positions and having staple prongs 1203. This lumbar facet staple has been thoroughly described in our previous co-pending patent applications, Serial No. 11/536,815, filed on September, 29, 2006, and Serial No. 11/208,644, filed on August 23, 2005, the relevant portion of each of which is hereby incorporated by reference hereinafter. The new improvement of this device includes a ratchet 1201. The staple 1200 can be incrementally closed with increased ratcheting over increasing number of spurs 1202. This achieves increasing calibrated levels of lumbar facet joint fusion, and conversely

diminishing joint flexibility. This new designs further enhances the capacity to achieve flexible fusions in the lumbar spine.

2. THE SURGICAL METHOD

[0083] Exemplary surgical steps for practicing one or more of the foregoing embodiments will now be described.

[0084] The posterior lumbar spine implantation of all the screw box 100, 200, 300 embodiments, with BDFT screws, and horizontal mini-plate 400 can be implanted via previously described posterior lumbar interbody fusion (PLIF) or posterior transforaminal lumbar interbody fusion (TLIF) procedures. The procedures can be performed open, microscopic, closed tubular or endoscopic. Fluoroscopic guidance can be used with any of these procedures.

[0085] After adequate induction of anesthesia, the patient is placed in the prone position. A midline incision is made for a PLIF procedure, and one or two parallel paramedian incisions or a midline incision is made for the TLIF procedure. For the PLIF, a unilateral or bilateral facet sparing hemi-laminotomy is created to introduce screw box 100, 200, 300 embodiments I-III into the disc space, after it is adequately prepared.

[0086]For the TLIF procedure, after unilateral or bilateral dissection and drilling of the inferior articulating surface and the medial superior articulating facet the far lateral disc space is entered and a circumferential discectomy is performed. The disc space is prepared and the endplates exposed.

[0087]Then one screw box 100, 200, 300 of either embodiments I-III is placed on either right, left or both sides. Then another screw box of embodiments 100, 200, 300 I-III is placed on the contralateral side. For embodiment I the external screw guide 505/ box expander is attached to the

screw box (Figures 5A-H). First the Allen key 501 is screwed until the box conforms perfectly to the height and depth of the space. Then a pilot hole can be drilled or an awl can start a pilot hole in the vertebral bodies. Then a transvertebral screw is screwed into the vertebral body via the built-in box screw guides 505. For difficult angles, an angled screw driver can be employed.

[0088]For embodiments II-III the same method is used for placing screws, except the Allen key 501 is not utilized in the absence of plate expansion.

[0089]If bilateral constructs have been inserted, bone is packed into the intervertebral space, as well as within the device. Then the horizontal intervertebral zero profile mini-plate 400 is slid beneath the thecal sac and is secured to both left and right screw boxes with small mini-plate screws 210 (Figures 4A-B). This prevents bone intrusion into the thecal sac and hence possible nerve root compression.

[0090]Figures 6A and B illustrate the process of insertion and final placement of the construct into the lumbar spine. The mini-plates 400 can come in different horizontal lengths and widths to accommodate different intra and inter-patient disc space diameters. The BDFT screws can come in different widths, lengths and thread designs.

[0091] The anterior thoracic and lumbar spine implantation of one, two or three screw box constructs 100, 200, 300 and BDFT screws can be performed in a similar manner to the posterior application. Likewise, a horizontal mini-plate 400 can be used to cap two or three screw box constructs 100, 200, 300 (one placed midline deeply, one placed left and one placed right, forming a triangulation). Alternatively two screw box constructs may be placed into a circumferential ring for anterior placement. Anterior placement of these devices can be performed into the L4/5 and L5/S1 spaces on the supine anesthetized patient via previously described open microscopic or endoscopic techniques. Once the disc space is exposed and discectomy and space preparation are performed, placement of one, two or three screw box

embodiments 100, 200, 300 (I-111) or a 2 in I construct can be placed. The screw placement is facilitated by the internal screw guides, and different positioning tools ((Figure 5). A right angled screw driver and/or ratchet could alternatively be employed A capping mini-plate 400 may be applied if desirable. The mechanism of screw placement and mini-plate 400 attachment are identical to what was described above.

[0092] The posterior placement of screw box constructs 100, 200, 300 alone or combined with horizontal mini-plates 400 into the thoracic spine can be performed via previously described transpedicular approaches; open or endoscopic. The anterior placement into the thoracic spine can be accomplished via a trans-thoracic approach. Once the disc space is exposed via either approach, any combination of the above mention Embodiments (I-111) can be inserted. Engagement of the devices is identical to what was mentioned above.

[0093] For posterior placement of cervical facet staple 700, 800 embodiments, after adequate induction of anesthesia the patient is flipped prone and his head and neck secured. A single midline or two para-median incisions are made for unilateral or bilateral or multilevel placement of staples. Ultimately the facet joint is exposed. Alternatively and preferably this can be performed percutaneously under fluoroscopic guidance with intravenous sedation. The staple 700, 800 (Embodiments I or II) is loaded into the impactor 900, 1000. The staple 700, 800 is placed on the two articulating cervical facets, and then impacted into the joint. To achieve modular calibrated fusion different combinations and permutations of cervical facet stales can be inserted ranging from a single unilateral two pronged staple providing a high degree of flexibility to a total of four bilaterally placed four pronged staples 800 (16 prongs) leading to the highest degree of rigidity. Additional bone may or may not be placed in its vicinity to facilitate permanent and solid fusion. This procedure can be performed open, closed, percutaneously, tubulary, endoscopically or microscopically. Figures 11 A-C illustrates placement of the staples 700, 800 in the cervical spine.

[0094] We have previously described surgical placement of the lumbar facet joint staple in our two co-pending patents. The surgical procedure for this device is identical to that which has been previously mentioned.

[0095] The present inventions may provide effective and safe techniques that overcome the problems associated with current transpedicular based cervical, thoracic and lumbar fusion technology, and for many degenerative stable and unstable spine disease. These inventions could replace much pedicle screw- based instrumentation in many but not all degenerative spine conditions.

[0096] The speed and simplicity of placement of cervical and lumbar facet staples, and placement of Lumbar screw box —BDFT constructs far exceeds that of current pedicle screw technology. Furthermore, these devices have markedly significantly decreased risk of misguided screw placement, and hence decreased risk of neural and vascular injury, and blood loss. In the lumbar spine BDFT screw constructs and facet staples could be applied modularly in different combinations to achieve different degrees of rigidity (flexibility). Patients having these devices would have decreased recovery and back to work time. These devices most likely lead to similar if not equal fusion with significantly less morbidity, and hence overall make them a major advance in the evolution of spinal instrumented technology leading to advances in the care of the spinal patient.

[0097] Another major novelty and advance is the introduction of simple and safe modular calibrated cervical flexible fusion. To our knowledge neither a similar device nor a similar mathematical concept of modular joint flexibility/fusion calibration has been postulated for the cervical spine or for any other articulating joint.

[0098] To our knowledge there have not been any previously described similar posterior lumbar and thoracic combined spacer and screw constructs. These devices can similarly be modified to stabilize bone fractures

throughout the entire body. To our knowledge the description of zero to subzero profile anterior or posterior horizontal spinal plates which traverse the diameter of the disc space

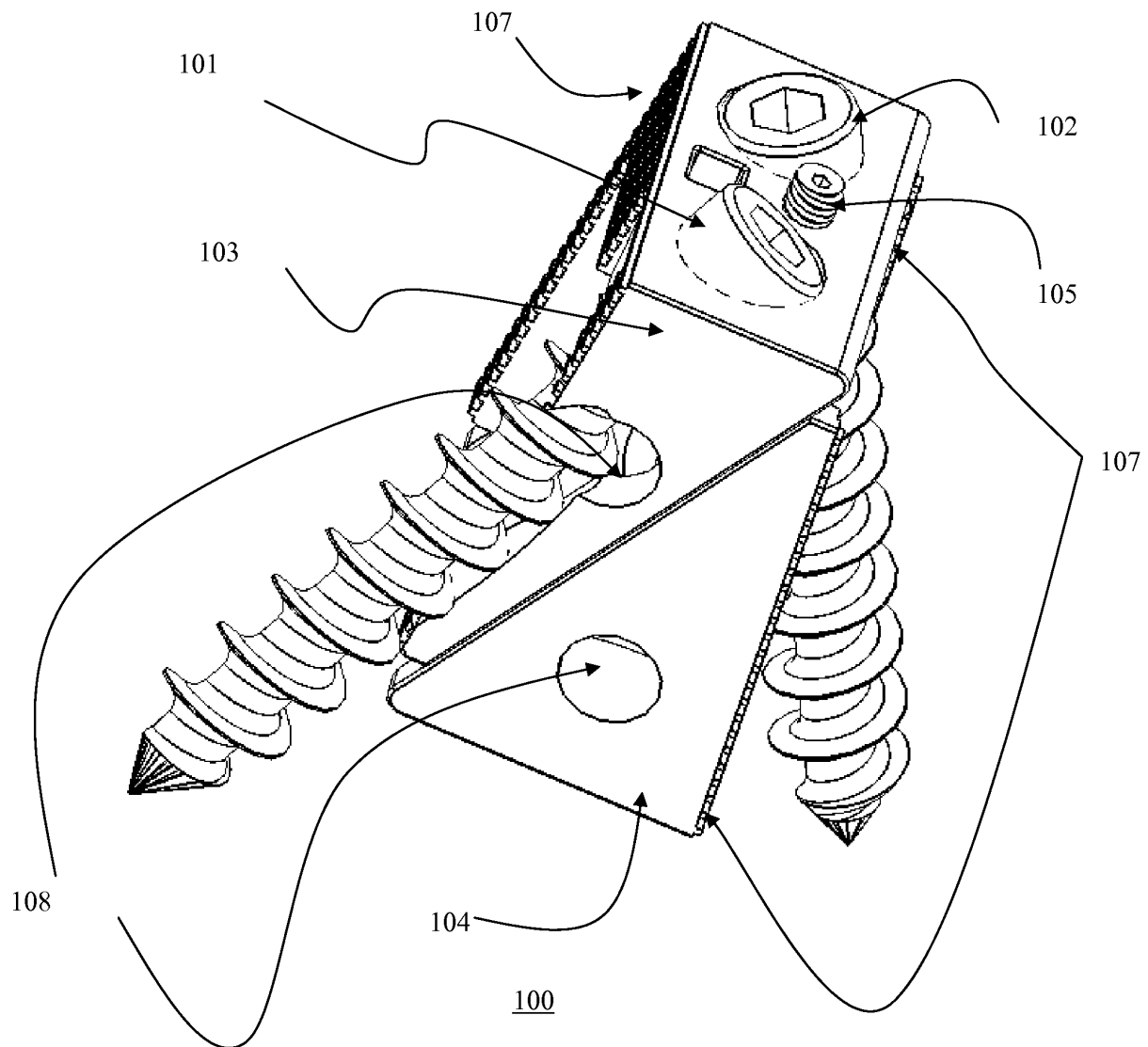


Fig. 1A

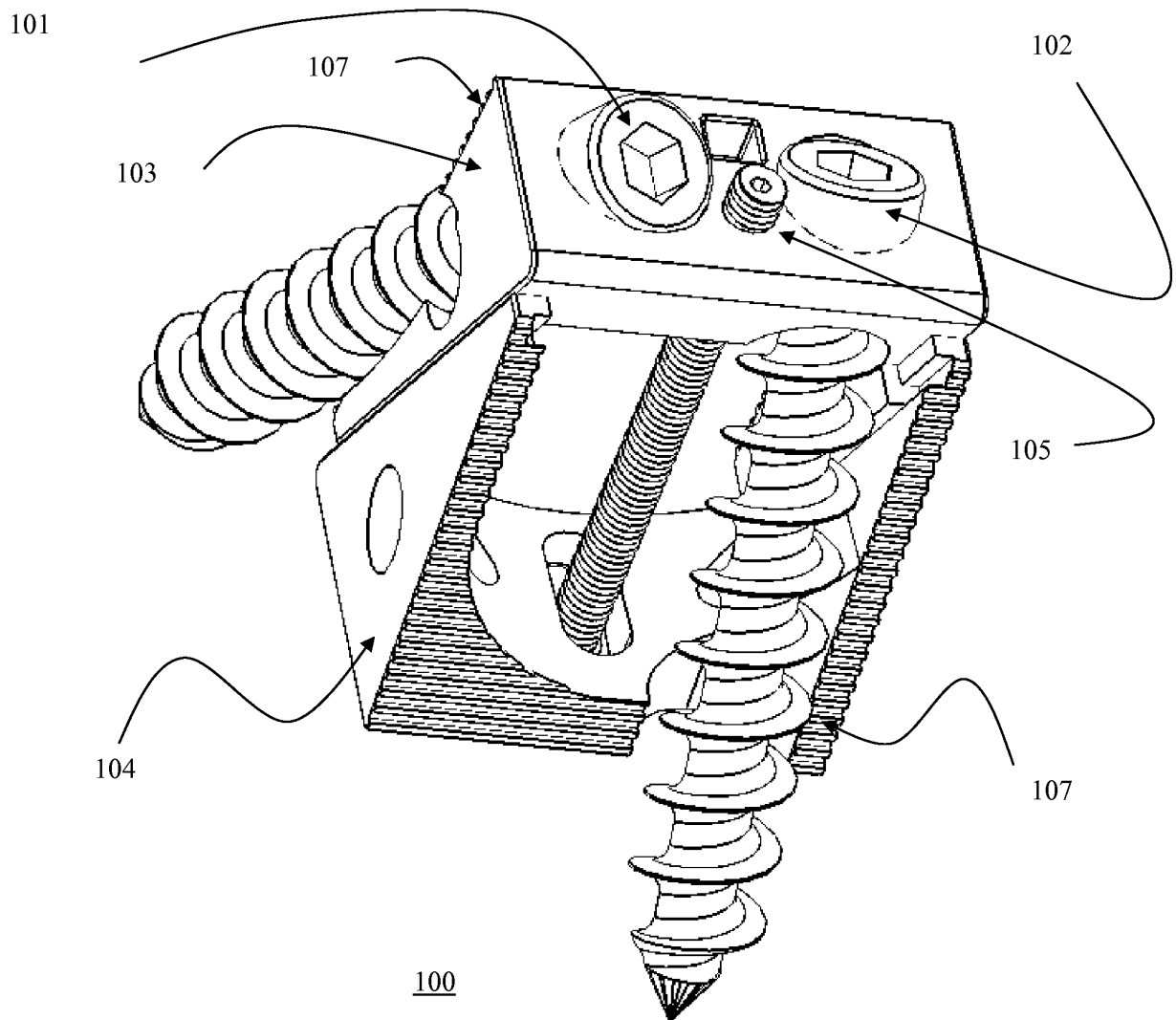


Fig. 1B

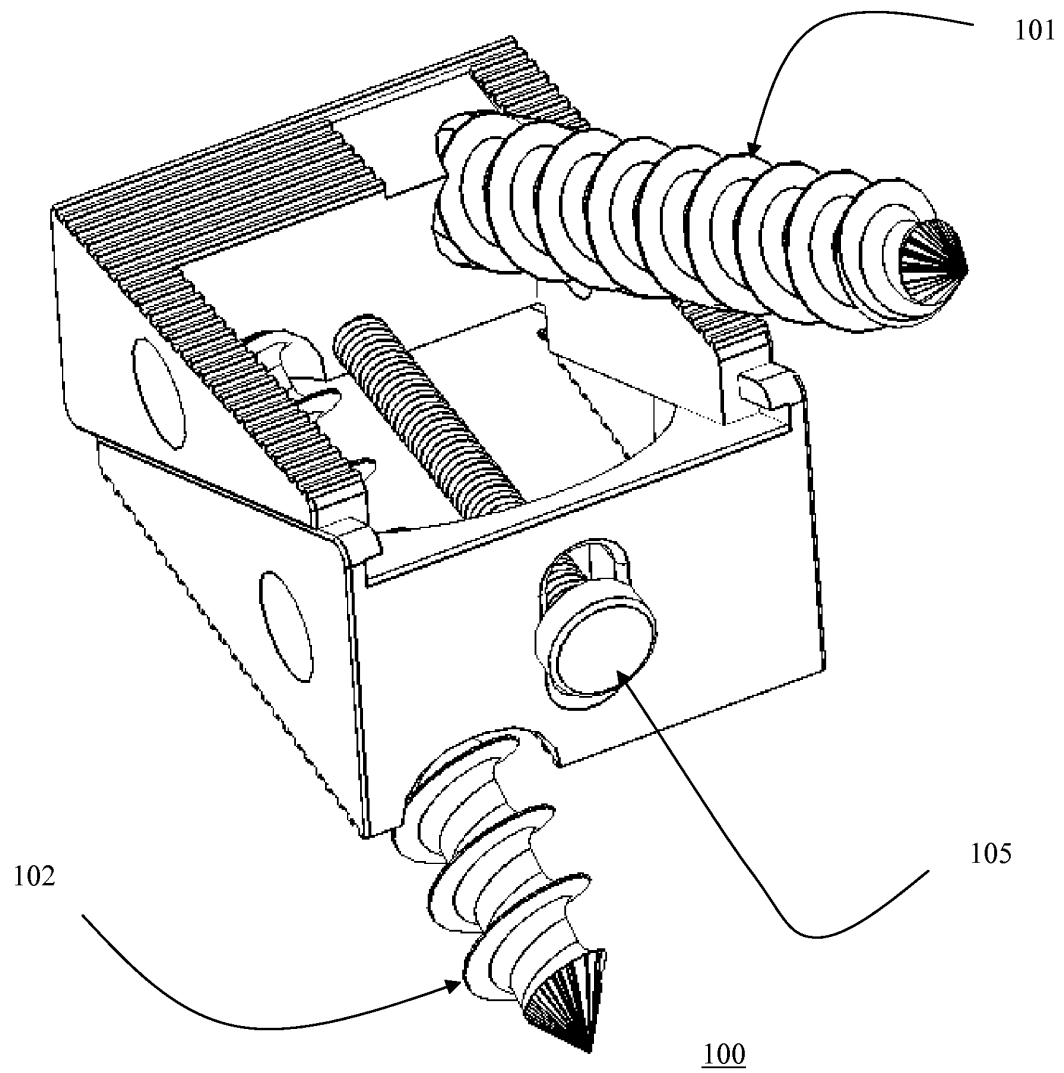


Fig. 1C

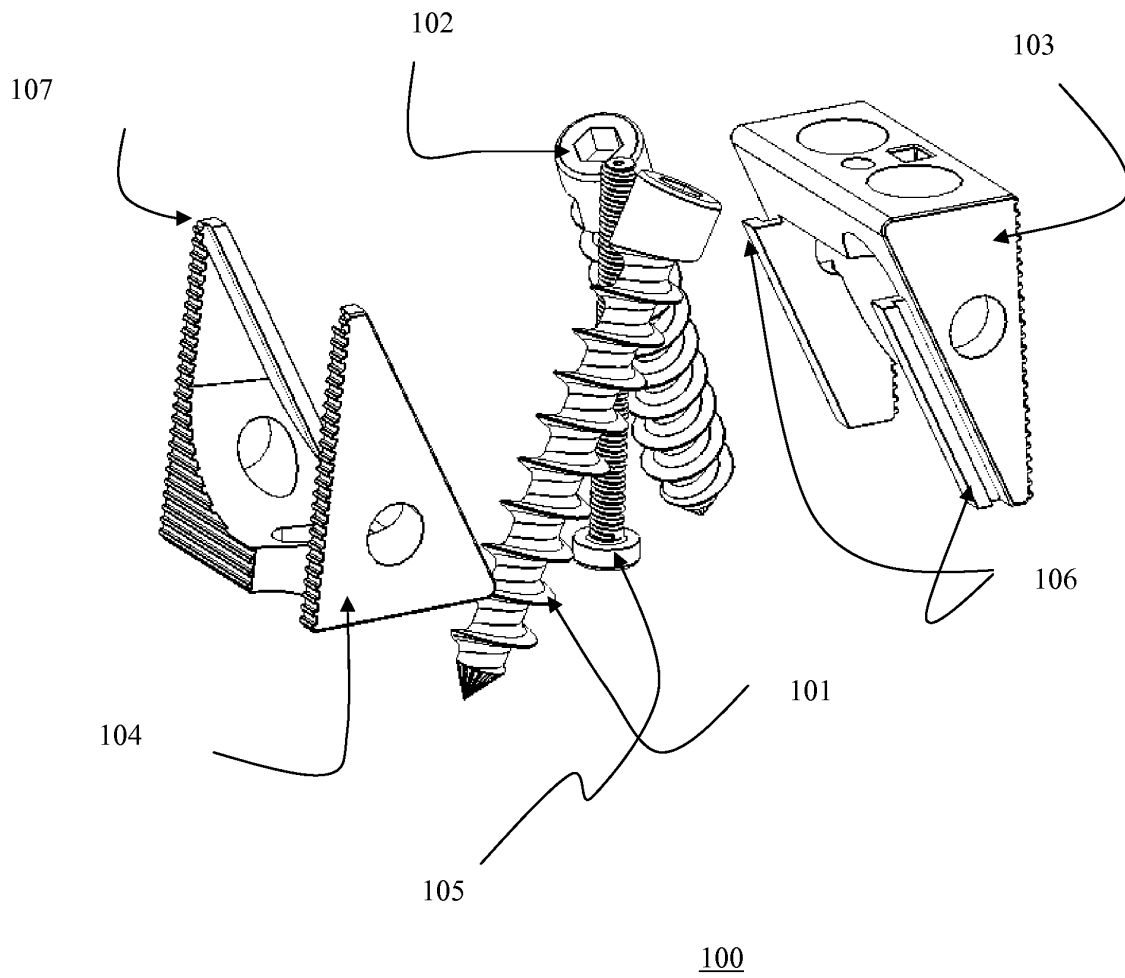


Fig. 1D

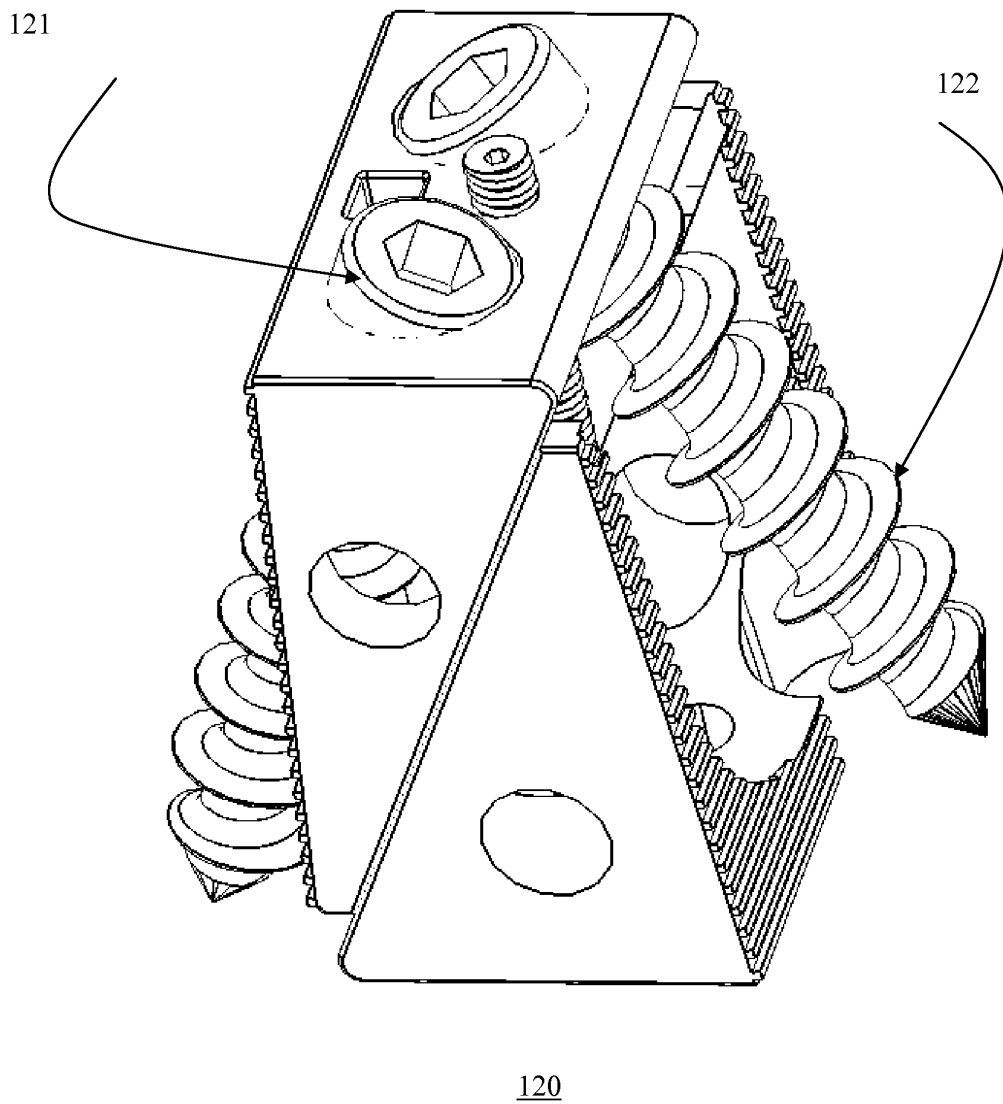


Fig. 1E

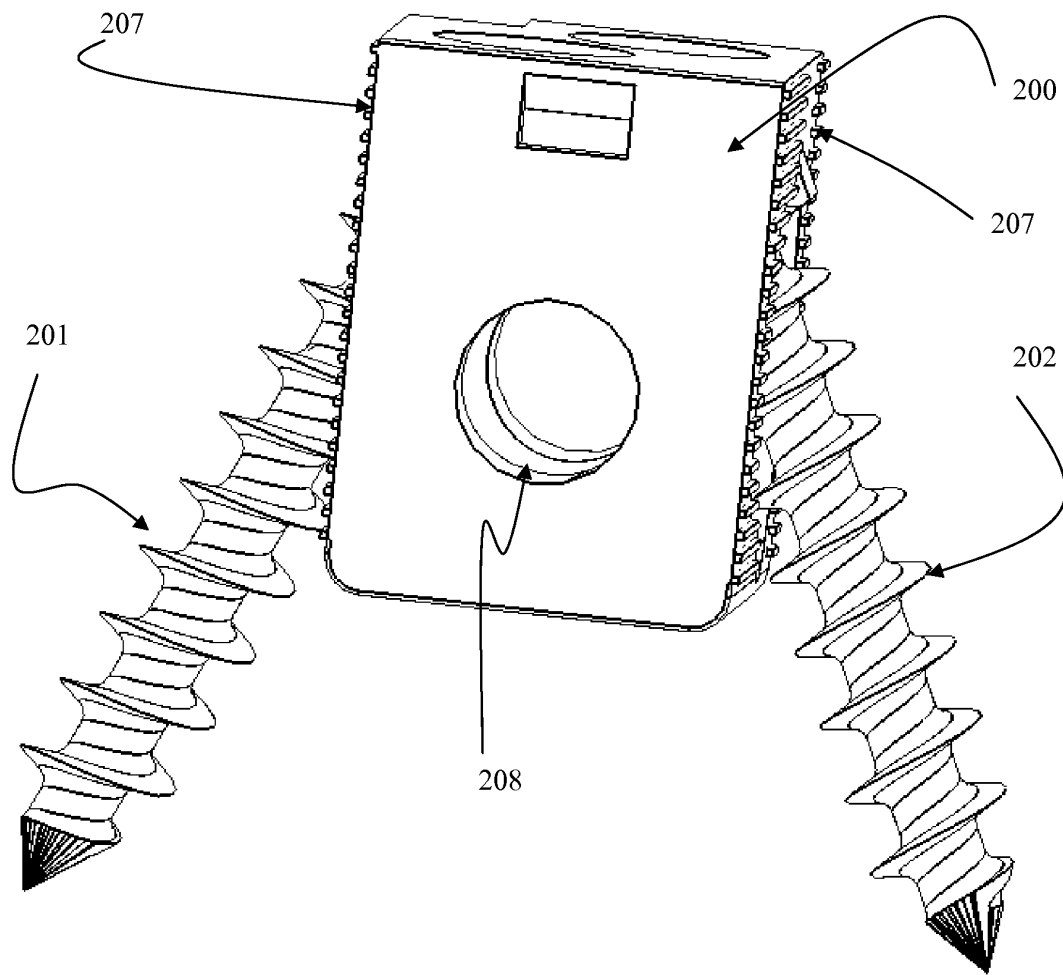


Fig. 2A

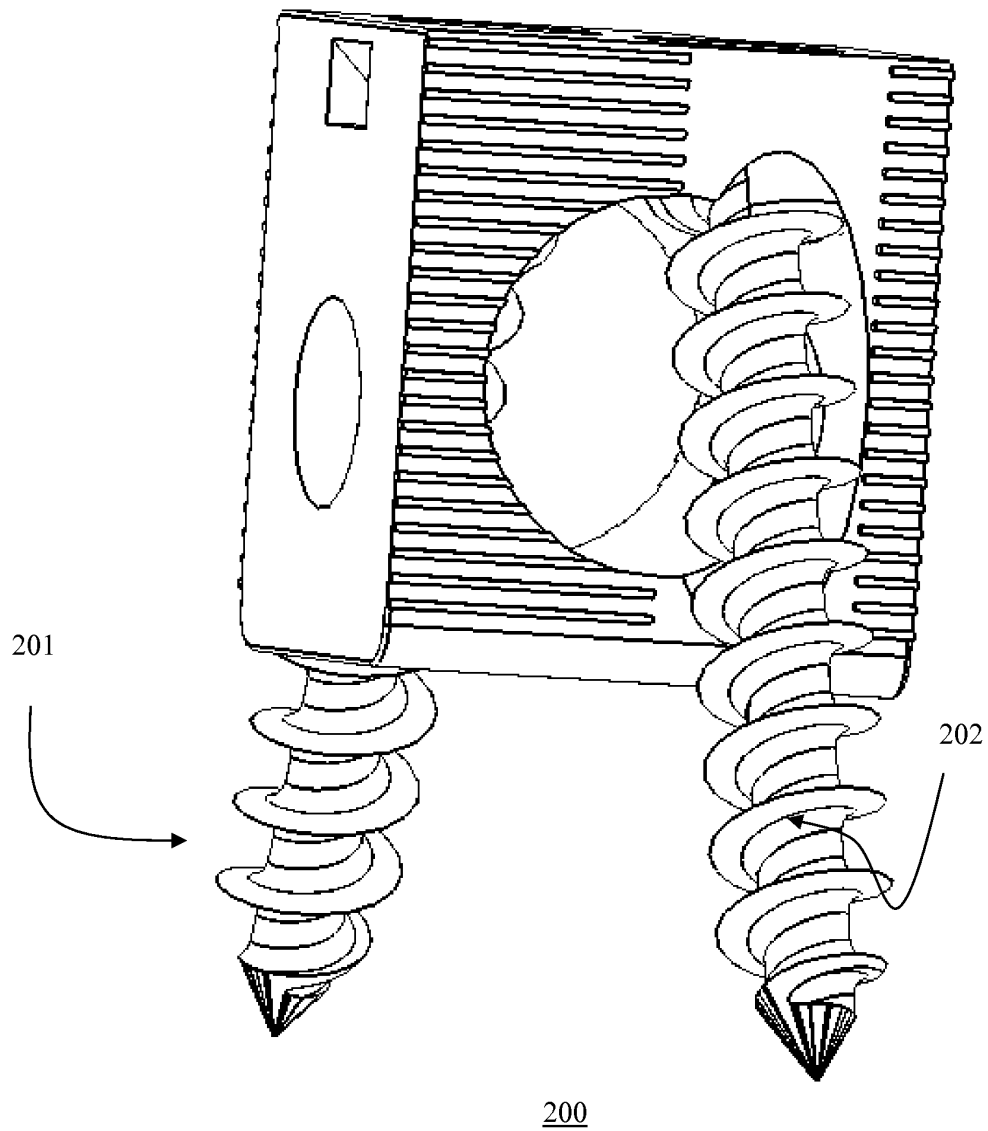


Fig. 2B

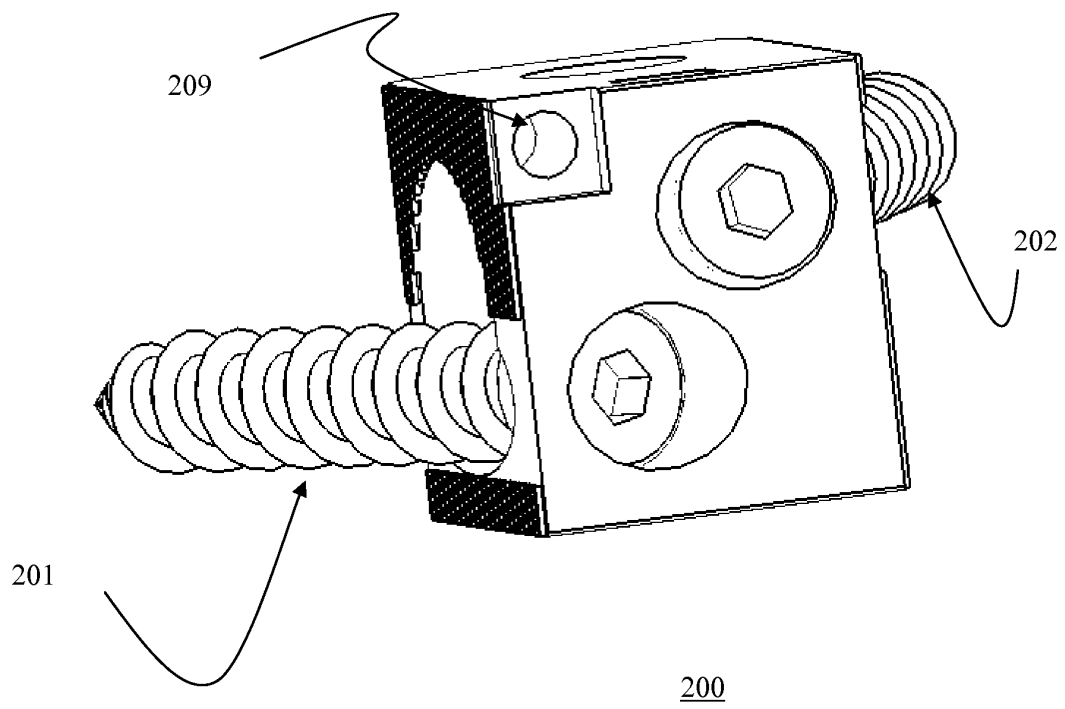


Fig. 2C

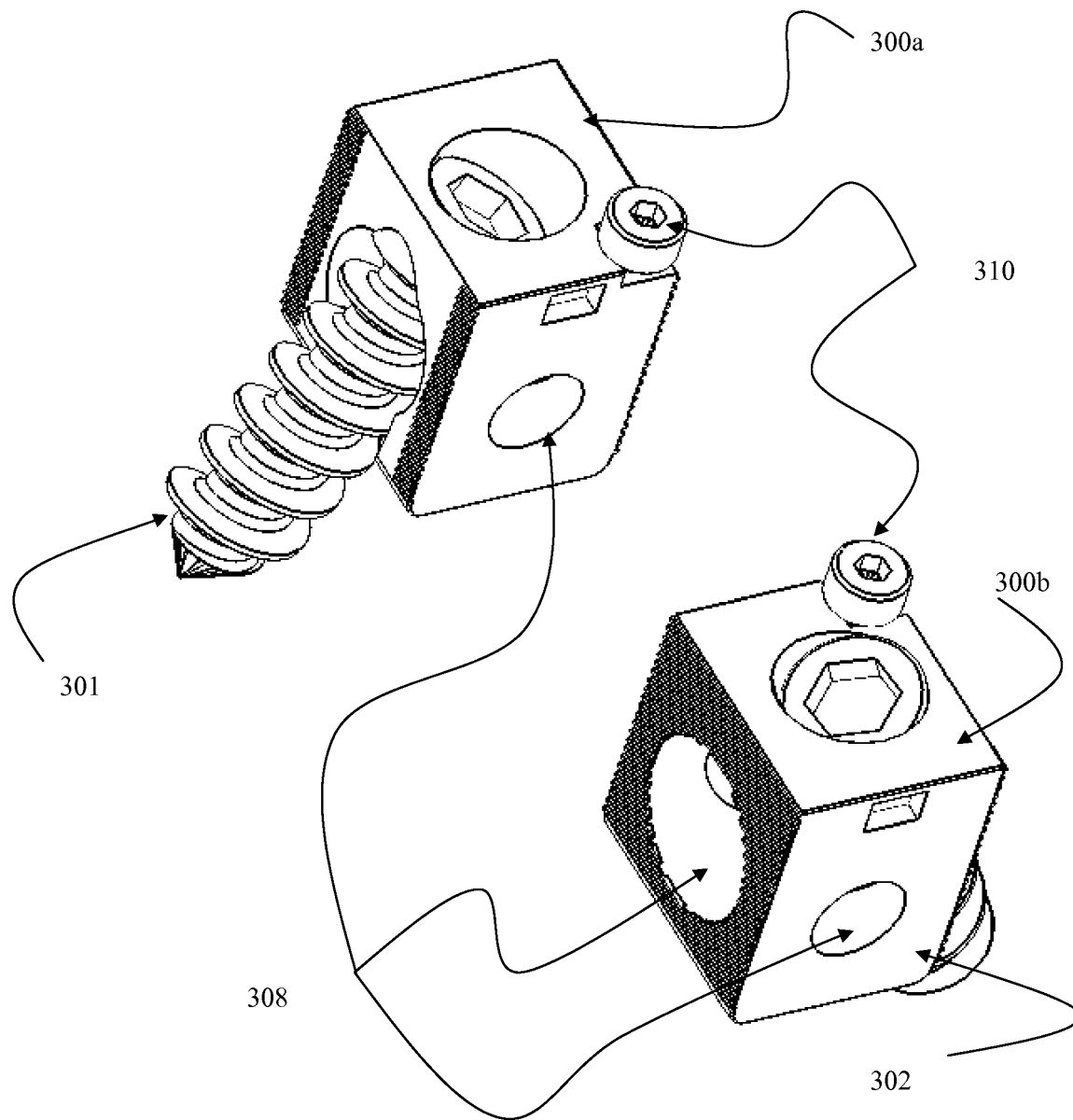


Fig. 3

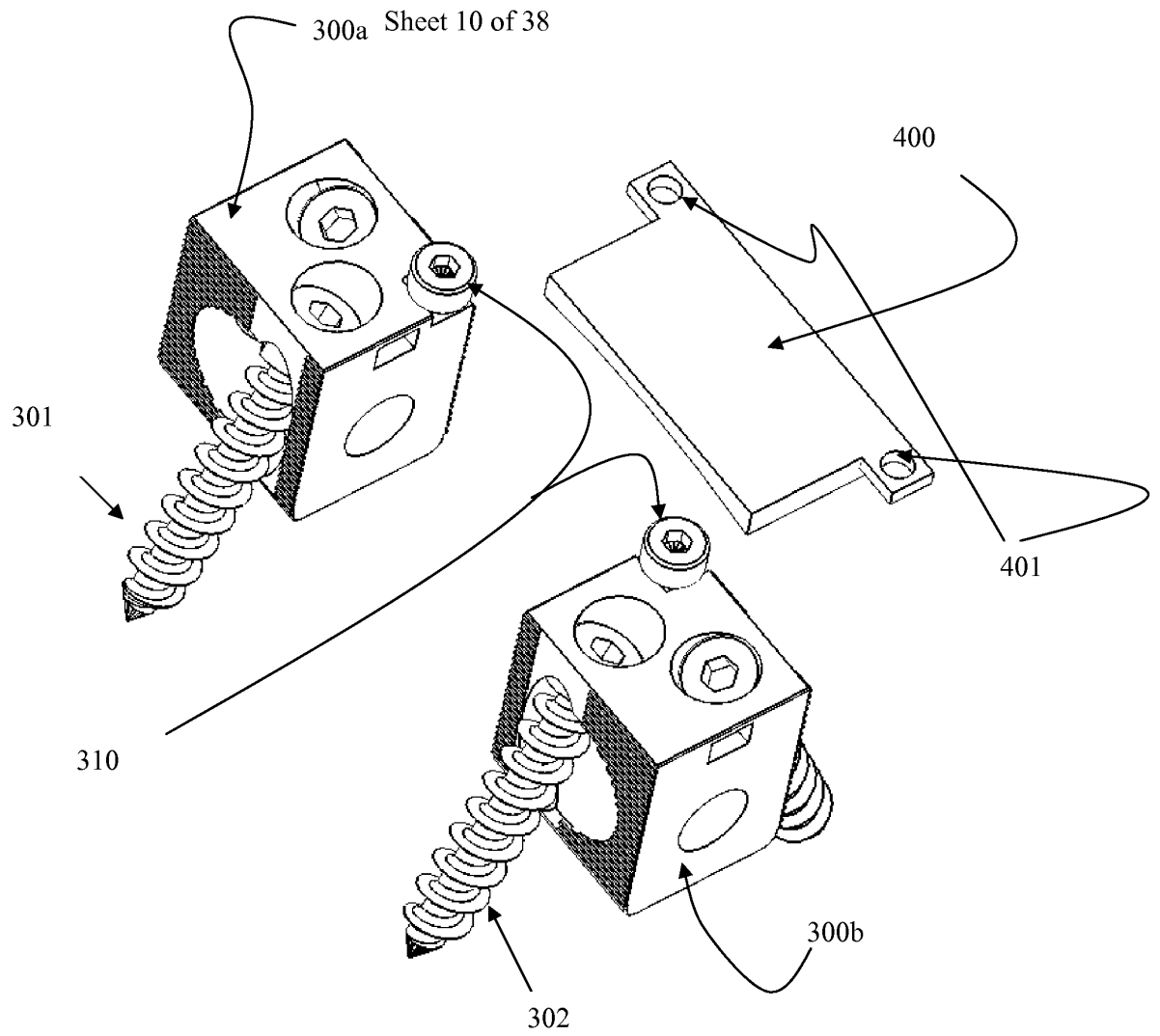


Fig. 4A

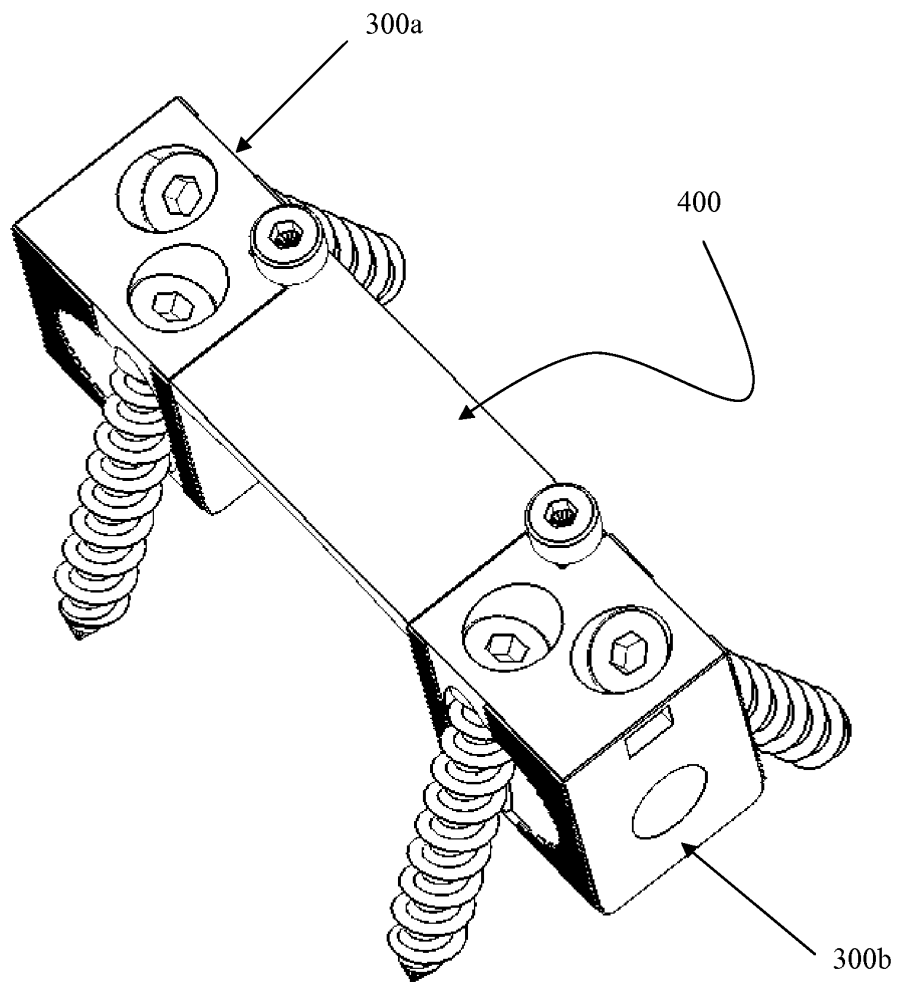


Fig. 4B

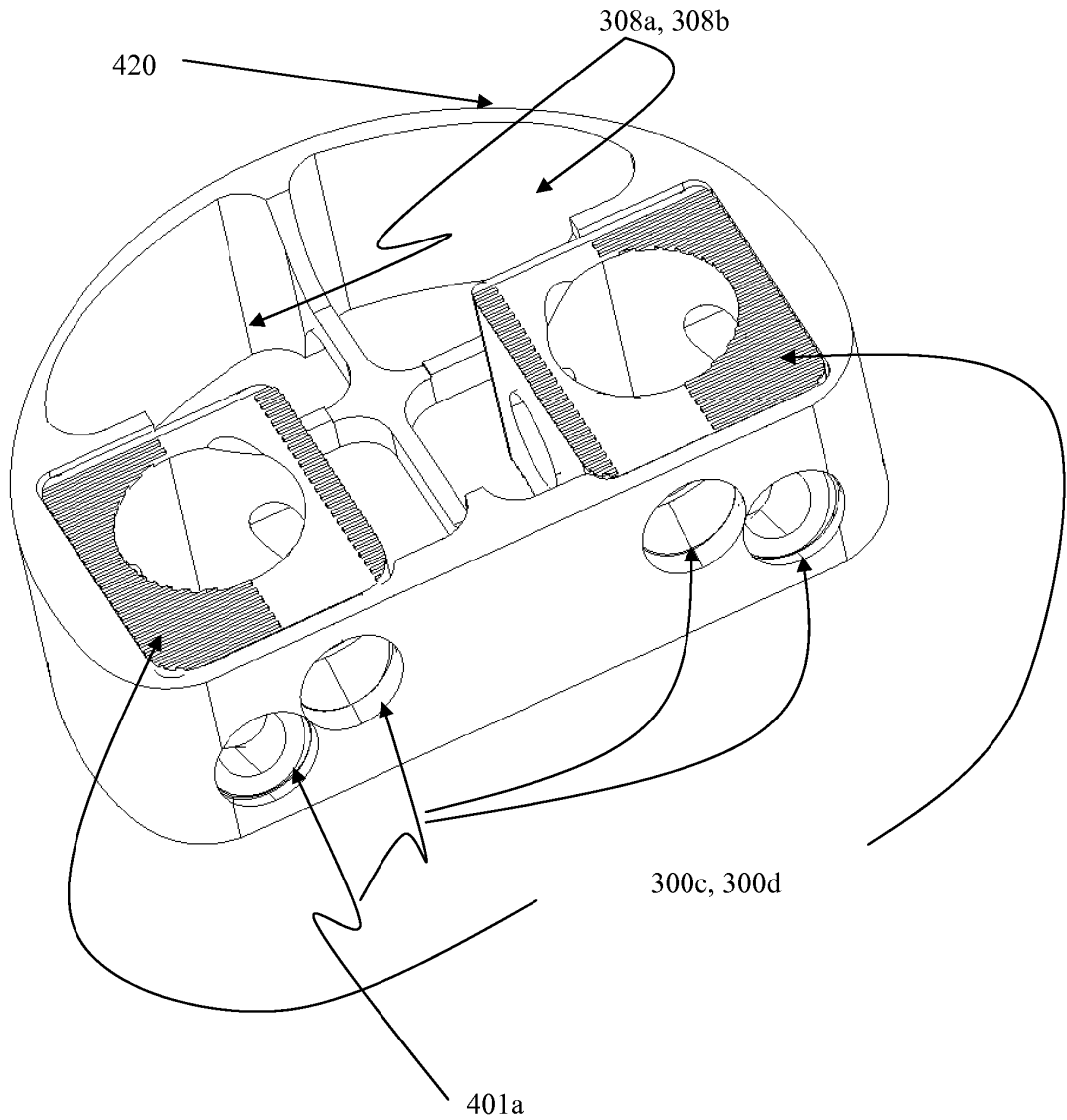


FIG. 4C

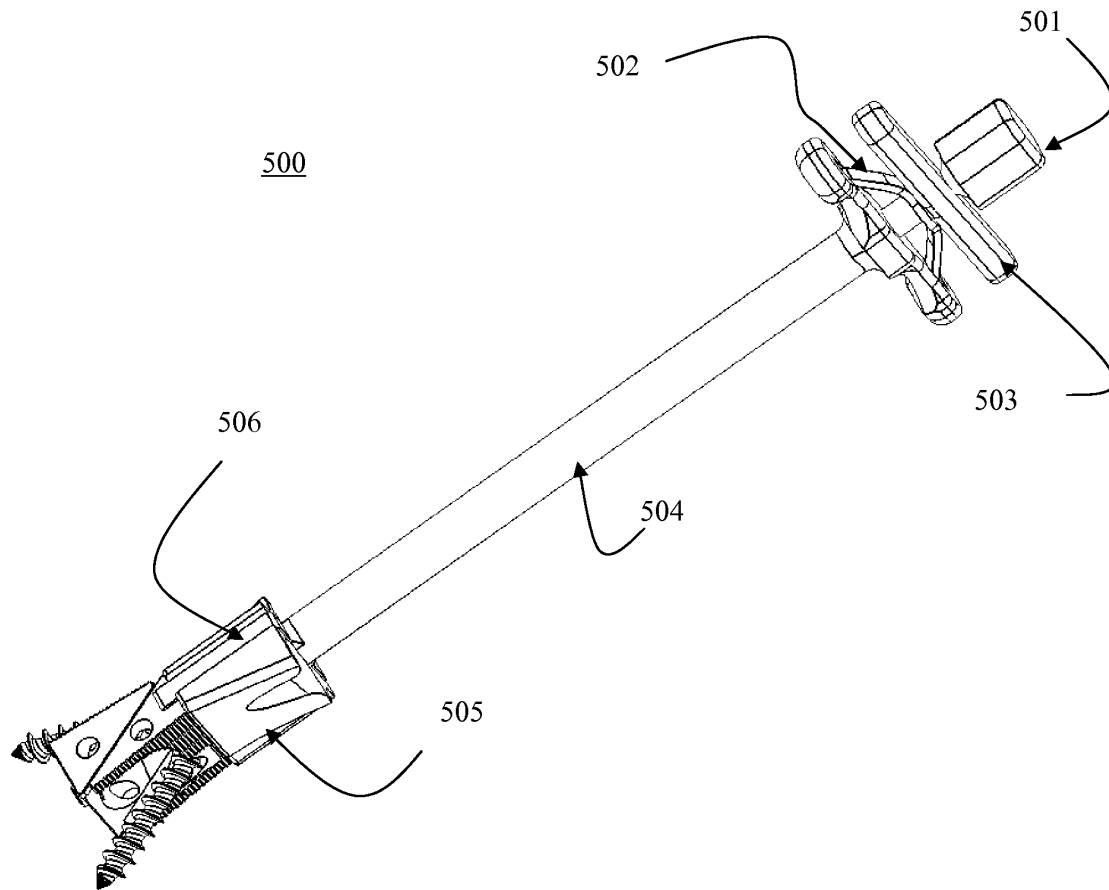


Fig. 5A

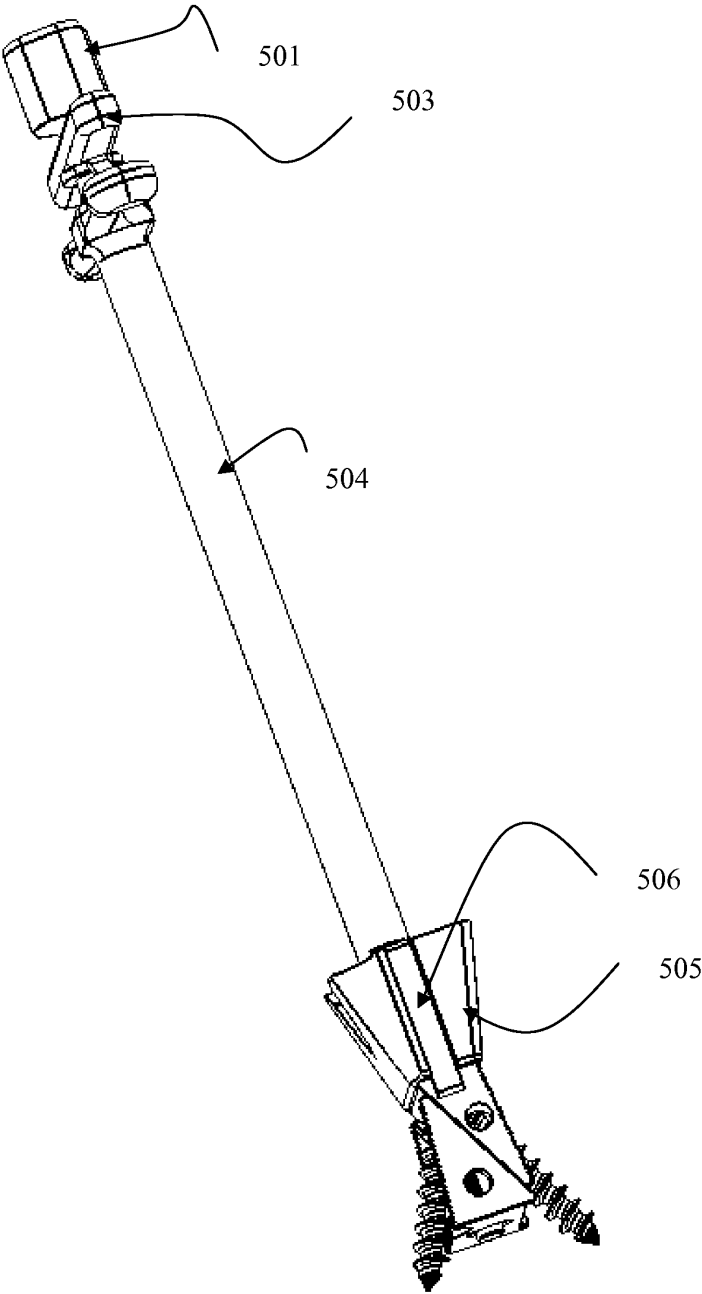


Fig. 5B

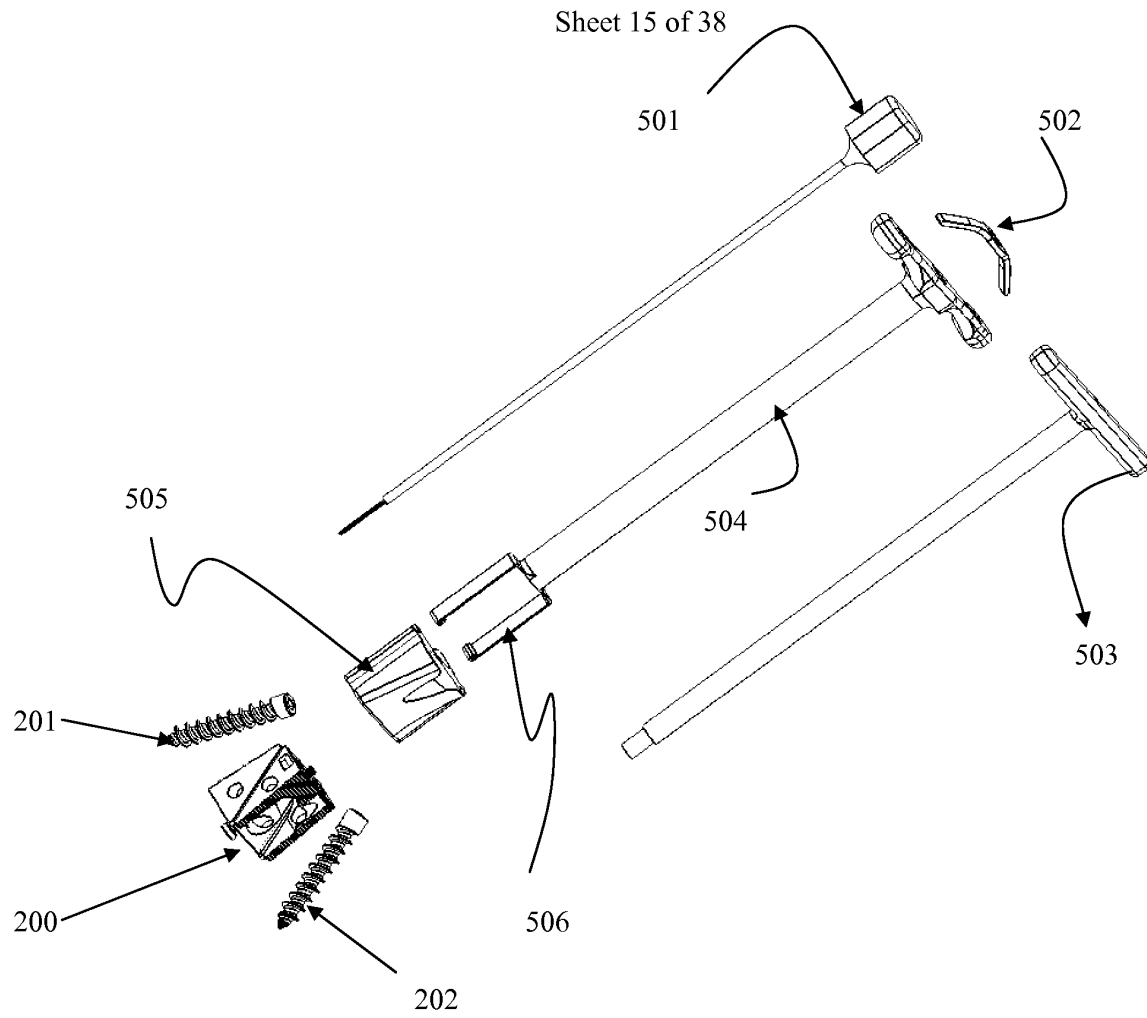


Fig. 5C

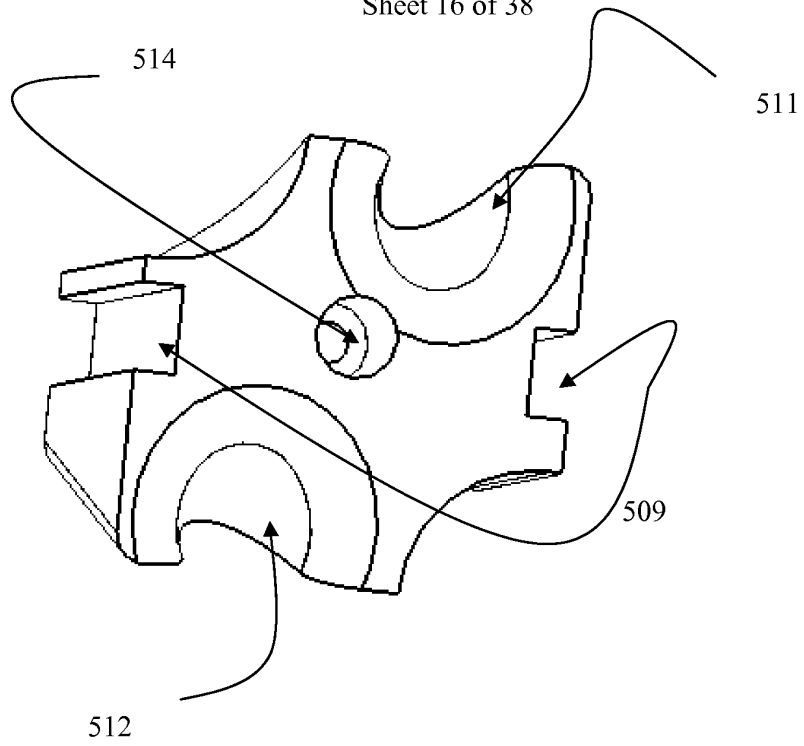


Fig. 5D

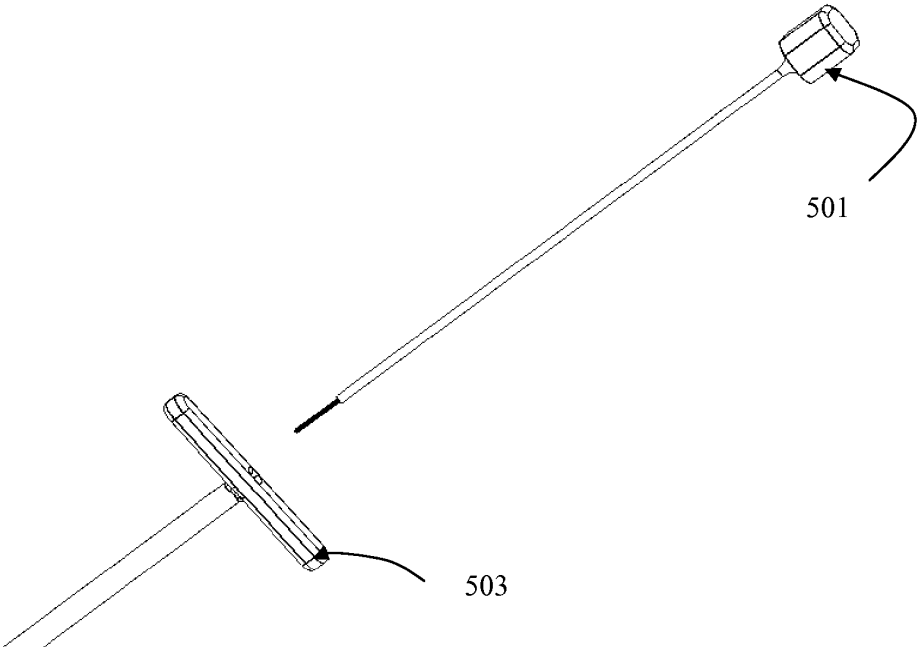


Fig. 5E

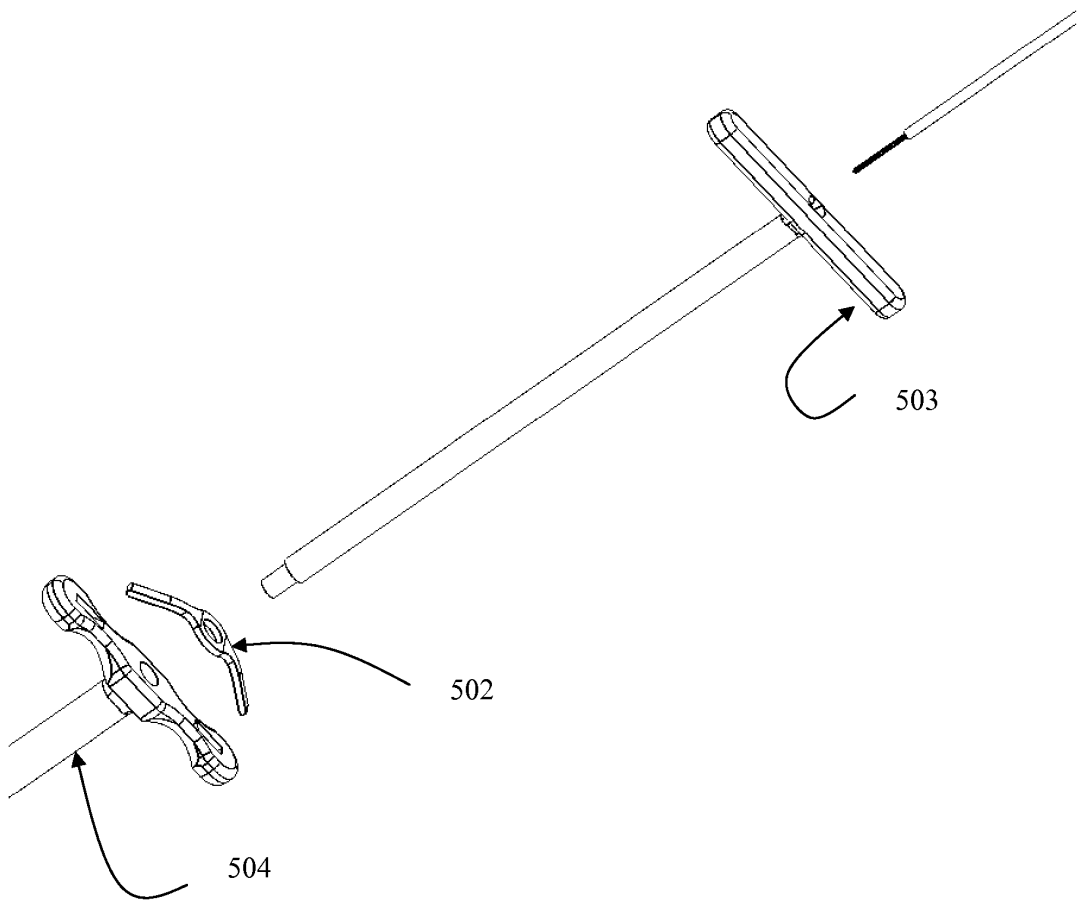


Fig. 5F

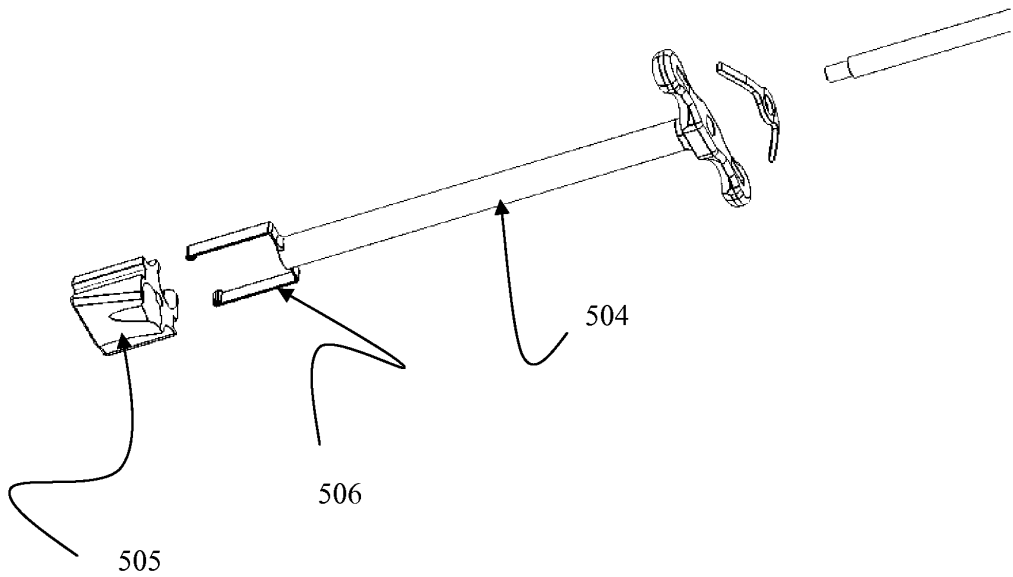


Fig. 5G

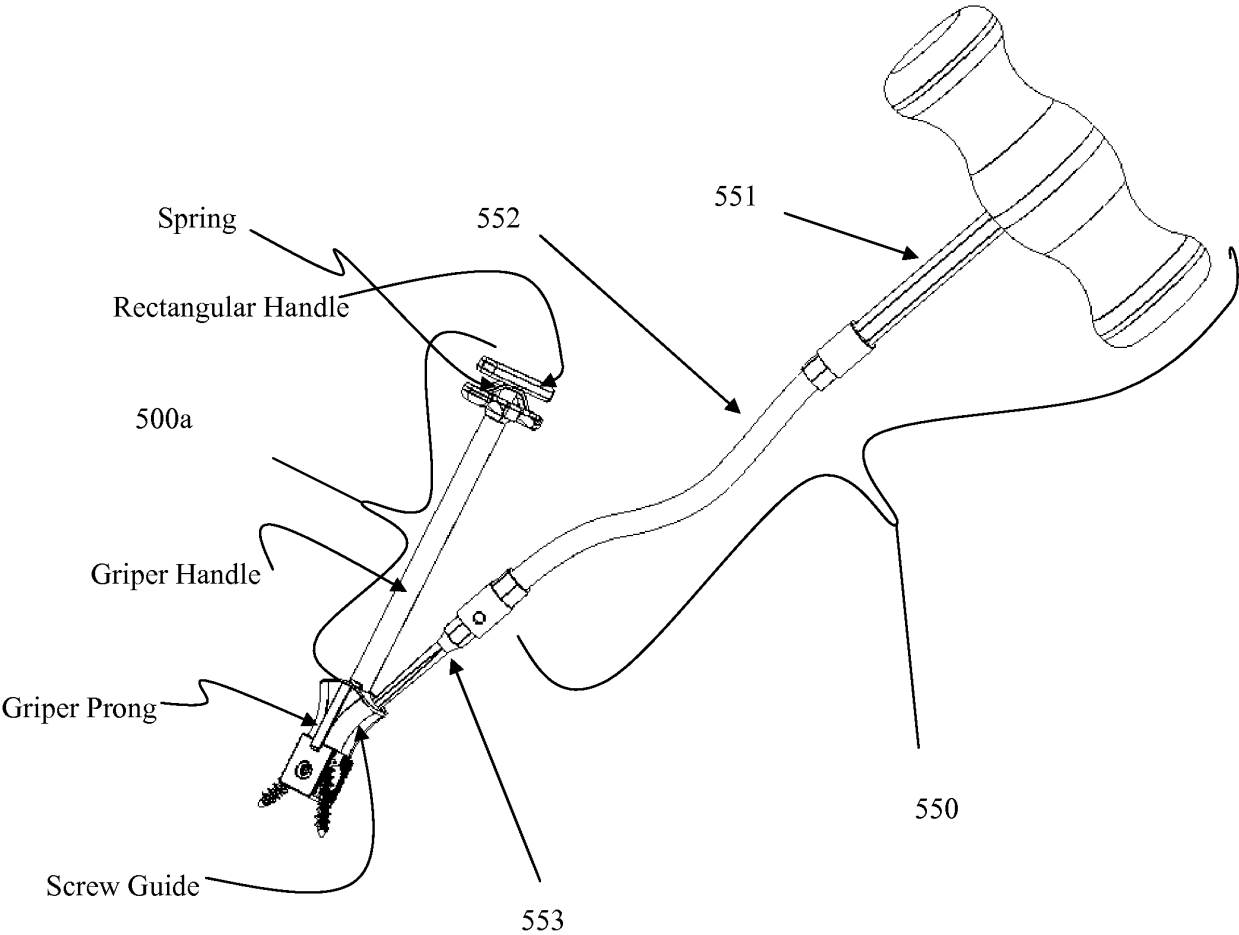


FIG. 5H

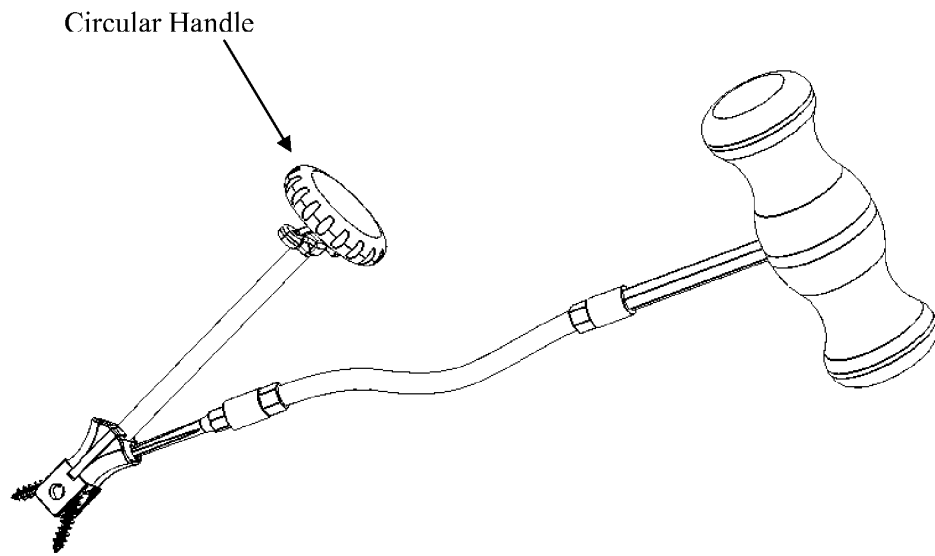


FIG. 5I

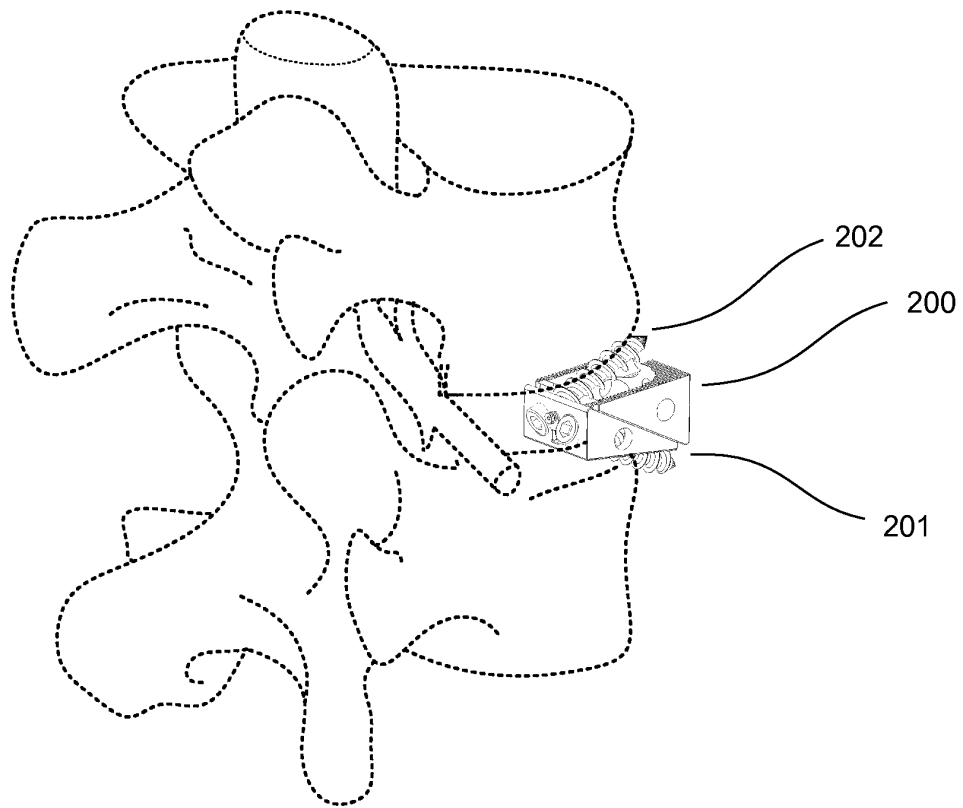


Fig. 6A

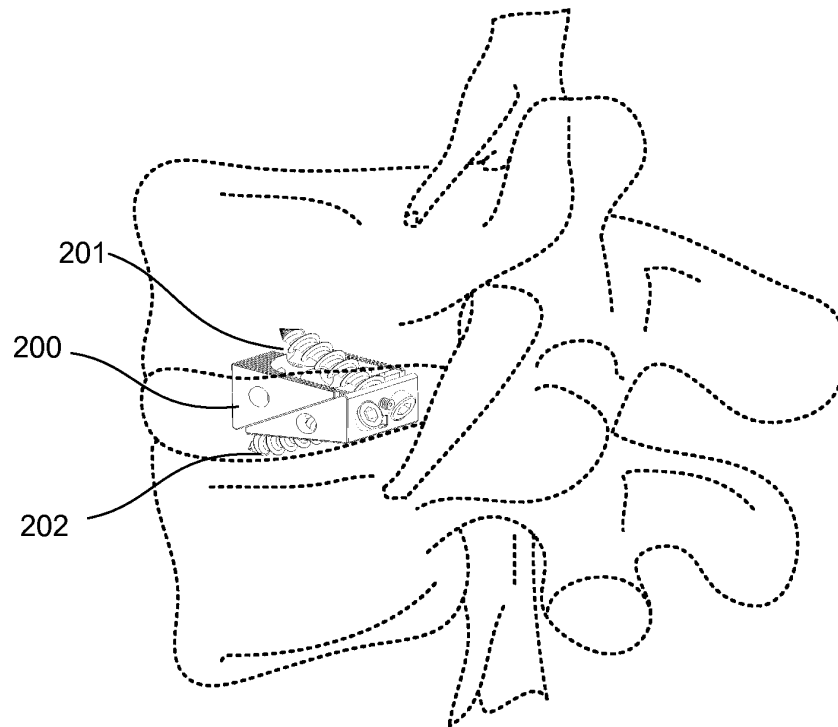


Fig. 6B

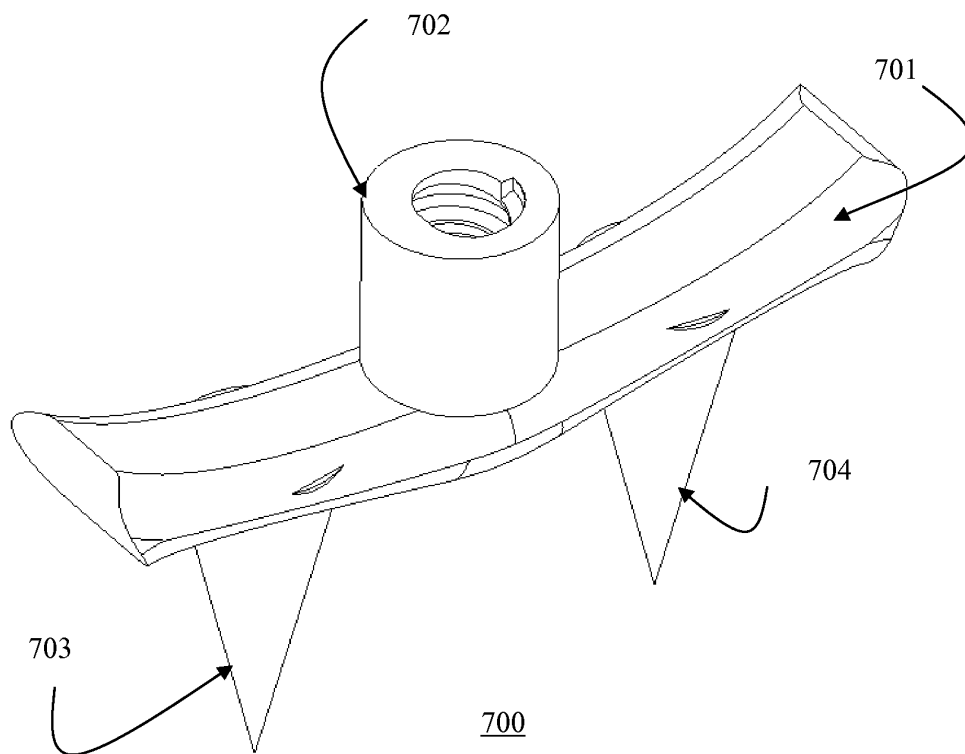


Fig. 7A

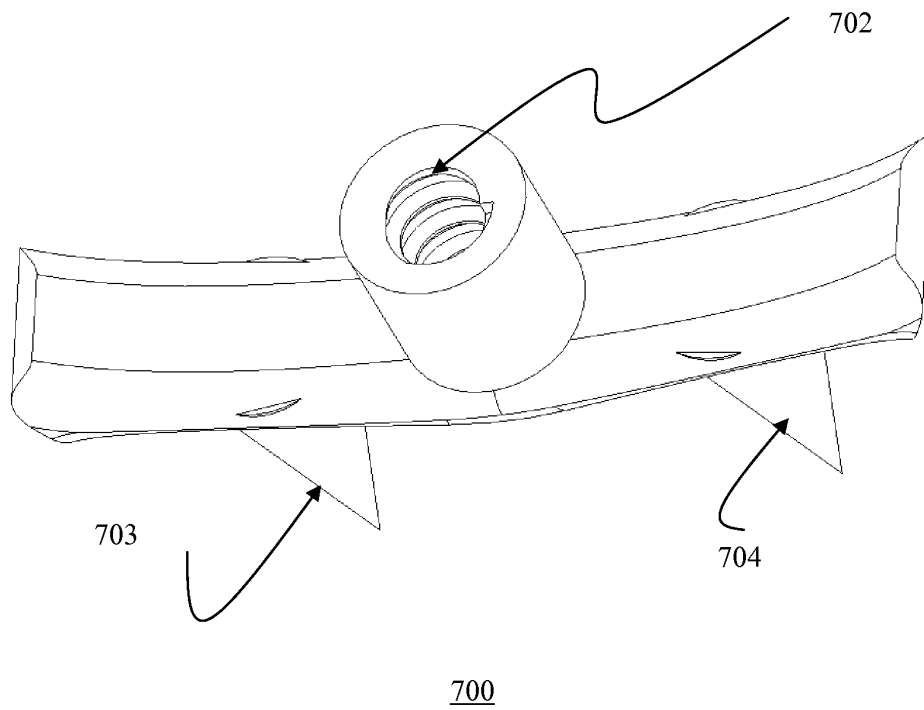


Fig. 7B

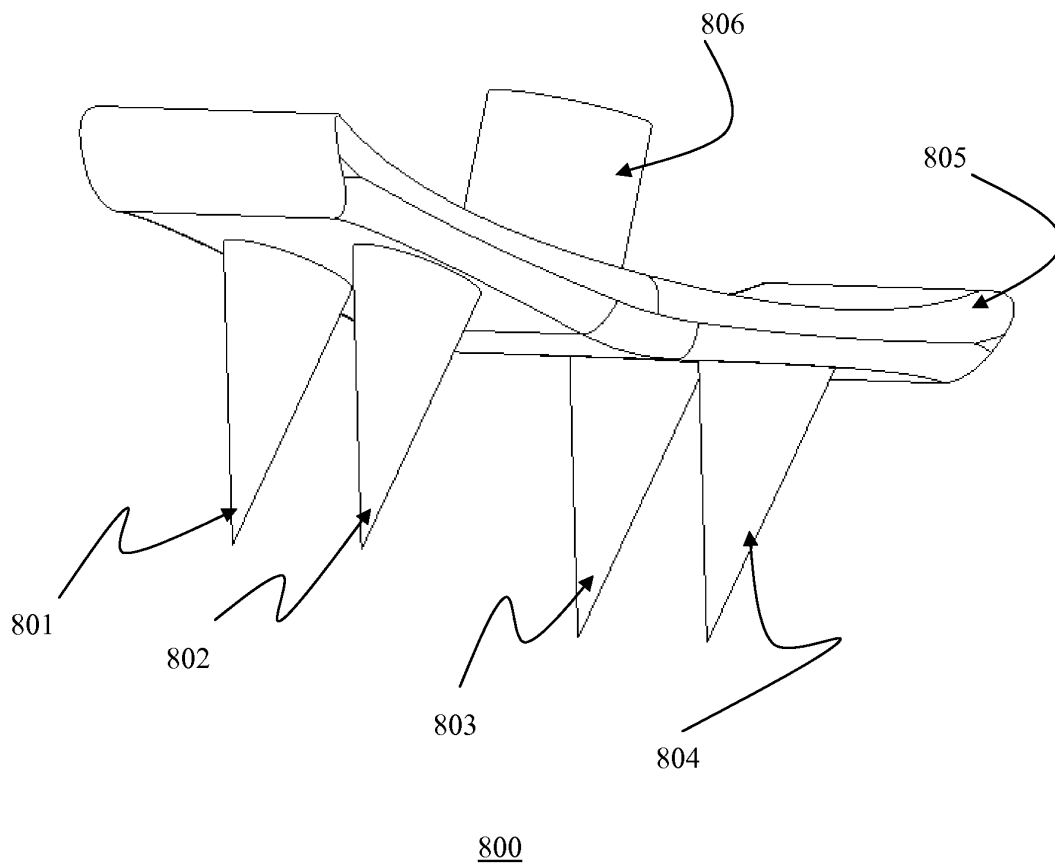


Fig. 8A

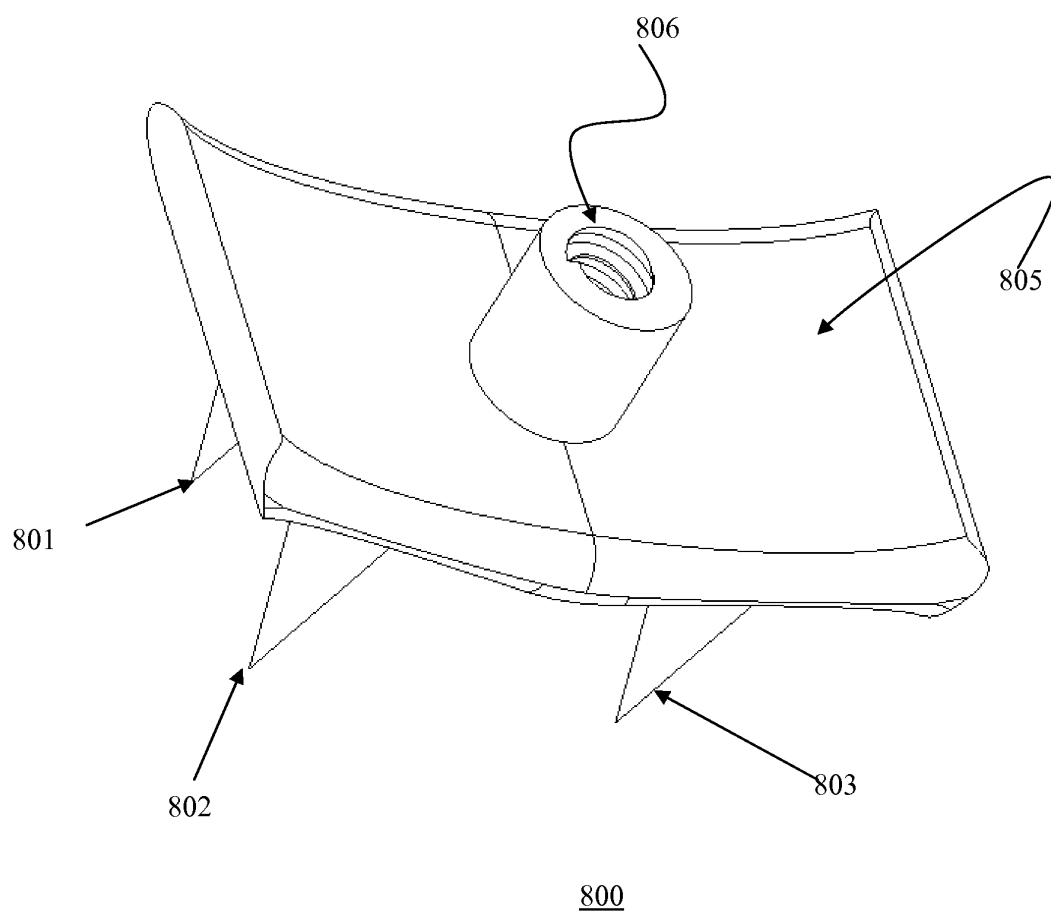


Fig. 8B

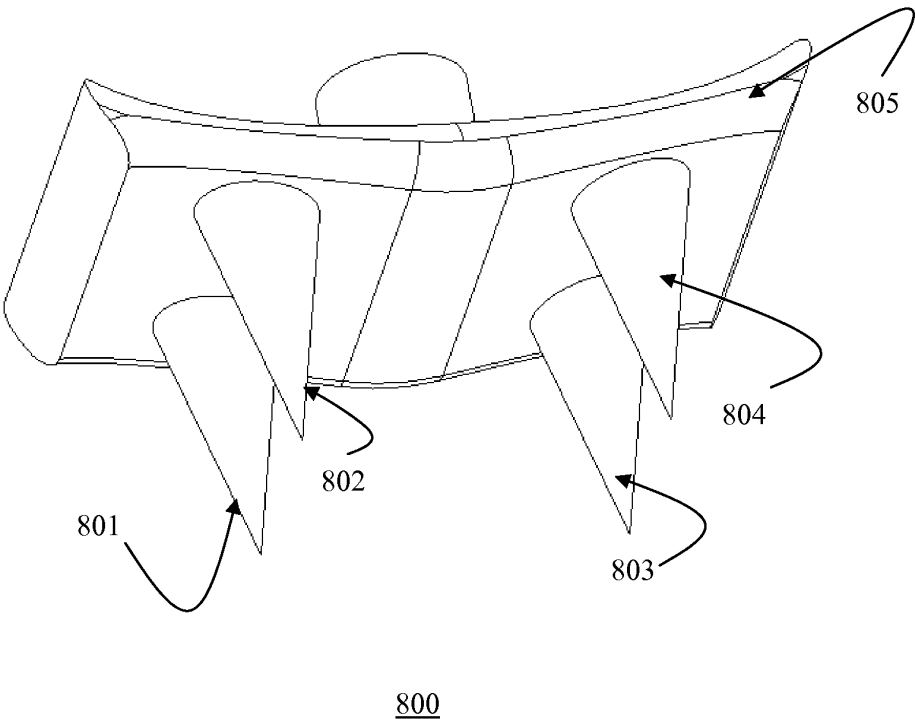


Fig. 8C

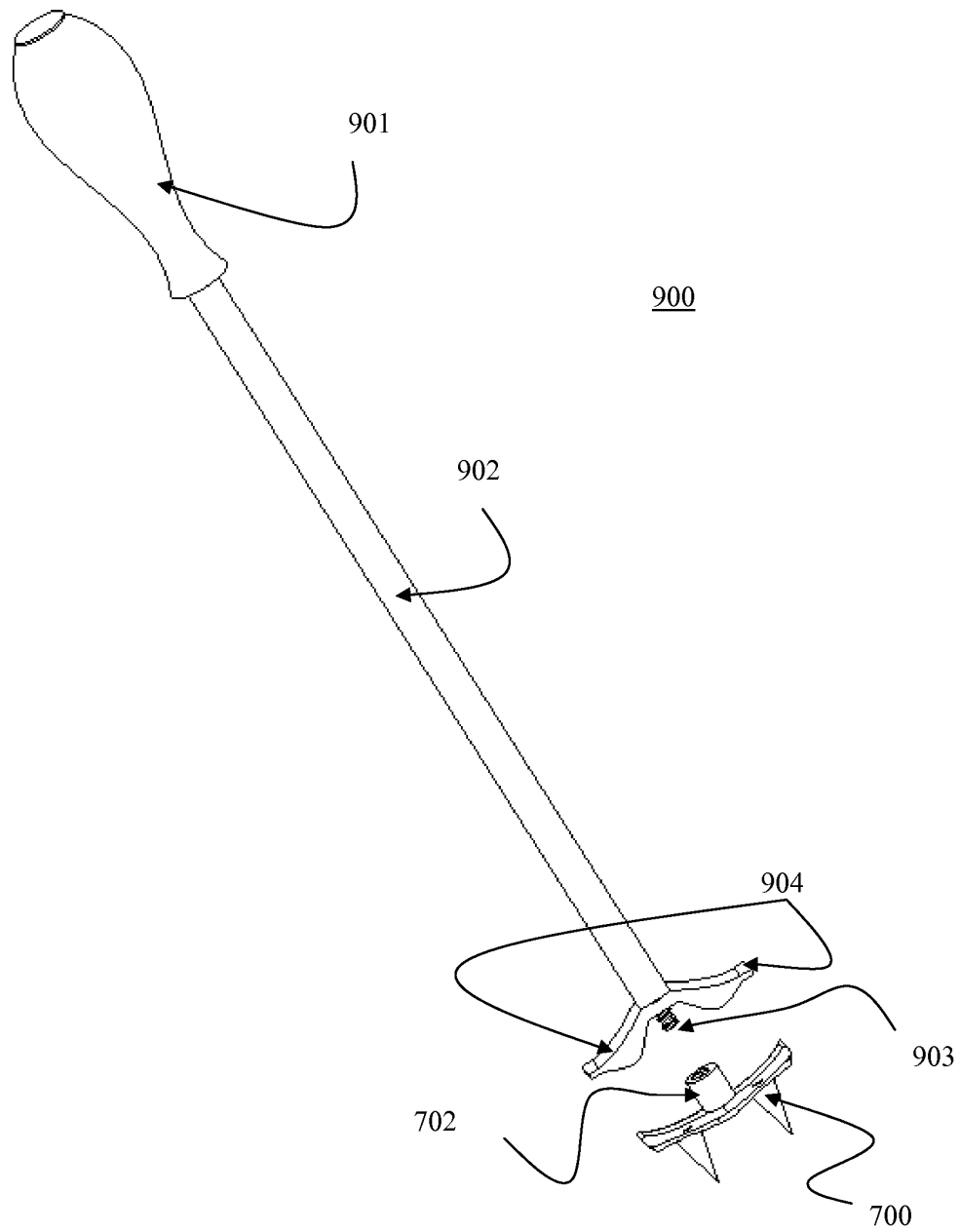


Fig. 9A

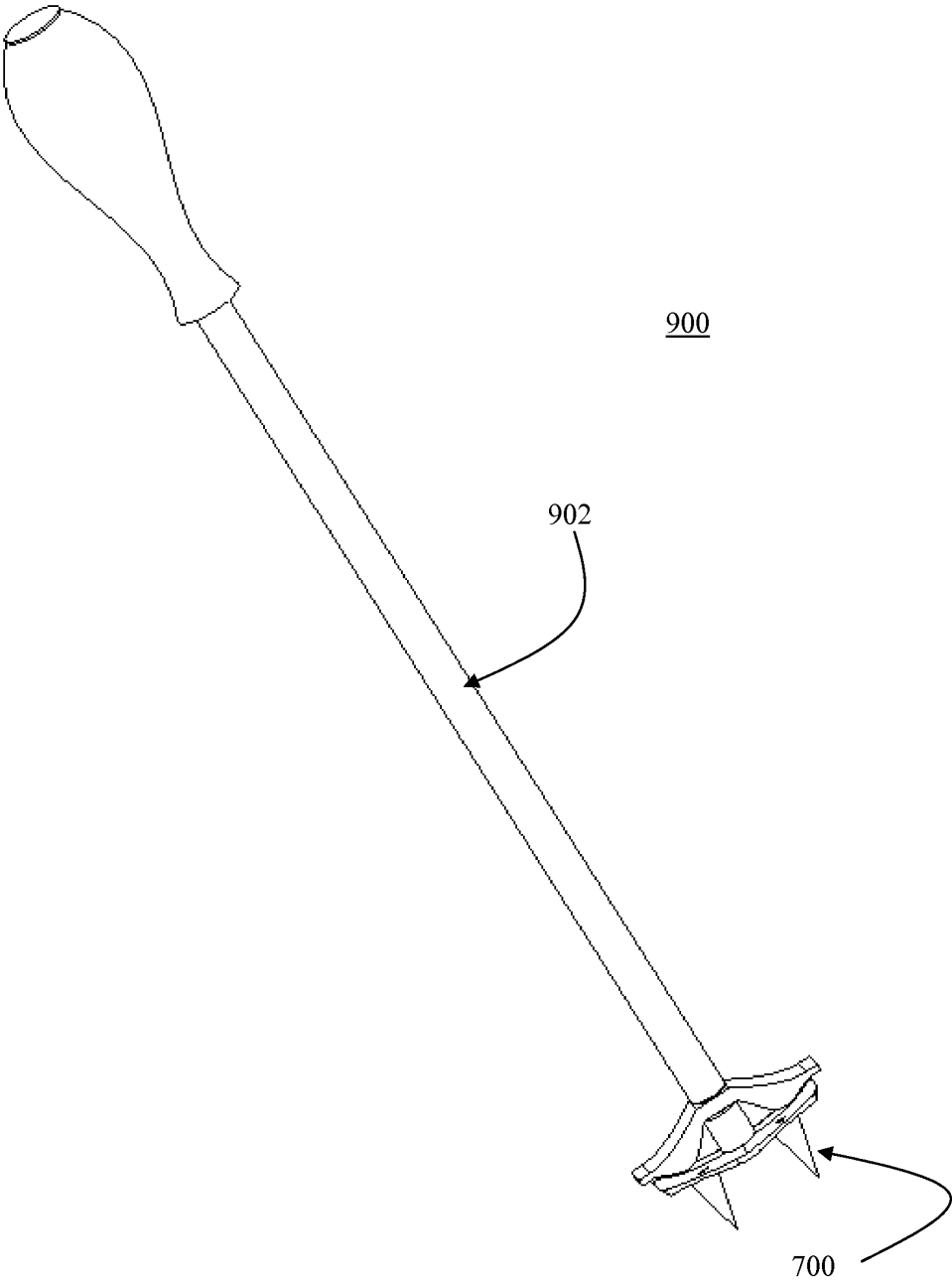


Fig. 9B

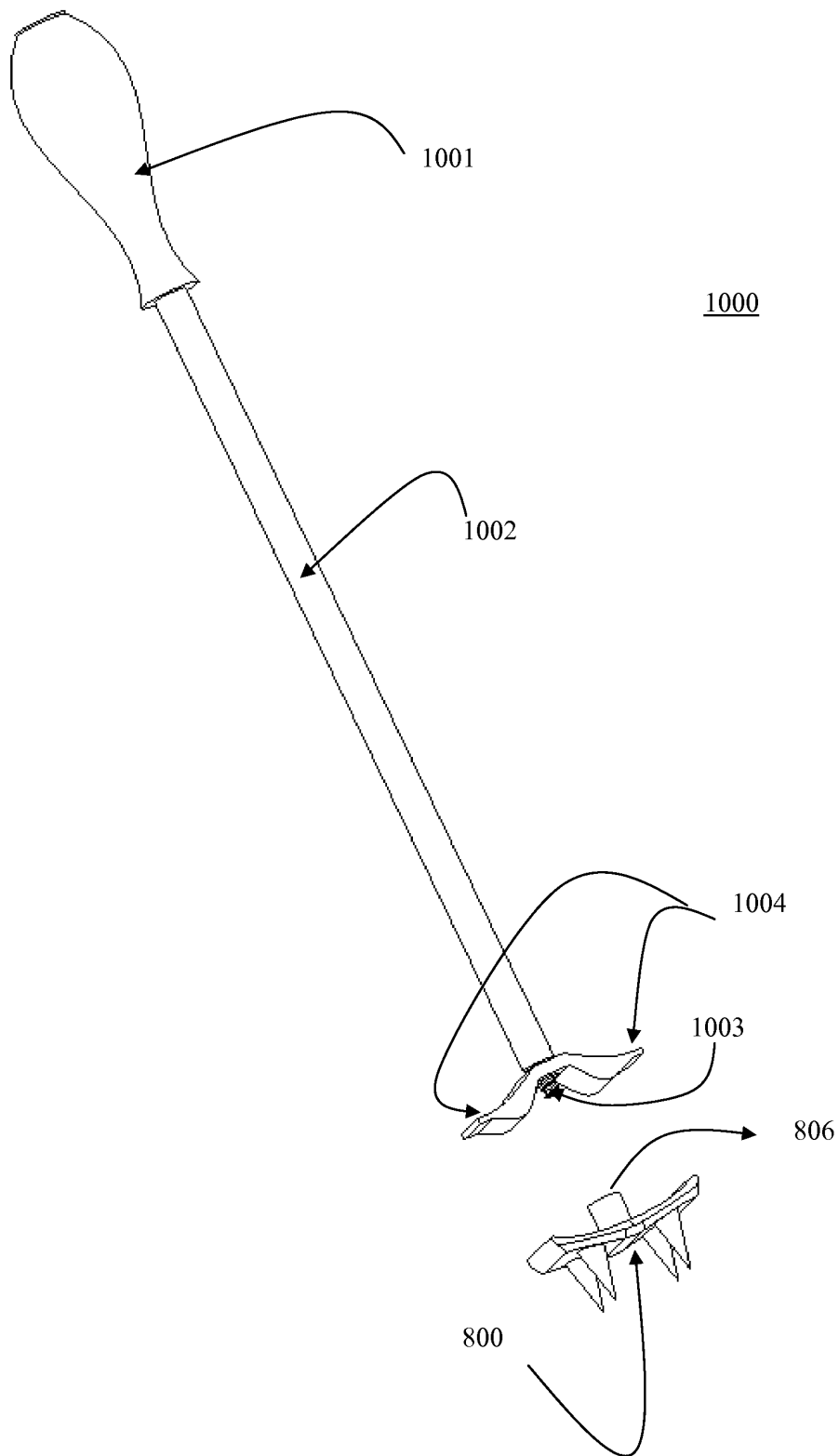


Fig. 10A

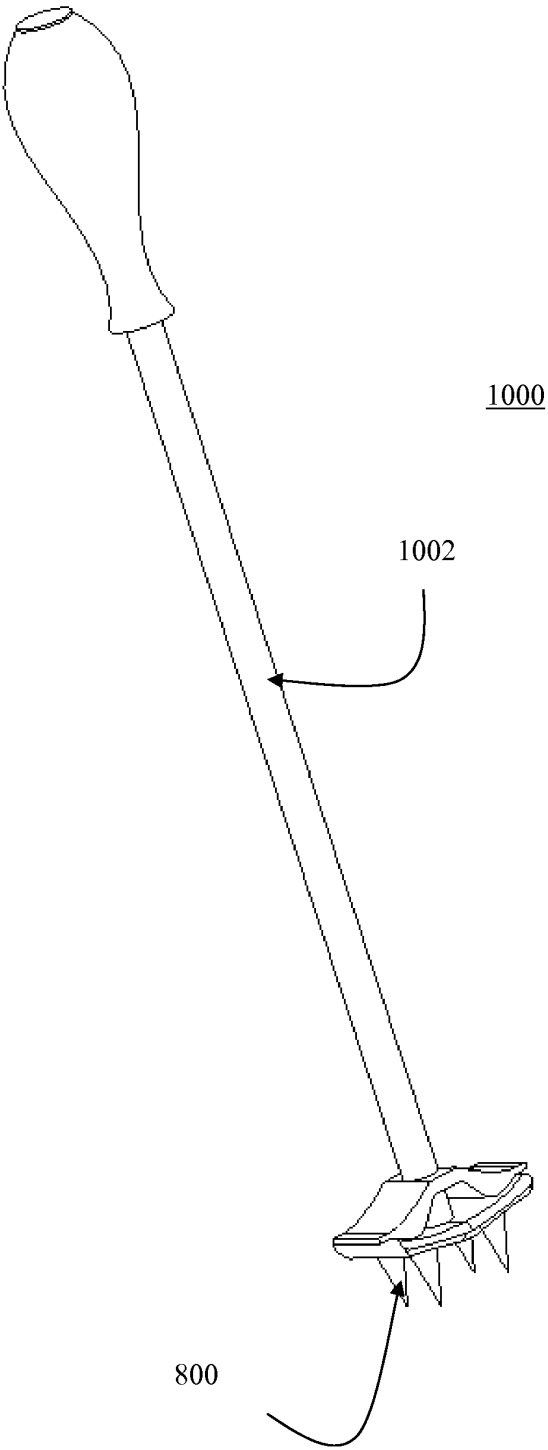


Fig. 10B

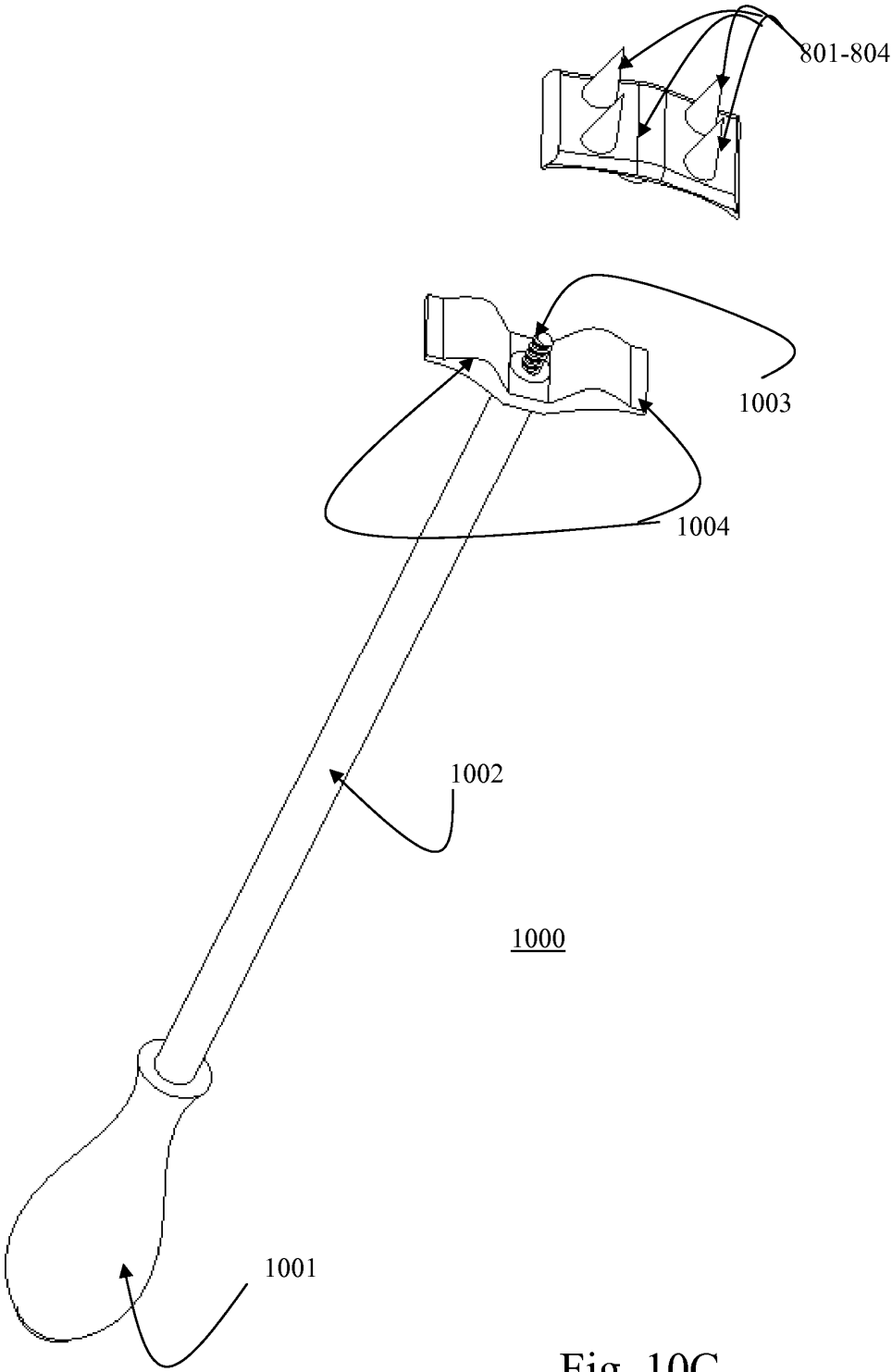


Fig. 10C

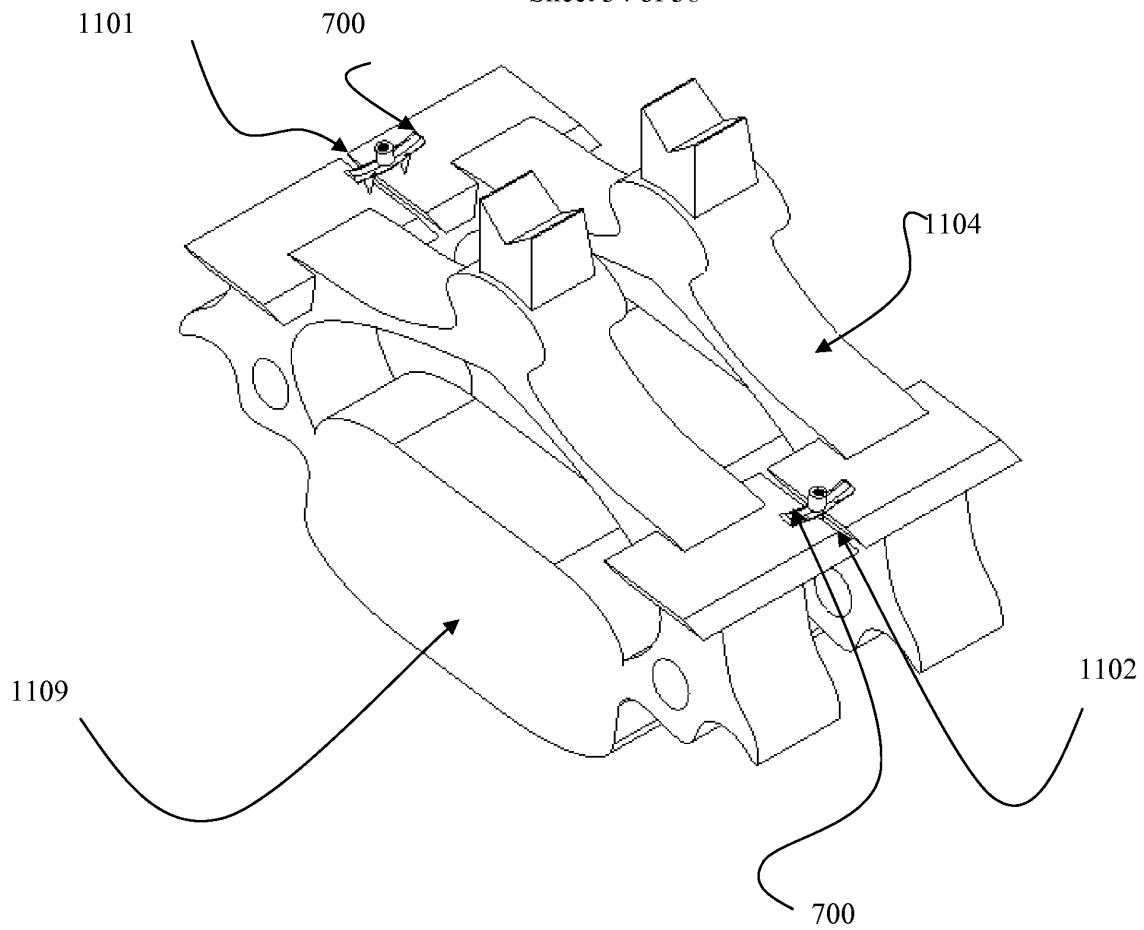


Fig. 11A

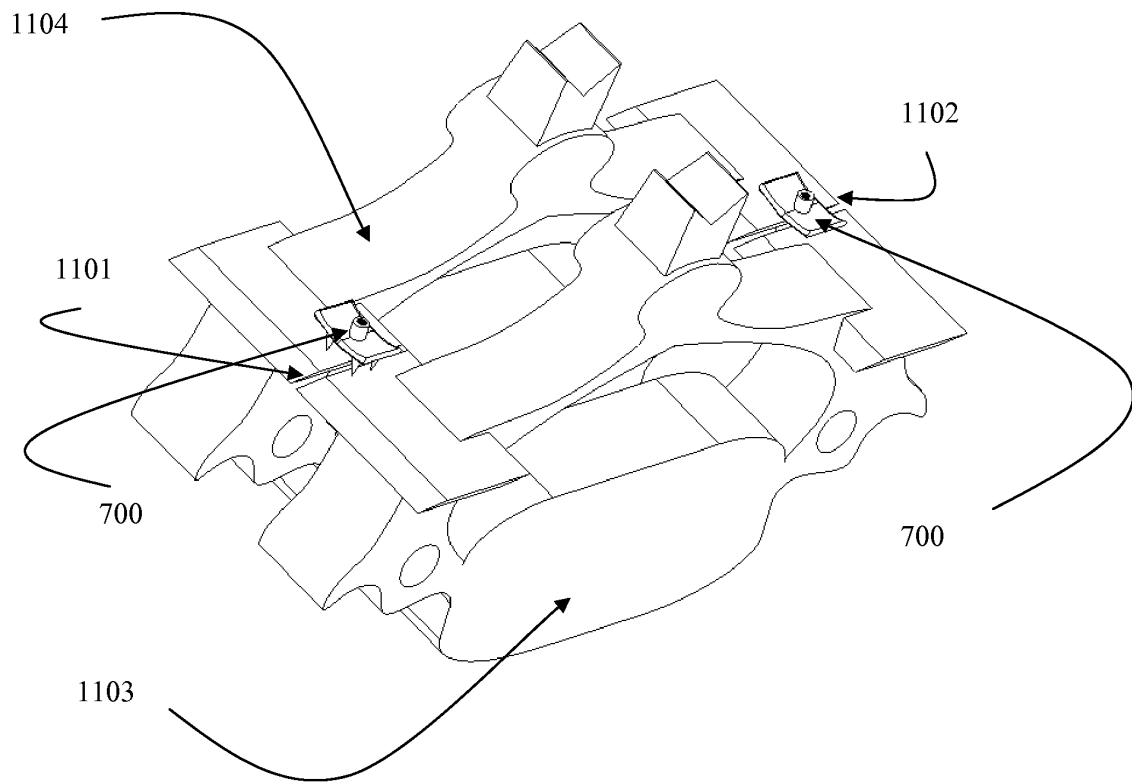


Fig. 11B

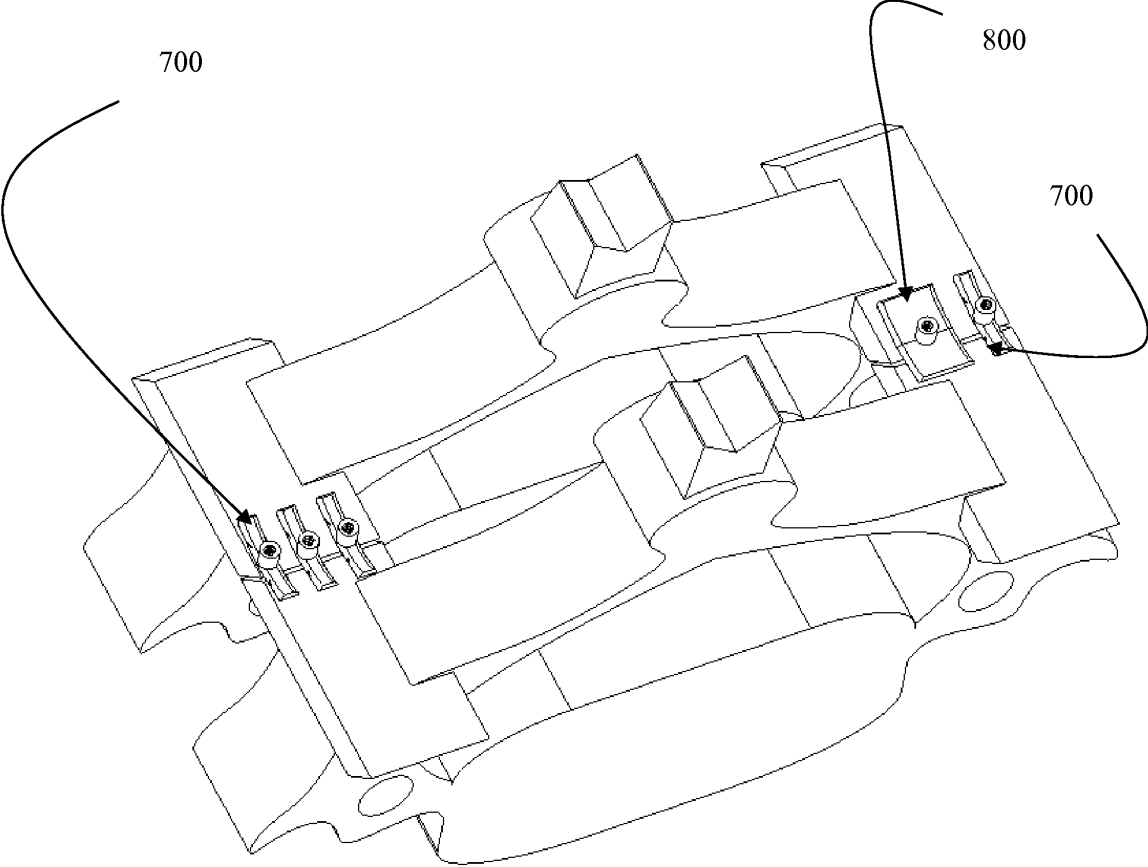


Fig. 11C

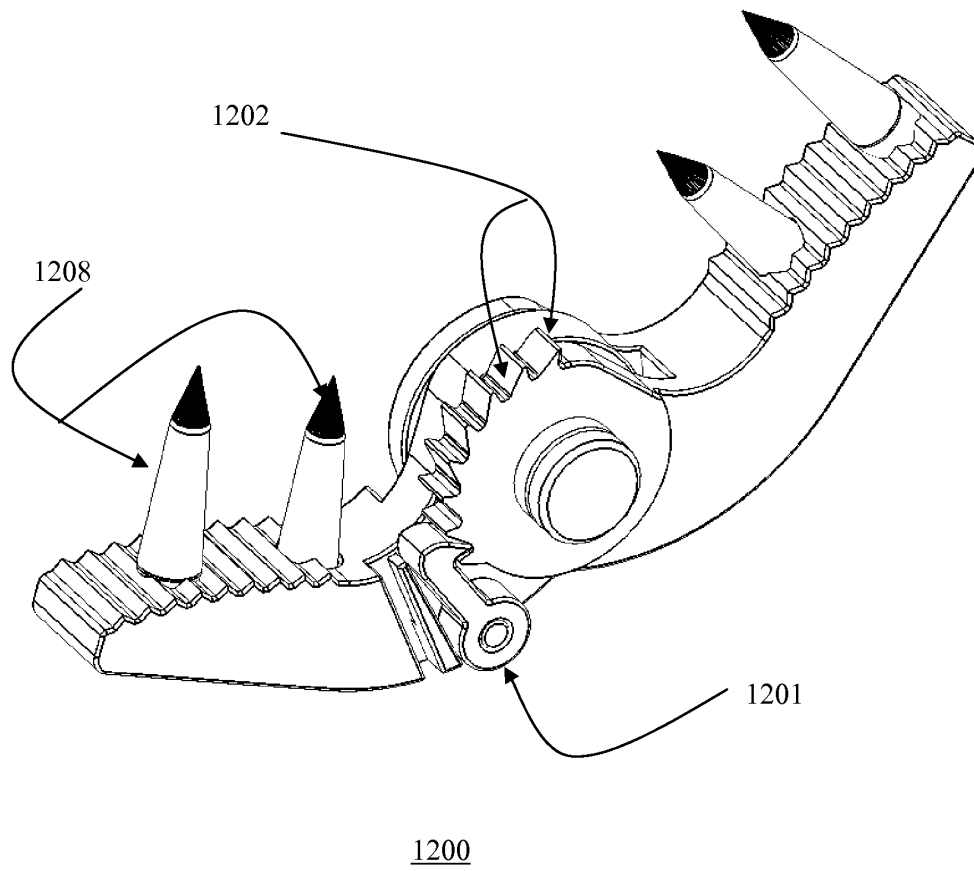


Fig. 12A

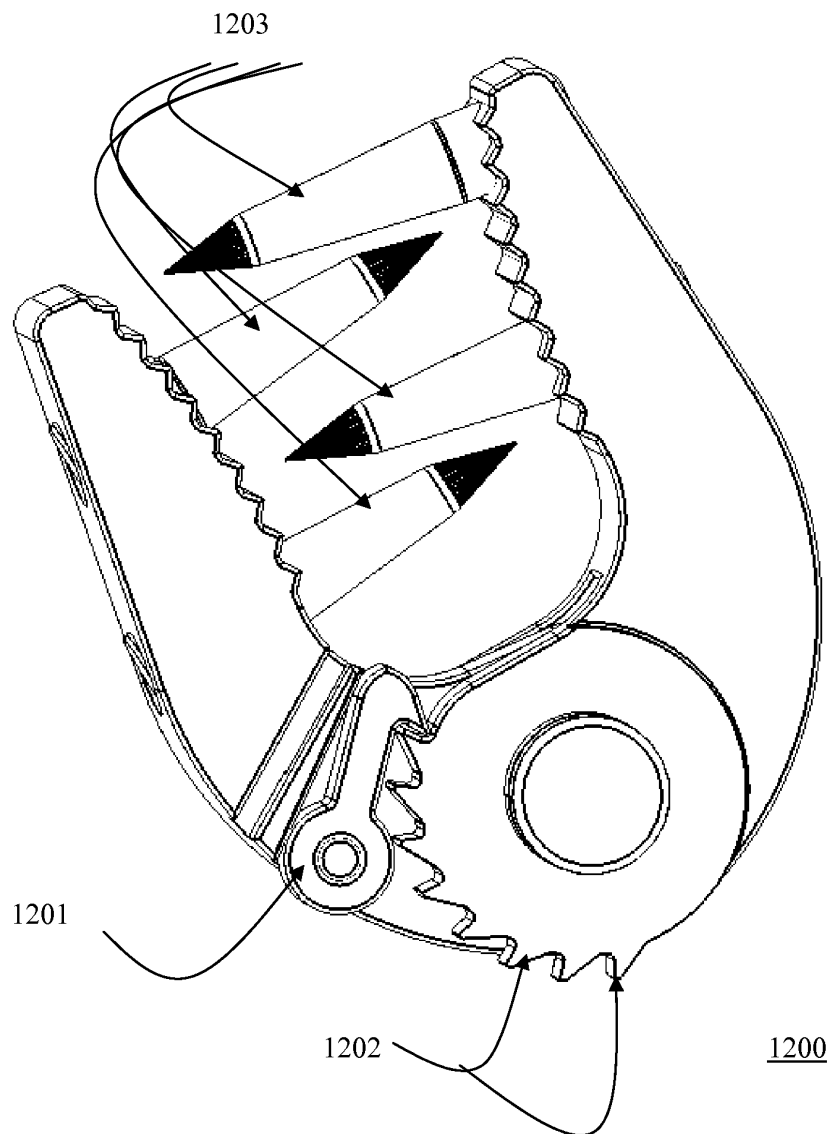


Fig. 12B

BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION

[0001] This application is a Continuation-In-Part Application of copending application Serial No. 11/536,815, filed on September, 29, 2006, which is a Continuation-In-Part Application of copending application Serial No. 11/208,644, filed on August 23, 2005 for which priority is claimed under 35, U.S.C. §120; and this application also claims priority under 35 U.S.C. § 119(e) of U.S. provisional application No. 60/670,231, filed on April 12, 2005; the entire contents of all the above identified patent applications are hereby incorporated by reference.

Field of Invention

[0002] The present invention relates to a unique universal bidirectional screw (BDS) system, and in particular its application to the spine, also referred to as bi-directional fixating transvertebral (BDFT) screws which can be used as a stand-alone intervertebral device which combines the dual functions of an intervertebral spacer which can be filled with bone fusion material(s), as well as a transvertebral bone fusion screw apparatus. In the posterior lumbosacral and thoracic spine, BDFT screw/box constructs can be used independently or supplemented with a novel horizontal mini-plate which prevents upward bone graft intrusion into the thecal sac and nerves. In the anterior lumbosacral spine BDFT screw box constructs can be inserted into and supplemented by a circumferential cage. These posteriorly and anteriorly placed stand-alone

intervertebral body fusion constructs may obviate the need for supplemental pedicle screw fixation.

[0003] The present invention also relates to stand-alone or supplemental posterior cervical and lumbar calibrated inter-articular joint stapling devices which may obviate and/or lessen the need for supplemental pedicle screw fixation.

Description of the Relevant Art

[0004] The history and evolution of instrumented spinal fusion in the entire human spine has been reviewed in our two prior copending applications Serial No. 11/536,815, filed on September, 29, 2006, and Serial No. 11/208,644, filed on August 23, 2005, the related contents of which are hereby incorporated by reference. Currently the majority of posterior cervical and almost all anterior and posterior lumbosacral and thoracic fusion techniques are typically supplemented with pedicle screw placement. Complications of pedicle screw placement in cervical, thoracic and lumbar spine include duration of procedure, significant tissue dissection and muscle retraction, misplaced screws with neural and/or vascular injury, excessive blood loss, need for transfusions, prolonged recovery, incomplete return to work, and excess rigidity leading to adjacent segmental disease requiring further fusions and re-operations. Recent advances in pedicle screw fixation including minimally invasive and image-guided technology, and the development of flexible rods, imperfectly address some but not all of these issues.

[0005] Complications of all current spinal interbody fusion devices is their lack of coverage of the majority of the cross- sectional area of the vertebral endplates, and their lack of adequate, if any capacity to penetrate bone, and hence the heightened risk of implant extrusion. Furthermore the bone and biological bone fusion agents which are packed into the intervertebral space can easily blossom and grow upward into the thecal sac causing neural compression, in the absence of a physical barrier between the fusing growing bone, and the thecal sac.

Summary

[0006] Herein we describe multiple device embodiments which combine in a single construct the dual functions of an intervertebral spacer maintaining disc space height, and transvertebral body fusion screws.

[0007] We also introduce an entirely novel horizontal mini-plate capping off the intervertebral space capable of functioning as a physical barrier preventing upward bone intrusion and/or compression of the ventral thecal sac, and traversing and exciting nerve roots.

[0008] Furthermore, we present an advanced mechanism in calibrated posterior facet joint stapling compared to our previous designs illustrated in our co-pending patents. We also introduce the entirely novel concept of posterior cervical facet staples to obviate and/or diminish the need for posterior cervical pedicle screw instrumented fusion. Using combinations and permutations of different embodiments of cervical facet staples in a modular manner advances

[0009] To achieve safe, effective and minimally invasive segmental spinal fusion, applicants propose the use of novel bi-directional fixating transvertebral (BDFT) screws which can be strategically inserted via anterior or posterior surgical spinal approaches into the anterior and middle columns of the intervertebral disc space. In our previous applications these bi-directional screws employed turning a wormed driving screw which turns a spur gear which in turn simultaneously turns a rostral oriented screw into the cephalad vertebral body, and a caudal directed screw into the caudal vertebral body. The vertebral bodies above and below the disc space by virtue of their engagement and penetration by the BDFT screws are thus linked, interlocked, and eventually biologically fused with placement of intervertebral bone agents.

[0010] In this current application one or more of the described embodiments may eliminate the intervening wormed driving screws and gears required by previous designs, e.g., a gearless screw box is achieved. We have designed a screw box to be placed inter-vertebrally, either unilaterally or bilaterally, in particular, posteriorly between vertebral bodies. The housing screw box incorporates built-in screw and/or drill guides which allow the direct placement and insertion of two self drilling screws which are driven in two opposing directions into superior and inferior vertebral bodies, respectively. One screw within the screw box is angled superiorly, and the other screw in the screw box is angled inferiorly.

[0011] In yet another embodiment, in addition to these features we designed an

expanding screw box with sliding triangular bases to house two screws driven in two opposing directions which can be expanded in two simultaneous directions , height and depth, by turning a built-in screw adjuster. This is accomplished by a combined positioning tool/screw guide/cage expander to further enhance trajectory precision and to simultaneously expand the screw box in height and depth to custom-fit the individual disc space height. This embodiment has two sub-embodiments; one has two laterally oriented BDFT screws, and the other has a lateral and a medial oriented BDFT screw. These innovations represent a continued evolution of our concept of expandable fusion cages described in our previous co-pending patents.

[0012] In yet another embodiment we designed a screw box which houses only one, instead of two screws. Each box allows the placement of one superior or inferior directed screw on one side (left or right) , and the contra lateral screw box device allows placement of an inferior or superior oriented screw which goes in the opposite direction of the contra lateral device. In totality these two separate single screw boxes fuse the superior and inferior vertebrae. The potential advantage of this embodiment is that it diminishes the width of the screw box in cases where it might be favorable to have less nerve root retraction with a smaller width device.

[0013] In all screw-box embodiments, a rostral-directed screw is passed through one built-in screw guide of the device which then is inserted and screwed into the superior vertebral body. Then a caudal directed screw is passed through an adjacent built-in screw guide which then is inserted and screwed into the inferior

vertebral body. The novelty of this design is the built-in prescribed angles of the integral screw guides which allow the posterior transvertebral penetration into the vertebral bodies. This is a truly amazing feat accomplished in the posterior lumbar spine considering the small anatomically restricted work zone within which to work, which is very narrowly prescribed by obtuse angulations between screw and intervertebral bone surfaces, and by nerve root, facet joint and pedicle. We have also designed a positioning tool for the placement of the non-expandable screw boxes which has a screwdriver with a flexible shaft specifically designed to fit these devices if a straight screw driver impedes screw placement. Hence these external tools provide the means in any circumstance to accomplish precision screw trajectory. The embodiments described herein compared to our previous co-pending patent designs, streamline and ease production of bi-directionally oriented transvertebral screws, and allows placement of longer and wider screws with greater bone penetration to provide yet a sturdier fusion construct. The designs are also easily modifiable for anterior placement into the cervical spine. The expandable embodiment of the screw box can also be enlarged and modified to be suitable for cervical, thoracic and lumbar vertebral body replacements.

[0014] The box casings have multiple perforations to allow both screw traversal and horizontal bone packing preventing upward vertical migration of bone. The boxes prevent subsidence. Both the inside of the denuded intervertebral space, and the screw boxes can be packed with autologous or allograft bone, BMP, DBX or similar osteoconductive material. Posteriorly or anteriorly in the lumbar

[0015] It is believed that BDFT- screw constructs provide as strong or stronger segmental fusion as pedicle screws without the complications arising from pedicle screw placement which include screw misplacement with potential nerve and/or vascular injury, violation of healthy facets, possible pedicle destruction, blood loss, and overly rigid fusions. By placing screws across the intervertebral space from vertebral body to vertebral body, engaging anterior and middle spinal columns, and not the vertebral bodies via the transpedicular route, the healthy facet joints, if they exist, are preserved. Because this technique accomplishes both anterior and middle column fusion, without rigidly fixating the posterior column, it in essence creates a flexible fusion. This device therefore is a flexible fusion device because the preserved posterior facet joints retain their function achieving at least a modicum of mobility and hence a less rigid (i.e. a flexible) fusion.

[0016] The very advantage of transpedicular screws which facilitate a strong solid fusion by rigidly engaging all three spinal columns is the same mechanical mechanism whereby complete inflexibility of all columns is incurred thereby leading to increasing rostral and caudal segmental stress which leads to an

increased rate of re-operation.

[0017] Transvertebral fusion also leads to far less muscle retraction, blood loss, and significant reduction in O.R. time. Thus the complication of pedicular screw pull-out and hence high re-operation rate associated with the current embodiment of flexible fusion pedicle screws/rods is obviated. The lumbosacral screw box embodiments and BDFT screws can be introduced via posterior lateral, transforaminal or anterior interbody fusion approaches /techniques. Although one can opt to supplement these screws with transpedicular screws there would be no absolute need for supplemental pedicle screw fixation with these operative techniques.

[0018] BDFT screw constructs outlined here can also be combined with novel zero-profile horizontal cervical and, lumbar/thoracic mini-plates. Likewise one or two of these devices can be inserted anteriorly with or without circumferential cage supplementation.

[0019] Because the BDFT screws engage a small percentage of the rostral and caudal vertebral body surface area, multi-level fusions can be performed with these devices.

[0020] Previous improvements included a novel calibrated lumbar /thoracic facet stapling device which staples the inferior articulating facet of the superior segment to the superior articulating facet of the caudal vertebral segment unilaterally or bilaterally, which may minimize motion until interbody fusion occurs. In the present patent application we introduce a new design of the staple enhancing its calibrating capability.

[0021] In this patent application we also introduce a novel posterior cervical facet stapling device which staples the inferior articulating facet of the superior cervical segment with the superior articulating facet of the caudal vertebral segment unilaterally or bilaterally.

[0022] The advantage of cervical facet staples is speed and safety. The risks of cervical facet pedicle screw fixation which include nerve root and vertebral artery injuries are completely obviated. Thus they thereby achieve the same function of pedicle screws without the risks.

[0023] Placement of different embodiments of the cervical facet staples along unilateral and/or bilateral facet joints in a modular manner, lead to differing degrees of calibrated motion joint motion hence introducing for the first time the concept of calibrated cervical fusion.

[0024] Currently failed anterior lumbar arthroplasties are salvaged by combined anterior and posterior fusions. BDFT screw constructs could be utilized as a one-step salvage operation for failed/extruded anteriorly placed lumbar artificial discs obviating the above salvage procedure which has far greater morbidity.

[0025] For example, in one general aspect, a self-drilling bone fusion screw apparatus includes a first sliding box, a second sliding box, positioned relative to the first sliding box, a first screw member having a tapered end and a threaded body disposed within the first sliding box, a second screw member having a tapered end and a threaded body disposed within the second sliding box, and an adjuster for adjusting the height of the sliding boxes.

[0026] Implementations of this aspect may include one or more of the following features. For example, the first and second screw members may be medially aligned. At least one of the first and second screw members may be laterally aligned. The first and second screw members are laterally aligned. One of the first and second screw members is laterally aligned and the other screw member is laterally aligned. The first and second sliding boxes may be substantially triangularly shaped. The triangularly shaped first and second sliding boxes may include a sliding rail and ridged surfaces. The triangularly shaped first and second sliding boxes may include holes for bone grafts. The adjuster may include a screw.

[0027] In another general aspect, a self-drilling bone fusion screw apparatus includes a box, a first screw member having a tapered end and a threaded body disposed at least partially within the box and laterally aligned with the box, a second screw member having a tapered end and a threaded body disposed at least partially within the box and laterally aligned with the box, and a plurality of ridges disposed on along the sides of the box.

[0028] Implementations of this aspect may include one or more of the following features. For example, the apparatus may include bone graft holes. The apparatus may be attachable to a second self-drilling fusion screw apparatus via a plate.

[0029] In another general aspect, a self-drilling bone fusion screw apparatus may include a first box, a first screw member having a tapered end and a threaded body disposed at least partially within the first box and laterally aligned

with the first box, a second box, a second screw member having a tapered end and a threaded body disposed at least partially within the second box and laterally aligned with the second box, and an attachment member for engaging the first and second boxes.

[0030] Implementations of this aspect may include one or more of the following features. For example, the self-drilling bone fusion screw apparatus may include bone graft holes. The plate may be directly joined to the first and second boxes by a plurality of screws. The attachment member for engaging the first and second boxes may include a plate or the attachment member may include a circumferential cage defining at least one recess. The first and the second boxes may be positioned within or securely held within the recess of the circumferential cage, e.g, with an interference fit.

[0031] In another general aspect, a tool assembly for manipulating a self-drilling bone fusion screw apparatus includes a handle, a gripper cooperating with the handle and having a plurality of prongs, a screw guide, held in place the plurality of prongs, for controlling the direction of self-drilling screws that are screwed into a vertebral body.

[0032] Implementations of this aspect may include one or more of the following features. For example, the tool assembly for manipulating a self-drilling bone fusion screw apparatus may include a key for controlling an adjustment device which controls the height of the self-drilling bone fusion screw apparatus. The tool assembly according to claim may include a driver assembly. The driver assembly may include a handle, a drive bit portion, and a flexible drive shaft

extending between the handle and the drive bit portion for manipulating a screw of an expandable or non-expandable screw box. The assembly may include one or more of an expandable screw box and/or a non-expandable screw box. The boxes may include one or more screws. The screw boxes may be joined by or include an attachment member, such as a plate and/or a circumferential cage.

[0033] In another general aspect, a cervical facet staple includes a curved staple base, at least two prongs attached to the bottom surface of the curved staple base, and an insertion member disposed on the top surface of the curved staple base.

[0034] Implementations of this aspect may include one or more of the following features. For example, the staple may include at least four prongs attached to the bottom surface of the curved staple base. The insertion member may include a threaded insert.

[0035] In another general aspect, an impaction tool for a cervical facet staple includes a handle, a stem attached to the handle, a plurality of wings for contacting the cervical facet staple, and an insertion member for coupling the cervical facet staple to the impaction tool.

[0036] Implementations of this aspect may include one or more of the following features. For example, the handle may include a flattened portion that can be struck by a mallet.

[0037] In another general aspect, a lumbar facet staple includes a pair of rotating arms, at least two prongs attached to the inner surfaces of the rotating

arms, a plurality of spurs attached to one of the rotating arms, and a ratchet attached to one of the rotating arms. The rotating arms and prongs are rotated to a closed position to staple a lumbar facet joint.

BRIEF DESCRIPTION OF DRAWINGS

[0038] Figures 1A-D illustrate the Lumbar intervertebral screw box with one lateral oriented BDFT screw and one medially oriented two BDFT screw (Embodiment IA) in sagittal-oblique (Figure 1A), superior perspective (Figure 1B), inferior perspective (Figure 1C) and exploded (Figure 1D) views.

[0039] Figure 1E illustrates the lumbar intervertebral expandable screw box with two lateral oriented BDFT screws (Embodiment IB; sagittal-oblique view).

[0040] Figures 2A-C illustrate the Lumbar intervertebral non-expandable screw box with two BDFT screws (Embodiment II) in lateral (Figure 2A), oblique (Figure 2B), and superior perspective (Figure 2C) views.

[0041] Figure 3 illustrates a superior oblique perspective view of left and right lumbar intervertebral non-expandable screw boxes with one BDFT screw (Embodiment III).

[0042] Figures 4A-B illustrate the horizontal intervertebral zero-profile mini-plate prior to insertion (Figure 4A), and after insertion (Figure 4B) into two non-expandable lumbar intervertebral screw boxes with two BDFT screws.

[0043] Figure 4C illustrates two non-expandable lumbar intervertebral screw

boxes with two screws within a large circumferential cage for anterior placement into the lumbar spine

[0044] Figures 5A-C illustrate the positioning tool / screw guide/box expander in oblique perspective (Figure 5A), lateral (Figure 5B), and exploded (Figure 5C) views.

[0045] Figure 5D illustrates a superior oblique perspective view of the positioning tool/drill guide/box expander component.

[0046] Figures 5E-G illustrate the sequential steps (I-III) of the positioning tool/screw guide/box expander assembly. Step I (Figure 5E), step II (Figure 5F), and step III (Figure 5G).

[0047] Figures 5H-I illustrate the positioning tool for impaction and placement of the non-expandable screw box with two transvertebral screws. Embodiment I has a rectangular positioning handle (Figure 5H), and embodiment II has a circular positioning handle (Figure 5I)

[0048] Figures 6A-B illustrate the insertion of expandable Lumbar bi-directional screw box with two BDFT screws into the Lumbar spine in oblique (Figure 6A) and lateral (Figure 6B) views.

[0049] Figures 7A-B illustrate the cervical facet staple (Embodiment I) in lateral (Figure 7A) and oblique (Figure 7B) views.

[0050] Figures 8A-C illustrate the cervical facet staple (Embodiment II) in oblique (Figure 8A), superior perspective (Figure 8B) and inferior-oblique (Figure 8C)

views.

[0051] Figure 9A illustrates the two-pronged cervical facet staple inserter/impactor (Embodiment I).

[0052] Figure 9B illustrates the two-pronged cervical facet staple inserter/impactor inserted into the staple (Embodiment I).

[0053] Figure 10A illustrates the four pronged cervical facet staple impactor (Embodiment II).

[0054] Figure 10B illustrates the four pronged cervical facet staple impactor inserted into the cervical facet staple (Embodiment II).

[0055] Figure 10C illustrates an inferior-oblique perspective view of the four – pronged cervical facet staple impactor (Embodiment II).

[0056] Figure 11A illustrates placement of two-pronged cervical facet staples in a three-dimensional cervical spine.

[0057] Figure 11B illustrates placement of four-pronged cervical facet staples in a three-dimensional cervical spine.

[0058] Figure 11C illustrates modular placement of two and four pronged cervical facet staples in a three-dimensional cervical spine to achieve differing calibrated degrees of flexibility.

[0059] Figures 12 A-B illustrate the Lumbar facet joint staple with a calibrated ratcheting mechanism in opened (Figure A) and closed (Figure B) positions.

DETAILED DESCRIPTION OF THE INVENTION

1. THE MEDICAL DEVICE

[0060] Referring to Figures 1-6, the above described problem can be solved in the thoracic and lumbar spine by insertion into the denuded intervertebral disc space multiple embodiments of screw box constructs with BDFT screws.

[0061] Figures 1A-D illustrate three-dimensional views of the Lumbar intervertebral expandable screw box 100 with two BDFT screws 101, 102; one lateral and one medially oriented (Embodiment IA). Figure 1E illustrates a sagittal-oblique view of the lumbar intervertebral expandable screw box 120 with two lateral oriented BDFT screws 121, 122 (Embodiment IB).

[0062] The expandable box 100 consists of top and bottom triangular sliding bases 103, 104 (Figures 1-D). The superior and inferior segments of the height/depth adjusting screw 105 are integrated and connected to the two separate top and bottom triangular bases 103, 104, respectively. By turning this adjusting screw 105 back and forth i.e. clock-wise, and counter clockwise, the sliding rails 106 of the top triangular base 103 (Figure 1D) slide up and down the rail inserts 107 on the bottom triangular base 104 (Figure 1D). This action will simultaneously alter the intervertebral height and depth of the screw box 100 allowing individualized custom fitting of the screw box 100 conforming to the dimensions of the disc space.

[0063] Transvertebral screw 101 penetrates the top base 103, and transvertebral screw 102 traverses the bottom base 104 of the screw box 100. The two screws 101, 102 traverse the screw box 100 in opposing directions, bi-

directionally (whether they are lateral or medially oriented). The external edges of the triangular bases 103, 104 in contact with vertebral body surfaces include ridges 107. This facilitates the screw box's 100 incorporation into and fusion with the superior and inferior vertebral bodies (Figures 1A-E). Both top and bottom screw box bases 103, 104 are perforated with holes 108 to allow bone placement for fusion. The entire construct, furthermore, is hollow to allow bone filling. Hence this device functions as both an intervertebral bone fusion spacer and bi-directional transvertebral screw fusion device.

[0064] Figures 2A-C illustrate three-dimensional views of the Lumbar intervertebral non-expandable screw box 200 with two BDFT screws 201, 202 (Embodiment II). Screws 201 and 202 perforate and orient in opposing, superior and inferior directions. There are holes 208 and hollow spaces allowing packaging with bone. There are also holes which allow the traversal of screws. The superior and inferior edges include ridges 207 to facilitate integration and fusion with superior and inferior vertebral bodies. The expandable screw box 200 may include a screw insert 209 to attach a horizontal mini-plate (not shown). The self-contained internalized drill guides are at a 25 degree angle. The screw boxes can be designed with the internalized drill guides with different angles and/or different positions within the box.

[0065] Figure 3 illustrates a three-dimensional view of left and right lumbar intervertebral non-expandable screw boxes 300a, 300b with one BDFT screw 301 or 302 (Embodiment III). It is roughly half the width of Embodiments I and II. Screw 301 is inserted into screw box 300a (left) and screw 302 is inserted into

screw box 300b (right). There are holes 308 and hollow spaces allowing packing of bone to achieve biological fusion. The combined effect of one superior oriented and one inferior oriented screw fuses the superior and inferior vertebral bodies with small constructs. This also enables placement of larger dimension screws compared to embodiments I and II.

[0066] Figures 4A and B illustrate three-dimensional views of the horizontal intervertebral zero profile mini-plate 400 with two non-expandable lumbar intervertebral screw boxes 300a, 300b housing two BDFT screws 301, 302. Figure 4A illustrates the perforations 401 within the plate 400 through which small plate securing screws 310 will be inserted to connect it to the built-in screw holes of the screw box 300a, 300b (Figure 4B). The horizontal mini-plate 400 together with the top surfaces of left and right screw boxes 300a, 300b provide a physical barrier between the underlying bone placed beneath it (not illustrated), and the thecal sac and nerve roots above it (not illustrated).

[0067] Figure 4C illustrates two screw boxes 300c, 300d within a circumferential cage 420 (2 in 1) construct which is designed for anterior placement into the lumbar spine. There are slots 308a, 308b for bone graft placement, both outside and inside the boxes. The circumferential cage 420 has perforations 401a for the placement of transvertebral screws (not shown).

[0068] Figures 5A-C illustrate three-dimensional views of the external drill /screw guide -box expander 500 which assists in screw trajectory and box expansion (embodiments IA-B). For embodiments II and III, the same instrument is utilized; however, an expanding Allen key component is not used.

[0069] The key components of this device include an Allen key 501, a spring 502, a handle 503, a griper 504 and a screw guide 505. The Allen key 501 when inserted in the insertion 514 and turned, turns the screw adjuster (Figure 5C) which in turn regulates top and bottom triangular screw box base sliding, and hence box 200 width and depth. The griper 504 has griper prongs 506 which insert into grooves of the screw guide 505 and the screw box 200 (Figures 5A-D) thus perfectly aligning them.

[0070] Figure 5D illustrates a superior oblique view of the screw guide 505 demonstrating insertions 509 for griper prong 506, built-in trajectory guides 511, 512 for insertions of screws 101 and 102, and the Allen key 501.

[0071] Figures 5E-G illustrate three-dimensional views of the sequential steps necessary for the external guide assembly. Figure 5E illustrates the insertion of the Allen key 501 into the handle 503. Figure 5F illustrates the insertion of the handle 503 through the spring 502 and griper 504. Figure 5G illustrates insertion of the griper 504 into the screw guide 505.

[0072] Figures 5H-I illustrate three-dimensional views of a positioning tool 500a for impaction and placement of two transvertebral screws 201, 202 in the non-expandable screw box 200. The driver assembly 550 consists of a screw driver 551, a flexible shaft 552 and a square recess bit 553. This facilitates turning the screws 201, 202 into the bone. The flexible shaft 552 facilitates the avoidance of spinous processes which might hinder the screw driving if the shaft 552 were straight. The positioning tool 500a can have a rectangular handle, Embodiment I (Figure 5H), or a circular handle, Embodiment II (Figure 5I). This serves to

position the screw box within the intervertebral space, and screws 201, 202 within the screw box. Once positioned, the screw box can be impacted by tapping the handle with a mallet (not shown). The positioning tool's 500a griper handle inserts into the screw guide and the box, which maintains alignment.

[0073] Figure 6A illustrates a three-dimensional view of insertion of the construct (Embodiment I) into the lumbar intervertebral disc space.

[0074] Figure 6B illustrates a three dimensional lateral view of insertion of the construct (Embodiment I) into the disc space with short screws. Placement with longer screws would capture more bone.

[0075] Figures 7A and B illustrate three-dimensional views of the two-pronged cervical facet staple 700 (Embodiment I). There is a staple base 701 which is contoured to align with the curved surface of the cervical facet joints. There is a superior impactor threaded insert 702. An impactor can be screwed into this insert 702 and then impacted with a mallet. The two spikes 703, 704 perforate the inferior and superior facets of the superior and inferior vertebral bodies hence leading to cervical facet joint fusion. The spikes can be designed with ridges and/or fishhooks to facilitate irreversible extraction.

[0076] Figures 8A-C illustrate three-dimensional views of the four-pronged cervical facet staple 800 (Embodiment II). Likewise it has a staple base 805 contoured specifically for the surface of the facet joint. It also has an impactor insert 806. The insertion of a device with four prongs 801-804 instead of two prongs further limits the degrees of motion of the joint hence making the fusion more rigid.

[0077] Figures 9 A-B illustrate a three-dimensional view of the two-pronged cervical staple impactor 900. It has a handle 901, a stem 902, and a screw insert 903 which can be screwed into the threaded staple insert. The impactor has two wings 904 which keep the staple base edges in place facilitating staple impaction. The handle 901 of the impactor 900 is broad in order to allow impaction by a mallet.

[0078] Figures 10A -C illustrate three-dimensional views of the four-pronged cervical staple impactor 1000 (Embodiment II). It has the same features as the two-pronged impactor 900, except its wings 1004 are broader accommodating the broader staple base. The impactor 1000 also includes a handle 1001, a stem 1002, and an impact screw 1003.

[0079] Figure 11A illustrates a three-dimensional view of placement of the two pronged cervical facet staple 700 into a cervical spine model having vertebral body 1103 and lamina 1104. One staple 700 is perched on the joint 1101 prior to impaction. The other staple 700 is impacted.

[0080] Figure 11B illustrates a three-dimensional view of placement of the four pronged cervical facet staple 800 into a cervical spine pre and post impaction.

[0081] Figure 11C illustrates the concept of modularity and incremental diminution of movement of the joint by the modular placement of different combinations and permutations of varying numbers of two and four pronged cervical facet staples 700, 800. If one wishes to have the most flexible (least rigid) fusion, one would place a unilateral two pronged staple 700. One can increase i.e. calibrate increasing degrees of rigidity by increasing the number of

prongs penetrating the facet joints bilaterally. In Figure 11C each facet joint is fused using a total number of six prongs. One side this is accomplished by using three two pronged staples 700, and on the other side using one four pronged staple 800 and one two pronged staple 700. These two embodiments can be mixed and matched unilaterally or bilaterally to vary the degree of rigidity and conversely flexibility of fusion. The most flexible fusion at one level would be accomplished by one staple 700 (2 prongs). The highest level of rigidity would be achieved by placing two four pronged staples 800 on both sides totaling sixteen prongs. Intermediate degrees of relative joint motion can be modulated by insertion into the cervical facet joints staples in two-four prong increments from 2-16. Each additional prong further limits the degree of facet joint motion hence increasing rigidity, and conversely decreasing flexibility. Thus the novel modular use of these embodiments heralds an era of flexible cervical spine fusion.

[0082] Figures 12 A - B illustrate a lumbar facet joint staple 1200 in open and closed positions and having staple prongs 1203. This lumbar facet staple has been thoroughly described in our previous co-pending patent applications, Serial No. 11/536,815, filed on September, 29, 2006, and Serial No. 11/208,644, filed on August 23, 2005, the relevant portion of each of which is hereby incorporated by reference hereinafter. The new improvement of this device includes a ratchet 1201. The staple 1200 can be incrementally closed with increased ratcheting over increasing number of spurs 1202. This achieves increasing calibrated levels of lumbar facet joint fusion, and conversely diminishing joint flexibility. This new designs further enhances the capacity to achieve flexible fusions in the lumbar

spine.

2. THE SURGICAL METHOD

[0083] Exemplary surgical steps for practicing one or more of the foregoing embodiments will now be described.

[0084] The posterior lumbar spine implantation of all the screw box 100, 200, 300 embodiments, with BDFT screws, and horizontal mini-plate 400 can be implanted via previously described posterior lumbar interbody fusion (PLIF) or posterior transforaminal lumbar interbody fusion (TLIF) procedures. The procedures can be performed open, microscopic, closed tubular or endoscopic. Fluoroscopic guidance can be used with any of these procedures.

[0085] After adequate induction of anesthesia, the patient is placed in the prone position. A midline incision is made for a PLIF procedure, and one or two parallel paramedian incisions or a midline incision is made for the TLIF procedure. For the PLIF, a unilateral or bilateral facet sparing hemi-laminotomy is created to introduce screw box 100, 200, 300 embodiments I-III into the disc space, after it is adequately prepared.

[0086] For the TLIF procedure, after unilateral or bilateral dissection and drilling of the inferior articulating surface and the medial superior articulating facet the far lateral disc space is entered and a circumferential discectomy is performed. The disc space is prepared and the endplates exposed.

[0087] Then one screw box 100, 200, 300 of either embodiments I-III is placed

on either right, left or both sides. Then another screw box of embodiments 100, 200, 300 I-III is placed on the contralateral side. For embodiment I the external screw guide 505/ box expander is attached to the screw box (Figures 5A-H). First the Allen key 501 is screwed until the box conforms perfectly to the height and depth of the space. Then a pilot hole can be drilled or an awl can start a pilot hole in the vertebral bodies. Then a transvertebral screw is screwed into the vertebral body via the built- in box screw guides 505. For difficult angles, an angled screw driver can be employed.

[0088] For embodiments II-III the same method is used for placing screws, except the Allen key 501 is not utilized in the absence of plate expansion.

[0089] If bilateral constructs have been inserted, bone is packed into the intervertebral space, as well as within the device. Then the horizontal intervertebral zero profile mini-plate 400 is slid beneath the thecal sac and is secured to both left and right screw boxes with small mini-plate screws 210 (Figures 4A-B). This prevents bone intrusion into the thecal sac and hence possible nerve root compression.

[0090] Figures 6A and B illustrate the process of insertion and final placement of the construct into the lumbar spine. The mini- plates 400 can come in different horizontal lengths and widths to accommodate different intra and inter -patient disc space diameters. The BDFT screws can come in different widths, lengths and thread designs.

[0091] The anterior thoracic and lumbar spine implantation of one, two or three screw box constructs 100, 200, 300 and BDFT screws can be performed in a

similar manner to the posterior application. Likewise, a horizontal mini-plate 400 can be used to cap two or three screw box constructs 100, 200, 300 (one placed midline deeply, one placed left and one placed right, forming a triangulation). Alternatively two screw box constructs may be placed into a circumferential ring for anterior placement. Anterior placement of these devices can be performed into the L4/5 and L5/S1 spaces on the supine anesthetized patient via previously described open microscopic or endoscopic techniques. Once the disc space is exposed and discectomy and space preparation are performed, placement of one, two or three screw box embodiments 100, 200, 300 (I-III) or a 2 in 1 construct can be placed. The screw placement is facilitated by the internal screw guides, and different positioning tools ((Figure 5). A right angled screw driver and/or ratchet could alternatively be employed. A capping mini-plate 400 may be applied if desirable. The mechanism of screw placement and mini-plate 400 attachment are identical to what was described above.

[0092] The posterior placement of screw box constructs 100, 200, 300 alone or combined with horizontal mini-plates 400 into the thoracic spine can be performed via previously described transpedicular approaches; open or endoscopic. The anterior placement into the thoracic spine can be accomplished via a trans-thoracic approach. Once the disc space is exposed via either approach, any combination of the above mention Embodiments (I-III) can be inserted. Engagement of the devices is identical to what was mentioned above.

[0093] For posterior placement of cervical facet staple 700, 800 embodiments, after adequate induction of anesthesia the patient is flipped prone and his head

and neck secured. A single midline or two para-median incisions are made for unilateral or bilateral or multilevel placement of staples. Ultimately the facet joint is exposed. Alternatively and preferably this can be performed percutaneously under fluoroscopic guidance with intravenous sedation. The staple 700, 800 (Embodiments I or II) is loaded into the impactor 900, 1000. The staple 700, 800 is placed on the two articulating cervical facets, and then impacted into the joint. To achieve modular calibrated fusion different combinations and permutations of cervical facet stales can be inserted ranging from a single unilateral two pronged staple providing a high degree of flexibility to a total of four bilaterally placed four pronged staples 800 (16 prongs) leading to the highest degree of rigidity. Additional bone may or may not be placed in its vicinity to facilitate permanent and solid fusion. This procedure can be performed open, closed, percutaneously, tubulary, endoscopically or microscopically. Figures 11 A-C illustrates placement of the staples 700, 800 in the cervical spine.

[0094] We have previously described surgical placement of the lumbar facet joint staple in our two co-pending patents. The surgical procedure for this device is identical to that which has been previously mentioned.

[0095] The present inventions may provide effective and safe techniques that overcome the problems associated with current transpedicular based cervical, thoracic and lumbar fusion technology, and for many degenerative stable and unstable spine disease. These inventions could replace much pedicle screw-based instrumentation in many but not all degenerative spine conditions.

[0096] The speed and simplicity of placement of cervical and lumbar facet

staples, and placement of Lumbar screw box –BDFT constructs far exceeds that of current pedicle screw technology. Furthermore, these devices have markedly significantly decreased risk of misguided screw placement, and hence decreased risk of neural and vascular injury, and blood loss. In the lumbar spine BDFT screw constructs and facet staples could be applied modularly in different combinations to achieve different degrees of rigidity (flexibility). Patients having these devices would have decreased recovery and back to work time. These devices most likely lead to similar if not equal fusion with significantly less morbidity, and hence overall make them a major advance in the evolution of spinal instrumented technology leading to advances in the care of the spinal patient.

[0097] Another major novelty and advance is the introduction of simple and safe modular calibrated cervical flexible fusion. To our knowledge neither a similar device nor a similar mathematical concept of modular joint flexibility/fusion calibration has been postulated for the cervical spine or for any other articulating joint.

[0098] To our knowledge there have not been any previously described similar posterior lumbar and thoracic combined spacer and screw constructs. These devices can similarly be modified to stabilize bone fractures throughout the entire body. To our knowledge the description of zero to subzero profile anterior or posterior horizontal spinal plates which traverse the diameter of the disc space has not been previously described.

We claim:

1. A self-drilling bone fusion screw apparatus, which comprises:
 - a first sliding box;
 - a second sliding box, positioned relative to the first sliding box;
 - a first screw member having a tapered end and a threaded body disposed within the first sliding box;
 - a second screw member having a tapered end and a threaded body disposed within the second sliding box;; and
 - an adjuster for adjusting the height of the sliding boxes.
2. The self-drilling bone fusion screw apparatus according to claim 1 wherein the first and second screw members are medially aligned.
3. The self-drilling bone fusion screw apparatus according to claim 1 wherein at least one of the first and second screw members is laterally aligned.
4. The self-drilling bone fusion screw apparatus according to claim 3 wherein both the first and second screw members are laterally aligned.
5. The self-drilling bone fusion screw apparatus according to claim 1 wherein one of the first and second screw members is laterally aligned and the other screw member is laterally aligned.

6. The self-drilling bone fusion screw apparatus according to claim 1 wherein the first and second sliding boxes are substantially triangularly shaped.

7. The self-drilling bone fusion screw apparatus according to claim 6 wherein the triangularly shaped first and second sliding boxes include a sliding rail and ridged surfaces.

8. The self-drilling bone fusion screw apparatus according to claim 7 wherein the triangularly shaped first and second sliding boxes include holes for bone grafts.

9. The self-drilling bone fusion screw apparatus according to claim 8 wherein the adjuster includes a screw.

10. A self-drilling bone fusion screw apparatus, which comprises:

- a box;

- a first screw member having a tapered end and a threaded body disposed at least partially within the box and laterally aligned with the box;

- a second screw member having a tapered end and a threaded body disposed at least partially within the box and laterally aligned with the box; and

- a plurality of ridges disposed on along the sides of the box.

11. The self-drilling bone fusion screw apparatus according to claim 10 which further includes bone graft holes.

12. The self-drilling bone fusion screw apparatus according to claim 11 which is attachable to a second self-drilling fusion screw apparatus via a plate.

13. A self-drilling bone fusion screw apparatus, which comprises:

- a first box;

- a first screw member having a tapered end and a threaded body disposed at least partially within the first box and laterally aligned with the first box;

- a second box;

- a second screw member having a tapered end and a threaded body disposed at least partially within the second box and laterally aligned with the second box; and

- an attachment member for engaging the first and second boxes.

14. The self-drilling bone fusion screw apparatus according to claim 13 which further includes bone graft holes.

15. The self-drilling bone fusion screw apparatus according to claim 13 wherein the plate is joined to the first and second boxes by a plurality of screws.

16. A tool assembly for manipulating a self-drilling bone fusion screw apparatus, which comprises:

- a handle;

- a gripper cooperating with the handle and having a plurality of prongs;

a screw guide, held in place the plurality of prongs, for controlling the direction of self-drilling screws that are screwed into a vertebral body.

17. The tool assembly for manipulating a self-drilling bone fusion screw apparatus, according to claim 16, which further includes a key for controlling an adjustment device which controls the height of the self-drilling bone fusion screw apparatus.

18. A cervical facet staple, comprising:

a curved staple base;

at least two prongs attached to the bottom surface of the curved staple base; and

an insertion member disposed on the top surface of the curved staple base.

19. The cervical facet staple, according to claim 18 further including at least four prongs attached to the bottom surface of the curved staple base.

20. The cervical facet staple, according to claim 19 wherein the insertion member includes a threaded insert.

21. An impaction tool for a cervical facet staple, comprising:

a handle;

- a stem attached to the handle;
- a plurality of wings for contacting the cervical facet staple; and
- an insertion member for coupling the cervical facet staple to the impaction tool.

22. The impaction tool for a cervical facet staple, according to claim 21 wherein the handle includes a flattened portion that can be struck by a mallet.

23. A lumbar facet staple, comprising:

- a pair of rotating arms;
- at least two prongs attached to the inner surfaces of the rotating arms;
- a plurality of spurs attached to one of the rotating arms; and
- a ratchet attached to one of the rotating arms;

wherein the rotating arms and prongs are rotated to a closed position to staple a lumbar facet joint.

24. The self-drilling bone fusion screw apparatus according to claim 13, wherein the attachment member for engaging the first and second boxes comprises a plate or a circumferential cage defining at least one recess, the first and the second boxes being positioned within the recess of the circumferential cage.

25. The tool assembly according to claim 16, further comprising a driver assembly, the driver assembly comprising:

a handle;

a drive bit portion; and

a flexible drive shaft extending between the handle and the drive bit portion for manipulating a screw of an expandable or non-expandable screw box.

ABSTRACT OF THE DISCLOSURE

A self-drilling bone fusion screw apparatus is disclosed which includes at least first and second sliding boxes. A first screw member having a tapered end and a threaded body is disposed within the first sliding box, and a second screw member having a tapered end and a threaded body disposed within the second sliding box. An adjuster adjusts the height of the sliding boxes. The screw members are screwed into vertebral bodies in order to fuse the vertebral bodies together. A plurality of the self-drilling bone fusion screw apparatuses may be attached together and/or integrated via a plate or cage. Also disclosed is a cervical facet staple that includes a curved staple base and at least two prongs attached to the bottom surface of the curved staple base. .

PATENT APPLICATION

DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION

ATTORNEY DOCKET NO. 3003/0105PUS1

As a below named inventor, I hereby declare that:

My residence/post office address and citizenship are as stated below next to my name;

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION the specification of which is attached hereto unless the following box is checked:

() was filed on _____ as US Application Serial No. or PCT International Application Number _____ and was amended on _____ (if applicable).

I hereby state that I have reviewed and understood the contents of the above-identified specification, including the claims, as amended by any amendment(s) referred to above. I acknowledge the duty to disclose all information which is material to patentability as defined in 37 CFR 1.56.

Foreign Application(s) and/or Claim of Foreign Priority

I hereby claim foreign priority benefits under Title 35, United States Code Section 119 of any foreign application(s) for patent or inventor(s) certificate listed below and have also identified below any foreign application for patent or inventor(s) certificate having a filing date before that of the application on which priority is claimed:

COUNTRY	APPLICATION NUMBER	DATE FILED	PRIORITY CLAIMED UNDER 35 U.S.C. 119
			YES: _____ NO: _____
			YES: _____ NO: _____

Provisional Application

I hereby claim the benefit under Title 35, United States Code Section 119(e) of any United States provisional application(s) listed below:

APPLICATION SERIAL NUMBER	FILING DATE
60/670,231	12 Apr 2005

U.S. Priority Claim

I hereby claim the benefit under Title 35, United States Code, Section 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code Section 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, Section 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

APPLICATION SERIAL NUMBER	FILING DATE	STATUS(patented/pending/abandoned)
11/536,815	September 29, 2006	Pending
11/208,644	August 23, 2005	Pending

POWER OF ATTORNEY:

As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) listed below to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full Name of Inventor: Aharon D. MOSKOWITZ Citizenship: US

Residence: 212 North Adams Street, Rockville, MD 20850 US

Post Office Address: Same

Inventor's Signature: Aharon D. Moskowitz Date: 8/21/07

**DECLARATION AND POWER OF ATTORNEY
FOR PATENT APPLICATION (continued)**

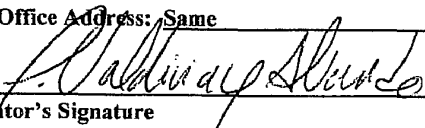
ATTORNEY DOCKET NO. 3003/0103PUS1

Full Name of Inventor: Pablo A Valdivia Y ALVARADO

Citizenship: BOLIVIA

Residence: 112 Pearl Street Apt#2, Cambridge MA 02139 US

Post Office Address: Same

Inventor's Signature 

Date 8/21/07

Full Name of Inventor: Mosheh T. MOSKOWITZ

Citizenship: US

Residence: 212 North Adams St., Rockville, MD 20850 US

Post Office Address: Same

Inventor's Signature _____

Date _____

Full Name of Inventor: Nathan C. MOSKOWITZ

Citizenship: US

Residence: 212 North Adams St., Rockville, MD 20850 US

Post Office Address: Same

Inventor's Signature _____

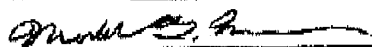
Date _____

DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION (continued)	ATTORNEY DOCKET NO. 2008103PUS1
---	---------------------------------

Full Name of Inventor: Edna A. Yañez Y. ALVARADO Citizenship: _____
 Residence: _____
 Post Office Address: None

Inventor's Signature: _____ Date: _____

Full Name of Inventor: Matthew T. MCKENNA Citizenship: US
 Residence: 211 North Adams St., Roselle, NJ 07068 US
 Post Office Address: None

 Date: 8/21/07

Inventor's Signature: _____ Date: _____
 Full Name of Inventor: Matthew C. MCKENNA Citizenship: US
 Residence: 211 North Adams St., Roselle, NJ 07068 US
 Post Office Address: None

Inventor's Signature: _____ Date: _____

**DECLARATION AND POWER OF ATTORNEY
FOR PATENT APPLICATION (continued)**

ATTORNEY DOCKET NO. 3003/0103PUS1

Full Name of Inventor: Pablo A. Valdivia Y ALVARADO

Citizenship: _____

Residence: _____

Post Office Address: Same

Inventor's Signature _____

Date _____

Full Name of Inventor: Mosheh T. MOSKOWITZ

Citizenship: US

Residence: 212 North Adams St., Rockville, MD 20850 US

Post Office Address: Same

Inventor's Signature _____

Date _____

Full Name of Inventor: Nathan C. MOSKOWITZ

Citizenship: US

Residence: 212 North Adams St., Rockville, MD 20850 US

Post Office Address: Same

Nathan C. Moskowitz
Inventor's Signature

8/21/07
Date

Electronic Acknowledgement Receipt	
EFS ID:	10740294
Application Number:	13210168
International Application Number:	
Confirmation Number:	1609
Title of Invention:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION
First Named Inventor/Applicant Name:	Ahmnon D Moskowitz
Customer Number:	87409
Filer:	John Jeremy Dresch
Filer Authorized By:	
Attorney Docket Number:	3003/0105PUS7
Receipt Date:	15-AUG-2011
Filing Date:	
Time Stamp:	18:22:14
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no				
File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Application Data Sheet	30030105PUS7_sb0014_fill.pdf	1032813 c38cead3542ef975e6e9917e0bf8069d2ffb88	no	6
Warnings:					
Information:					

2	Power of Attorney	30030105PUS1_POA_ahmnon-moskowitz_readyforfiling.pdf	57377 896578bcf16c4d3025becb706ef44a1426c40c14	no	1
Warnings:					
Information:					
3	Power of Attorney	30030105PUS1_POA_mosheh-moskowitz_readyforfiling.pdf	57865 860551ebc6d2b42b017c607c11a0b3fa2f625217	no	1
Warnings:					
Information:					
4	Power of Attorney	30030105PUS1_POA_nathan-moskowitz_readyforfiling.pdf	55715 401543190d7d5ad28c1bd1c3e4f9e7781f8dff4d	no	1
Warnings:					
Information:					
5	Power of Attorney	30030105PUS1_POA_pablo_alvarado_readyforfiling.pdf	676300 59ae634f5520e354eacb029db06b716d4a4974a	no	1
Warnings:					
Information:					
6	Preliminary Amendment	30030105PUS7_prelim_amend_readyforfiling.pdf	113339 cc81cb8b20a25c3775409db316f5eea84f6e229c	no	17
Warnings:					
Information:					
7	Specification	30030105PUS7_substitute_spec_clean_version.pdf	105712 23bc544836ddd3028dc38d88150d72a4d9e83a10	no	25
Warnings:					
Information:					
8	Specification	30030105PUS7_substitute_spec_markup_version_READYFORFILING.pdf	168003 c4354f046af4da24b97d6b9f91ece9b31b9fc86e	no	24
Warnings:					
Information:					
9	Drawings-only black and white line drawings	0105PUS7_Figures_readytofile_with_Repl_.pdf	1051433 6354d1a67552cb3c11fadf6921095867bfc2aea3	no	38
Warnings:					
Information:					
10	Specification	0105PUS7_SPEC_fromparent_readyforfiling.pdf	1961732 f38d153b944298ef0596595deea8554b2afcfa7	no	34
Warnings:					
Information:					

11	Oath or Declaration filed	0105PUS7_DEC_fromparent. pdf	225111 66073142198e5b65d3d964d8c17f2eb5b5c 3e4e4	no	4
Warnings:					
Information:					
Total Files Size (in bytes):			5505400		
<p>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.</p> <p><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.</p> <p><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.</p> <p><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.</p>					

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

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	3003/0105PUS7
		Application Number	
Title of Invention	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION		
<p>The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.</p> <p>This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.</p>			

Secrecy Order 37 CFR 5.2

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Applicant Information:

Applicant 1					Remove		
Applicant Authority		☒ Inventor		☐ Legal Representative under 35 U.S.C. 117		☐ Party of Interest under 35 U.S.C. 118	
Prefix	Given Name	Middle Name	Family Name		Suffix		
	Ahmnon	D.	MOSKOWITZ				
Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service							
City	Rockville	State/Province	MD	Country of Residence i	US		
Citizenship under 37 CFR 1.41(b) i		US					
Mailing Address of Applicant:							
Address 1		212 North Adams St.					
Address 2							
City	Rockville	State/Province	MD				
Postal Code	20850	Country i	US				
Applicant 2					Remove		
Applicant Authority		☒ Inventor		☐ Legal Representative under 35 U.S.C. 117		☐ Party of Interest under 35 U.S.C. 118	
Prefix	Given Name	Middle Name	Family Name		Suffix		
	Mosheh	T.	MOSKOWITZ				
Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service							
City	Rockville	State/Province	MD	Country of Residence i	US		
Citizenship under 37 CFR 1.41(b) i		US					
Mailing Address of Applicant:							
Address 1		212 North Adams St.					
Address 2							
City	Rockville	State/Province	MD				
Postal Code	20850	Country i	US				
Applicant 3					Remove		
Applicant Authority		☒ Inventor		☐ Legal Representative under 35 U.S.C. 117		☐ Party of Interest under 35 U.S.C. 118	
Prefix	Given Name	Middle Name	Family Name		Suffix		
	Nathan	C.	MOSKOWITZ				
Residence Information (Select One) ☒ US Residency ☐ Non US Residency ☐ Active US Military Service							
City	Rockville	State/Province	MD	Country of Residence i	US		

Application Data Sheet 37 CFR 1.76		Attorney Docket Number		3003/0105PUS7	
		Application Number			
Title of Invention	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION				
Citizenship under 37 CFR 1.41(b) i		US			
Mailing Address of Applicant:					
Address 1		212 North Adams St.			
Address 2					
City	Rockville	State/Province	MD		
Postal Code	20850	Country ⁱ	US		
Applicant 4					Remove
Applicant Authority ☒ Inventor		☐ Legal Representative under 35 U.S.C. 117		☐ Party of Interest under 35 U.S.C. 118	
Prefix	Given Name	Middle Name	Family Name	Suffix	
	Pablo	A Valdivia Y	ALVARADO		
Residence Information (Select One)		☒ US Residency ☐ Non US Residency ☐ Active US Military Service			
City	Cambridge	State/Province	MA	Country of Residence ⁱ	US
Citizenship under 37 CFR 1.41(b) i		BO			
Mailing Address of Applicant:					
Address 1		112 Pearl Street			
Address 2		Apt. #2			
City	Cambridge	State/Province	MA		
Postal Code	02139	Country ⁱ	US		
All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the Add button.					Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below. For further information see 37 CFR 1.33(a).	
☐ An Address is being provided for the correspondence Information of this application.	
Customer Number	87409
Email Address	mailroom@dreschiplaw.com Add Email Remove Email

Application Information:

Title of the Invention	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION		
Attorney Docket Number	3003/0105PUS7	Small Entity Status Claimed	☒
Application Type	Nonprovisional		
Subject Matter	Utility		
Suggested Class (if any)		Sub Class (if any)	
Suggested Technology Center (if any)			
Total Number of Drawing Sheets (if any)	38	Suggested Figure for Publication (if any)	2A

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	3003/0105PUS7
		Application Number	
Title of Invention	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION		

Publication Information:

☐	Request Early Publication (Fee required at time of Request 37 CFR 1.219)
☐	Request Not to Publish. I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application has not and will not be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32). Enter either Customer Number or complete the Representative Name section below. If both sections are completed the Customer Number will be used for the Representative Information during processing.			
Please Select One:	☒ Customer Number	☐ US Patent Practitioner	☐ Limited Recognition (37 CFR 11.9)
Customer Number	87409		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, or 365(c) or indicate National Stage entry from a PCT application. Providing this information in the application data sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78(a)(2) or CFR 1.78(a)(4), and need not otherwise be made part of the specification.					
Prior Application Status	Pending	Remove			
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)		
	Continuation of	13084543	2011-04-11		
Prior Application Status	Pending	Remove			
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)		
	Continuation of	13108982	2011-05-16		
Prior Application Status	Patented	Remove			
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
13084543	Division of	11842855	2007-08-21	7942903	2011-05-17
Prior Application Status	Patented	Remove			
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
13108982	Continuation of	11842855	2007-08-21	7942903	2011-05-17
Prior Application Status	Patented	Remove			
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
11842855	Continuation in part of	11536815	2006-09-29	7846188	2010-12-07
Prior Application Status	Patented	Remove			

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

Application Data Sheet 37 CFR 1.76		Attorney Docket Number		3003/0105PUS7	
		Application Number			
Title of Invention		BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION			
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
11536815	Continuation in part of	11208644	2005-08-23	7704279	2010-04-27
Prior Application Status		Expired		Remove	
Application Number		Continuity Type		Prior Application Number	Filing Date (YYYY-MM-DD)
11208644		non provisional of		60670231	2005-04-12
Prior Application Status				Remove	
Application Number		Continuity Type		Prior Application Number	Filing Date (YYYY-MM-DD)
60670231					
Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the Add button.					Add

Foreign Priority Information:

This section allows for the applicant to claim benefit of foreign priority and to identify any prior foreign application for which priority is not claimed. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55(a).			
Remove			
Application Number	Country ⁱ	Parent Filing Date (YYYY-MM-DD)	Priority Claimed
			☒ Yes ☐ No
Additional Foreign Priority Data may be generated within this form by selecting the Add button.			Add

Assignee Information:

Providing this information in the application data sheet does not substitute for compliance with any requirement of part 3 of Title 37 of the CFR to have an assignment recorded in the Office.				
Assignee 1 Remove				
If the Assignee is an Organization check here. ☐				
Prefix	Given Name	Middle Name	Family Name	Suffix
Mailing Address Information:				
Address 1				
Address 2				
City		State/Province		
Country ⁱ		Postal Code		
Phone Number		Fax Number		
Email Address				
Additional Assignee Data may be generated within this form by selecting the Add button.				Add

Signature:

A signature of the applicant or representative is required in accordance with 37 CFR 1.33 and 10.18. Please see 37 CFR 1.4(d) for the form of the signature.
--

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Application Data Sheet 37 CFR 1.76		Attorney Docket Number		3003/0105PUS7	
		Application Number			
Title of Invention	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION				
Signature	/John J. Dresch/			Date (YYYY-MM-DD)	2011-08-15
First Name	John	Last Name	Dresch	Registration Number	46672

This collection of information is required by 37 CFR 1.76. 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 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet 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.

PTO/SB/81 (01-09)

Approved for use through 11/30/2011. OMB 0651-0035

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

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POWER OF ATTORNEY OR REVOCATION OF POWER OF ATTORNEY WITH A NEW POWER OF ATTORNEY AND CHANGE OF CORRESPONDENCE ADDRESS	Application Number	11/842,855
	Filing Date	08/21/2007
	First Named Inventor	MOSKOWITZ, ET AL.
	Title	BIDIRECTIONAL FIXATING TRANSVERTEBRAL ...
	Art Unit	3733
	Examiner Name	Philogene, Pedro
	Attorney Docket Number	3003/0105PUS1

I hereby revoke all previous powers of attorney given in the above-identified application.

☐ A Power of Attorney is submitted herewith.

OR

☒ I hereby appoint Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith:

87409

OR

☐ I hereby appoint Practitioner(s) named below as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith:

Practitioner(s) Name	Registration Number

Please recognize or change the correspondence address for the above-identified application to:

☒ The address associated with the above-mentioned Customer Number.

OR

☐ The address associated with Customer Number:

87409

OR

Firm or Individual Name	DRESCH IP LAW, PLLC		
Address	PO BOX 650903		
City	POTOMAC FALLS	State	VA
Country	US	Zip	20165
Telephone	571-333-0930	Email	mailroom@dreschiplaw.com

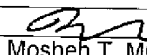
I am the:

☒ Applicant/Inventor.

OR

☐ Assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) (Form PTO/SB/96) submitted herewith or filed on _____

SIGNATURE of Applicant or Assignee of Record

Signature		Date	10/28/10
Name	Moshen T. MOSKOWITZ	Telephone	
Title and Company			

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

☒ *Total of 4 forms are submitted.

This collection of information is required by 37 CFR 1.31, 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.

PTO/SB/81 (01-09)

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POWER OF ATTORNEY OR REVOCATION OF POWER OF ATTORNEY WITH A NEW POWER OF ATTORNEY AND CHANGE OF CORRESPONDENCE ADDRESS	Application Number	11/842,855
	Filing Date	08/21/2007
	First Named Inventor	MOSKOWITZ, ET AL.
	Title	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL ...
	Art Unit	3733
	Examiner Name	Phlogene, Pedro
	Attorney Docket Number	3003/0105PUS1

I hereby revoke all previous powers of attorney given in the above-identified application.

☐ A Power of Attorney is submitted herewith.

OR

☒ I hereby appoint Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith:

87409

OR

☐ I hereby appoint Practitioner(s) named below as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith:

Practitioner(s) Name	Registration Number

Please recognize or change the correspondence address for the above-identified application to:

☒ The address associated with the above-mentioned Customer Number.

OR

☐ The address associated with Customer Number:

87409

OR

☐ Firm or Individual Name	DRESCH IP LAW, PLLC				
Address	PO BOX 650903				
City	POTOMAC FALLS	State	VA	Zip	20165
Country	US				
Telephone	571-333-0930	Email	mailroom@dreschiplaw.com		

I am the:

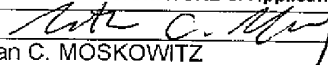
☒ Applicant/Inventor.

OR

☐ Assignee of record of the entire interest. See 37 CFR 3.71.

Statement under 37 CFR 3.73(b) (Form PTO/SB/96) submitted herewith or filed on _____

SIGNATURE of Applicant or Assignee of Record

Signature		Date	10/28/10
Name	Nathan C. MOSKOWITZ	Telephone	301-873-9232
Title and Company			

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

☒ *Total of 4 forms are submitted.

This collection of information is required by 37 CFR 1.31, 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.

POWER OF ATTORNEY OR REVOCATION OF POWER OF ATTORNEY WITH A NEW POWER OF ATTORNEY AND CHANGE OF CORRESPONDENCE ADDRESS	Application Number	11/842,855
	Filing Date	08/21/2007
	First Named Inventor	MOSKOWITZ, ET AL.
	Title	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL ...
	Art Unit	3733
	Examiner Name	Philogene, Pedro
	Attorney Docket Number	3003/0105PUS1

I hereby revoke all previous powers of attorney given in the above-identified application.

☐ A Power of Attorney is submitted herewith.
OR
☒ I hereby appoint Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith: 87409

OR
☐ I hereby appoint Practitioner(s) named below as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith:

Practitioner(s) Name	Registration Number

Please recognize or change the correspondence address for the above-identified application to:

☒ The address associated with the above-mentioned Customer Number.
OR
☐ The address associated with Customer Number: 87409

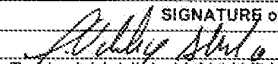
OR

☐ Firm or Individual Name	DRESCH IP LAW, PLLC		
Address	PO BOX 650903		
City	POTOMAC FALLS	State	VA Zip 20165
Country	US		
Telephone	571-333-0930	Email	mailroom@dreschiplaw.com

I am the:

☒ Applicant/Inventor.
OR
☐ Assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) (Form PTO/SB/96) submitted herewith or filed on _____.

SIGNATURE of Applicant or Assignee of Record

Signature		Date	Nov. 05. 2010
Name	Pablo A Valdivia Y ALVARADO	Telephone	
Title and Company	RESEARCH SCIENTIST MIT-SINGAPORE ALLIANCE		

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

☒ *Total of 4 forms are submitted.

This collection of information is required by 37 CFR 1.31, 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.

PTO/SB/81 (01-09)

Approved for use through 11/30/2011. OMB 0651-0035

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

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POWER OF ATTORNEY OR REVOCATION OF POWER OF ATTORNEY WITH A NEW POWER OF ATTORNEY AND CHANGE OF CORRESPONDENCE ADDRESS	Application Number	11/842,855
	Filing Date	08/21/2007
	First Named Inventor	MOSKOWITZ, ET AL.
	Title	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL ...
	Art Unit	3733
	Examiner Name	Philogene, Pedro
	Attorney Docket Number	3003/0105PUS1

I hereby revoke all previous powers of attorney given in the above-identified application.

☐ A Power of Attorney is submitted herewith.

OR

☒ I hereby appoint Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith:

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OR

☐ I hereby appoint Practitioner(s) named below as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith:

Practitioner(s) Name	Registration Number

Please recognize or change the correspondence address for the above-identified application to:

☒ The address associated with the above-mentioned Customer Number.

OR

☐ The address associated with Customer Number:

87409

OR

☐ Firm or Individual Name	DRESCH IP LAW, PLLC				
Address	PO BOX 650903				
City	POTOMAC FALLS	State	VA	Zip	20165
Country	US				
Telephone	571-333-0930	Email	mailroom@dreschiplaw.com		

I am the:

☒ Applicant/Inventor.

OR

☐ Assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) (Form PTO/SB/96) submitted herewith or filed on _____.

SIGNATURE of Applicant or Assignee of Record			
Signature	<i>Ahmon D. Moskowitz</i>	Date	10/30/10
Name	Ahmon D. MOSKOWITZ	Telephone	301-442-5160
Title and Company			

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☒ *Total of 4 forms are submitted.

This collection of information is required by 37 CFR 1.31, 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.

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UNITED STATES DEPARTMENT OF COMMERCE
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www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
13/210,168	08/15/2011	Ahmnnon D. MOSKOWITZ	3003/0105PUS7

CONFIRMATION NO. 1609

FORMALITIES LETTER



OC000000049511350

Date Mailed: 08/29/2011

87409
Dresch IP Law, PLLC
P.O. Box 650903
Potomac Falls, VA 20165

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

Items Required To Avoid Abandonment:

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The statutory basic filing fee is missing.
Applicant must submit \$82 to complete the basic filing fee for a small entity.

The applicant needs to satisfy supplemental fees problems indicated below.

The required item(s) identified below must be timely submitted to avoid abandonment:

- Additional claim fees of **\$1040** as a small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due.
- A surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.16(f) of **\$65** for a small entity in compliance with 37 CFR 1.27, must be submitted.

SUMMARY OF FEES DUE:

Total fee(s) required within **TWO MONTHS** from the date of this Notice is **\$1702** for a small entity

- **\$82** Statutory basic filing fee.
- **\$65** Surcharge.
- The application search fee has not been paid. Applicant must submit **\$270** to complete the search fee.
- The application examination fee has not been paid. Applicant must submit **\$110** to complete the examination fee for a small entity in compliance with 37 CFR 1.27.
- The specification and drawings submitted electronically contain the equivalent of more than 100 pages. Applicant owes **\$135** for 1 pages in excess of 100 pages for a small entity in compliance with 37 CFR 1.27.
- Total additional claim fee(s) for this application is **\$1040**
 - **\$1040** for 40 total claims over 20.

Replies should be mailed to:

Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web.
<https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html>

For more information about EFS-Web please call the USPTO Electronic Business Center at **1-866-217-9197** or visit our website at <http://www.uspto.gov/ebc>.

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

/mkibret/

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

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875						Application or Docket Number 13/210,168			
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 <small>(37 CFR 1.16(a), (b), or (c))</small>	N/A	N/A	N/A	82		N/A			
SEARCH FEE <small>(37 CFR 1.16(k), (l), or (m))</small>	N/A	N/A	N/A	270		N/A			
EXAMINATION FEE <small>(37 CFR 1.16(o), (p), or (q))</small>	N/A	N/A	N/A	110		N/A			
TOTAL CLAIMS <small>(37 CFR 1.16(i))</small>	60	minus 20 = * 40	x 26 =	1040					
INDEPENDENT CLAIMS <small>(37 CFR 1.16(h))</small>	3	minus 3 = *	x 110 =	0.00					
APPLICATION SIZE FEE <small>(37 CFR 1.16(s))</small>	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$270 (\$135 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).			135					
MULTIPLE DEPENDENT CLAIM PRESENT <small>(37 CFR 1.16(j))</small>				0.00					
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	1637		TOTAL			
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 <small>(37 CFR 1.16(i))</small>	*	Minus	**	=	x	=	x	=
	Independent <small>(37 CFR 1.16(h))</small>	*	Minus	***	=	x	=	x	=
	Application Size Fee <small>(37 CFR 1.16(s))</small>								
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM <small>(37 CFR 1.16(j))</small>								
					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 <small>(37 CFR 1.16(i))</small>	*	Minus	**	=	x	=	x	=
	Independent <small>(37 CFR 1.16(h))</small>	*	Minus	***	=	x	=	x	=
	Application Size Fee <small>(37 CFR 1.16(s))</small>								
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM <small>(37 CFR 1.16(j))</small>								
					TOTAL ADD'L FEE			TOTAL ADD'L FEE	
<div style="font-size: x-small;"> * 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. </div>									



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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
13/210,168	08/15/2011	3733	0.00	3003/0105PUS7	60	3

CONFIRMATION NO. 1609

87409

Dresch IP Law, PLLC
P.O. Box 650903
Potomac Falls, VA 20165

FILING RECEIPT



0000000049511349

Date Mailed: 08/29/2011

Receipt is acknowledged of this non-provisional 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 APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Applicant(s)

Ahmnnon D. MOSKOWITZ, Rockville, MD;
Pablo A Valdivia Y ALVARADO, Cambridge, MA;
Mosheh T. MOSKOWITZ, Rockville, MD;
Nathan C. MOSKOWITZ, Rockville, MD;

Power of Attorney: The patent practitioners associated with Customer Number 87409

Domestic Priority data as claimed by applicant

This application is a CON of 13/084,543 04/11/2011
and is a CON of 13/108,982 05/16/2011
and said 13/084,543 04/11/2011
is a DIV of 11/842,855 08/21/2007 PAT 7,942,903
and said 13/108,982 05/16/2011
is a CON of 11/842,855 08/21/2007 PAT 7,942,903
which is a CIP of 11/536,815 09/29/2006 PAT 7,846,188
which is a CIP of 11/208,644 08/23/2005 PAT 7,704,279
which claims benefit of 60/670,231 04/12/2005

Foreign Applications (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see <http://www.uspto.gov> for more information.)

If Required, Foreign Filing License Granted: 08/25/2011

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 13/210,168**

Projected Publication Date: To Be Determined - pending completion of Missing Parts

page 1 of 3

Non-Publication Request: No

Early Publication Request: No

**** SMALL ENTITY ****

Title

BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION

Preliminary Class

606

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at <http://www.uspto.gov/web/offices/pac/doc/general/index.html>.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, <http://www.stopfakes.gov>. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

LICENSE FOR FOREIGN FILING UNDER
Title 35, United States Code, Section 184
Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).



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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
13/210,168	08/15/2011	Ahmnon D. MOSKOWITZ	3003/0105PUS7

CONFIRMATION NO. 1609

POA ACCEPTANCE LETTER



OC000000049523163

87409
Dresch IP Law, PLLC
P.O. Box 650903
Potomac Falls, VA 20165

Date Mailed: 08/29/2011

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 08/15/2011.

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.

/mkibret/

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

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Dresch IP Law, PLLC
P.O. Box 650903
Potomac Falls, VA 20165



**Courtesy Reminder for
Application Serial No: 13/210,168**

Attorney Docket No: 3003/0105PUS7

Customer Number: 87409

Date of Electronic Notification: 08/29/2011

This is a courtesy reminder that new correspondence is available for this application. The official date of notification of the outgoing correspondence will be indicated on the form PTOL-90 accompanying the correspondence.

An email notification regarding the correspondence was sent to the following email address(es) associated with your customer number:

mailroom@dreschiplaw.com

jdresch@dreschiplaw.com

john_dresch@hotmail.com

Please verify that these email addresses are correct.

To view your correspondence online or update your email addresses, please visit us anytime at <https://sportal.uspto.gov/secure/myportal/privatepair>. If you have any questions, please email the Electronic Business Center (EBC) at EBC@uspto.gov or call 1-866-217-9197.

UNITED STATES PATENT AND TRADEMARK OFFICE

Application Number: 13/210,168
Filing Date: 08/15/2011
Group Art Unit: 3733
Examiner: Not yet assigned
Confirmation No.: 1609
Title: BI-DIRECTIONAL FIXATING TRANSVERTEBRAL
BODY SCREWS AND POSTERIOR CERVICAL AND
LUMBAR INTERARTICULATING JOINT
CALIBRATED STAPLING DEVICES FOR SPINAL
FUSION

Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY TO NOTICE TO FILE CORRECTED APPLICATION PAPERS

Sir:

This is in response to a Notice to File Corrected Application Papers under 37 CFR 1.53(b) dated August 29, 2011.

Regarding the alleged excess pages fee, Applicants respectfully submit that contrary to the assertions in the Notice, the specification and drawings submitted electronically do **not** exceed 100 pages. The present application includes **seventy-seven (77) total pages**, which is **less than 100 pages**, as follows:

- (a) Substitute Specification (**25** pages), which replaces the original application,
- (b) Claims (from preliminary Amendment; **13** pages),
- (c) Abstract (**1** sheet), and
- (d) Drawings (**38** sheets).

Applicants respectfully submit that only the “Clean Version” of the Substitute Specification is included in the total number of pages of the specification and drawings, **not** the “Marked-Up Version” of the Substitute Specification (which is required under 37 CFR 1.125(c)).

Thus, **no excess page fees are due** since the total pages of the specification and drawings is **seventy-seven (77) pages**, which is **less than** 100 pages.

Enclosed are the following documents and fees to complete the filing requirements of the above-identified application.

- (X) Excess Claim Fees \$1,040.00 (Small Entity).
- (X) Filing Fees \$462.00 (Small Entity - filing fee, search fee, exam fee)
- (X) Surcharge - Late filing fee, search fee, examination fee \$ 65.00 (Small Entity)
- (X) Total Fees Paid: \$ 1,567.00 (X) PTO-2038

CONCLUSION

If the Examiner has any questions regarding this Reply, the Examiner is requested to contact the undersigned. Please charge Deposit Account No. 505364 for any deficiency or overpayment.

Respectfully submitted,

/John J. Dresch/

John J. Dresch
Attorney for Applicant(s)
Registration No. 46,672
September 25, 2011

Dresch IP Law, PLLC
PO BOX 650903
Potomac Falls, VA 20165
Tel. 1.571.333.0930
Fax 1.703.485.0278
jdresch@dreschiplaw.com
*** Customer No. 87409 ***

Electronic Patent Application Fee Transmittal				
Application Number:		13210168		
Filing Date:		15-Aug-2011		
Title of Invention:		BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION		
First Named Inventor/Applicant Name:		Ahmnon D. MOSKOWITZ		
Filer:		John Jeremy Dresch		
Attorney Docket Number:		3003/0105PUS7		
Filed as Small Entity				
Utility under 35 USC 111(a) Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Utility filing Fee (Electronic filing)	4011	1	82	82
Utility Search Fee	2111	1	270	270
Utility Examination Fee	2311	1	110	110
Pages:				
Claims:				
Claims in excess of 20	2202	40	26	1040
Miscellaneous-Filing:				
Late filing fee for oath or declaration	2051	1	65	65

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				1567

Electronic Acknowledgement Receipt	
EFS ID:	11044533
Application Number:	13210168
International Application Number:	
Confirmation Number:	1609
Title of Invention:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION
First Named Inventor/Applicant Name:	Ahmnon D. MOSKOWITZ
Customer Number:	87409
Filer:	John Jeremy Dresch
Filer Authorized By:	
Attorney Docket Number:	3003/0105PUS7
Receipt Date:	25-SEP-2011
Filing Date:	15-AUG-2011
Time Stamp:	23:00:50
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$1567
RAM confirmation Number	18553
Deposit Account	
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
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1	Applicant Response to Pre-Exam Formalities Notice	30030105PUS7_ReplyToNTFMP_readyforfiling.pdf	93028 0c037ee05b3341d98a68fe814b346ec77f310711	no	2
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	38603 574476237e98d56bad93bf7e767e11fe3f8b1b92	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			131631		
<p>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.</p> <p><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.</p> <p><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.</p> <p><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.</p>					



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
13/210,168	08/15/2011	Ahmnnon D. MOSKOWITZ	3003/0105PUS7

CONFIRMATION NO. 1609

FORMALITIES LETTER



OC00000050179651

Date Mailed: 10/05/2011

87409
Dresch IP Law, PLLC
P.O. Box 650903
Potomac Falls, VA 20165

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

Items Required To Avoid Abandonment:

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

SUMMARY OF FEES DUE:

Total fee(s) required within **TWO MONTHS** from the date of this Notice is **\$155** for a small entity

- The specification and drawings submitted electronically contain the equivalent of more than 100 pages.

Applicant owes **\$155** for 1 pages in excess of **100** pages for a small entity in compliance with 37 CFR 1.27.

Replies should be mailed to:

Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web.

<https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html>

For more information about EFS-Web please call the USPTO Electronic Business Center at **1-866-217-9197** or visit our website at <http://www.uspto.gov/ebc>.

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

/tgebre/

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

page 1 of 1



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UNITED STATES DEPARTMENT OF COMMERCE
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
13/210,168	08/15/2011	Ahmnon D. MOSKOWITZ	3003/0105PUS7

CONFIRMATION NO. 1609

WITHDRAWAL NOTICE



Date Mailed: 10/05/2011

87409
Dresch IP Law, PLLC
P.O. Box 650903
Potomac Falls, VA 20165

Letter Regarding a New Notice and/or the Status of the Application

If a new notice or Filing Receipt is enclosed, applicant may disregard the previous notice mailed on 08/29/2011. The time period for reply runs from the mail date of the new notice. Within the time period for reply, applicant is required to file a reply in compliance with the requirements set forth in the new notice to avoid abandonment of the application.

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web.
<https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html>

For more information about EFS-Web please call the USPTO Electronic Business Center at **1-866-217-9197** or visit our website at <http://www.uspto.gov/ebc>.

If the reply is not filed electronically via EFS-Web, the reply must be accompanied by a copy of the new notice.

If the Office previously granted a petition to withdraw the holding of abandonment or a petition to revive under 37 CFR 1.137, the status of the application has been returned to pending status.

/tgebre/

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



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UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	TOT CLAIMS	IND CLAIMS
13/210,168	08/15/2011	3733	1567	3003/0105PUS7	60	3

CONFIRMATION NO. 1609

87409

Dresch IP Law, PLLC
P.O. Box 650903
Potomac Falls, VA 20165

FILING RECEIPT



0000000050179650

Date Mailed: 10/05/2011

Receipt is acknowledged of this non-provisional 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 APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Applicant(s)

Ahmnnon D. MOSKOWITZ, Rockville, MD;
Pablo A Valdivia Y ALVARADO, Cambridge, MA;
Mosheh T. MOSKOWITZ, Rockville, MD;
Nathan C. MOSKOWITZ, Rockville, MD;

Power of Attorney: The patent practitioners associated with Customer Number 87409

Domestic Priority data as claimed by applicant

This application is a CON of 13/084,543 04/11/2011
and is a CON of 13/108,982 05/16/2011
and said 13/084,543 04/11/2011
is a DIV of 11/842,855 08/21/2007 PAT 7,942,903
and said 13/108,982 05/16/2011
is a CON of 11/842,855 08/21/2007 PAT 7,942,903
which is a CIP of 11/536,815 09/29/2006 PAT 7,846,188
which is a CIP of 11/208,644 08/23/2005 PAT 7,704,279
which claims benefit of 60/670,231 04/12/2005

Foreign Applications (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see <http://www.uspto.gov> for more information.)

If Required, Foreign Filing License Granted: 08/25/2011

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 13/210,168**

Projected Publication Date: To Be Determined - pending completion of Missing Parts

page 1 of 3

Non-Publication Request: No

Early Publication Request: No

**** SMALL ENTITY ****

Title

BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION

Preliminary Class

606

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at <http://www.uspto.gov/web/offices/pac/doc/general/index.html>.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, <http://www.stopfakes.gov>. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

LICENSE FOR FOREIGN FILING UNDER
Title 35, United States Code, Section 184
Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875						Application or Docket Number 13/210,168				
APPLICATION AS FILED - PART I										
(Column 1)		(Column 2)		SMALL ENTITY		OTHER THAN SMALL ENTITY				
FOR	NUMBER FILED	NUMBER EXTRA		RATE(\$)	FEE(\$)		RATE(\$)			
BASIC FEE <small>(37 CFR 1.16(a), (b), or (c))</small>	N/A	N/A		N/A	95		N/A			
SEARCH FEE <small>(37 CFR 1.16(k), (l), or (m))</small>	N/A	N/A		N/A	310		N/A			
EXAMINATION FEE <small>(37 CFR 1.16(o), (p), or (q))</small>	N/A	N/A		N/A	125		N/A			
TOTAL CLAIMS <small>(37 CFR 1.16(i))</small>	60	minus 20 =	*	40	x 30 =	1200				
INDEPENDENT CLAIMS <small>(37 CFR 1.16(h))</small>	3	minus 3 =	*		x 125 =	0.00				
APPLICATION SIZE FEE <small>(37 CFR 1.16(s))</small>	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).				155					
MULTIPLE DEPENDENT CLAIM PRESENT <small>(37 CFR 1.16(j))</small>					0.00					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	1885		TOTAL			
APPLICATION AS AMENDED - PART II										
(Column 1)		(Column 2)		(Column 3)		SMALL ENTITY		OTHER THAN SMALL ENTITY		
AMENDMENT A		CLAIMS REMAINING AFTER AMENDMENT	MINUS	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)		RATE(\$)	
	Total <small>(37 CFR 1.16(i))</small>	*	Minus	**	=	x	=		x	
	Independent <small>(37 CFR 1.16(h))</small>	*	Minus	***	=	x	=		x	
	Application Size Fee <small>(37 CFR 1.16(s))</small>									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM <small>(37 CFR 1.16(j))</small>									
					TOTAL ADD'L FEE				TOTAL ADD'L FEE	
AMENDMENT B		CLAIMS REMAINING AFTER AMENDMENT	MINUS	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)		RATE(\$)	
	Total <small>(37 CFR 1.16(i))</small>	*	Minus	**	=	x	=		x	
	Independent <small>(37 CFR 1.16(h))</small>	*	Minus	***	=	x	=		x	
	Application Size Fee <small>(37 CFR 1.16(s))</small>									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM <small>(37 CFR 1.16(j))</small>									
					TOTAL ADD'L FEE				TOTAL ADD'L FEE	
<div style="font-size: x-small;"> * 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. </div>										

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COMMISSIONER FOR PATENTS
P.O. BOX 1450
ALEXANDRIA VA 22313-1451

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Dresch IP Law, PLLC
P.O. Box 650903
Potomac Falls, VA 20165



**Courtesy Reminder for
Application Serial No: 13/210,168**

Attorney Docket No: 3003/0105PUS7

Customer Number: 87409

Date of Electronic Notification: 10/05/2011

This is a courtesy reminder that new correspondence is available for this application. The official date of notification of the outgoing correspondence will be indicated on the form PTOL-90 accompanying the correspondence.

An email notification regarding the correspondence was sent to the following email address(es) associated with your customer number:

mailroom@dreschiplaw.com

jdresch@dreschiplaw.com

john_dresch@hotmail.com

Please verify that these email addresses are correct.

To view your correspondence online or update your email addresses, please visit us anytime at <https://sportal.uspto.gov/secure/myportal/privatepair>. If you have any questions, please email the Electronic Business Center (EBC) at EBC@uspto.gov or call 1-866-217-9197.



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
13/210,168	08/15/2011	Ahmnnon D. MOSKOWITZ	3003/0105PUS7

CONFIRMATION NO. 1609

87409
Dresch IP Law, PLLC
P.O. Box 650903
Potomac Falls, VA 20165

ABANDONMENT/TERMINATION LETTER



Date Mailed: 08/23/2012

NOTICE OF ABANDONMENT UNDER 37 CFR 1.53 (f) OR (g)

The above-identified application is abandoned for failure to timely or properly reply to the Notice to File Missing Parts (Notice) mailed on 10/05/2011.

- No reply was received.

If a complete reply to the notice was previously filed by applicant within the time period set forth in the notice, applicant may request for reconsideration of the holding of abandonment within 2 months from the mailing of this notice of abandonment by filing a petition to withdraw the holding of abandonment under 37 CFR 1.181(a). No petition fee is required. The petition must be accompanied by a true copy of the originally filed reply and the item(s) identified in one of the following:

1. A properly itemized date-stamped postcard receipt (see MPEP § 503);
2. If the originally filed reply included a certificate of mailing or transmission in compliance with 37 CFR 1.8(a), a copy of the certificate of mailing or transmission and a statement in compliance with 37 CFR 1.8(b) (see MPEP § 512); or
3. If the reply was filed via "Express Mail," a submission satisfying the requirements of 37 CFR 1.10(e) including, for example, a copy of the "Express Mail" mailing label showing the "date-in" (see MPEP § 513).

Any petition to withdraw the holding of abandonment should be directed to OPAP.

If applicant did not previously file a complete reply within the time period set forth in the notice, applicant may file a petition to revive the application under 37 CFR 1.137.

Under 37 CFR 1.137(a), a petition requesting the application be revived on the grounds of **UNAVOIDABLE DELAY** must be filed promptly after the applicant becomes aware of the abandonment and such petition must be accompanied by: (1) an adequate showing of the cause of unavoidable delay; (2) the required reply to the above-identified Notice; (3) the petition fee set forth in 37 CFR 1.17(l); and (4) a terminal disclaimer if required by 37 CFR 1.137(d). See MPEP § 711.03(c) and Form PTO/SB/61.

Under 37 CFR 1.137(b), a petition requesting the application be revived on the grounds of **UNINTENTIONAL DELAY** must be filed promptly after applicant becomes aware of the abandonment and such petition must be accompanied by: (1) a statement that the entire delay was unintentional; (2) the required reply to the above-identified Notice; (3) the petition fee set forth in 37 CFR 1.17(m); and (4) a terminal disclaimer if required by 37 CFR 1.137(d). See MPEP § 711.03(c) and Form PTO/SB/64.

Any questions concerning petitions to revive should be directed to the "Office of Petitions" at (571) 272-3282.

A copy of this notice MUST be returned with the reply.

/mbeyene/

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

**PETITION FOR REVIVAL OF AN APPLICATION FOR PATENT
ABANDONED UNINTENTIONALLY UNDER 37 CFR 1.137(b)**Docket Number (Optional)
3003/0105PUS7First named inventor: MOSKOWITZ et al.Application No.: 13/210,168Art Unit: 3733Filed: 08/15/2011Examiner: Not yet assignedTitle: BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR

Attention: Office of Petitions

Mail Stop Petition

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

FAX (571) 273-8300

NOTE: If information or assistance is needed in completing this form, please contact Petitions
Information at (571) 272-3282.The above-identified application became abandoned for failure to file a timely and proper reply to a notice or action by the
United States Patent and Trademark Office. The date of abandonment is the day after the expiration date of the period set
for reply in the office notice or action plus any extensions of time actually obtained.**APPLICANT HEREBY PETITIONS FOR REVIVAL OF THIS APPLICATION**

NOTE: A grantable petition requires the following items:

- (1) Petition fee;
- (2) Reply and/or issue fee;
- (3) Terminal disclaimer with disclaimer fee - required for all utility and plant applications filed
before June 8, 1995; and for all design applications; and
- (4) Statement that the entire delay was unintentional

1. Petition Fee☒ Small entity-fee \$ 930.00 (37 CFR 1.17(m)). Application claims small entity status. See 37 CFR 1.27.☐ Other than small entity-fee \$ _____ (37 CFR 1.17(m))**2. Reply and/or fee**A. The reply and/or fee to the above-noted Office action in
the form of Reply to Notice to File Corrected Application (identify type of reply):☐ has been filed previously on _____.☒ is enclosed herewith.

B. The issue fee and publication fee (if applicable) of \$ _____.

☐ has been paid previously on _____.☐ is enclosed herewith.

[Page 1 of 2]

This collection of information is required by 37 CFR 1.137(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 1.0 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: Mail Stop Petition, 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.

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

3. Terminal disclaimer with disclaimer fee

- ☒ Since this utility/plant application was filed on or after June 8, 1995, no terminal disclaimer is required.
- ☐ A terminal disclaimer (and disclaimer fee (37 CFR 1.20(d)) of \$ _____ for a small entity or \$ _____ for other than a small entity) disclaiming the required period of time is enclosed herewith (see PTO/SB/63).

4. STATEMENT: The entire delay in filing the required reply from the due date for the required reply until the filing of a grantable petition under 37 CFR 1.137(b) was unintentional. [NOTE: The United States Patent and Trademark Office may require additional information if there is a question as to whether either the abandonment or the delay in filing a petition under 37 CFR 1.137(b) was unintentional (MPEP 711.03(c), subsections (III)(C) and (D)).]

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

/John J. Dresch/

Signature

September 9, 2012

Date

John J. Dresch

46672

Type or Printed name

Registration Number, If applicable

P.O. BOX 650903

571-333-0930

Address

Telephone Number

POTOMAC FALLS, VA 20165

Address

Enclosures:

- ☒ Fee Payment
- ☒ Reply
- ☐ Terminal Disclaimer Form
- ☐ Additional sheets containing statements establishing unintentional delay
- ☒ Other: Fee of \$155.00 for excess pages

CERTIFICATE OF MAILING OR TRANSMISSION [37 CFR 1.8(a)]

I hereby certify that this correspondence is being:

- ☐ Deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to: Mail Stop Petition, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.
- ☐ Transmitted by facsimile on the date shown below to the United States Patent and Trademark Office at (571) 273-8300.

Date

Signature

Typed or printed name of person signing certificate

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.

UNITED STATES PATENT AND TRADEMARK OFFICE

Application Number: 13/210,168
Filing Date: 08/15/2011
Group Art Unit: 3733
Examiner: Not yet assigned
Confirmation No.: 1609
Title: BI-DIRECTIONAL FIXATING TRANSVERTEBRAL
BODY SCREWS AND POSTERIOR CERVICAL AND
LUMBAR INTERARTICULATING JOINT
CALIBRATED STAPLING DEVICES FOR SPINAL
FUSION

Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY TO
NOTICE TO FILE CORRECTED APPLICATION PAPERS

Sir:

This is in response to a Notice to File Corrected Application Papers under 37 CFR 1.53(b) dated October 5, 2011.

This Response is accompanied by the excess page fee of \$155.00. Please charge Deposit Account No. 505364 for any deficiency or overpayment.

This Response also is accompanied by a PETITION FOR REVIVAL OF AN APPLICATION FOR PATENT ABANDONED UNINTENTIONALLY UNDER 37 CFR 1.137(b).

The Notice to File Corrected Application Papers maintains the assertion in the previous Notice dated August 29, 2011, that the specification and drawings submitted

electronically contain the equivalent of more than 100 pages, but does not provide any explanation as to how the Office arrived at the 101 page count.

Applicants respectfully submit that contrary to the assertions in the Notice, the specification and drawings submitted electronically do not exceed 100 pages (total number of pages * 0.75 for electronic filing).

The Notice appears to err in counting both the “Clean Version” of the Substitute Specification and the “Marked-Up Version” of the Substitute Specification (which is required under 37 CFR 1.125(c) to accompany the “Clean Version”) in the page count in order to arrive at the alleged 101 page count.

Applicants respectfully submit that only the “Clean Version” of the Substitute Specification should be included in the total number of pages of the specification and drawings. The “Marked-Up Version” of the Substitute Specification simply shows the changes to the “Clean Version” as required under 37 CFR 1.125(c) and is not part of the specification. Thus, no excess page fees are due since the total pages of the specification and drawings is less than 100 pages (total number of pages * 0.75 for electronic filing).

Notwithstanding the above, this Response is accompanied by the fee of \$155.00 for the alleged pages in excess of 100 pages in order to advance prosecution and avoid further delay.

Please charge Deposit Account No. 505364 for any deficiency or overpayment.

CONCLUSION

If the Examiner has any questions regarding this Reply, the Examiner is requested to contact the undersigned.

Respectfully submitted,

/John J. Dresch/

John J. Dresch
Attorney for Applicant(s)
Registration No. 46,672

September 9, 2012

Dresch IP Law, PLLC
PO BOX 650903
Potomac Falls, VA 20165
Tel. 1.571.333.0930
Fax 1.703.485.0278
jdresch@dreschiplaw.com
***** Customer No. 87409 *****

Electronic Patent Application Fee Transmittal				
Application Number:		13210168		
Filing Date:		15-Aug-2011		
Title of Invention:		BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION		
First Named Inventor/Applicant Name:		Ahmnon D. MOSKOWITZ		
Filer:		John Jeremy Dresch		
Attorney Docket Number:		3003/0105PUS7		
Filed as Small Entity				
Utility under 35 USC 111(a) Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Utility Appl Size fee per 50 sheets >100	2081	1	155	155
Claims:				
Miscellaneous-Filing:				
Petition:				
Petition-revive unintent. abandoned appl	2453	1	930	930
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				1085

Electronic Acknowledgement Receipt	
EFS ID:	13693415
Application Number:	13210168
International Application Number:	
Confirmation Number:	1609
Title of Invention:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION
First Named Inventor/Applicant Name:	Ahmnon D. MOSKOWITZ
Customer Number:	87409
Filer:	John Jeremy Dresch
Filer Authorized By:	
Attorney Docket Number:	3003/0105PUS7
Receipt Date:	09-SEP-2012
Filing Date:	15-AUG-2011
Time Stamp:	23:16:26
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$1085
RAM confirmation Number	9188
Deposit Account	
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
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1	Petition for review by the Office of Petitions.	30030105PUS7_sb0064_PETITIONWITHDRAWABANDON_RFF.pdf	206306 e5257fd58f969fd9e793419d10ea3dcd1c28a	no	3
Warnings:					
Information:					
2	Applicant Response to Pre-Exam Formalities Notice	30030105PUS7_ReplyToNTFMP_B_readyforfiling.pdf	97894 ace259cfc32544a965c710de55a205554f60ba8	no	3
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	32729 701bdaa4a22d1f90f05f22b793c0613c95412ce	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			336929		
<p>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.</p> <p><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.</p> <p><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.</p> <p><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.</p>					



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Dresch IP Law, PLLC
P.O. Box 650903
Potomac Falls VA 20165

MAILED
SEP 25 2012
OFFICE OF PETITIONS

In re Application of	:	
Moskowitz et al.	:	
Application No. 13/210,168	:	DECISION ON PETITION
Filed: August 15, 2011	:	
Attorney Docket Number: 3003/0105PUS7	:	
For: BI-DIRECTIONAL FIXATING	:	
TRANVERSE BRACKETS AND	:	
POSTERIOR CERVICAL AND LUMBAR	:	
INTERARTICULATING JOINT	:	
CALIBRATED STAPLING DEVICES FOR	:	
SPINAL FUSION	:	

This is a decision on the petition under the unintentional provisions of 37 CFR 1.137(b), filed September 9, 2012, to revive the above-identified application.

The petition is **GRANTED**.

On October 5, 2011, the Office mailed a Notice to File Missing Parts, which set a two month shortened statutory period to reply. No extension of time pursuant to 37 CFR 1.136(a) was obtained. The application became abandoned on December 6, 2011, for failure to submit a complete response to the October 5, 2011 Notice. A Notice of Abandonment was mailed on August 24, 2012.

The petition satisfies the requirements of 37 CFR 1.137(b) in that petitioner has supplied (1) the reply in the form of utility application size fee (2) the petition fee of \$ 930.00, and (3) a proper statement of unintentional delay.

Telephone inquiries concerning this decision should be directed to the undersigned at (571) 272-3215.

This application is being referred to the Office of Patent Application Processing for appropriate action in the normal course of business.

Charlema Grant
Attorney Advisor
Office of Petitions



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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Alexandria, Virginia 22313-1450
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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
13/210,168	08/15/2011	3733	1722	3003/0105PUS7	60	3

CONFIRMATION NO. 1609

87409

Dresch IP Law, PLLC

P.O. Box 650903

Potomac Falls, VA 20165

UPDATED FILING RECEIPT



0000000056901835

Date Mailed: 10/09/2012

Receipt is acknowledged of this non-provisional 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 APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Inventor(s)

Ahmnon D. MOSKOWITZ, Rockville, MD;
Pablo A Valdivia Y ALVARADO, Cambridge, MA;
Mosheh T. MOSKOWITZ, Rockville, MD;
Nathan C. MOSKOWITZ, Rockville, MD;

Applicant(s)

Ahmnon D. MOSKOWITZ, Rockville, MD;
Pablo A Valdivia Y ALVARADO, Cambridge, MA;
Mosheh T. MOSKOWITZ, Rockville, MD;
Nathan C. MOSKOWITZ, Rockville, MD;

Power of Attorney: The patent practitioners associated with Customer Number 87409

Domestic Priority data as claimed by applicant

This application is a CON of 13/084,543 04/11/2011
and is a CON of 13/108,982 05/16/2011
and said 13/084,543 04/11/2011
is a DIV of 11/842,855 08/21/2007 PAT 7942903
and said 13/108,982 05/16/2011
is a CON of 11/842,855 08/21/2007 PAT 7942903
which is a CIP of 11/536,815 09/29/2006 PAT 7846188
which is a CIP of 11/208,644 08/23/2005 PAT 7704279
which claims benefit of 60/670,231 04/12/2005

Foreign Applications (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see <http://www.uspto.gov> for more information.)

If Required, Foreign Filing License Granted: 08/25/2011

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 13/210,168**

Projected Publication Date: 01/17/2013

Non-Publication Request: No

Early Publication Request: No

**** SMALL ENTITY ****

Title

BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION

Preliminary Class

606

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at <http://www.uspto.gov/web/offices/pac/doc/general/index.html>.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, <http://www.stopfakes.gov>. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

LICENSE FOR FOREIGN FILING UNDER
Title 35, United States Code, Section 184
Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
13/210,168		Ahmnon D. MOSKOWITZ	3003/0105PUS7

CONFIRMATION NO. 1609

WITHDRAWAL NOTICE



OC000000056901822

Date Mailed: 10/09/2012

87409
Dresch IP Law, PLLC
P.O. Box 650903
Potomac Falls, VA 20165

Letter Regarding a New Notice and/or the Status of the Application

If a new notice or Filing Receipt is enclosed, applicant may disregard the previous notice mailed on 08/23/2012. The time period for reply runs from the mail date of the new notice. Within the time period for reply, applicant is required to file a reply in compliance with the requirements set forth in the new notice to avoid abandonment of the application.

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web.
<https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html>

For more information about EFS-Web please call the USPTO Electronic Business Center at **1-866-217-9197** or visit our website at <http://www.uspto.gov/ebc>.

If the reply is not filed electronically via EFS-Web, the reply must be accompanied by a copy of the new notice.

If the Office previously granted a petition to withdraw the holding of abandonment or a petition to revive under 37 CFR 1.137, the status of the application has been returned to pending status.

/ktesfaye/

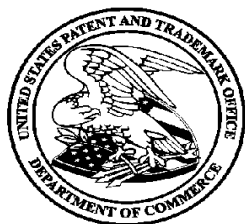
Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875						Application or Docket Number 13/210,168				
APPLICATION AS FILED - PART I										
(Column 1)		(Column 2)		SMALL ENTITY		OTHER THAN SMALL ENTITY				
FOR	NUMBER FILED	NUMBER EXTRA		RATE(\$)	FEE(\$)		RATE(\$)			
BASIC FEE <small>(37 CFR 1.16(a), (b), or (c))</small>	N/A	N/A		N/A	98		N/A			
SEARCH FEE <small>(37 CFR 1.16(k), (l), or (m))</small>	N/A	N/A		N/A	310		N/A			
EXAMINATION FEE <small>(37 CFR 1.16(o), (p), or (q))</small>	N/A	N/A		N/A	125		N/A			
TOTAL CLAIMS <small>(37 CFR 1.16(i))</small>	60	minus 20 =	*	40	x 31 =	1240				
INDEPENDENT CLAIMS <small>(37 CFR 1.16(h))</small>	3	minus 3 =	*		x 125 =	0.00				
APPLICATION SIZE FEE <small>(37 CFR 1.16(s))</small>	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).				160					
MULTIPLE DEPENDENT CLAIM PRESENT <small>(37 CFR 1.16(j))</small>					0.00					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	1933		TOTAL			
APPLICATION AS AMENDED - PART II										
(Column 1)		(Column 2)		(Column 3)		SMALL ENTITY		OTHER THAN SMALL ENTITY		
AMENDMENT A		CLAIMS REMAINING AFTER AMENDMENT	MINUS	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)		RATE(\$)	
	Total <small>(37 CFR 1.16(i))</small>	*	Minus	**	=	x	=		x	
	Independent <small>(37 CFR 1.16(h))</small>	*	Minus	***	=	x	=		x	
	Application Size Fee <small>(37 CFR 1.16(s))</small>									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM <small>(37 CFR 1.16(j))</small>									
						TOTAL ADD'L FEE			TOTAL ADD'L FEE	
AMENDMENT B		CLAIMS REMAINING AFTER AMENDMENT	MINUS	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)		RATE(\$)	
	Total <small>(37 CFR 1.16(i))</small>	*	Minus	**	=	x	=		x	
	Independent <small>(37 CFR 1.16(h))</small>	*	Minus	***	=	x	=		x	
	Application Size Fee <small>(37 CFR 1.16(s))</small>									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM <small>(37 CFR 1.16(j))</small>									
						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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Dresch IP Law, PLLC
P.O. Box 650903
Potomac Falls, VA 20165



**Courtesy Reminder for
Application Serial No: 13/210,168**

Attorney Docket No: 3003/0105PUS7

Customer Number: 87409

Date of Electronic Notification: 10/09/2012

This is a courtesy reminder that new correspondence is available for this application. The official date of notification of the outgoing correspondence will be indicated on the form PTOL-90 accompanying the correspondence.

An email notification regarding the correspondence was sent to the following email address(es) associated with your customer number:

mailroom@dreschiplaw.com

jdresch@dreschiplaw.com

john_dresch@hotmail.com

Please verify that these email addresses are correct.

To view your correspondence online or update your email addresses, please visit us anytime at <https://sportal.uspto.gov/secure/myportal/privatepair>. If you have any questions, please email the Electronic Business Center (EBC) at EBC@uspto.gov or call 1-866-217-9197.



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
13/210,168	08/15/2011	Ahmnnon D. MOSKOWITZ	3003/0105PUS7

CONFIRMATION NO. 1609

PUBLICATION NOTICE



OC000000058720490

87409
Dresch IP Law, PLLC
P.O. Box 650903
Potomac Falls, VA 20165

Title:BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION

Publication No.US-2013-0018469-A1

Publication Date:01/17/2013

NOTICE OF PUBLICATION OF APPLICATION

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/210,168	08/15/2011	Ahmnnon D. MOSKOWITZ	3003/0105PUS7	1609

87409 7590 06/10/2014
Dresch IP Law, PLLC
P.O. Box 650903
Potomac Falls, VA 20165

EXAMINER

PHILOGENE, PEDRO

ART UNIT	PAPER NUMBER
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3733

NOTIFICATION DATE	DELIVERY MODE
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06/10/2014

ELECTRONIC

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

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

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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jdresch@dreschiplaw.com
linda.logan@dreschiplaw.com

Office Action Summary	Application No. 13/210,168	Applicant(s) MOSKOWITZ ET AL.	
	Examiner PEDRO PHILOGENE	Art Unit 3733	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/15/11.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 26-85 is/are pending in the application.
5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 26-85 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) ☒ Notice of References Cited (PTO-892) | 3) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
Paper No(s)/Mail Date ____. | 4) ☐ Other: ____. |

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

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the claims at issue are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the reference application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO internet Web site contains terminal disclaimer forms which may be used. Please visit <http://www.uspto.gov/forms/>. The filing date of the application will determine what form should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to <http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp>.

Claims 26-85 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-31 of copending Application No. 12/471,340. Although the conflicting claims are not identical, they are not patentably distinct from each other because it is clear that all the element of claims of the present application are to be found in claims of the copending application. The difference between claims of the present application and claims of the copending application lies in the fact that the copending application claims include many more elements and are thus much more specific. Thus the invention of claims of the copending application is in effect a “species” of the “generic” invention of claims of the present application. It has been held that the generic invention is “anticipated” by the “species”. See *in re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claims of the present application are anticipated by claims of the copending application, they are not patentably distinct.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 26-85 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-88 of copending Application No. 13/418,323. Although the conflicting claims are not identical, they are not patentably distinct from each other because it is clear that all the element of claims of the present application are to be found in claims of the copending application. The difference between claims of the present application and claims of the copending application lies in the fact that the copending application claims include many more elements and are thus much more specific. Thus the invention of claims of the copending application is in effect a “species” of the “generic” invention of claims of the present application. It has been held that the generic invention is “anticipated” by the “species”. See *in re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claims of the present application are anticipated by claims of the copending application, they are not patentably distinct.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 26-85 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-31 of copending Application No. 13/401,829. Although the conflicting claims are not identical, they are not patentably distinct from each other because it is clear that all the element of claims of the present application are to be found in claims of the copending application. The difference between claims of the present application and claims of the copending

application lies in the fact that the copending application claims include many more elements and are thus much more specific. Thus the invention of claims of the copending application is in effect a “species” of the “generic” invention of claims of the present application. It has been held that the generic invention is “anticipated” by the “species”. See *in re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claims of the present application are anticipated by claims of the copending application, they are not patentably distinct.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 26-85 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-88 of copending Application No. 13/418,335. Although the conflicting claims are not identical, they are not patentably distinct from each other because it is clear that all the element of claims of the present application are to be found in claims of the copending application. The difference between claims of the present application and claims of the copending application lies in the fact that the copending application claims include many more elements and are thus much more specific. Thus the invention of claims of the copending application is in effect a “species” of the “generic” invention of claims of the present application. It has been held that the generic invention is “anticipated” by the “species”. See *in re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claims of the present application are anticipated by claims of the copending application, they are not patentably distinct.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 26-85 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 26-92 of copending Application No. 13/210,162. Although the conflicting claims are not identical, they are not patentably distinct from each other because it is clear that all the element of claims of the present application are to be found in claims of the copending application. The difference between claims of the present application and claims of the copending application lies in the fact that the copending application claims include many more elements and are thus much more specific. Thus the invention of claims of the copending application is in effect a “species” of the “generic” invention of claims of the present application. It has been held that the generic invention is “anticipated” by the “species”. See *in re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claims of the present application are anticipated by claims of the copending application, they are not patentably distinct.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 26-85 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 26-82 of copending Application No. 13/210,150. Although the conflicting claims are not identical, they are not patentably distinct from each other because it is clear that all the element of claims of the present application are to be found in claims of the copending application.

The difference between claims of the present application and claims of the copending application lies in the fact that the copending application claims include many more elements and are thus much more specific. Thus the invention of claims of the copending application is in effect a “species” of the “generic” invention of claims of the present application. It has been held that the generic invention is “anticipated” by the “species”. See *in re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claims of the present application are anticipated by claims of the copending application, they are not patentably distinct.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 26-85 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 26-83 of copending Application No. 13/210,157. Although the conflicting claims are not identical, they are not patentably distinct from each other because it is clear that all the element of claims of the present application are to be found in claims of the copending application. The difference between claims of the present application and claims of the copending application lies in the fact that the copending application claims include many more elements and are thus much more specific. Thus the invention of claims of the copending application is in effect a “species” of the “generic” invention of claims of the present application. It has been held that the generic invention is “anticipated” by the “species”. See *in re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claims of the

present application are anticipated by claims of the copending application, they are not patentably distinct.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 26-85 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 26-93 of copending Application No. 13/108,982. Although the conflicting claims are not identical, they are not patentably distinct from each other because it is clear that all the element of claims of the present application are to be found in claims of the copending application. The difference between claims of the present application and claims of the copending application lies in the fact that the copending application claims include many more elements and are thus much more specific. Thus the invention of claims of the copending application is in effect a “species” of the “generic” invention of claims of the present application. It has been held that the generic invention is “anticipated” by the “species”. See *in re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claims of the present application are anticipated by claims of the copending application, they are not patentably distinct.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 26-85 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-31 of patent 7,972,363. Although the conflicting claims are not identical, they are not patentably distinct from each other

because it is clear that all the element of claims of the present application are to be found in claims of the patent. The difference between claims of the present application and claims of the patent lies in the fact that the patent claims include many more elements and are thus much more specific. Thus the invention of claims of the patent is in effect a "species" of the "generic" invention of claims of the present application. It has been held that the generic invention is "anticipated" by the "species". See in re Goodman, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claims of the present application are anticipated by claims of the patent, they are not patentably distinct.

Claim Rejections - 35 USC § 103

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

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

Claims 26-82 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Lin (6,626,998) in view of Bagga et al (7,238,203).

With respect to claims 26, 84, 85, Lin discloses a bi-directional fixating transvertebral (BDFT) screw/cage apparatus, comprising: an intervertebral cage (100); as best seen in FIG.1-8, for maintaining disc height, the intervertebral cage including a first internal screw guide (111) and a second internal screw guide (112); a first screw member (200) having a tapered end and a threaded body disposed within the first intervertebral cage; as best seen in FIGS.1-8; and a second screw member (250)

having a tapered end and a threaded body disposed within the intervertebral cage; as best seen in FIGS.1-8; a bone graft cavity (121) for receiving bone packing material for bone fusion between the first vertebral body and the second vertebral body; as best seen in FIG.8.

The screw guides are angled to orient the first screw member and the second screw bi-directionally in opposite directions; as best seen in FIGS.1-8. The screws are angled superiorly and inferiorly; as best seen in FIGS.1-8. The guides are aligned along the longitudinal axis and are symmetrically disposed and includes a tunnel that permit only a predetermined angled trajectory and the trajectory is different for each screw guide; as best seen in FIGS.1-8; and as set forth in column 2, lines 20-67, column 3, lines 1-40. The exterior surface of the intervertebral cage includes a plurality of ridges (122) the ridges are disposed on a superior surface and/or inferior surface of the intervertebral cage; as best seen in FIGS.1-5. The intervertebral cage includes at least one cavity (121) for receiving bone fusion material. The cage is fully capable of being use in any of a Lumbar and/or cervical disc space, either posteriorly or anteriorly or antero-laterally. The use of quadrants or the use a plurality of screw guides and screws in the quadrants is old in well known in the art; as best seen in the cited arts, e.g, Michelson '209, '019.

With respect to claims 27-83, Lin discloses or teaches all the limitations, as best seen in FIGS.1-8, and as set forth in column 2, lines 20-67, column 3, lines 1-40. As to the screw guide having a 25 degrees angulation, it would have been obvious to one having ordinary skill in the art at the time the invention was made to reach this

optimum range, since it has been held where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

It is noted that Lin does not teach of a surface of each longitudinal end of the intervertebral cage includes a tool mating feature for engaging a distal end of a prong of an implantation cage, as claimed by applicant. However, in similar art, Bagga et al provide the evidences the use of an implant with a surface of each longitudinal end of the intervertebral cage includes a tool mating feature for engaging a distal end of a prong of an implantation cage to manipulate the implant.

Therefore, given the teaching of Bagga et al, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Lin, as taught by Bagga et al., by incorporating a tool mating feature in the implant of Li to manipulate the implant.

With respect to the method claim, the method steps, as set forth, would have been obviously carried out in the operation of the device, as set forth above.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

7,033,394	4-2006	Michelson
7,326,248	2-2008	Michelson
6,432,106	8-2002	Fraser
6,558,423	5-2003	Michelson

6,342,074	1-2002	Simpson
7,442,209	10-2008	Michelson
6,824,564	11-2004	Crozet
6,972,019	12-2005	Michelson
6,974,480	12-2005	Messerli et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PEDRO PHILOGENE whose telephone number is (571)272-4716. The examiner can normally be reached on Monday to Friday 8:00 AM to 4:30 PM.

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

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

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Art Unit: 3733

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/PEDRO PHILOGENE/
Primary Examiner, Art Unit 3733
June 3, 2014

Notice of References Cited	Application/Control No. 13/210,168	Applicant(s)/Patent Under Reexamination MOSKOWITZ ET AL.	
	Examiner PEDRO PHILOGENE	Art Unit 3733	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-6,974,480	12-2005	Messerli et al.	623/17.16
*	B	US-7,238,203	07-2007	Bagga et al.	623/17.11
*	C	US-7,972,363	07-2011	Moskowitz et al.	606/246
*	D	US-6,629,998	10-2003	Lin, Chih-I	623/17.11
*	E	US-7,033,394	04-2006	Michelson, Gary K.	623/17.11
*	F	US-7,326,248	02-2008	Michelson, Gary K.	623/17.11
*	G	US-6,432,106	08-2002	Fraser, Robert	623/17.11
*	H	US-6,558,423	05-2003	Michelson, Gary K.	623/17.11
*	I	US-6,342,074	01-2002	Simpson, Nathan S.	623/17.11
*	J	US-7,442,209	10-2008	Michelson, Gary K.	623/17.11
*	K	US-6,824,564	11-2004	Crozet, Yves	623/17.11
*	L	US-6,972,019	12-2005	Michelson, Gary K.	606/86A
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	30	moskowitz near ahmnon.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/06/03 13:15
L2	15	moskowitz near ahmnon.in. & screw near guide same screw & predetermined near angle & degree near angulation	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/06/03 13:17
L3	15	screw near guide same screw & predetermined near angle & degree near angulation	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/06/03 13:17
L4	180	intervertebral near (cage or implant or disc or spacer) & screw same screw near guide & angle\$	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2014/06/03 13:19
L5	1	"20130018469"	US-PGPUB; USPAT	OR	ON	2014/06/03 13:21
L6	1	5 AND ((A61B17/0642 OR A61B17/7064 OR A61B17/809 OR A61B17/86 OR A61B17/8894 OR A61B2017/0641 OR A61B2017/0648 OR A61B2017/922 OR A61F2002/2835 OR A61F2002/30133 OR A61F2002/30387 OR A61F2002/30448 OR A61F2002/30507 OR A61F2002/3055 OR A61F2002/30579 OR A61F2002/30604 OR A61F2002/30772 OR A61F2002/30878 OR A61F2002/4475 OR A61F2002/448 OR A61F2002/4627 OR A61F2002/4681 OR A61F2220/0025 OR A61F2220/005 OR A61F2230/0015 OR A61F2250/0007 OR A61F2/4465 OR A61F2/447 OR A61F2/4611).CPC. OR (623/17.11-17.16 OR 606/300-305 OR 606/246 OR 606/99 OR 606/144 OR 606/151 OR 606/251 OR 606/266 OR 227/181.1).OCLS. OR (A61F2/44).IPC.)	US-PGPUB; USPAT	OR	ON	2014/06/03 13:23
L7	103	4 AND ((A61B17/0642 OR A61B17/7064 OR A61B17/809 OR A61B17/86 OR	US-PGPUB; USPAT	OR	ON	2014/06/03 13:24

		A61B17/8894 OR A61B2017/0641 OR A61B2017/0648 OR A61B2017/922 OR A61F2002/2835 OR A61F2002/30133 OR A61F2002/30387 OR A61F2002/30448 OR A61F2002/30507 OR A61F2002/3055 OR A61F2002/30579 OR A61F2002/30604 OR A61F2002/30772 OR A61F2002/30878 OR A61F2002/4475 OR A61F2002/448 OR A61F2002/4627 OR A61F2002/4681 OR A61F2220/0025 OR A61F2220/005 OR A61F2230/0015 OR A61F2250/0007 OR A61F2/4465 OR A61F2/447 OR A61F2/4611).CPC. OR (623/17.11-17.16 OR 606/300-305 OR 606/246 OR 606/99 OR 606/144 OR 606/151 OR 606/251 OR 606/266 OR 227/181.1).OCLS. OR (A61F2/44).IPCR.)				
L8	10	((("7972363") or ("6629998") or ("7033394") or ("7326248") or ("6432106") or ("6558423") or ("6342074") or ("7442209") or ("6824564") or ("6972019")).PN.	USPAT; USOCR	OR	OFF	2014/06/03 13:26
L9	207	("4599086" "4743256" "4834757" "4878915" "5192327" "5306309" "5397364" "5425772" "5443515" "5522899" "5607424" "5658335" "5658337" "5716415" "5755798" "5766252" "5776199" "5782832" "5800550" "5824094" "5861041" "5865845" "5888227" "5888228" "5904683" "5961554" "5964807" "5976187" "6019793" "6045579" "6080193" "6093205" "6096080" "6113638" "6120503" "6156037" "6168596" "6176882" "6231610" "6235069").PN. OR ("6432106").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2014/06/03 13:32
L10	3	((("5888227") or ("7238203") or ("6974480")).PN.	USPAT; USOCR	OR	OFF	2014/06/03 13:45

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<i>Index of Claims</i> 	Application/Control No. 13210168	Applicant(s)/Patent Under Reexamination MOSKOWITZ ET AL.
	Examiner PEDRO PHILOGENE	Art Unit 3733

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

☐ Claims renumbered in the same order as presented by applicant										☐ CPA										☐ T.D.										☐ R.1.47									
CLAIM			DATE																																				
Final	Original	06/03/2014																																					
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Final	Original	06/03/2014								
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	75	✓								
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CONFIRMATION NO. 1609

SERIAL NUMBER	FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.		
13/210,168	08/15/2011	606	3733	3003/0105PUS7		
RULE						
APPLICANTS INVENTORS Ahmnon D. MOSKOWITZ, Rockville, MD; Pablo A Valdivia Y ALVARADO, Cambridge, MA; Mosheh T. MOSKOWITZ, Rockville, MD; Nathan C. MOSKOWITZ, Rockville, MD;						
** CONTINUING DATA ***** This application is a CON of 13/084,543 04/11/2011 PAT 8353913 and is a CON of 13/108,982 05/16/2011 and said 13/084,543 04/11/2011 is a DIV of 11/842,855 08/21/2007 PAT 7942903 and said 13/108,982 05/16/2011 is a CON of 11/842,855 08/21/2007 PAT 7942903 which is a CIP of 11/536,815 09/29/2006 PAT 7846188 which is a CIP of 11/208,644 08/23/2005 PAT 7704279 which claims benefit of 60/670,231 04/12/2005						
** FOREIGN APPLICATIONS ***** ** IF REQUIRED, FOREIGN FILING LICENSE GRANTED *** SMALL ENTITY ** 08/25/2011						
Foreign Priority claimed	☐ Yes ☒ No	☐ Met after Allowance	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
35 USC 119(a-d) conditions met	☐ Yes ☒ No		MD	38	60	3
Verified and	/PEDRO PHILOGENE/	Initials				
Acknowledged	Examiner's Signature					
ADDRESS Dresch IP Law, PLLC P.O. Box 650903 Potomac Falls, VA 20165 UNITED STATES						
TITLE BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION						
FILING FEE RECEIVED 1722	FEES: Authority has been given in Paper No. _____ to charge/credit DEPOSIT ACCOUNT No. _____ for following:			☐ All Fees		
				☐ 1.16 Fees (Filing)		
				☐ 1.17 Fees (Processing Ext. of time)		
				☐ 1.18 Fees (Issue)		
				☐ Other _____		
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Search Notes 	Application/Control No. 13210168	Applicant(s)/Patent Under Reexamination MOSKOWITZ ET AL.
	Examiner PEDRO PHILOGENE	Art Unit 3733

CPC- SEARCHED		
Symbol	Date	Examiner
A61B17/0642, A61B17/809, A61B17/8894, A61F2/4465, A61F2/447, A61F2/4611, A61B17/7064	6/3/2014	/P.P./
A61F2250/0007, A61B17/86, A61B2017/0641, A61B2017/0648, A61B2017/922, A61F2002/2835, A61F2002/30133, A61F2002/30387, A61F2002/30448, A61F2002/30507		
A61F2002/3055, A61F2002/30579, A61F2002/30604, A61F2002/30772, A61F2002/30878, A61F2002/4475, A61F2002/448, A61F2002/4627, A61F2002/4681, A61F2220/0025, A61F2220/005, A61F2230/0015		

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
623	17.11-17.16	6/3/2014	/P.P./
606	300-305,246, 99, 144, 151, 251, 266		
227	181.1		

SEARCH NOTES		
Search Notes	Date	Examiner
EAST search enclosed	6/3/2014	/P.P./

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

	/PEDRO PHILOGENE/ Primary Examiner.Art Unit 3733
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Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)

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

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		13210168
	Filing Date		2011-08-15
	First Named Inventor	Ahmnon D. MOSKOWITZ et al.	
	Art Unit	3733	
	Examiner Name	Pedro PHILOGENE	
	Attorney Docket Number	3003/0105PUS7	

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	5123926		1992-06-23	Pisharodi	
	2	5514180		1996-05-07	Heggeness et al.	
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	13210168
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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	20040088054		2004-05-06	Berry	

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	13	20100305704		2010-12-02	Messerli et al.	
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	1	2004093749	WO	A1	2004-11-04	MAGERL et al.		☐
	2	2006091503	WO	A1	2006-08-31	SHATTUCK et al.		☐

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	1	Vincent C. TRAYNELIS, "Prosthetics and Biologics: The Wave of the Future," CLINICAL NEUROSURGERY, Volume 50, Proceedings of the Congress of Neurological Surgeons, Philadelphia, PA 2002, Chapter 9, pages 207-219.						☐
	2	E.K. WAI et al., "Disk Replacement Arthroplasties: Can The Success of Hip and Knee Replacements be Repeated in the Spine?," Seminars in Spine Surgery, Vol. 15, No. 4 (December) 2003, pp 473-482.						☐
	3	Richard D. GUYER et al., "Intervertebral Disc Prostheses," SPINE JOURNAL, Volume 28, Number 15S, Supp. To 8/1/03, pages S15-S23.						☐
	4	DIETER GROB et al., "Clinical Experience With the Dynesys Semirigid Fixation System for the Lumbar Spine," SPINE, Vol. 30, No. 3, 2005, pp. 324-331.						☐

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	Attorney Docket Number	3003/0105PUS7

5	International Search Report (ISR) and Written Opinion of the International Searching Authority, 03 December 2007, International Application No. PCT/US 07/05005.	☐
6	International Search Report (ISR) and Written Opinion of the International Searching Authority, 21 May 2008, International Application No. PCT/US2007/021015	☐
7	International Search Report (ISR) and Written Opinion of the International Searching Authority, 09 July 2008, International Application No. PCT/US2007021013	☐

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	Examiner Name	Pedro PHILOGENE
	Attorney Docket Number	3003/0105PUS7

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	/John J. Dresch/	Date (YYYY-MM-DD)	2014-08-28
Name/Print	John J. Dresch	Registration Number	46,672

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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(19) Weltorganisation für geistiges Eigentum
Internationales Büro



(43) Internationales Veröffentlichungsdatum
4. November 2004 (04.11.2004)

PCT

(10) Internationale Veröffentlichungsnummer
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(51) Internationale Patentklassifikation⁷: **A61F 2/44**, 2/46

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23. April 2004 (23.04.2004)

(25) Einreichungssprache: Deutsch

(26) Veröffentlichungssprache: Deutsch

(30) Angaben zur Priorität:
03405284.5 23. April 2003 (23.04.2003) EP

(71) Anmelder (für alle Bestimmungsstaaten mit Ausnahme von
US): **SEPITEC FOUNDATION** [LI/LI]; Kirchstrasse 12,
FL-9490 Vaduz (LI).

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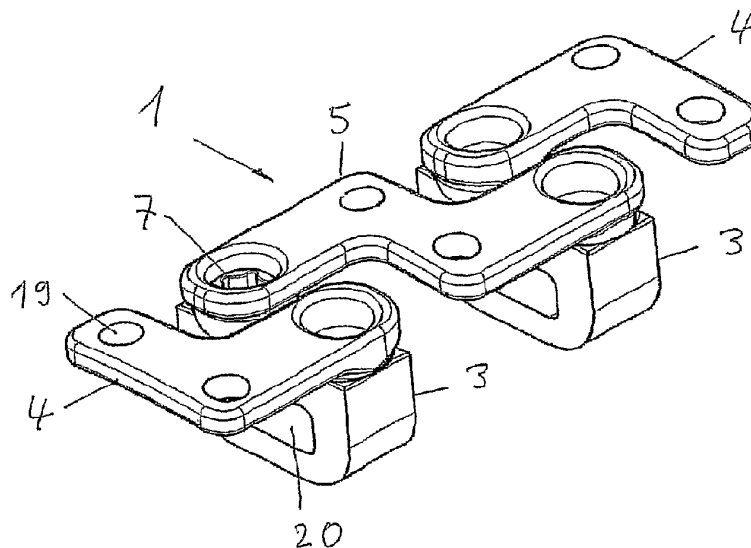
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(54) **Title:** SPONDYLODESIS DEVICE

(54) **Bezeichnung:** VORRICHTUNG FÜR DIE SPONDYLODESE



(57) **Abstract:** Disclosed is a device comprising at least one intervertebral implant (3) and at least one plate (4, 5) that is to be connected to the intervertebral implant (3) and an adjacent spine (21-23). The intervertebral implant (3) is connected to at least two spaced-apart plates (4, 5). One end of both plates (4, 5) respectively forms a fixable joint along with the intervertebral implant (3). Preferably, at least one of the plates (5, 4) is embodied in a Z-shaped or L-shaped manner. The inventive device provides for great adaptability to the anatomic characteristics of the spinal column and a modular structure while the number of parts is kept small.

[Fortsetzung auf der nächsten Seite]

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Zur Erklärung der Zweibuchstaben-Codes und der anderen Abkürzungen wird auf die Erklärungen ("Guidance Notes on Codes and Abbreviations") am Anfang jeder regulären Ausgabe der PCT-Gazette verwiesen.

(57) **Zusammenfassung:** Die Vorrichtung weist wenigstens ein Intervertebrallimplantat (3) und wenigstens eine Platte (4,5) auf, die mit dem Intervertebrallimplantat (3) und einem benachbarten Wirbel (21-23) zu verbinden ist. Das Intervertebrallimplantat (3) ist mit wenigstens zwei im Abstand zueinander angeordneten Platten (4,5) verbunden. Beide Platten (4,5) bilden jeweils an einem Ende mit dem Intervertebrallimplantat (3) ein fixierbares Gelenk. Vorzugsweise ist wenigstens eine der Platten (5,4) Z-förmig oder L-förmig ausgebildet. Die Vorrichtung ermöglicht eine hohe Anpassungsfähigkeit an die anatomischen Gegebenheiten der Wirbelsäule und bei kleinerer Teilezahl einen modularen Aufbau.

Vorrichtung für die Spondylodese

Die Erfindung betrifft eine Vorrichtung für die Spondylodese und insbesondere für die vordere interkorporelle Spondylodese an der Halswirbelsäule, mit wenigstens einem Intervertebralimplantat, und mit wenigstens einer Verbindungsplatte, die mit dem Intervertebralimplantat und einem benachbarten Wirbel zu verbinden ist.

Als Spondylodese wird die chirurgische Versteifung oder Verblockung eines Abschnittes der Wirbelsäule verstanden. Hierzu wird nach der klassischen Methode Knochen- oder Knochenersatzmaterial verwendet, welches zwischen die Wirbelkörper eingesetzt wird, sogenannte interkorporelle Spondylodese, oder über die hinteren Wirbelelemente angelagert wird, sogenannte dorsale Spondylodese. Hierdurch entsteht mit der Zeit eine knöcherne Brücke, welche die Wirbel verbindet, so dass sie sich nicht mehr gegeneinander bewegen können. Damit eine Verknöcherung stattfinden kann, ist es erforderlich, dass der betreffende Abschnitt der Wirbelsäule ruhiggestellt wird. Letzteres geschieht durch geeignete Implantate. Diese können mit dem Intervertebralimplantat verbunden oder von diesem unabhängig angebracht werden.

Mit konservativen Behandlungsmassnahmen nicht beeinflussbare Schmerzen, Rückenmark- oder Nervenwurzelkompressionen sowie Fehlstellungen sind Indikationen für Spondylodesen. Schmerzen können prinzipiell von allen krankhaft veränderten Strukturen der Wirbelsäule ausgehen. Für die Entwicklung von Rückenmark- oder Nervenwurzelkompressionen sind Verengungen des Wirbelkanals

oder der Zwischenwirbellöcher verantwortlich. Mit einem chirurgischen Eingriff werden die pathologischen Veränderungen beseitigt und die Stabilität der Wirbelsäule durch die Spondylodese wieder hergestellt.

Weil bei der interkorporellen Spondylodese immer Bandscheiben ausgeräumt werden und dies die Stabilität der Wirbelsäule beeinträchtigt, ist diese immer wieder herzustellen. Dies kann beispielsweise mit druckfesten Knochenspänen geschehen, die man vom Patienten entnimmt, sogenannte autogene Knochenspäne, und zwischen den Wirbelkörpern einsetzt. Da die Belastbarkeit solcher Späne oft unsicher und ihre Verfügbarkeit begrenzt ist, und zudem die durch eine Spanentnahme verursachte Morbidität erheblich sein kann, benutzt man anstelle von autogenen Knochenspänen zunehmend aus körperfremden Materialien hergestellte Intervertebralimplantate, auch „Cages“ genannt.

Ein Intervertebralimplantat funktioniert als druckaufnehmender Platzhalter, welcher die Spondylodese stabilisiert, die Einstellung der Wirbelkörper zueinander sichert und gewährleistet, dass sich zwischen den benachbarten Wirbelkörpern eine solide Knochenbrücke bildet. In die Intervertebralimplantate eingefülltes und/oder um sie herum angelagertes Knochen- oder Knochenersatzmaterial bilden eine Matrix für eine Knochenneubildung. Für den Ossifikationsprozess spielt die Stabilität der Spondylodese eine entscheidende Rolle. Innerhalb der Spondylodese stattfindende Bewegungen verzögern oder verhindern deren knöcherne Konsolidierung.

Im Stand der Technik sind zahlreiche Intervertebralimplantate bekannt geworden, die mit einer Platte mit Wirbeln verbunden werden.

So zeigt beispielsweise die US 6,235,059 B eine Vorrichtung mit einem Intervertebralimplantat, mit dem zwei Wirbel aneinander stabilisiert werden können. Am Intervertebralimplantat ist eine zweiarmige Platte befestigt, die starr oder schwenkbar mit dem Intervertebralimplantat verbunden ist. Jeder Arm besitzt eine Durchgangsbohrung, durch die eine Knochenschraube in den entsprechenden Wirbelkörper einschraubbar ist. Eine Anpassung an die jeweiligen anatomischen Gegebenheiten und insbesondere an die sagittale Krümmung ist hier sehr beschränkt. Das Intervertebralimplantat kann nur mit den benachbarten Wirbeln verbunden werden.

Die WO 00/24343 offenbart eine Vorrichtung mit einem Intervertebralimplantat, das am Umfang Windungen besitzt und ähnlich einer Schraube zwischen die Wirbel eingeschraubt werden kann. An einem vorderen Ende des Intervertebralimplantates ist eine flügel förmige zweiarmige Platte befestigt. Die Befestigung ist hier so ausgeführt, dass die Platte zur Anpassung an die anatomischen Gegebenheiten bewegbar ist. Die beiden Arme der Platte weisen jeweils ein Langloch für die Aufnahme einer Knochenschraube auf. Auch bei dieser Vorrichtung kann das Intervertebralimplantat nur mit den benachbarten Wirbeln verbunden werden. Die Anpassbarkeit an die anatomischen Gegebenheiten ist sehr beschränkt.

Die FR 2 727 005 offenbart eine Vorrichtung mit mehreren Intervertebralimplantaten, die mit einem gemeinsamen Band miteinander verbunden werden. Das Band weist Löcher zur Befestigung des Bandes und jeweils ein Intervertebralimplantat und Löcher zur Aufnahme einer Knochenschraube auf. Mit dieser Vorrichtung können zwar mehrere Intervertebralimplantate miteinander verbunden werden, die Anpassbarkeit an die anatomischen Gegebenheiten ist auch hier jedoch sehr beschränkt. Um eine solche Anpassbarkeit zu gewährleisten, müssten hier entsprechend unterschiedliche

Bänder zur Verfügung stehen. Die Abstände zwischen den Intervertebralimplantaten ist vorgegeben.

Die EP 0 179 695 A offenbart ein Intervertebralimplantat, an dem Ösen angeformt sind, mit denen das Implantat an benachbarten Wirbeln festschraubbar ist. Auch hier ist die Anpassbarkeit an anatomische Gegebenheiten sehr beschränkt. Insbesondere ist es hier in der Regel nicht möglich, die Knochenschrauben an der geeigneten Stelle in den Wirbelkörper einzusetzen. Es können auch hier nur zwei Wirbel mit einem Intervertebralimplantat verbunden werden.

Die US 5,360,430 offenbart ein Intervertebralimplantat, welches einen Wirbel ganz oder teilweise ersetzt, welches mit Platten an den oberen resp. unteren Wirbeln befestigt wird und welches zwischen diesen Wirbeln eine gewisse ungefederte oder gefederte Beweglichkeit erlaubt.

Die S 5,443,515 offenbart ebenfalls ein Implantat, welches einen Wirbelkörper ersetzen soll. Es ist aus Tantalschaum hergestellt.

Die Stabilisierung von Intervertebralimplantaten mit herkömmlichen Platten erfordert somit wegen der grossen individuellen und krankheitsbedingten anatomischen Variabilität insbesondere der Halswirbelsäule ein grosses Sortiment verschieden langer Platten mit unterschiedlichen Lochabständen. Die Länge der Platten richtet sich dabei nach der Position der oberen und unteren Endlöcher. Wenn bei mehrsegmentalen Spondylodesen die Platten nur an die Endwirbel befestigt werden, besteht die Gefahr, dass die Platten an einem Endwirbel ausreissen. Es ist deshalb ratsam, die Platten auch an die zwischen den Endwirbeln liegenden Wirbelkörper mit Schrauben zu fixieren. Die bei herkömmlichen Platten dafür vorgesehenen Schraubenlöcher liegen aber nicht immer genau so, dass die betreffenden Schrauben gut in die zwischen

den Endwirbeln liegenden Wirbelkörper eingesetzt werden können. Zudem kann bei verschiedenen Plattentypen nur jeweils eine Schraube im Wirbelkörper befestigt werden.

Der Erfindung liegt die Aufgabe zugrunde, eine Vorrichtung der genannten Art zu schaffen, die optimaler an die jeweiligen anatomischen Gegebenheiten anpassbar ist.

Die Aufgabe ist bei einer gattungsgemässen Vorrichtung dadurch gelöst, dass das Intervertebralimplantat mit zwei im Abstand zueinander angeordneten Platten verbunden ist, wobei die beiden Platten jeweils an einem Ende mit dem Intervertebralimplantat ein fixierbares Gelenk bilden. Die beiden mit dem Intervertebralimplantat verbundenen Platten können unabhängig voneinander in mehreren Freiheitsgraden bewegt und in einer gewünschten Endstellung winkelstabil fixiert werden. Ein wesentlicher Vorteil der erfindungsgemässen Vorrichtung besteht darin, dass auch Mehretagenspondylodesen hergestellt werden können, wobei benachbarte Intervertebralimplantate direkt miteinander verbunden werden können. Dadurch ergibt sich eine besonders hohe Stabilität und damit Sicherheit. Die Intervertebralimplantate bilden somit mit den Platten eine besonders stabile Einheit. Es können auch unterschiedlich grosse Intervertebralimplantate kombiniert und mit unterschiedlichen Platten untereinander winkelstabil verbunden werden. Insbesondere ist eine Anpassung an unterschiedliche Krümmungen der Wirbelsäule und an unterschiedliche Abstände zwischen Intervertebralimplantaten und Wirbeln möglich. Die Erfindung eignet sich insbesondere für Platten, die plastisch nicht deformierbar sind, und beispielsweise aus Titan oder einem Verbundwerkstoff bestehen.

Die Vorrichtung eignet sich insbesondere für die Spondylodese an der Halswirbelsäule. Hier empfiehlt es sich, die Spondylodese mit an die Vorderfläche der Halswirbelkörper fixierten Platten

abzusichern. Es ist insbesondere ein Modularsystem möglich, das sowohl in der Herstellung als auch in der Praxis vorteilhaft ist. Die Anpassbarkeit ist mit einem überraschend kleinen Sortiment aus Einzelteilen möglich.

Nach einer Weiterbildung der Erfindung ist vorgesehen, dass wenigstens eine Platte Z-förmig oder L-förmig ausgebildet ist. Mit solchen Platten ist eine besonders hohe Anpassbarkeit und ein besonders stabiler Verbund möglich. Z-förmige Platten eignen sich insbesondere zum Verbinden benachbarter Intervertebralimplantate und damit zur Stabilisierung von drei Wirbeln. Solche Z-förmige Platten können in einem mittleren Bereich beispielsweise mit zwei Knochenschrauben verankert werden. L-förmige Platten ermöglichen ebenfalls eine Befestigung solcher Platten mit zwei Knochenschrauben. Auf dieselbe Art können auch mehr als drei Wirbel resp. mehr als zwei Intervertebralimplantate untereinander verbunden werden. Als Implantatbrücken eignen sich auch gerade Platten, welche durch fixierbare Gelenke an die Intervertebralimplantate und Knochenschrauben an den zwischen Intervertebralimplantaten liegenden Wirbelkörper befestigt werden. Denkbar ist auch eine Ausführung, bei welcher zwei Intervertebralimplantate nicht direkt durch eine sie verbindende Platte (Implantatbrücke) aneinander fixiert werden, sondern indirekt über den zwischen den beiden Intervertebralimplantaten liegenden Wirbelkörper. Für diesen Fall sind kurze Platten vorgesehen, welche durch fixierbare Gelenke an das jeweilige Intervertebralimplantat und mit Knochenschrauben an den Wirbelkörper befestigt werden, wobei dann die am oberen Intervertebralimplantat angebrachte Platte nach unten und die am unteren Intervertebralimplantat angebrachte Platte nach oben gerichtet ist, sodass die Plattenenden mit den Knochenschrauben am Zwischenwirbel nebeneinander liegen. Somit ist dann jedes der beiden Intervertebralimplantate mit durch eine Platte und mindestens eine Knochenschraube mit dem Zwischenwirbel verbunden.

Die Erfindung betrifft auch einen Bausatz zur Herstellung einer Vorrichtung gemäss Anspruch 1.

Ausführungsbeispiele der Erfindung werden nachfolgend anhand der Zeichnungen näher erläutert. Es zeigen:

- Fig. 1 schematisch eine räumliche Ansicht einer erfindungsgemässen Vorrichtung,
- Fig. 2 eine weitere Ansicht der erfindungsgemässen Vorrichtung gemäss Fig. 1,
- Fig. 3 einen Schnitt entlang der Linie III - III der Fig. 2,
- Fig. 4 eine weitere Ansicht der erfindungsgemässen Vorrichtung gemäss Fig. 1,
- Fig. 5 eine weitere Ansicht der erfindungsgemässen Vorrichtung gemäss Fig. 1,
- Fig. 6 eine räumliche Ansicht einer Variante der erfindungsgemässen Vorrichtung,
- Fig. 7 eine räumliche Ansicht einer Variante der erfindungsgemässen Vorrichtung,
- Fig. 8 eine räumliche Ansicht einer geraden Platte mit einem Gelenk,
- Fig. 9 eine räumliche Ansicht einer geraden Platte mit zwei Gelenken, und

Fig. 10-15 schematisch Ansichten eines Abschnittes einer Wirbelsäule mit jeweils einer erfindungsgemässen Vorrichtung, welche Wirbel miteinander verbindet.

Die in den Fig. 1 bis 4 gezeigte Vorrichtung 1 weist zwei Intervertebralimplantate 3 auf, die gemäss den Fig. 10 und 11 jeweils in den Bandscheibenraum benachbarter Wirbel 21 und 22 bzw. 22 und 23 einer Wirbelsäule 24 eingesetzt sind. Die Wirbel 21 bis 23 sind hier insbesondere Wirbel der Halswirbelsäule, wobei mit 26 die Vorderfläche der Halswirbelsäule bezeichnet ist. In der

Fig. 10 liegen links vor der Vorderfläche hier nicht gezeigte Speiseröhre und grosse Blutgefässe.

Die beiden Intervertebralimplantate 3 bestehen aus Metall, insbesondere Titan oder einem geeigneten Kunststoff und sind interkorporelle und druckaufnehmende Körper. Sie weisen jeweils eine nach aussen offene Ausnehmung 20 auf, die zur Aufnahme von Knochen oder Knochenersatzmaterial dient. Die Ausnehmungen 20 werden vom Knochen des Patienten durchwachsen, so dass sich eine knöcherne Brücke zwischen den benachbarten Wirbeln 21 und 22 bzw. 22 und 23 bildet. Die Wirbel 21, 22 und 23 können damit fest miteinander verbunden werden.

Die beiden Intervertebralimplantate 3 sind mit einer Z-förmigen Platte 5 fest miteinander verbunden. Diese Platte 5 weist gemäss Fig. 2 zwei Arme 5a und 5b sowie einen quer zu diesen verlaufenden mittleren Bereich 5c auf. Die beiden Arme 5a und 5b sind vorzugsweise gleich ausgebildet, so dass die Platte 5 bezüglich eines mittleren Punktes P drehsymmetrisch ist. Die beiden Arme 5a weisen jeweils an einem freien Ende eine halbkugelförmige Vertiefung 27 auf, durch die mittig eine Durchgangsöffnung 17 hindurch geht. Diese halbkugelförmigen Vertiefungen 27 und die

Durchgangsöffnungen 17 nehmen jeweils eine Kugelkopfschraube 7 auf, die mit einem Gewindenschaft 12 in eine Bohrung 13 eines Intervertebralimplantates 3 eingeschraubt ist. Die Kugelkopfschrauben 7 weisen jeweils einen Kopf 9 mit einem Werkzeugangriff 8 und einer ebenfalls halbkugelförmigen Unterseite 10 auf. Zwischen dem Schaft 12 und dem Kopf 9 ist ein Hals 11 angeordnet, dessen Durchmesser kleiner ist als derjenige des Schaftes 12 und der Durchgangsöffnung 28. Die halbkugelförmige Unterseite 10 liegt an der halbkugelförmigen Vertiefung 27 an. Sind die beiden Schrauben 12 fest in das jeweilige Intervertebralimplantat 3 eingeschraubt, so ist die Platte 5 an ihren beiden freien Enden fest am jeweiligen Intervertebralimplantat 3 durch Klemmung fixiert. Die Klemmflächen werden durch eine halbkugelförmige Fläche 15 und eine ebenfalls halbkugelförmige Fläche 14 des entsprechenden Intervertebralimplantates 3 gebildet. Sind die beiden Kugelkopfschrauben 7 nicht vollständig eingeschraubt, so bilden die beiden Verbindungen der Platte 5 zu den Intervertebralimplantaten 3 jeweils eine Art Kugelgelenk, die jeweils an beiden Befestigungspunkten Bewegungen in mehreren Freiheitsgraden ermöglichen.

Die Platte 5 und die beiden Intervertebralimplantate 3 können somit gegeneinander bewegt werden und in jeder gewünschten Position können diese Teile durch Festziehen der Schrauben 7 winkelt stabil miteinander verbunden werden. Nach dem Festziehen der Kugelkopfschrauben 7 bilden die beiden Intervertebralimplantate 3 und die Z-förmige Platte 5 eine stabile Einheit. Nötigenfalls können die Schrauben 7 jederzeit gelöst und damit wieder der bewegliche Zustand hergestellt werden.

An den beiden Intervertebralimplantaten 3 ist jeweils eine weitere Platte 4 angeordnet, die vorzugsweise L- bzw. winkelförmig ausgebildet sind. Diese Platten 4 weisen jeweils zwei Arme 4a und 4b auf, die gleich oder unterschiedlich sein können. Der

Arm 4a weist an seiner Unterseite einen kugelförmigen Gelenkteil 18 mit einer kugelförmigen Innenfläche 16 und einer ebenfalls halbkugelförmigen Aussenfläche 15 auf. Der Gelenkteil 18 weist eine Durchgangsöffnung 17 auf. Der Gelenkteil 18 sitzt in einer halbkugelförmigen Vertiefung 14 des entsprechenden Intervertebralimplantates 3. Um die Platte 4 am entsprechenden Intervertebralimplantat 3 zu befestigen, wird gleich wie zur Befestigung der Z-förmigen Platte 5 in den Gelenkteil 18 von oben eine Kugelpfandschraube 7 eingesetzt und in die Bohrung 13 des entsprechenden Intervertebralimplantates 3 eingeschraubt. In den Fig. 1 - 3 sind diese Schrauben 7 aus zeichnerischen Gründen nicht eingezeichnet. Vor dem Festziehen der Schraube 7 kann die entsprechende Platte 4 aufgrund der kugelgelenkartigen Verbindung bewegt und an die anatomischen Gegebenheiten angepasst werden. Ist die optimale Position erreicht, so werden die entsprechenden Schrauben 7 angezogen und damit die Platten 4 winkelstabil bezüglich des entsprechenden Intervertebralimplantates 3 fixiert.

Die beiden Platten 4 weisen im Arm 4b jeweils zwei im Abstand zueinander angeordnete Durchgangsöffnung 19 auf, die jeweils zur Aufnahme einer Knochenschraube 25 dienen, wie dies in Fig. 7 schematisch dargestellt ist. Solche Knochenschrauben 25 sind an sich bekannt. Die Verbindung kann mit einer Schraube gemäss der WO 01/30251 winkelstabil oder alternativ auch beweglich sein. Mit diesen Schrauben 25 werden die beiden Platten 4 im entsprechenden Wirbelkörper 21 bzw. 23 befestigt. Diese Knochenschrauben 25 sollten möglichst in der Mitte des entsprechenden Wirbelkörpers 21 bzw. 23 liegen. Andernfalls könnte ihr Halt beeinträchtigt werden. Diese Schrauben sollten ferner nicht in eine gesunde Bandscheibe eindringen und zudem sollten die Arme 4b nicht eine gesunde Bandscheibe berühren. Dies würde zu Zerstörungen bzw. Degenerationen der betreffenden Bandscheiben führen. Aufgrund der Einstellbarkeit der Platten 4 ist es nun möglich,

diese so auszurichten, dass die Schrauben wie oben erläutert in geeigneten Positionen in die Wirbelkörper 21 bzw. 23 eingeschraubt werden können. Ebenfalls kann damit vermieden werden, dass die Arme 4b eine Bandscheibe berühren.

Die genannte Einstellbarkeit der Platten 4 lassen sich diese an die unterschiedlichen Krümmungen und Formen der Vorderfläche 26 der Halswirbelsäule anpassen. Dies ist auch dann möglich, wenn Intervertebralimplantate 3 wie gewünscht nicht an der Vorderseite 26 vorstehen. Die Intervertebralimplantate 3 dürfen an der Vorderfläche 26 nicht vorstehen, da sie dadurch Verletzungen der vor der Halswirbelsäule 24 angeordneter Gebilde und insbesondere der Speiseröhre und grosser Blutgefässe verursachen könnten.

Die beiden Platten 4 verbinden somit bei festgezogenen Kugelschrauben 7 jeweils ein Intervertebralimplantat 3 winkelstabil mit einem Wirbelkörper 21 und 22 bzw. 22 und 23. Die Platte 5 verbindet die beiden Intervertebralimplantate 3 winkelstabil miteinander. Zudem weist die Platte 5 im mittleren und quer verlaufen Bereich 5c zwei Durchgangsöffnungen 6 auf, welche jeweils eine Knochenschraube 25 aufnehmen, die in den mittleren Wirbelkörper 22 eingeschraubt sind und mit denen dadurch die Platte 5 an diesem mittleren Wirbel 22 verankert wird. Auch hier ist eine winkelstabile oder bewegliche Verbindung zwischen Platte 4 und Knochenschraube 25 möglich.

Die beiden Platten 4 und die Platte 5 können gemäss den Fig. 4 und 5 in einer Ebene liegen. Aufgrund der genannten Gelenkverbindungen ist eine solche ebene Anordnung jedoch nicht zwingend. So können die beiden Platten 4 gemäss den Doppelpfeilen 29 der Fig. 4 unabhängig voneinander in einen vergleichsweise grossen Bereich nach oben und nach unten verschwenkt werden. Diese beiden Platten 4 können auch unabhängig voneinander gemäss den Doppelpfeilen 29 bis 31 der Fig. 2, 4, 5 und 6 verschwenkt werden.

Aufgrund der kugelgelenkartigen Verbindungen sind hier aber auch noch andere Bewegungen bzw. Freiheitsgrade möglich. So steht insbesondere die in Fig. 5 mit dem Doppelpfeil 31 angedeutete Schwenkbewegung zur Verfügung. Jede mögliche Position ist durch Festziehen der entsprechenden Kugelkopfschraube 7 fixierbar. Damit ist wie oben erläutert eine optimale Anpassung an die jeweiligen anatomischen Gegebenheiten möglich.

Die Fig. 6 zeigt eine erfindungsgemäße Vorrichtung 2, die lediglich ein Intervertebralimplantat 3 sowie zwei L- bzw. winkelförmige Platten 4 aufweist. Die Platten 4 sind wie bereits oben erläutert jeweils mit einer Kugelkopfschraube 7 am Intervertebralimplantat 3 befestigt. Die Verbindung ist wie oben erläutert kugelgelenkartig. Die beiden Platten 4 können ebenfalls wie oben erläutert vor dem Festziehen der beiden Schrauben 7 bewegt werden. In der Fig. 6 ist lediglich eine der beiden Kugelkopfschrauben 7 gezeigt. Die beiden Platten 4 sind in der gezeigten Ausführung gleich ausgebildet. Die Platten 4 können jedoch auch unterschiedlich sein, beispielsweise unterschiedlich lang sein. Sie müssen nicht zwingend L- bzw. winkelförmig sein, sondern können auch gerade längliche Platten sein. Dies gilt auch für die Platten 4 der Vorrichtung 1. Die Vorrichtung 2 dient zum Verbinden von zwei benachbarten Wirbeln 21 und 22 bzw. 22 und 23. Selbstverständlich können an einer Wirbelsäule 24 mehrere solche Vorrichtungen 2 angebracht werden. Die entsprechenden Intervertebralimplantate 3 sind dann jedoch nur über zwischenliegende Wirbel miteinander verbunden. Eine direkte Verbindung wie bei der Vorrichtung 1 ist damit hier nicht vorhanden.

Die Platten 4 und 5 sowie die Intervertebralimplantate 3 sind vorzugsweise aus einem geeigneten Kunststoff, beispielsweise aus einem faserverstärkten Kunststoff hergestellt. Solche Kunststoffe sind an sich bekannt und haben den wesentlichen Vorteil, dass sie für Röntgenstrahlen durchlässig sind. Mit solchen Materia-

lien können auch sehr stabile Platten 4 und 5 hergestellt werden, die zudem sehr biegesteif sind. Damit ist es möglich, Bewegungen innerhalb der Spondylodese und damit das Risiko einer mitunter folgeschweren sekundären Implantatdislokation zu mindern. Grundsätzlich können die Platten 4 und 5 aber auch aus einem anderen Werkstoff, beispielsweise auch aus Titan hergestellt werden.

Möglich ist auch eine hier nicht gezeigte Vorrichtung mit mehr als zwei Intervertebralimplantaten 3, die mit einer entsprechenden Anzahl von Z-förmigen Platten 5 direkt miteinander verbunden sind. Beispielsweise kann eine solche Vorrichtung drei Intervertebralimplantate 3 aufweisen, die mit zwei Z-förmigen Platten 5 miteinander verbunden sind. An den beiden äusseren Intervertebralimplantaten ist dann jeweils noch eine L-förmige Platte 4 befestigt.

Die Figur 7 zeigt eine Ausführung einer erfindungsgemässen Vorrichtung, welche zwei L-förmigen Platten 4 und eine gerade Platte 32 aufweist. Die lange Platte 32 ist an ihren Enden jeweils mit einer Kugelschraube 7 mit einem Intervertebralimplantat 3 verbunden. Die Verbindungen zu den Intervertebralimplantaten 3 sind Gelenke, die polyaxial beweglich und durch Festziehen der Schrauben 7 fixierbar sind. Die Ausbildung der langen und geraden Platte 32 ergibt sich auch aus der Fig. 9.

Die Figur 8 zeigt zudem eine vergleichsweise kurze Platte 33, die eine Kugelschraube 7 und eine Knochenschraube 25 aufnehmen kann und die insbesondere gemäss Fig. 13 verwendbar ist.

Nachfolgend wird ein Verfahren zur Versteifung eines Abschnittes einer Wirbelsäule mit der erfindungsgemässen Vorrichtung näher erläutert.

Nach einer entsprechenden Freilegung des zu versteifenden Abschnittes der Wirbelsäule wird die befallene Bandscheibe ausgeräumt. Mit einem geeigneten Instrument wird der ausgeräumte Bandscheibenraum erweitert bzw. vergrössert. Nun wird ein passendes Intervertebralimplantat 3 ausgewählt und in den ausgeräumten Bandscheibenraum eingesetzt, wo es zwischen den benachbarten Wirbeln verklemmt. Gegebenenfalls wird eine weitere Bandscheide ausgeräumt und entsprechend ein weiteres Intervertebralimplantat 3 eingesetzt.

Nun werden Abstände zwischen dem Intervertebralimplantat 3 bzw. den Intervertebralimplantaten 3 und geeigneten Positionen für die Knochenschrauben ermittelt. Bei zwei Intervertebralimplantaten 3 wird auch der Abstand zwischen diesen gemessen. Entsprechend diesen Abständen werden passende Platten 4 und gegebenenfalls 5 gewählt und diese lose am Intervertebralimplantat 3 bzw. an den Intervertebralimplantaten fixiert. Die Platten 4 werden so gewählt, dass sie benachbarte Bandscheiben nicht berühren, wie dies in den Figuren 7 und 8 ersichtlich ist. Die lose fixierten Platten 4 und 5 werden an die Wirbel angelegt und mit Knochenschrauben 25 fixiert. Nun werden die Platten 4 und gegebenenfalls 5 durch Festziehen der Schrauben 7 fest mit dem Intervertebralimplantat 3 bzw. Intervertebralimplantaten verbunden.

Die Figuren 10 und 11 zeigen drei Wirbel 21 bis 23, die mit einer erfindungsgemässen Vorrichtung miteinander verbunden sind. Die Platte 5 verbindet wie ersichtlich zwei Intervertebralimplantate 3 miteinander und ist zudem mit Knochenschrauben 25 mit dem Wirbel 22 verbunden. Werden lediglich zwei Wirbel miteinander verbunden, wird die Vorrichtung 2 gemäss Figur 6 verwendet, bei der eine Z-förmige Platte 5 nicht vorgesehen ist.

Die Fig. 11-15 zeigen fünf von den denkbaren Ausführungsmöglich-

keiten der erfindungsgemässen Vorrichtung, mit welchen zwei oder mehr Wirbel miteinander verbunden werden können. In den Fig. 11 bis 15 ist die Halswirbelsäule von vorne zu sehen und in der Fig. 10 von der Seite.

Die Fig. 14 zeigt eine Verbindung von zwei Wirbeln mit Hilfe von zwei L-förmigen Platten 4 und einem Intervertebralimplantat 3. Die L-Platten 4 sind mit je zwei Knochenschrauben 25 an die Wirbelkörper und je einer Kugelkopfschraube 7 an das Intervertebralimplantat 3 befestigt.

Die Fig. 11 zeigt eine Verbindung von drei Wirbeln 21-23. Die Intervertebralimplantate 3 sind durch eine Implantatbrücke direkt miteinander verbunden. Sie besteht in diesem Fall aus einer Z-förmigen Platte 5. Die Z-Platte 5 wird durch zwei Knochenschrauben 25 an den Körper des mittleren Wirbels 22 befestigt.

Die Fig. 10 zeigt eine Ansicht einer Halswirbelsäule von der Seite mit der den Halswirbelkörpern vorne anliegenden erfindungsgemässen Vorrichtung gemäss Fig. 11.

Die Fig. 12 zeigt eine Verbindung von vier Wirbelkörpern, wobei gerade Platten 32 die Implantatbrücke zu den Intervertebralimplantaten 3 bilden. Jede gerade Platte 32 ist mit einer Knochenschraube 25 an den unter der betreffenden Platte 32 liegenden Wirbelkörpern befestigt.

Bei dem Ausführungsbeispiel gemäss Fig. 13 werden drei Intervertebralimplantate 3 nicht direkt durch Implantatbrücken miteinander verbunden, sondern indirekt über den jeweils zwischen zwei Intervertebralimplantaten 3 liegenden Wirbelkörpern, indem kurze Platten 33 an die Intervertebralimplantate 3 und die zwischen ihnen liegenden Wirbelkörper befestigt werden.

Die Fig. 15 zeigt eine Verbindung von vier Wirbeln, wobei wiederum Z-Platten 5 die Implantatbrücken zu Intervertebralimplantaten 3 bilden. Die Z-Platten 5 werden mit je zwei Knochenschrauben 25 an dem unter der jeweiligen Platte befindlichen Wirbelkörper befestigt. Die Verbindung zum oberen und unteren Wirbel erfolgt wie in Fig. 14 beschrieben. Die Verbindung wird in diesem Fall ausschliesslich mit Z-Platten 5 hergestellt.

Ein wesentlicher Vorteil der Erfindung ist, dass das erfindungsgemässe Implantat dank der gelenkigen Cage-Plattenverbindungen einem Sortiment verschieden langer Platten und verschieden grosser (hoher) Intervertebralimplantate den individuell zuweilen sehr unterschiedlichen anatomischen Gegebenheiten, insbesondere der vorderen Oberfläche der Halswirbelsäule, genau angepasst werden kann. Diese kann eben, mehr oder weniger konvex oder sogar konkav oder von Wirbel zu Wirbel wechselnd konvex oder konkav sein. Die Halswirbelsäule kann von vorne gesehen auch etwas krumm oder um die Längsachse etwas verdreht sein. Das alles ist dank der freien Beweglichkeit der Platten ausgleichbar.

Bei der vorliegenden Erfindung geht es insbesondere nicht nur um stabile Verbindungen der Implantate untereinander sowie um ebenso stabile Verbindungen zwischen den Endwirbeln des mit Hilfe der Vorrichtung verblockten Abschnitts der Wirbelsäule, sondern vor allem um die vollständige Anpassbarkeit der Vorrichtung an die jeweiligen anatomischen Gegebenheiten (Krümmungen, Grössenverhältnisse, Unebenheiten). Diese Anpassbarkeit ist besonders an der Halswirbelsäule von grosser Bedeutung, weil die Implantate von der Vorderfläche der Halswirbelsäule nicht vorragen dürfen. Sie dürfen nicht dicker als 2 mm bis höchstens 3 mm sein und müssen den Wirbelkörpern gut anliegen. Anderenfalls besteht die Gefahr, dass eine schwere Komplikation auftreten kann, wenn z.B. der Vorderfläche der Halswirbelsäule eng anliegende Gebilde wie Speiseröhre und Blutgefässe mit der Zeit arrodieren werden.

Unsere Vorrichtung zeichnet sich durch ein niedriges Profil aus, d.h. durch eine niedrige Bauhöhe.

Die Anpassbarkeit der erfindungsgemässen Vorrichtung beruht insbesondere auf

- den blockierbaren Kugelgelenken mit je drei Freiheitsgraden
- einem Sortiment verschieden langer Platten (sowohl L- und Z-Platten)
- einem Sortiment verschieden grosser Intervertebralimplantate.

Bezugzeichenliste

1	Vorrichtung	14	Fläche
2	Vorrichtung	15	Fläche
3	Intervertebralimplantat	17	Durchgangsöffnung
4	Platte	18	Gelenkteil
4a	Arm	19	Durchgangsöffnung
4b	Arm	21-23	Wirbel
5	Platte	24	Halswirbelsäule
5a	Arme	25	Knochenschraube
5b	Arme	26	Vorderfläche
5c	mittlerer Bereich	27	Vertiefung
6	Durchgangsöffnung	28	Durchgangsöffnung
7	Kugelkopfschraube	29-31	Doppelpfeile
8	Werkzeugangriff	32	gerade Platten
9	Kopf	33	kurze Platte
10	Unterseite	P	mittlerer Punkt
11	Hals		
12	Gewindeschäft		
13	Bohrung		

Patentansprüche

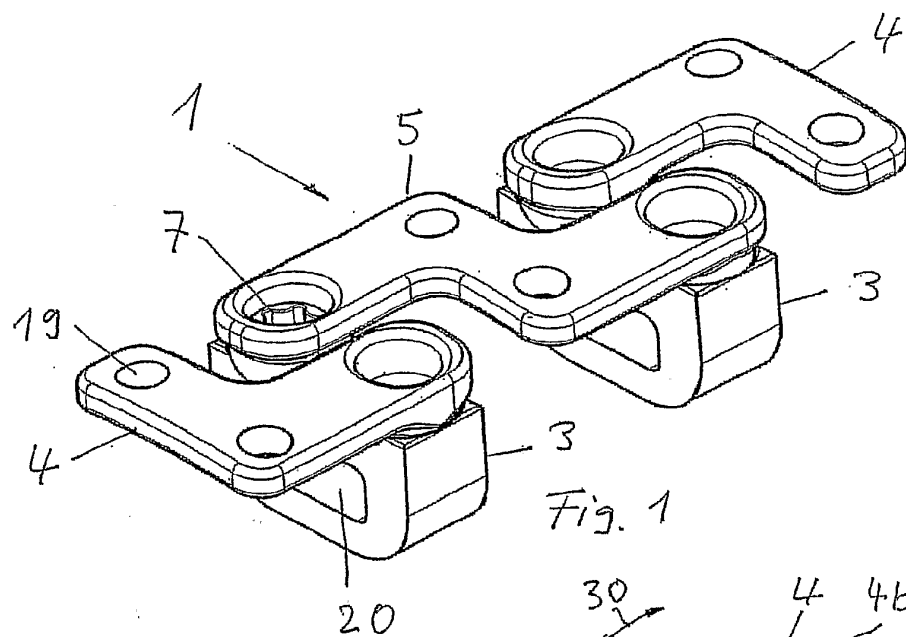
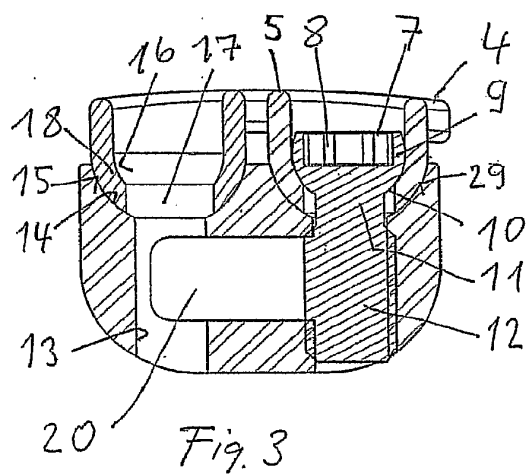
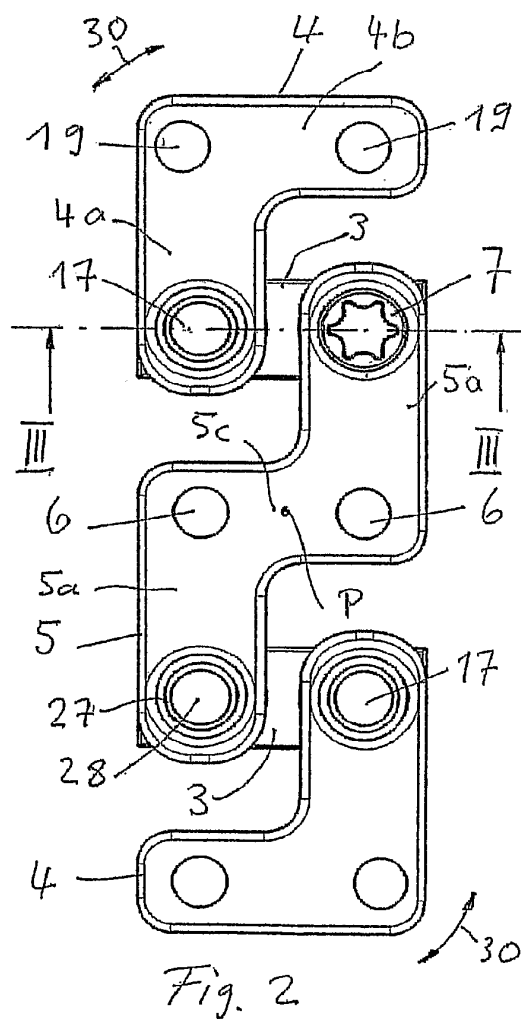
1. Vorrichtung für die Spondylodese und insbesondere für die vordere interkorporelle Spondylodese an der Halswirbelsäule, mit wenigstens einem Intervertebralimplantat (3) und mit wenigstens einer Platte (4,5), die mit dem Intervertebralimplantat (3) und einem benachbarten Wirbel (21-23) zu verbinden ist, dadurch gekennzeichnet, dass das Intervertebralimplantat (3) mit wenigstens zwei im Abstand zueinander angeordneten Platten (4,5) verbunden ist, wobei die beiden Platten (4,5) jeweils an einem Ende mit dem Intervertebralimplantat (3) ein fixierbares Gelenk bilden.
2. Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, dass wenigstens eine der Platten (5, 4) Z-förmig, I-förmig oder L-förmig ausgebildet ist.
3. Vorrichtung nach Anspruch 1 oder 2, dadurch gekennzeichnet, dass wenigstens eine Platte (5) in einem mittleren und quer zur Längsachse der Wirbelsäule (24) verlaufenden Bereich (5c) wenigstens einen Durchgang (6) für eine Knochenschraube (25) aufweist, derart, dass diese Platte (5) mit einem Wirbel (22) verbindbar ist.
4. Vorrichtung nach Anspruch 3, dadurch gekennzeichnet, dass der genannte Bereich (5c) zwei im Abstand zueinander angeordnete Durchgänge (6) für jeweils eine Knochenschraube (25) aufweist.

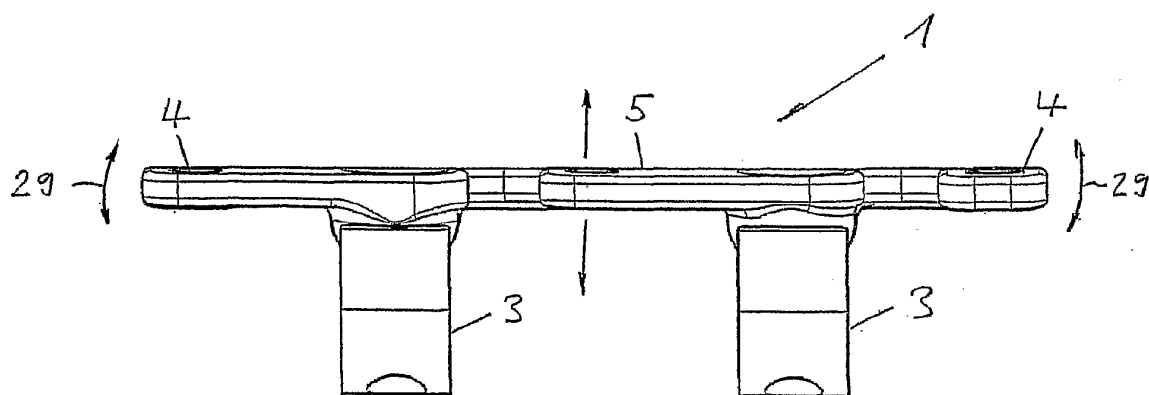
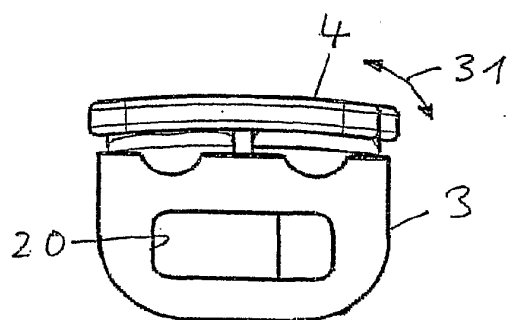
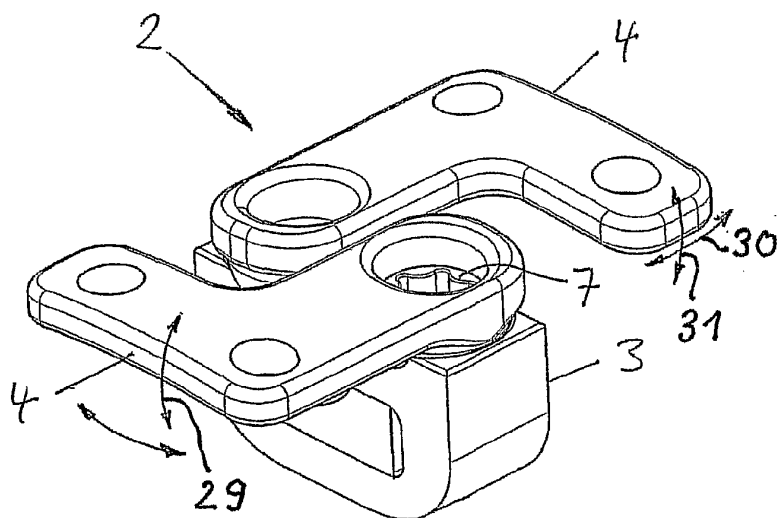
5. Vorrichtung nach einem der Ansprüche 1 - 4, dadurch gekennzeichnet, dass wenigstens eine Platte (4,5) an wenigstens einem Ende einen halbkugelförmigen und vorstehenden Gelenkteil (18) aufweist, der einen Durchgang (17) für eine Befestigungsschraube (7) aufweist und der in eine halbkugelförmige Vertiefung (14) eines Intervertebralimplantates (3) eingreift, derart, dass ein Kugelgelenk gebildet wird.
6. Vorrichtung nach Anspruch 5, dadurch gekennzeichnet, dass wenigstens zwei Platten (4,5) jeweils über ein polyaxiales Gelenk, insbesondere ein Kugelgelenk mit einem Intervertebralimplantat (3) verbunden sind.
7. Vorrichtung nach einem der Ansprüche 1 - 6, dadurch gekennzeichnet, dass wenigstens zwei L-förmige Platten (4) mit einem Intervertebralimplantat (3) verbunden sind.
8. Vorrichtung nach Anspruch 7, dadurch gekennzeichnet, dass die beiden Platten (4) jeweils in einem quer zur Längsrichtung der Wirbelsäule (24) verlaufenden Arm (4b) wenigstens zwei im Abstand zueinander angeordnete Durchgänge (19) zur Aufnahme jeweils einer Knochenschraube (25) aufweisen.
9. Vorrichtung nach einem der Ansprüche 1 - 8, dadurch gekennzeichnet, dass zwei Intervertebralimplantate (3) mit einer Z-förmigen Platte (5) miteinander verbunden sind.
10. Vorrichtung nach einem der Ansprüche 1 - 9, dadurch gekennzeichnet, dass zwei Intervertebralimplantate (3) vorgesehen sind, die mit einer Z-förmigen Platte (5) miteinander verbunden sind und an denen jeweils eine L-förmige oder I-förmige Platte (4) befestigt ist, wobei sämtliche Verbindungen zwischen den Platten (4,5) und den Intervertebra-

limplantaten (3) als polyaxiale Gelenke, insbesondere Kugelgelenke ausgebildet sind.

11. Vorrichtung nach einem der Ansprüche 1 - 10, dadurch gekennzeichnet, dass wenigstens eine Platte (4,5) und/oder ein Intervertebralimplantat (3) aus einem röntgendurchlässigen Werkstoff hergestellt ist bzw. sind.
12. Vorrichtung nach einem der Ansprüche 1 - 11, dadurch gekennzeichnet, dass sie für eine Spondylodese der Halswirbelsäule vorgesehen ist.
13. Bausatz zur Herstellung einer Vorrichtung nach einem der Ansprüche 1 - 12, mit wenigstens einem Intervertebralimplantat (3) und wenigstens einer Platte (4,5) zum Verbinden des Intervertebralimplantates (3) mit wenigstens einem Wirbel (21-23), dadurch gekennzeichnet, dass wenigstens eine Platte (4) L-förmig und wenigstens eine Platte (5) Z-förmig ausgebildet ist und dass wenigstens ein Intervertebralimplantat (3) im Abstand zueinander zwei Bohrungen (13) zur Aufnahme jeweils einer Befestigungsschraube (7) aufweist.
14. Bausatz nach Anspruch 13, dadurch gekennzeichnet, dass das Intervertebralimplantat (3) und die Platten (4,5) jeweils mindestens ein Gelenkteil (18) zum Bilden eines Kugelgelenkes aufweisen.
15. Bausatz nach Anspruch 13 oder 14, dadurch gekennzeichnet, dass das Intervertebralimplantat (3) und die Platten (4,5) aus einem röntgendurchlässigen Werkstoff hergestellt sind.

16. Bausatz nach einem der Ansprüche 13 - 15, gekennzeichnet durch mehrere Knochenschrauben (25) und mehrere Befestigungsschrauben (7).
17. Bausatz nach Anspruch 16, dadurch gekennzeichnet, dass die Befestigungsschrauben Kugelkopfschrauben sind, die einen Schraubenkopf (8) aufweisen, der an seiner Unterseite im Wesentlichen halbkugelförmig ausgebildet ist.





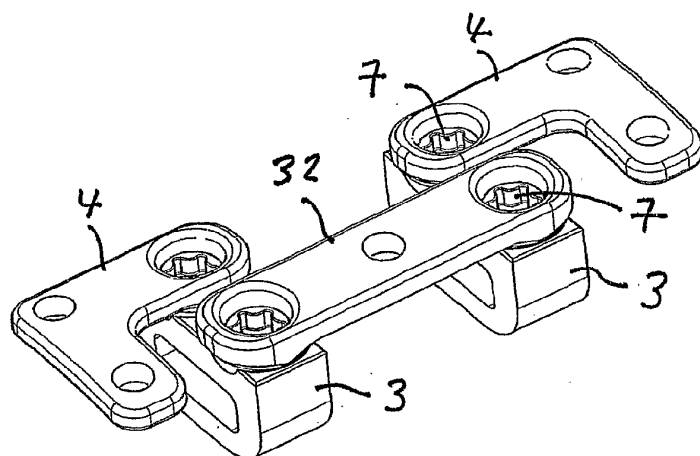


Fig. 7

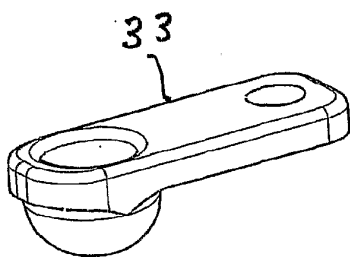


Fig. 8

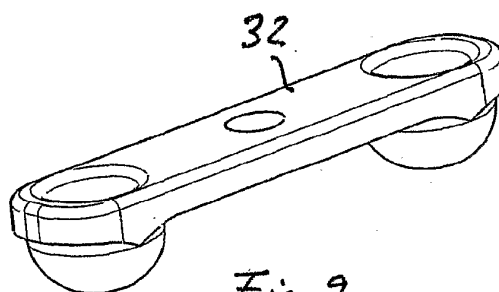


Fig. 9

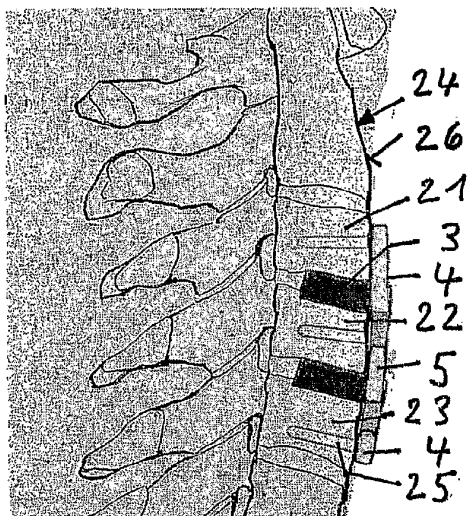


Fig. 10

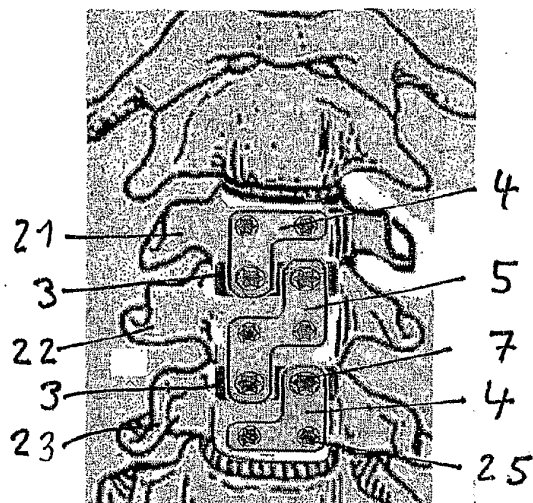


Fig. 11

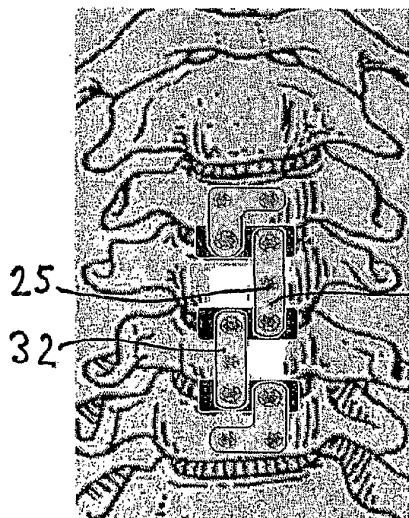


Fig. 12

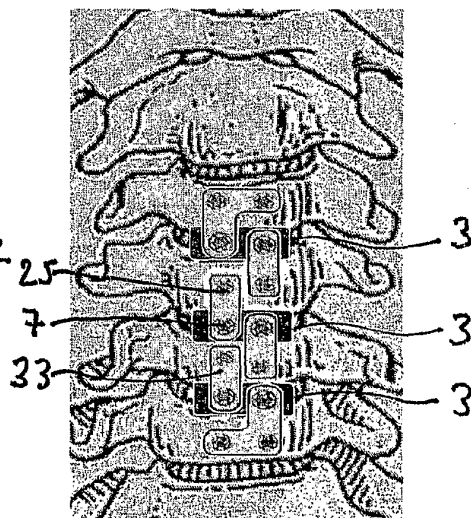


Fig. 13

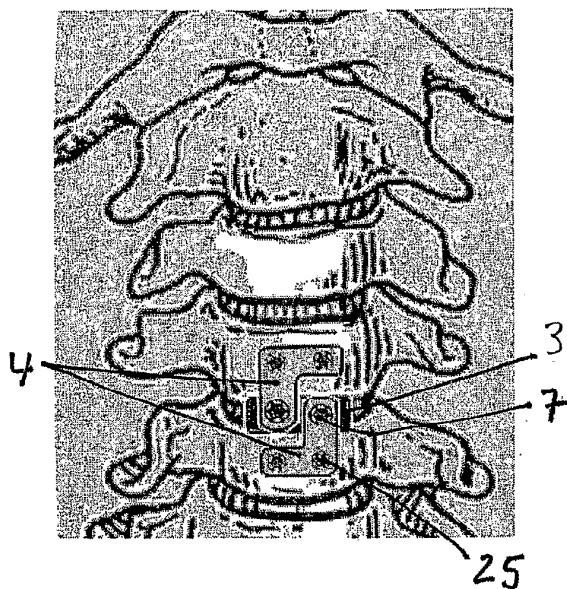


Fig. 14

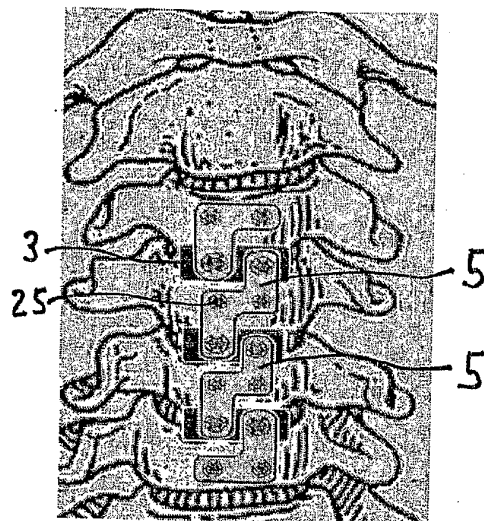


Fig. 15

INTERNATIONAL SEARCH REPORT

International Application No
PCT/CH2004/000244

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/44 A61F2/46

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 360 430 A (LIN CHIH-I) 1 November 1994 (1994-11-01) cited in the application claim 1; figures 1,2A-2H,2L-3	1,2,7, 11,12
Y		
A		8 13,16
X	US 5 443 515 A (COHEN ROBERT C ET AL) 22 August 1995 (1995-08-22) cited in the application figures 1-5 column 7, line 12 - line 48	1,2,7, 11,12
A		13,16
	----- -/--	



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

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Date of the actual completion of the international search

30 July 2004

Date of mailing of the international search report

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INTERNATIONAL SEARCH REPORT

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PCT/CH2004/000244

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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A	----- US 6 156 037 A (LEHUEC JEAN-CHARLES ET AL) 5 December 2000 (2000-12-05) claim 1; figures 2-6,13-16 column 3, line 51 - column 4, line 14	1-4,7,9, 13
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A	----- GB 1 243 353 A (LUMB WILLIAM) 18 August 1971 (1971-08-18) figures 5,7 page 2, line 91 - line 124 page 3, line 50 - line 105	1,2,10, 11
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/CH2004/000244

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INTERNATIONALER RECHERCHENBERICHT

nales Aktenzeichen

PCT/CH2004/000244

A. KLASSIFIZIERUNG DES ANMELDUNGSGEGENSTANDES
IPK 7 A61F2/44 A61F2/46

Nach der Internationalen Patentklassifikation (IPK) oder nach der nationalen Klassifikation und der IPK

B. RECHERCHIERTE GEBIETE

Recherchierte Mindestprüfstoff (Klassifikationssystem und Klassifikationssymbole)

IPK 7 A61B A61F

Recherchierte aber nicht zum Mindestprüfstoff gehörende Veröffentlichungen, soweit diese unter die recherchierten Gebiete fallen

Während der internationalen Recherche konsultierte elektronische Datenbank (Name der Datenbank und evtl. verwendete Suchbegriffe)

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C. ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie°	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
X	US 5 360 430 A (LIN CHIH-I) 1. November 1994 (1994-11-01) in der Anmeldung erwähnt Anspruch 1; Abbildungen 1,2A-2H,2L-3	1,2,7, 11,12
Y		8
A		13,16
X	US 5 443 515 A (COHEN ROBERT C ET AL) 22. August 1995 (1995-08-22) in der Anmeldung erwähnt Abbildungen 1-5 Spalte 7, Zeile 12 - Zeile 48	1,2,7, 11,12
A		13,16
	----- --/--	



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Angaben zu Veröffentlichungen, die zur selben Patentfamilie gehören

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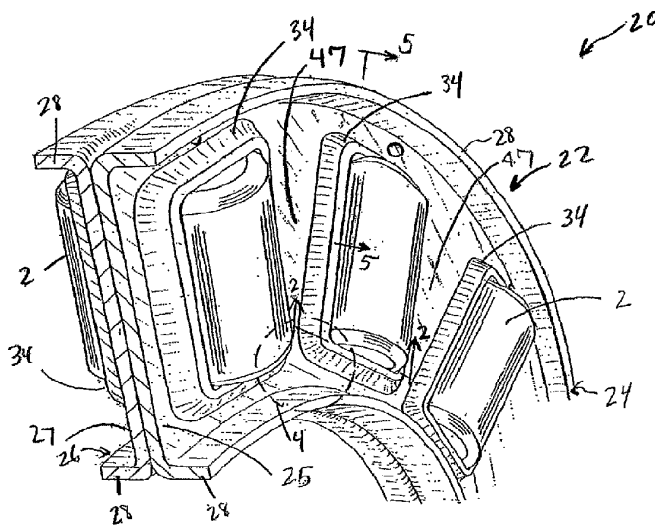
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(54) Title: THRUST BEARING ASSEMBLY



(57) Abstract: A thrust bearing assembly (20) generally includes a cage (22) and a plurality of rolling elements (2). The cage (22) has first and second cage halves (24,26) with each cage half having a respective radial segment (25,27) with a plurality of circumferentially spaced openings (30,32). Each opening has an opening perimeter. The cage halves (24,26) are interconnected with portions of the radial segments (25,27) circumferentially between the plurality of openings (30,32) abutting along a given plane and the respective openings (30,32) aligned to defined rolling element pockets. The rolling elements (2) are positioned in the rolling element pockets such that a centerline of each rolling element (2) lies in or in proximity to the given plane (P). A flange (34) extends along at least a portion of each opening perimeter to retain the rolling elements (2) within a respective one of the rolling element pockets.

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THRUST BEARING ASSEMBLY

CROSS REFERENCE TO OTHER APPLICATIONS

[0001] This application claims priority under 35 U.S.C. sec. 119 to provisional patent application no. 60/654,916, filed on Feb. 22, 2005, the entire contents of which is hereby incorporated by reference.

FIELD OF THE INVENTION

[0002] The present invention relates to a thrust bearing assembly and in particular to a needle roller thrust bearing assembly.

BACKGROUND OF THE INVENTION

[0003] Referring to Figs. 11 and 12, an example of a prior art needle roller thrust bearing 1 is shown. The bearing 1 includes a plurality of cylindrical rolling elements 2 arranged radially from a center of rotation. The rolling elements 2 are retained and guided by a bearing cage 3, which forms the primary structure of the bearing 1.

[0004] There are several types of construction currently used to produce metallic needle roller bearing cages 3. Figs. 13 and 14 show a thrust bearing 1A with a cage 3A that is constructed of two halves 4. Each half 4 has rectangular window openings 5 which are slightly smaller in width than the diameter of the rolling elements 2. Each cage half 4 also has circumferential flanges 6 which are directed inwardly towards the opposite member. When joined together, these two cage halves 4 form a box which provides structural integrity for the assembly, along with guidance for the rolling elements 2 and their retention in both directions.

[0005] A prior art thrust bearing 1B with a cage 3B having another construction is shown in Figs. 15 and 16. In this construction, the cage 3B is formed from a single piece of metal into a shape which, along with specially shaped openings, retains and guides the rolling elements 2. In cross-section, this type of cage 3B has a shape similar to that of the Greek letter sigma (Σ).

[0006] Another thrust bearing 1C having a cage 3C of yet another construction is shown in Figs. 17 and 18. Here, the cage 3C has a material thickness close to the diameter of

the rolling elements 2 and has rectangular openings 5 to accept the rolling elements 2. Retention is provided by staking 7 or otherwise forming the cage face near the openings 5 so that these are made smaller than the diameter of the rolling element 2.

SUMMARY OF THE INVENTION

[0007] In one embodiment, a thrust bearing assembly includes a cage and a plurality of rolling elements. The cage has first and second cage halves with each cage half having a respective radial segment with a plurality of circumferentially spaced openings. Each opening has an opening perimeter. The cage halves are interconnected with portions of the radial segments circumferentially between the plurality of openings abutting along a given plane and the respective openings aligned to define rolling element pockets. The rolling elements are positioned in the rolling element pockets such that a centerline of each rolling element lies in or in proximity to the given plane. A flange extends along at least a portion of each opening perimeter to retain the rolling elements within a respective one of the rolling element pockets. The flange may include a smooth rolled surface adjacent to each rolling element.

[0008] In another embodiment, a thrust bearing assembly includes a cage and a plurality of rolling elements. The cage has first and second cage halves with each cage half having a respective radial segment with a plurality of openings. Each opening has an opening perimeter and the cage halves are interconnected with portions of the radial segments abutting along a given plane. The respective openings are aligned to define rolling element pockets. The rolling elements are positioned in the rolling element pockets such that a centerline of each rolling element lies in or in proximity to the given plane. A flange extends along the entire perimeter of each respective opening to guide and retain the rolling elements within a respective one of the rolling element pockets.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] Fig. 1 is a partial isometric view of a needle roller thrust bearing assembly that is a first embodiment of the present invention;

[0010] Fig. 2 is a cross-sectional view along the line 2-2 in Fig. 1;

[0011] Fig. 3 is a cross-sectional view similar to Fig. 2 showing another embodiment of a thrust bearing assembly;

[0012] Fig. 4 is an exploded view of a portion of the cage as indicated by the circle 4 in Fig. 1 with the rolling elements removed for clarity;

[0013] Fig. 5 is a cross-sectional view along the lines 5-5 in Fig. 1;

[0014] Figs. 6-8 are cross-sectional views similar to Fig. 5 illustrating other embodiments of a thrust bearing assembly;

[0015] Fig. 9 is a cross-sectional view illustrating the needle roller thrust bearing assembly of Fig. 1 positioned between a pair of bearing surfaces;

[0016] Fig. 10 is a cross-sectional view similar to Fig. 9 showing another embodiment of a thrust bearing assembly;

[0017] Fig. 11 is a cross-sectional view along line 11-11 in Fig. 12;

[0018] Fig. 12 is a front elevation view of a prior art thrust bearing;

[0019] Fig. 13 is a partial cross-sectional view of an alternative prior art thrust bearing;

[0020] Fig. 14 is a partial isometric view of the cage of the thrust bearing of Fig. 13;

[0021] Fig. 15 is an isometric view of a cage of another prior art thrust bearing;

[0022] Fig. 16 is a partial cross-sectional view of the alternative thrust bearing using the cage of Fig. 15;

[0023] Fig. 17 is an isometric view of yet another alternative prior art thrust bearing;

[0024] Fig. 18 is a cross-sectional view along the line 18-18 in Fig. 17;

[0025] Fig. 19 is a cross-sectional view along the line 19-19 in Fig. 13; and

[0026] Fig. 20 is an exploded view of a portion of the cage as indicated by the circle 20 in Fig. 14.

DETAILED DESCRIPTION

[0027] The present invention will be described with reference to the accompanying drawing figures wherein like numbers represent like elements throughout. Certain terminology, for example, “top”, “bottom”, “right”, “left”, “front”, “frontward”, “forward”, “back”, “rear” and “rearward”, is used in the following description for relative descriptive clarity only and is not intended to be limiting.

[0028] Referring to Figs. 1 and 2, a needle roller thrust bearing assembly 20 that is a first embodiment of the present invention is shown. The thrust bearing assembly 20 includes a cage 22 supporting a plurality of preferably cylindrical rolling elements 2 arranged radially from a center of rotation (not shown). The cage 22 comprises two cage halves 24, 26. Each cage half 24, 26 includes a radially extending segment 25, 27 respectively with circumferentially spaced openings 30, 32 respectively. Each radially extending segment 25, 27 includes portions 47, 48 circumferentially between the plurality of openings 30, 32.

[0029] The openings 30, 32 are preferably generally rectangular and configured to receive the rolling elements 2. The cage halves 24, 26 are interconnected with the openings 30, 32 radially and circumferentially aligned and with at least portions such as portions 47, 48 of the radially extending segments 25, 27 abutting one another along a plane P. The centerline of each of the rolling elements 2 lies in or in proximity to the plane P. In this embodiment, circumferential flanges 28 are provided at the inner and outer diameters of the radial portions 25, 27 to provide a piloting surface for the thrust bearing assembly 20 and to provide additional structural rigidity for the cage 22.

[0030] Each opening 30, 32 has a flange 34 about at least a portion of or the entire opening perimeter. Each flange 34 extends outwardly from the plane P. The flanges 34 are formed in such a way as to guide and retain the rolling elements 2. An advantage of this design over the prior art cage 3 constructions is that any portion of the cage 22 of the present invention that contacts the rolling elements 2 has a smooth rolled and formed surface. In contradistinction, as shown in Fig. 19, the surfaces that contact the rolling elements 2 of the cage 3A are pierced such that the opening 5 is defined by rough pierced surfaces 10 which can interfere with proper lubrication and also lead to wear.

[0031] Fig. 2 illustrates how the configuration of the thrust bearing assembly 20 allows an effective lubricant film to be developed. Specifically, lubricant can be captured in the

generally triangular area defined between the rolling element 2 and the two abutting cage halves 24, 26. The abutting portions 47 and 48 close off the triangular area between the flanges 34 and prevent the lubricant from escaping circumferentially from adjacent the rolling element 2. Lubricant that either splashes into or is carried by adhesion to the rolling element 2 into this generally triangular area will tend to accumulate in this area and help promote a hydrodynamic lubricant film between the rolling element 2 and the surfaces 35 of the flanges 34. The smooth, generally convex surfaces 35 of the flanges 34 will minimize the "scraping" of lubricant off the rolling element 2 and will help maintain the presence of lubricant in the generally triangular area adjacent the rolling element 2. The smooth surfaces 35 also minimize direct contact between the rolling elements 2 and the cage 22, thereby reducing friction and wear.

[0032] Another form of the flange construction for rolling element openings 30, 32 is shown in Fig. 3. In this case, the cage halves 24A, 26A still abut on the plane P extending along or approximately along the centerline of the rolling elements 2, however, the flanges 34A along the length of the rolling elements 2 are divided into separate tabs 37. These tabs 37 are formed to present a smooth, generally conforming surface to the rolling elements, which is a variation of the smooth, generally convex surfaces 35 shown in Fig. 2. However, the tabs 37 are directed towards the opposite side of the rolling elements 2 rather than the closest side. In order to secure retention of the rolling elements in both directions, the tabs 37 are arranged so as to alternate on a portion of the perimeter such as along the length of the rolling elements 2. This sturdier construction allows a greater length of flange 34A. This additional length allows for greater flexibility in the shape of the flange 34A and is particularly useful for bearing assembly 20 with rolling elements having smaller diameters and that have tighter space restrictions for the cage 22.

[0033] In addition to improved wear and lubrication, another advantage of the cage 22 of thrust bearing assembly 20 is the substantially greater strength it provides compared to existing types of cage construction. This is particularly important in those areas with high concentrations of stress, such as the corners of the cage openings. Figure 20 shows a portion of a prior art cage 3A, taken near the inner diameter. It can be seen that the corners 13 of the cage openings 5 must be at right angles and relatively sharp to clear the rolling elements. The trapezoidal shape of the cage bars 14 between the openings 5 exacerbates this situation in the prior art designs because there is minimal cage material to resist stresses caused by radial and

torsional loads on the cage. Referring to Fig. 4, the flanges 34 of the thrust bearing assembly 20 includes a continuous surface at the corners 31 of the generally rectangular openings 30, 32. This structure can increase the cage strength in two ways. First, the flanges 34 provide additional material all around the openings 30 for the rolling elements 2. In the areas of high stress, such as corners 31 near the inner diameter, the flanges 34 can as much as double the amount of material available to resist these stresses. The cage openings 30 are further strengthened by the actual shape of the flanges 34. The flanges 34 are designed in such a way that the stresses are directed away from the corners 31 of the openings 30. The combination of additional material and optimized stress flow results in cage strength that is several times greater than that of the prior art constructions.

[0034] There are several possible ways to interconnect the two cage halves 24, 26 to form the rigid cage 22. Using the embodiment of the sealed bearing assembly 20 as shown in Figure 3, the rolling elements 3 can be snapped past the tabs 37 to join the cage halves 24A, 26A and form a unitary thrust bearing assembly 20.

[0035] Several additional examples of interconnecting the cage halves 24, 26 are shown in Figs. 5-8, however, other methods may also be utilized. Referring to Fig. 5, the cage halves 24, 26 are spot welded 40 at various points along the abutting radial portions 25 and 27. Fig. 6 illustrates a mechanical joint 42 created by partially piercing the radial portions 25, 27 and locking the two halves 24, 26 together. Referring to Fig. 7, a circumferential band 44 is secured to the inner and/or outer diameters of the cage halves 24, 26 about the inner or outer flanges 28 to secure the halves 24, 26 together. In the embodiment shown in Fig. 8, one of the cage halves 26B does not have a flange, but instead terminates in the radial portion 27. The other cage half 24B has a flange 46 extending from the radial portion 25 that extends toward and wraps around the radial portion 27. While the flange 46 is illustrated as being along the cage outer diameter, it is also possible to provide the flange 46 along the cage inner diameter.

[0036] Another advantage of the current invention is that various combinations of differently sized circumferential flanges 28 at the inner and outer diameter of the cage 22 can be used to control lubricant flow within the bearing assembly 20. In some cases it is desirable to restrict or partially restrict the lubrication flow, while in other cases it is desirable to allow as much flow as possible. For example, Fig. 9 shows the thrust bearing assembly 20 of Fig. 1 positioned between two structures 50 and 52. As can be seen, the inner and outer

diameter circumferential flanges 28 restrict the radial oil flow past the bearing assembly 20. Fig. 10 shows another embodiment thrust bearing assembly 20C positioned between structures 50, 52. The thrust bearing assembly 20C includes a cage 22C with interconnected halves 24C and 26C. Both halves 24C and 26C are without flanges which thereby allows more oil flow past the bearing assembly 20C. Other designs could incorporate partial or shorter flanges 28 to partially restrict flow.

[0037] The present invention addresses the essential requirements of a thrust bearing cage, namely, structure, guidance and retention, in a manner than greatly improves both the strength, rigidity, lubrication advantages, and the efficiency of the bearing assembly. Further, a low profile of the bearing assembly can be achieved.

[0038] Various features and advantages of the invention are set forth in the following claims.

CLAIMS

What is claimed is:

1. A thrust bearing assembly comprising:
a cage having first and second cage halves, each cage half having a respective radial segment with a plurality of circumferentially spaced openings, each opening having an opening perimeter, the cage halves being interconnected with portions of the radial segments circumferentially between the plurality of openings abutting along a given plane and the respective openings aligned to defined rolling element pockets;
a plurality of rolling elements positioned in the rolling element pockets such that a centerline of each rolling element lies in or in proximity to the given plane; and
a flange extending along at least a portion of each opening perimeter to retain the rolling elements within a respective one of the rolling element pockets.
2. The thrust bearing assembly of claim 1, wherein the centerline of each rolling element lies in the given plane.
3. The thrust bearing assembly of claim 1, wherein each flange extends along the entire perimeter of a respective opening.
4. The thrust bearing assembly of claim 1, wherein the openings are generally rectangular.
5. The thrust bearing assembly of claim 4, wherein each flange includes a continuous surface at corners of the generally rectangular openings.
6. The thrust bearing assembly of claim 1, wherein each flange is formed as a plurality of tabs, and tabs from one cage half alternate with tabs of the other cage half on at least a portion of a respective opening perimeter.
7. The thrust bearing assembly of claim 1, wherein at least one cage half includes a flange along an outer radius, the flange extending away from the given plane.

8. The thrust bearing assembly of claim 1, wherein at least one cage half includes a flange along an inner radius, the flange extending away from the given plane.

9. The thrust bearing assembly of claim 1, wherein the cage halves are joined together by one of spot welding, a mechanical joint, a circumferentially extending clamping band, and a portion of one cage half overlapping and clamping a portion of the other cage half.

10. The thrust bearing assembly of claim 1, wherein the cage halves are identical.

11. A thrust bearing assembly comprising:

a cage having first and second cage halves, each cage half having a respective radial segment with a plurality of openings, each opening having an opening perimeter, the cage halves being interconnected with respective openings of the halves being aligned to define rolling element pockets and with portions of the radial segments abutting along a given plane;

a plurality of rolling elements positioned in the rolling element pockets such that a centerline of each rolling element lies in or in proximity to the given plane; and

a flange extending along the entire perimeter of each opening to guide and retain the rolling elements within a respective one of the rolling element pockets.

12. The thrust bearing assembly of claim 11, wherein the centerline of each rolling element lies in the given plane.

13. The thrust bearing of claim 11, wherein the flange includes a smooth curved surface adjacent the rolling element.

14. The thrust bearing assembly of claim 11, wherein the openings are generally rectangular, and each flange includes a continuous surface at corners of the generally rectangular openings.

15. The thrust bearing assembly of claim 11, wherein each flange is formed as a plurality of tabs, and tabs from one cage half alternate with tabs of the other cage half on at least a portion of a respective opening perimeter.

16. The thrust bearing assembly of claim 11, wherein each cage half includes a flange along an outer radius, the flange extending away from the given plane.

17. The thrust bearing assembly of claim 11, wherein each cage half includes a flange along an inner radius, the flange extending away from the given plane.

18. The thrust bearing assembly of claim 11, wherein the cage halves are joined together by one of spot welding, a mechanical joint, a circumferentially extending clamping band, and a portion of one cage half overlapping and clamping a portion of the other cage half.

19. A thrust bearing assembly comprising:

a cage having first and second cage halves, each cage half having a plurality of circumferentially spaced openings and radial portions circumferentially between the plurality of openings, each opening having an opening perimeter, the cage halves being interconnected with the openings of respective halves being aligned to define rolling element pockets and with the radial portions abutting along a given plane;

a plurality of rolling elements positioned in the rolling element pockets such that a centerline of each rolling element lies in or in proximity to the given plane; and

a flange extending along the entire perimeter of each opening to guide and retain the rolling elements within a respective one of the rolling element pockets.

20. The thrust bearing assembly of claim 19, wherein each flange is formed as a plurality of tabs, and tabs from one cage half alternate with tabs of the other cage half on at least a portion of a respective opening perimeter.

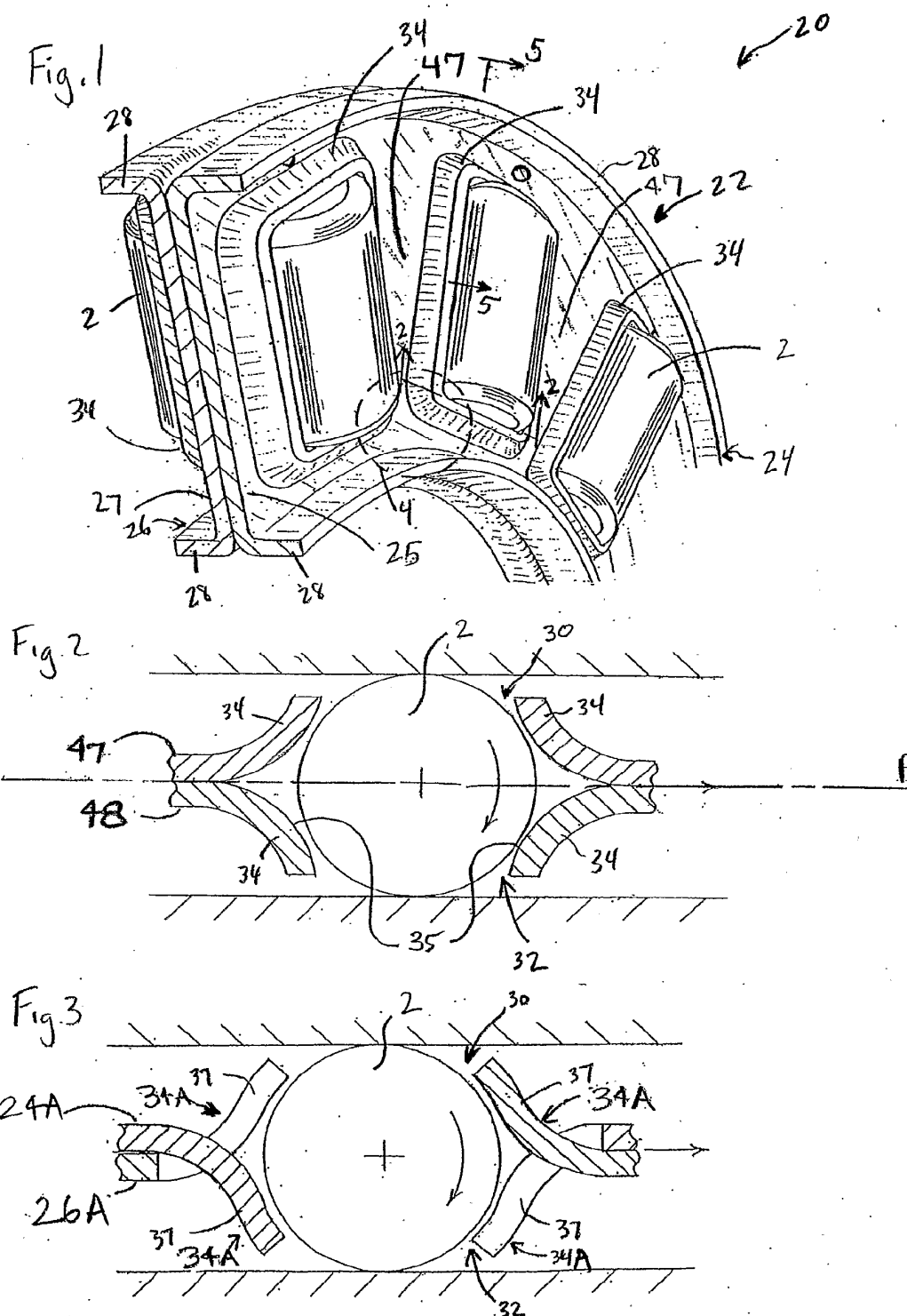


Fig. 4

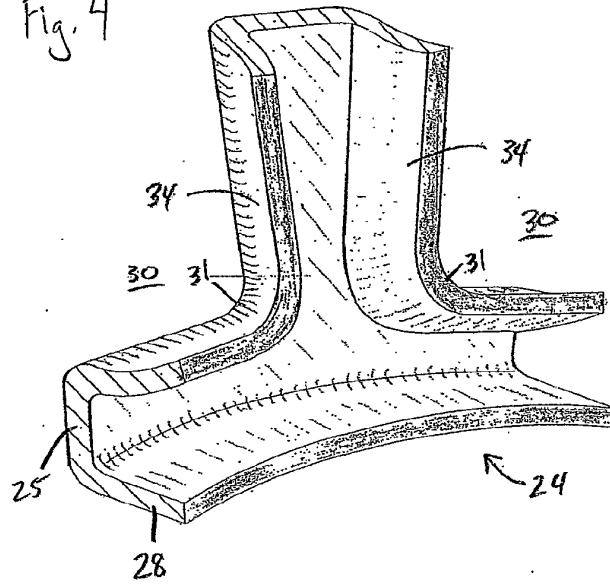
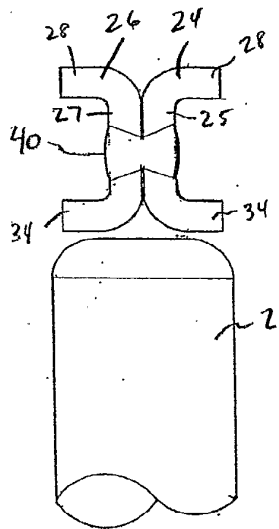


Fig. 5

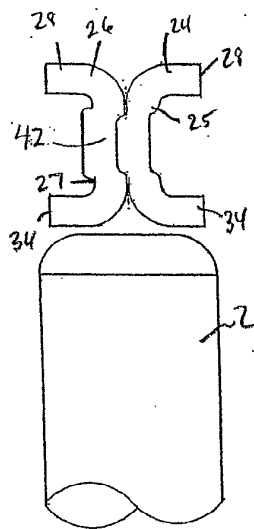


Fig. 6

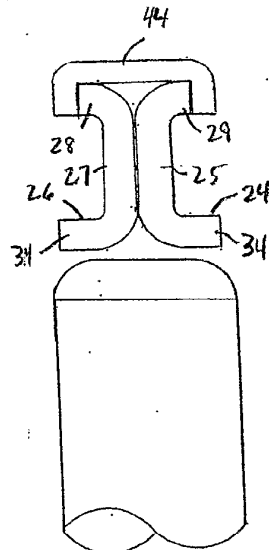


Fig. 7

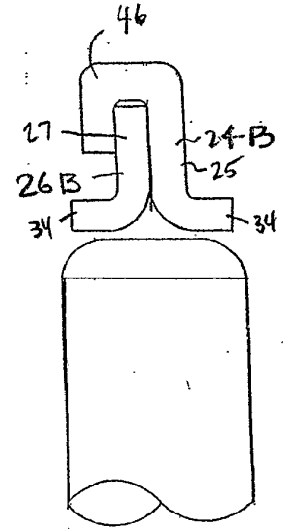


Fig. 8

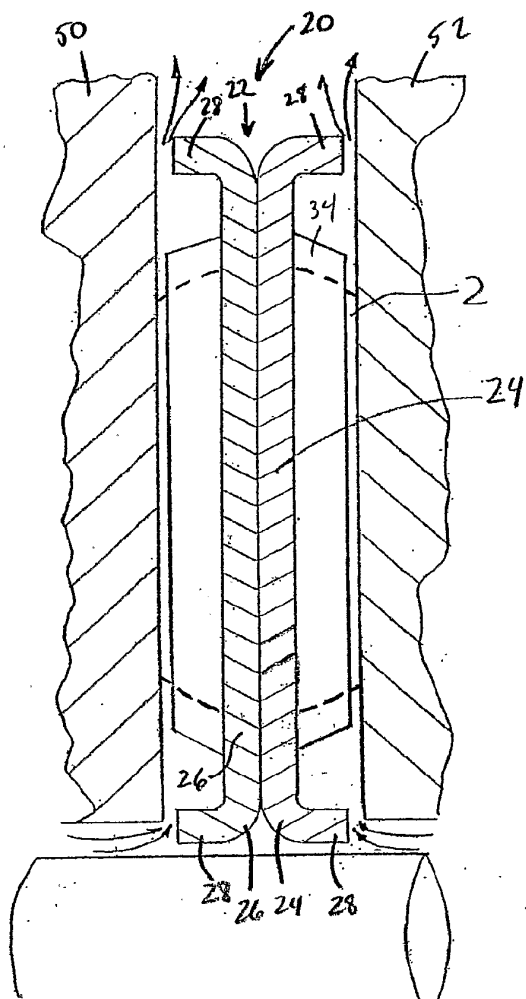


Fig. 9

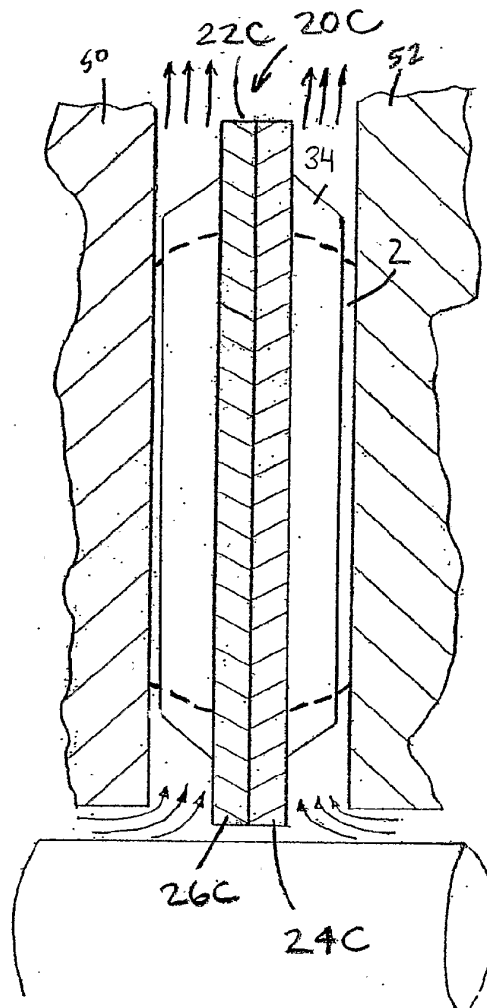
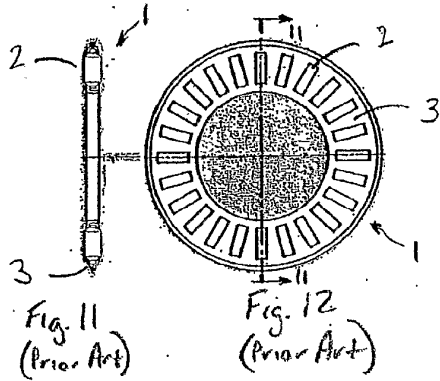
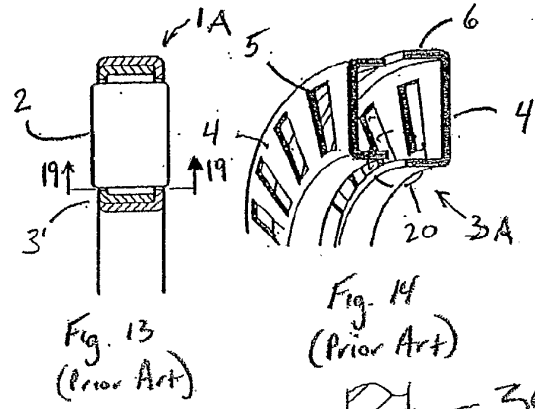
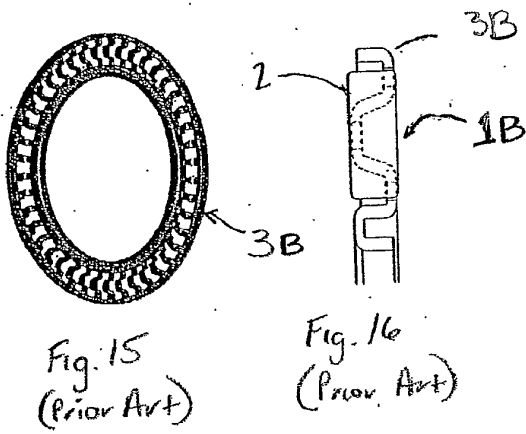
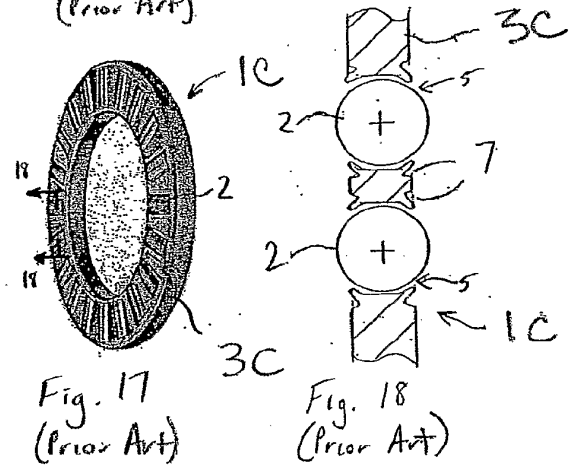
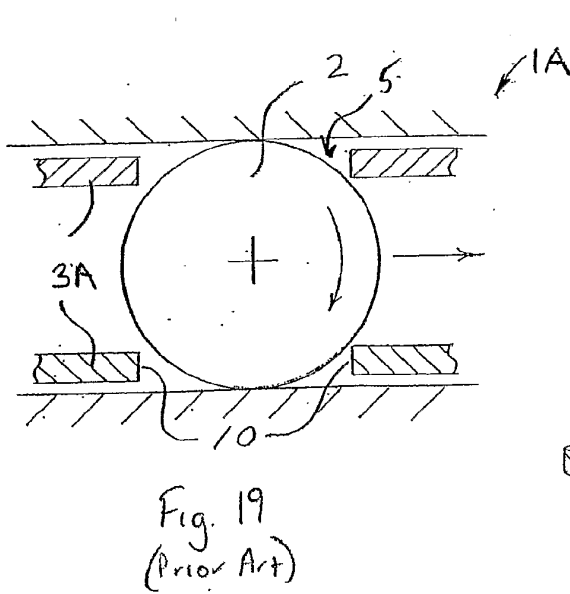
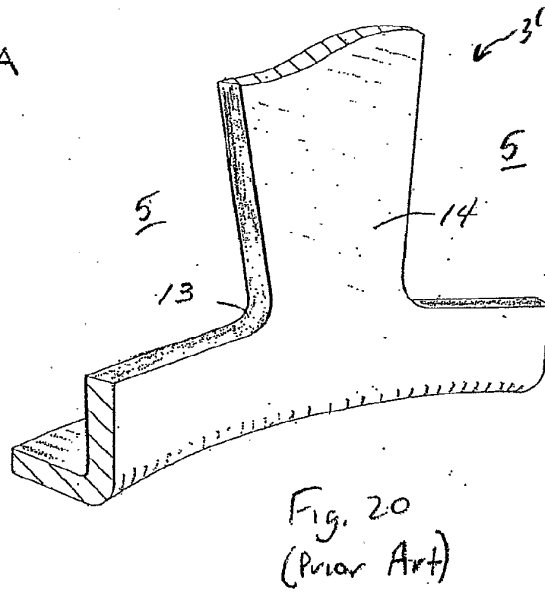


Fig. 10



INTERNATIONAL SEARCH REPORT

International application No
PCT/US2006/005789

A. CLASSIFICATION OF SUBJECT MATTER
INV. F16C33/54 F16C19/30

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
F16C

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	FR 2 242 595 A (SKF INDUSTRIAL TRADING DEV CY BV,NL; SKF INDUSTRIAL TRADING DEV CY BV) 28 March 1975 (1975-03-28) page 3, line 5 - line 11; figures 5-7 -----	1-5, 9-14,18, 19
X	US 2 978 282 A (FISHER WALTER) 4 April 1961 (1961-04-04) the whole document -----	1,2,4, 7-10
X	US 1 353 044 A (KEIPER HENRY B) 14 September 1920 (1920-09-14) page 1, line 59 - page 2, line 36; figures 1-4 -----	1-3,7-9, 11-13, 16-19
X A	US 1 734 222 A (MARLES HENRY) 5 November 1929 (1929-11-05) page 1, line 31 - line 83; figures 1-4 ----- -/--	1,2,4, 7-10 6

☒ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- * & * document member of the same patent family

Date of the actual completion of the international search

15 June 2006

Date of mailing of the international search report

30/06/2006

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Axelsson, T

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2006/005789

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	DE 21 14 697 A1 (INDUSTRIWERK SCHAEFFLER OHG) 12 October 1972 (1972-10-12) page 3; figures -----	1,6

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2006/005789

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
FR 2242595	A	28-03-1975	NONE	
US 2978282	A	04-04-1961	NONE	
US 1353044	A	14-09-1920	NONE	
US 1734222	A	05-11-1929	NONE	
DE 2114697	A1	12-10-1972	NONE	

Form PCT/ISA/210 (patent family annex) (April 2005)

RECEIVED

PATENT COOPERATION TREATY

DEC 6 2007

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

MG-IP Law, PLLC

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

To: Richard McGrath McGrath, Geissler, Olds & Richardson, PLLC P.O. Box 1364 Fairfax, Virginia 22038

CFJ 12/6/07
OUG: 2/3/08

Date of mailing (day month year)	03 DEC 2007
Applicant's or agent's file reference 3003/101 PWO2	FOR FURTHER ACTION See paragraphs 1 and 4 below
International application No. PCT/US 07/05005	International filing date (day month year) 28 February 2007 (28.02.2007)
Applicant MOSKOWITZ, Nathan	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Facsimile No.: +41 22 740 14 35

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to the protest against payment of (an) additional fee(s) under Rule 40.2,** the applicant is notified that:

☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774
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Form PCT/ISA/220 (January 2004)

(See notes on accompanying sheet)

From the INTERNATIONAL BUREAU

PCT

FIRST NOTICE INFORMING THE APPLICANT OF
THE COMMUNICATION OF THE INTERNATIONAL
APPLICATION (TO DESIGNATED OFFICES WHICH
DO NOT APPLY THE 30 MONTH TIME LIMIT
UNDER ARTICLE 22(1))

(PCT Rule 47.1(c))

Date of mailing (<i>day/month/year</i>) 22 November 2007 (22.11.2007)		To: MCGRATH, Richard McGrath, Geissler, Olds & Richardson, PLLC P.O. Box 1364 Fairfax, Virginia 22038 ETATS-UNIS D'AMERIQUE	
Applicant's or agent's file reference 3003/101PWO2			
International application No. PCT/US2007/005005		International filing date (<i>day/month/year</i>) 28 February 2007 (28.02.2007)	Priority date (<i>day/month/year</i>) 04 April 2006 (04.04.2006)
Applicant MOSKOWITZ, Nathan et al			

IMPORTANT NOTICE

1. **ATTENTION:** For any designated Office(s), for which the time limit under Article 22(1), as in force from 1 April 2002 (30 months from the priority date), **does apply**, please see Form PCT/IB/308(Second and Supplementary Notice) (to be issued promptly after the expiration of 28 months from the priority date).

2. Notice is hereby given that the following designated Office(s), for which the time limit under Article 22(1), as in force from 1 April 2002, **does not apply**, has/have requested that the communication of the international application, as provided for in Article 20, be effected under Rule 93bis.1. The International Bureau has effected that communication on the date indicated below:
15 November 2007 (15.11.2007)

None

In accordance with Rule 47.1(c-bis)(i), those Offices will accept the present notice as conclusive evidence that the communication of the international application has duly taken place on the date of mailing indicated above and no copy of the international application is required to be furnished by the applicant to the designated Office(s).

3. The following designated Offices, for which the time limit under Article 22(1), as in force from 1 April 2002, **does not apply**, have not requested, as at the time of mailing of the present notice, that the communication of the international application be effected under Rule 93bis.1:

CH, LU, TZ, UG

In accordance with Rule 47.1(c-bis)(ii), those Offices accept the present notice as conclusive evidence that the Contracting State for which that Office acts as a designated Office does not require the furnishing, under Article 22, by the applicant of a copy of the international application.

4. TIME LIMITS for entry into the national phase

For the designated Office(s) listed above, and unless a demand for international preliminary examination has been filed before the expiration of **19 months** from the priority date (see Article 39(1)), the applicable time limit for entering the national phase will, **subject to what is said in the following paragraph**, be **20 MONTHS** from the priority date.

In practice, **time limits other than the 20-month time limit** will continue to apply, for various periods of time, in respect of certain of the designated Offices listed above. For **regular updates on the applicable time limits** (20 or 21 months, or other time limit), Office by Office, refer to the *PCT Gazette*, the *PCT Newsletter* and the *PCT Applicant's Guide*, Volume II, National Chapters, all available from WIPO's Internet site, at <http://www.wipo.int/pct/en/index.html>.

It is the applicant's **sole responsibility** to monitor all these time limits.

RECEIVED**DEC 3 2007**CF3 1214107
51A

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer MG-IP Law, PLLC Beate Giffo-Schmitt <i>CF3</i>
Facsimile No. +41 22 338 82 70	e-mail: pt03.pct@wipo.int

Form PCT/IB/308(First Notice) (January 2004)

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

To: Richard McGrath McGrath, Geissler, Olds & Richardson, PLLC P.O. Box 1364 Fairfax, Virginia 22038	<div style="text-align: center; font-size: 1.2em; font-weight: bold;">03 DEC 2007</div>
Applicant's or agent's file reference 3003/101 PWO2	FOR FURTHER ACTION See paragraphs 1 and 4 below
International application No PCT/US 07/05005	International filing date (day month year) 28 February 2007 (28.02.2007)
Applicant MOSKOWITZ, Nathan	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:
 The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
 1211 Geneva 20, Switzerland, Facsimile No.: +41 22 740 14 35

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:**

☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90*bis*.1 and 90*bis*.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: <div style="text-align: center; margin-top: 10px;">Lee W. Young</div> <div style="font-size: 0.8em; margin-top: 10px;"> PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774 </div>
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Form PCT/ISA/220 (January 2004)

(See notes on accompanying sheet)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 3003/101 PWO2	FOR FURTHER ACTION	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/US 07/05005	International filing date <i>(day/month/year)</i> 28 February 2007 (28.02.2007)	(Earliest) Priority Date <i>(day/month/year)</i> 04 April 2006 (04.04.2006)
Applicant MOSKOWITZ, Nathan		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 2 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of:

☒ the international application in the language in which it was filed.

☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6bis(a)).

c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (see Box No. II).

3. ☐ **Unity of invention is lacking** (see Box No. III).

4. With regard to the **title**,

☐ the text is approved as submitted by the applicant.

☒ the text has been established by this Authority to read as follows:

ARTIFICIAL DISC FOR POSTERIOR PLACEMENT IN THE LUMBAR SPINE

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

a. the figure of the **drawings** to be published with the abstract is Figure No. 17A

☐ as suggested by the applicant.

☐ as selected by this Authority, because the applicant failed to suggest a figure.

☒ as selected by this Authority, because this figure better characterizes the invention.

b. ☐ none of the figures is to be published with the abstract.

Form PCT/ISA/210 (first sheet) (April 2007)

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 07/05005

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61F 2/44 (2007.01)

USPC - 623/17.15

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
USPC: 623/17.15Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC: All classes (text search--see keywords)Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PubWEST (PGPB, USPT, EPAB, JPAB), Google Scholar, Google Patents
Keywords: Expand, expandable, frame, scaffold, structure, implant, prosthetic, disc, vertebrae, spine, bifunctional, screw, worm, nut, sliding, tray, plate, lateral, thread, oblique, spike, tooth, conical

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2005/0278026 A1 (GORDON et al.) 15 December 2005 (15.12.2005) para [0148], [0163], [0253], [0259], [0262]; Fig 40, 41, 47a, 50a, 50b	16 and 21-23
Y	US 2005/0216084 A1 (FLEISCHMANN et al.) 29 September 2005 (29.09.2005) Fig 1a, 3a	3-4
Y	US 2005/0027362 A1 (WILLIAMS et al.) 03 February 2005 (03.02.2005) para [0062], [0066], [0067]; Fig 5c, 5e	10, 17, 19 and 20
Y	US 2005/0049590 A1 (ALLEYNE et al.) 03 March 2005 (03.03.2005) para [0033]; Fig 5b, 9b, 10a	1-10
Y	US 2004/0254644 A1 (TAYLOR) 16 December 2004 (16.12.2004) para [0071]; Fig 1, 8	1-10
X		11-15 and 18
--	US 4,997,432 A (KELLER) 05 March 1991 (05.03.1991) col 1, ln 19-29; col 4, ln 59 to col 5, ln 39; col 5, ln 58 to col 6, ln 2; Fig 1-3, 5, 7	1-10, 16, 17 and 19-23
Y		

☐ Further documents are listed in the continuation of Box C.

* Special categories of cited documents:	"I" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier application or patent but published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

03 October 2007 (03.10.2007)

Date of mailing of the international search report

03 DEC 2007

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-3201

Authorized officer:

Lee W. Young

PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (April 2007)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: Richard McGrath
McGrath, Geissler, Olds & Richardson, PLLC
P.O. Box 1364
Fairfax, Virginia 22038

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing (day/month/year) 03 DEC 2007	
Applicant's or agent's file reference 3003/101 PWO2	FOR FURTHER ACTION See paragraph 2 below
International application No. PCT/US 07/05005	International filing date (day month year) 28 February 2007 (28.02.2007)
Priority date (day month year) 04 April 2006 (04.04.2006)	
International Patent Classification (IPC) or both national classification and IPC IPC(8) - A61F 2/44 (2007.01) USPC - 623/17.15	
Applicant MOSKOWITZ, Nathan	

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Date of completion of this opinion 03 October 2007 (03.10.2007)	Authorized officer: Lee W. Young <small>PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774</small>
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Form PCT/ISA/237 (cover sheet) (April 2007)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US 07/05005

Box No. 1 Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed.
 - ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of:
 - a. type of material
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material
 - ☐ on paper
 - ☐ in electronic form
 - c. time of filing/furnishing
 - ☐ contained in the international application as filed
 - ☐ filed together with the international application in electronic form
 - ☐ furnished subsequently to this Authority for the purposes of search
4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US 07/05005

Box No. V	Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
1. Statement			
Novelty (N)	Claims	1-10, 14-17 and 19-23	YES
	Claims	11-13 and 18	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-23	NO
Industrial applicability (IA)	Claims	1-23	YES
	Claims	None	NO
2. Citations and explanations:			
<p>Claims 11-13 and 18 lack novelty under PCT Article 33(2) as being anticipated by US 4,997,432 A (Keller).</p> <p>As pertaining to claim 11, Keller teaches a disc comprising: a pair of substantially parallel plates 3, that move apart along a first axis, in order to occupy a space defined by vertebral endplates 1 (col 4, ln 54-59; Fig 1); an expansion device 9, that moves the pair of plates 3 along the first axis (col 5, ln 3-39; Fig 2); a core 4, disposed between the pair of plates 3, that permits the vertebral endplates to move relative to one another (col 4, ln 67 to col 5, ln 2; Fig 1); and a limiter 7 which prevents the core 4 from being extruded from between the substantially parallel plates 3 (col 4, ln 67 to col 5, ln 1; Fig 1).</p> <p>As pertaining to claim 12, Keller teaches the above disc of claim 11. Keller also teaches a disc wherein the limiter 7 includes a substantially ring shaped member having a raised edge, and the core 4 is disposed within said limiter (Fig 1).</p> <p>As pertaining to claim 13, Keller teaches the above disc of claim 12. Keller also teaches a disc wherein the limiter 3 includes a second substantially ring shaped member, said first and second substantially ring shaped members include raised barriers that prevent the extrusion of the core 4 (Fig 1).</p> <p>As pertaining to claim 18, Keller teaches the above disc of claim 11. Keller also teaches a disc wherein the limiter 3 includes a ring shaped member having raised edges that surround said core 4 (Fig 1).</p> <p>Claims 14 and 15 lack an inventive step under PCT Article 33(3) as being obvious over Keller.</p> <p>As pertaining to claim 14, Keller teaches the above disc of claim 13. Keller also teaches a disc wherein at least one of the substantially ring shaped members fits into a groove formed in the core (Fig 1). Keller also teaches a disc wherein the plates slide with respect to each other (col 1, ln 19-29). While Keller does not expressly show rotation of the plates, it would have been obvious to one of ordinary skill in the art that a set of circular plates placed around a circular core with no rotational limiters would allow the plates to rotate with respect to each other.</p> <p>As pertaining to claim 15, Keller teaches the above disc of claim 14. Keller also teaches a disc wherein the core 4 includes an ellipsoidal shaped member having superior and inferior domes, and the groove is formed in the exterior periphery of the core (Fig 1).</p> <p>Claims 16 and 21-23 lack an inventive step under PCT Article 33(3) as being obvious over Keller in view of US 2005/0278026 A1 to GORDON et al. (hereinafter 'Gordon').</p> <p>As pertaining to claim 16, Keller teaches the above disc of claim 15. Gordon also teaches a disc wherein the substantially parallel plates include alignment holes 182 (para [0163]). It would have been obvious for one of ordinary skill in the art to combine these references as both teach replacement discs, with Gordon teaching a disc which may allow disc rotation but will not allow rotation beyond a certain point, preventing over-rotation of the spine.</p> <p>---Continued in Supplemental Box---</p>			

Form PCT/ISA/237 (Box No. V) (April 2007)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US 07/05005

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:
Box V, Sect. 2

As pertaining to claim 21, Keller teaches a tool comprising:

a pair of manipulators 10 and 11 each having a cradle for each of said plates 3 (col 5, ln 29-39; Fig 2, 3),

wherein the manipulators force the spikes 6 of said plates into the vertebral end plates 1 (col 4, ln 59-64; Fig 1, 5); and

wherein the tool is used to insert the pair of plates, disposed in the cradles of the separators, between a pair vertebral endplates (col 6, ln 29-50).

Keller does not show alignment members, a wedge separator, or posterior insertion.

Gordon teaches a tool comprising:

a pair of manipulators each having a cradle 716 for a plate 488 and an insert 470, said cradles including threaded alignment members 726 (Fig 40, 41, 47a); and

a wedge separator 778 disposed between a pair of manipulators 780 and 782 (para [0253]; Fig 50a, 50b);

wherein the tool is used to posteriorly insert the pair of plates, disposed in the cradles of the separators, between a pair vertebral endplates (para [0253], [0259], [0262]);

wherein said wedge separator is used to separate said pair of plates (para [0253], [0262]).

While Gordon does not show that the alignment members cooperate with the first alignment members of the plates, it would have been obvious to one of ordinary skill in the art that the alignment members would have to cooperate with the first alignment members in order to expand the plate assembly of claim 10, as the assembly of claim 10 is expanded by means of the first alignment member (see claims 1 and 10).

As pertaining to claim 22, Keller and Gordon teach the above tool of claim 21. Gordon also teaches a tool wherein the separator 778 is actuated by a push/pull rod 782 (para [0253]; Fig 50a, 50b). While Gordon does not show that the rod includes digit inserts for operator of the tool, it would have been obvious to one of ordinary skill in the art that such a modification would allow for more precise maneuvering of the tool.

As pertaining to claim 23, Keller and Gordon teach the above tool of claim 22. Keller also teaches a tool wherein a separator 4 is attached to a manipulator 23 (col 5, ln 58 to col 6, ln 2; Fig 7). While Keller does not show that the separator is attached by a transmission linkage, it does teach that the cradle manipulators 10 and 11 may be interconnected by a linkage 12 (Fig 2). It would have been obvious to one of ordinary skill in the art that the separator mechanism might be attached to a manipulator by a transmission linkage in order to reduce the complexity of the procedure and reduce the size of the incision needed to insert the required tools.

Claims 17, 19 and 20 lack an inventive step under PCT Article 33(3) as being obvious over Keller in view of US 2005/0027362 A1 to WILLIAMS et al. (hereinafter 'Williams').

As pertaining to claim 17, Keller teaches the above disc of claim 11. Keller also teaches a disc wherein the substantially parallel plates contain an array of spikes 6 (col 4, ln 59-64; Fig 1, 5). Williams teaches a disc wherein the substantially parallel plates contain an array of spikes, said spikes including conical and angled spikes (para [0062], [0067]; Fig 5c, 5e). While Williams does not show pyramidal spikes, it does teach square spikes, which are very similar in form and function to pyramidal spikes. It would have been obvious to one of ordinary skill in the art that the conical spike should be central, as it will be subjected to varying forces from all angles. It would have been obvious to one of ordinary skill in the art that the pyramidal spikes should be on the edge, as the forces on them will tend to come perpendicular and parallel to the edge. It would have been obvious to one of ordinary skill in the art that the angled spikes should be between the pyramidal pikes and the center, as the forces on them will tend to come from the closer edge of the implant. It would have been obvious for one of ordinary skill in the art to combine these references as both teach replacement discs, with Keller teaching a disc with securing spikes and Williams teaching the specific configuration of said spikes.

As pertaining to claim 19, Keller teaches the above disc of claim 18. Williams teaches a disc wherein the disc may be constructed of radiolucent or traditional materials (para [0066]). While Williams does not specifically show that radiopaque materials are used in the ring-shaped member, it would have been obvious to one of ordinary skill in the art that such a composition would allow for radiographic identification of the disc and easier placement of the core while not obscuring the vertebral endplates.

As pertaining to claim 20, Keller and Williams teach the above disc of claim 19. Keller teaches a disc wherein the core 4 includes superior and inferior domes (Fig 1).

---Continued in Supplemental Box---

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 07/05005

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:
Box V, Sect. 2

Claims 1, 2 and 5-9 lack an inventive step under PCT Article 33(3) as being obvious over Keller in view of US 2004/0254644 A1 (TAYLOR) and US 2005/0049590 A1 to ALLEYNE et al. (hereinafter 'Alleyne').

As pertaining to claim 1, Keller teaches a disc comprising:

a pair of substantially parallel plates 3, that move apart along a first axis, in order to occupy a space defined by vertebral endplates 1 (col 4, ln 54-59; Fig 1);

a core 4, disposed between the pair of plates 3, that permits the vertebral endplates to move relative to one another (col 4, ln 67 to col 5, ln 2; Fig 1); and

a limiter 7 which prevents the core 4 from being extruded from between the substantially parallel plates 3 (col 4, ln 67 to col 5, ln 1; Fig 1). Keller does not teach plate expansion or multi-axial expansion.

Taylor teaches a disc comprising at least one pair of substantially parallel plates 12 and 14 which occupy a space defined by vertebral endplates, each of said parallel plates including a first plate 12 or 14 and a second extending plate 18 that moves along a horizontal axis (para [0044], [0053]; Fig 1). While Taylor does not show that the second plates slide, it would have been obvious to one of ordinary skill in the art that the plates slide with regards to the extending wedge 97 and that the hinges 22 could be replaced with sliding track members similar to the wedge track 95 (para [0071]; Fig 1, 8).

Alleyne teaches an expansion device that expands a fixation member 112 and 126 along horizontal or vertical axes, respectively, with respect to the fixation driver 120 (Fig 9b, 10a). While Alleyne does not show in these embodiments that the members are moved along both axes in the same device, it does teach that the device may be expanded both horizontally and vertically (para [0033]). It would have been obvious to one of ordinary skill in the art that the two mechanisms could be combined for fixation along two axes to provide a more secure fixation along four planes rather than two.

It would have been obvious for one of ordinary skill in the art to combine these references as all teach spinal replacement systems, with Keller teaching the basic disc system, Taylor teaching a method of expanding plates to accommodate larger vertebrae, and Alleyne teaching a system which can expand the system along two axes.

As pertaining to claim 2, Keller, Taylor, and Alleyne teach the above disc of claim 1. Keller also teaches a disc wherein the limiter 7 includes a substantially ring shaped member having a raised edge, and the core 4 is disposed within said limiter (Fig 1).

As pertaining to claim 5, Keller, Taylor, and Alleyne teach the above disc of claim 1. Alleyne also teaches an expansion device wherein the expansion device includes a plurality of threaded worm gears that expand a fixation member 112 or 126 along horizontal or vertical axes, respectively, with respect to the fixation driver 104 or 120 (Fig 9b, 10a). While Alleyne does not show that the members are moved along both axes in the same device, it would have been obvious to one of ordinary skill in the art that the two mechanisms would be combined to provide for fixation in two axes to provide a more secure fixation along four planes rather than two. It would also have been obvious to one of ordinary skill in the art that a screw could be substituted for the threaded worm gear.

As pertaining to claim 6, Keller, Taylor, and Alleyne teach the above disc of claim 5. Alleyne also teaches an expansion device wherein the expansion device further includes a plurality of adjustment screws 126 and slotted worm nuts 122 and 124 that cooperate with the threaded worm gear 120 (Fig 10a).

As pertaining to claim 7, Keller, Taylor, and Alleyne teach the above disc of claim 6. Alleyne also teaches an expansion device wherein the threaded worm gears 120 include threads which cooperate with the slots on the worm nuts 122 and 124, said worm nuts being internally threaded and cooperating with threads disposed on the adjustment screws 126 (Fig 10a). Alleyne also teaches a device wherein the driving screw 31 includes threads which cooperate with openings disposed on a first plate 30 (Fig 5b).

As pertaining to claim 8, Keller, Taylor, and Alleyne teach the above disc of claim 7. While Alleyne does not show that the expansion device is removed upon completion of the expansion, Alleyne's device does not use a mobile core (Fig 9b, 10a). It would have been obvious to one of ordinary skill in the art that in order for a flexion-permitting core to be introduced and properly used, the expansion device would have to be removed.

As pertaining to claim 9, Keller, Taylor, and Alleyne teach the above disc of claim 8. Keller also teaches a disc which further includes a trough 7 disposed in the center of the parallel plates 3 which receives the core 4 (Fig 1).

Claims 3 and 4 lack an inventive step under PCT Article 33(3) as being obvious over Keller in view of Taylor, in further view of Alleyne, and still in view of US 2005/0216084 A1 to FLEISCHMANN et al. (hereinafter 'Fleischmann').

As pertaining to claim 3, Keller, Taylor, and Alleyne teach the above disc of claim 2. Fleischmann teaches a disc wherein the limiter includes two substantially ring shaped members 10b, wherein the core includes a pair of flanges 20 at the top and bottom of the core, and wherein the flanges of the core are ensconced within the two ring shaped members of said limiter (Fig 1a, 3a). It would have been obvious for one of ordinary skill in the art to combine these references as Keller teaches a disc with a core and Fleischmann teaches a way of securing such a core.

As pertaining to claim 4, Keller, Taylor, Alleyne, and Fleischmann teach the above disc of claim 3. Keller also teaches a disc which further includes a trough 7 disposed in the center of the parallel plates 3 which receives the core 4 (Fig 1).

---Continued in Supplemental Box---

NOTES TO FORM PCT/ISA/220 (continued)

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers, claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
2. [Where originally there were 15 claims and after amendment of all claims there are 11]:
"Claims 1 to 15 replaced by amended claims 1 to 11."
3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
4. [Where various kinds of amendments are made]:
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under Article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international application is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments and any accompanying statement, under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the time of filing the amendments (and any statement) with the International Bureau, also file with the International Preliminary Examining Authority a copy of such amendments (and of any statement) and, where required, a translation of such amendments for the procedure before that Authority (see Rules 55.3(a) and 62.2, first sentence). For further information, see the Notes to the demand form (PCT/IPEA/401).

If a demand for international preliminary examination is made, the written opinion of the International Searching Authority will, except in certain cases where the International Preliminary Examining Authority did not act as International Searching Authority and where it has notified the International Bureau under Rule 66.1bis(b), be considered to be a written opinion of the International Preliminary Examining Authority. If a demand is made, the applicant may submit to the International Preliminary Examining Authority a reply to the written opinion together, where appropriate, with amendments before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later (Rule 43bis.1(c)).

Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see the *PCT Applicant's Guide*, Volume II.

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To: MATTHEW T. SHANLEY
McGrath Geissler Olds & Richardson, PLLC
PO Box 1364
Fairfax, Virginia 22082

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Date of mailing (day/month/year) 09 JUL 2008	
Applicant's or agent's file reference 30030105pwo1	FOR FURTHER ACTION See paragraphs 1 and 4 below
International application No. PCT/US2007/021013	International filing date (day/month/year) 01 October 2007
Applicant MOSKOWITZ, Ahmnon D.	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Facsimile No.: +41 22 740 14 35

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.
3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:
- ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
- ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90*bis*.1 and 90*bis*.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-3201

Authorized officer:

Blaine R. Copenheave

Telephone No. 571-272-7774

RECEIVED

Form PCT/ISA/220 (January 2004)

(See notes on accompanying sheet)

JUL 10 2008

ENTERED
JUL 11 10 08
DUE: 8/9/08

MG-IP Law, PLLC

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

To: MATTHEW T. SHANLEY
McGrath Geissler Olds & Richardson, PLLC
PO Box 1364
Fairfax, Virginia 22082

Date of mailing
(day/month/year) **09 JUL 2008**

Applicant's or agent's file reference
30030105pwo1

FOR FURTHER ACTION See paragraphs 1 and 4 below

International application No.
PCT/US2007/021013

International filing date
(day/month/year) 01 October 2007

Applicant **MOSKOWITZ, Ahmnon D.**

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Facsimile No.: +41 22 740 14 35

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to the protest against payment of (an) additional fee(s) under Rule 40.2,** the applicant is notified that:

☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. Reminders

Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-3201

Authorized officer:

Blaine R. Copenheaver

Telephone No. 571-272-7774

Form PCT/ISA/220 (January 2004)

(See notes on accompanying sheet)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 30030105pwo1	<div style="display: flex; justify-content: space-between;"> <div> FOR FURTHER ACTION </div> <div> see Form PCT/ISA/220 as well as, where applicable, item 5 below. </div> </div>	
International application No. PCT/US2007/021013	International filing date (<i>day/month/year</i>) 01 October 2007	(Earliest) Priority Date (<i>day/month/year</i>) 29 September 2006
Applicant MOSKOWITZ, Ahmnon D.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 3 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of:

- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

b. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (see Box No. II)

3. ☒ **Unity of invention is lacking** (see Box No. III)

4. With regard to the **title**,

- ☒ the text is approved as submitted by the applicant
- ☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

- ☒ the text is approved as submitted by the applicant
- ☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings**,

a. the figure of the **drawings** to be published with the abstract is Figure No. 1A

- ☒ as suggested by the applicant
- ☐ as selected by this Authority, because the applicant failed to suggest a figure
- ☐ as selected by this Authority, because this figure better characterizes the invention

b. ☐ none of the figures is to be published with the abstract

Form PCT/ISA/210 (first sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2007/021013

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

Group I, claims 1-15 and 24, drawn to a self drilling bone fusion screw apparatus comprising a first box and first and second screw members.

Group II, claims 16-17 and 25, drawn to a tool assembly comprising a gripper and screw guide held in place by the plurality of prongs.

Group III, claims 18-22, drawn to a cervical facet staple and impaction tool comprising an insertion member disposed on the top surface of the curved staple base.

Group IV, claim 23, drawn to a lumbar facet staple comprising a pair of rotating arms and a ratchet attached to one of the rotating arms.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-15, 24

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

Form PCT/ISA/210 (continuation of first sheet (2)) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2007/021013

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61F 2/44 (2008.04)

USPC - 623/17.11

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC(8) - A61F 2/44 (2008.04)

USPC - 17.11

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

USPTO EAST System (US, USPG-PUB, EPO, DERWENT), PatBase

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,290,312 A (KOJIMOTO et al) 01 March 1994 (01.03.1994) entire document	1, 2
Y		3-15, 24
Y	US 2005/0177235 A1 (BAYNHAM et al) 11 August 2005 (11.08.2005) entire document	6-9
Y	US 2002/0068977 A1 (JACKSON) 06 June 2002 (06.06.2002) entire document	10-15, 24

☐ Further documents are listed in the continuation of Box C.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

25 June 2008

Date of mailing of the international search report

09 JUL 2008

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450

Facsimile No. 571-273-3201

Authorized officer:

Blaine R. Copenheaver

PCT Helpdesk: 571-272-4300

PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (April 2005)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To: **MATTHEW T. SHANLEY**
McGrath Geissler Olds & Richardson, PLLC
PO Box 1364
Fairfax, Virginia 22082

Date of mailing
(day/month/year) **09 JUL 2008**

Applicant's or agent's file reference
30030105pwo1

FOR FURTHER ACTION

See paragraph 2 below

International application No.
PCT/US2007/021013

International filing date (day/month/year)
01 October 2007

Priority date (day/month/year)
29 September 2006

International Patent Classification (IPC) or both national classification and IPC
IPC(8) - A61F2/44 (2008.01)
USPC - 17.11

Applicant **MOSKOWITZ, Ahmnon D.**

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-3201

Date of completion of this opinion
25/June/2008

Authorized officer:

Blaine Copenheaver

PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774

Form PCT/ISA/237 (cover sheet) (April 2007)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US2007/021013

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed.
 - ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of:
 - a. type of material
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material
 - ☐ on paper
 - ☐ in electronic form
 - c. time of filing/furnishing
 - ☐ contained in the international application as filed
 - ☐ filed together with the international application in electronic form
 - ☐ furnished subsequently to this Authority for the purposes of search
4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US2007/021013

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has, within the applicable time limit:
- ☐ paid additional fees
 - ☐ paid additional fees under protest and, where applicable, the protest fee
 - ☐ paid additional fees under protest but the applicable protest fee was not paid
 - ☒ not paid additional fees
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with
 - ☒ not complied with for the following reasons:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claims 1-15 and 24, drawn to a self drilling bone fusion screw apparatus comprising a first box and first and second screw members.

Group II, claims 16-17 and 25, drawn to a tool assembly comprising a gripper and screw guide held in place by the plurality of prongs.

Group III, claims 18-22, drawn to a cervical facet staple and impaction tool comprising an insertion member disposed on the top surface of the curved staple base.

Group IV, claim 23, drawn to a lumbar facet staple comprising a pair of rotating arms and a ratchet attached to one of the rotating arms.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical feature of Group I, a self drilling bone fusion screw apparatus comprising a first box and first and second screw members, is not present in Groups II, III and/or IV; the special technical feature of Group II, a tool assembly comprising a gripper and screw guide held in place by the plurality of prongs, is not present in Groups I, III and/or IV; the special technical feature of Group III, a cervical facet staple and impaction tool comprising an insertion member disposed on the top surface of the curved staple base, is not present in Groups I, II and/or IV; the special technical feature of Group IV, a lumbar facet staple comprising a pair of rotating arms and a ratchet attached to one of the rotating arms, is not present in Groups I, II and/or III.

Since none of the special technical features of the Group I, Group II, Group III or Group IV inventions is found in more than one of the inventions, unity of invention is lacking.

4. Consequently, this opinion has been established in respect of the following parts of the international application:
- ☐ all parts
 - ☒ the parts relating to claims Nos. 1-15, 24

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US2007/021013

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	3-15, 24	YES
	Claims	1, 2	NO
Inventive step (IS)	Claims	None.	YES
	Claims	1-15, 24	NO
Industrial applicability (IA)	Claims	1-15, 24	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1 and 2 lack novelty under PCT Article 33(2) as being anticipated by Kojimoto et al.

Regarding claim 1, Kojimoto et al. discloses a self-drilling bone fusion screw apparatus, which comprises: a first sliding box (fig. 2, 18); a second sliding box (fig. 2, 20), positioned relative to the first sliding box; a first screw member having a tapered end and a threaded body disposed within the first sliding box (fig. 2, 70); a second screw member having a tapered end and a threaded body disposed within the second sliding box (fig. 2, 78); and an adjuster for adjusting the height of the sliding boxes (fig. 2, 88; col. 6, lines 60-66 wherein screw 88 engages both the first and second sliding boxes to fix movement of the second box axially within the first box when screwed in).

Regarding claim 2, Kojimoto et al. discloses the self-drilling bone fusion screw apparatus according to claim 1 wherein the first and second screw members are medially aligned (fig. 2, 70 and 78).

Claims 3-5 lack an inventive step under PCT Article 33(3) as being obvious over Kojimoto et al.

Regarding claims 3-5, Kojimoto et al. discloses the self-drilling bone fusion screw apparatus according to claim 1. Kojimoto et al. does not disclose [claim 3] wherein at least one of the first and second screw members is laterally aligned; [claim 4] the self-drilling bone fusion screw apparatus according to claim 3 wherein both the first and second screw members are laterally aligned; and [claim 5] wherein one of the first and second screw members is laterally aligned and the other screw member is laterally aligned. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to change or allow differentiation in the orientation of the screw members in order to give the fusion cage added stability, since the provision of adjustability, where needed, involves only routine skill in the art.

Claims 6-9 lack an inventive step under PCT Article 33(3) as being obvious over Kojimoto et al in view of Baynham et al.

Regarding claims 6-9, Kojimoto et al. discloses the self-drilling bone fusion screw apparatus according to claim 1. Kojimoto et al. does not disclose [claim 6] wherein the first and second sliding boxes are substantially triangularly shaped; [claim 7] wherein the triangularly shaped first and second sliding boxes include a sliding rail and ridged surfaces; [claim 8] wherein the triangularly shaped first and second sliding boxes include holes for bone grafts and [claim 9] wherein the adjuster includes a screw. However, Baynham et al. discloses a spinal fusion device which consists of two substantially triangular sections which are adjustable (fig. 1, 12 and 14) using a screw (fig. 1, 40). Baynham et al. additionally discloses a hole in the device for promoting bone ingrowth (paragraph 0021) and wherein the triangularly shaped first and second sliding boxes include a sliding rail (formed by walls 35 and 36 about which flange 26 slides in and engages (paragraph 0021) and ridged surface (ridges 15-18; see figs. 1 and 3). It would have been obvious to one skilled in the art at the time of the invention to incorporate the triangular shaped device further including an adjusting screw, sliding rail, ridged surfaces and holes for bone grafts taught by Baynham et al. into the spinal prosthetic disclosed by Kojimoto et al. in order to provide an adjustable height fusion cage that remains secure in the intervertebral space and also promotes bone growth.

Claims 10-12 lack an inventive step under PCT Article 33(3) as being obvious over Kojimoto et al in view of Jackson.

Regarding claim 10, Kojimoto et al. discloses a self-drilling bone fusion screw apparatus, which comprises: a box (fig. 2, 18); a first screw member and a second member having a tapered end and a threaded body disposed at least partially within the box (fig. 2, 68 and 70). Kojimoto et al. does not disclose where the first and second screw members are laterally aligned; however it would have been obvious to one of ordinary skill in the art at the time the invention was made to change or allow differentiation in the orientation of the screw members in order to give the fusion cage added stability, since the provision of adjustability, where needed, involves only routine skill in the art. Kojimoto et al. further does not disclose a plurality of ridges disposed on along side of the box. However, Jackson discloses an anterior variable expandable fusion cage which includes ridges (fig. 1, 15). It would have been obvious to one skilled in the art at the time of the invention to include ridges as taught by Jackson to the device disclosed by Kojimoto et al. in order to increase the gripping ability of the device to the adjacent bone.

Regarding claims 11 and 12, Kojimoto et al. in view of Jackson disclose the self-drilling bone fusion screw apparatus according to claim 10. Kojimoto et al. does not disclose [claim 11] where the device further includes bone graft holes or [claim 12] which is attachable to a second self-drilling fusion screw apparatus via a plate. However, Jackson discloses side windows (paragraph 0046) and a plate to add a second screw device (paragraph 0050). It would have been obvious to one skilled in the art at the time of the invention to incorporate bone graft holes and a connector plate as taught by Jackson to the fusion device disclosed by Kojimoto et al. in order to promote bone ingrowth as well as allow the addition of a second fusion device for added stability.

See Supplemental Box.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US2007/021013

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

Box No. V

Claims 13-15 and 24 lack an inventive step under PCT Article 33(3) as being obvious over Jackson in view of Kojimoto et al.

Regarding claim 13, Jackson discloses a bone fusion apparatus, which comprises: a first box; a second box (fig. 10, 5); and an attachment member for engaging the first and second boxes (fig. 14, 80). Jackson does not disclose a first screw member having a tapered end and a threaded body disposed at least partially within the first box and laterally aligned with the first box; a second screw member having a tapered end and a threaded body disposed at least partially within the second box and laterally aligned with the second box. However, Kojimoto et al. discloses an artificial vertebral body that includes first and second screw members (fig. 2, 70 and 78). It would have been obvious to one skilled in the art at the time of the invention to include multiple screws as taught by Kojimoto et al. to the fusion devices as disclosed by Jackson in order to further secure the boxes into the intervertebral space.

Regarding claims 14, 15 and 24, Jackson in view of Kojimoto et al. disclose the self-drilling bone fusion screw apparatus according to claim 13, [claim 14] further including bone graft holes (paragraph 0046), [claim 15] wherein the plate is joined to the first and second boxes by a plurality of screws (paragraph 0050) and [claim 24] wherein the attachment member for engaging the first and second boxes comprises a plate or a circumferential cage defining at least one recess, the first and the second boxes being positioned within the recess of the circumferential cage (fig. 13, 80 and fig. 18, 180).

Claim 1-15 and 24 the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under Article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the *PCT Applicant's Guide*, a publication of WIPO.

In these Notes, "Article," "Rule" and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report and the written opinion of the International Searching Authority, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only (see *PCT Applicant's Guide*, Volume I/A, Annexes B1 and B2).

The attention of the applicant is drawn to the fact that amendments to the claims under Article 19 are not allowed where the International Searching Authority has declared, under Article 17(2), that no international search report would be established (see *PCT Applicant's Guide*, Volume I/A, paragraph 296).

What parts of the international application may be amended ?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Preliminary Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When ? Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments ?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How ? Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments ?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

PATENT COOPERATION TREATY

RECEIVED

From the INTERNATIONAL SEARCHING AUTHORITY

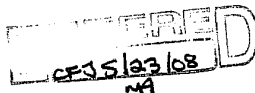
MAY 23 2008

PCT

MG-IP LAW, PLLC

CEJ

To: Matthew T. Shanley
McGrath Geissler Olds & Richardson, PPLC
PO Box 1364
Fairfax, Virginia 22082



NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference 30030104PW02	Date of mailing (day/month/year)
International application No. PCT/US2007/021015	International filing date (day/month/year) 01 October 2007
Applicant MOSKOWITZ, Nathan	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Facsimile No.: +41 22 740 14 35

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. Reminders

Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver Telephone No. 571-272-7774
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Form PCT/ISA/220 (January 2004)

(See notes on accompanying sheet)

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

To: Matthew T. Shanley McGrath Geissler Olds & Richardson, PPLC PO Box 1364 Fairfax, Virginia 22082	<div style="text-align: center; font-weight: bold; font-size: 1.2em;">PCT</div> <p style="text-align: center;">NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION</p> <p style="text-align: center;">(PCT Rule 44.1)</p>
Applicant's or agent's file reference 30030104PW02	<div style="display: flex; justify-content: space-between; align-items: center;"> <div style="text-align: left;"> Date of mailing <i>(day/month/year)</i> </div> <div style="font-size: 1.5em; font-weight: bold;">21 MAY 2008</div> </div>
International application No. PCT/US2007/021015	<div style="display: flex; justify-content: space-between; align-items: center;"> <div style="text-align: left;"> International filing date <i>(day/month/year)</i> </div> <div>01 October 2007</div> </div>
Applicant MOSKOWITZ, Nathan	

1.	☒	The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith. Filing of amendments and statement under Article 19: The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46): When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report. Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes 1211 Geneva 20, Switzerland, Facsimile No.: +41 22 740 14 35 For more detailed instructions, see the notes on the accompanying sheet.
2.	☐	The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.
3.	☐	With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that: ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices. ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.
4.		Reminders Shortly after the expiration of 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication. The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date. Within 19 months from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later); otherwise, the applicant must, within 20 months from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices. In respect of other designated Offices, the time limit of 30 months (or later) will apply even if no demand is filed within 19 months. See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the <i>PCT Applicant's Guide</i> , Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver Telephone No. 571-272-7774
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Form PCT/ISA/220 (January 2004)

(See notes on accompanying sheet)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 30030104PW02	FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/US2007/021015	International filing date <i>(day/month/year)</i> 01 October 2007	(Earliest) Priority Date <i>(day/month/year)</i> 29 September 2006
Applicant MOSKOWITZ, Nathan		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 4 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of:

- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

b. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (see Box No. II)

3. ☒ **Unity of invention is lacking** (see Box No. III)

4. With regard to the **title**,

- ☒ the text is approved as submitted by the applicant
- ☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

- ☐ the text is approved as submitted by the applicant
- ☒ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings**,

- a. the figure of the **drawings** to be published with the abstract is Figure No. 1A
- ☐ as suggested by the applicant
- ☒ as selected by this Authority, because the applicant failed to suggest a figure
- ☐ as selected by this Authority, because this figure better characterizes the invention
- b. ☐ none of the figures is to be published with the abstract

Form PCT/ISA/210 (first sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2007/021015

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

Group I, claims 1-14, drawn to a self-drilling screw apparatus comprising a drive mechanism including a gear disposed between the first and second screw members for driving first and second screw members from a gear box.

Group II, claims 15-17, drawn to a staple for joining facets comprising a second rotatable segment having a plurality of bone piercing elements disposed on serrated surfaces.

Group III, claims 18-21, drawn to a stapling apparatus comprising a pair of grip handles disposed at a first end of a cylinder.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-14

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

Form PCT/ISA/210 (continuation of first sheet (2)) (April 2005)

Box No. IV Text of the abstract (Continuation of item 5 of the first sheet)

An apparatus and method for joining members together using a self-drilling screw apparatus or stapling apparatus are disclosed. The screw apparatus includes a worm drive screw, a spur gear and superior and inferior screws which turn simultaneously. A rotating mechanism drives the first and second screw members in opposite directions and causes the screw members to embed themselves in the members to be joined. The screw apparatus can be used to join members such as bones, portions of the spinal column, vertebral bodies, wood, building materials, metals, masonry, or plastics. A device employing two screws can be combined with a capping mini-plate. A device employing three screws can be combined in enclosures. The stapling apparatus includes handles, transmission linkages, a drive rod a fulcrum and a cylinder. The staple has superior and inferior segments with serrated interfaces, a toothed unidirectional locking mechanism and four facet piercing elements.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2007/021015

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61F 2/44 (2008.04)

USPC - 623/17

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC(8) - A61F 2/44 (2008.04)

USPC - 623/17

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

PatBase

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4,636,217 A (OGILVIE et al) 13 January 1987 (13.01.1987) entire document	1-8, 11
Y		9-10, 12-14
Y	US 2002/0143338 A1 (ORBAY et al) 03 October 2002 (03.10.2002) entire document	10
Y	WO 2004/093749 A1 (MAGERL et al) 04 November 2004 (04.11.2004) entire document	9-10
Y	WO 2006/091503 A1 (SHATTUCK et al) 31 August 2006 (31.08.2006) entire document	12-14

☐ Further documents are listed in the continuation of Box C.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

05 May 2008

Date of mailing of the international search report

21 MAY 2008

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents

P.O. Box 1450, Alexandria, Virginia 22313-1450

Facsimile No. 571-273-3201

Authorized officer:

Blaine R. Copenheaver

PCT Helpdesk: 571-272-4300

PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (April 2005)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To: Matthew T. Shanley McGrath Geissler Olds & Richardson, PLLC PO Box 1364 Fairfax, Virginia 22082		Date of mailing <i>(day/month/year)</i> 21 MAY 2008	
Applicant's or agent's file reference 30030104PW02		FOR FURTHER ACTION See paragraph 2 below	
International application No. PCT/US2007/021015	International filing date <i>(day/month/year)</i> 01 October 2007	Priority date <i>(day/month/year)</i> 29 September 2006	
International Patent Classification (IPC) or both national classification and IPC IPC(8) - A61F 2/44 (2008.04) USPC - 623/17			
Applicant MOSKOWITZ, Nathan			

<p>1. This opinion contains indications relating to the following items:</p> <p>☒ Box No. I Basis of the opinion</p> <p>☐ Box No. II Priority</p> <p>☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p>☒ Box No. IV Lack of unity of invention</p> <p>☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>☐ Box No. VI Certain documents cited</p> <p>☐ Box No. VII Certain defects in the international application</p> <p>☐ Box No. VIII Certain observations on the international application</p> <p>2. FURTHER ACTION</p> <p>If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.</p> <p>If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.</p> <p>For further options, see Form PCT/ISA/220.</p> <p>3. For further details, see notes to Form PCT/ISA/220.</p>

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Date of completion of this opinion 05 May 2008	Authorized officer: Blaine Copenheaver <small>PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774</small>
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Form PCT/ISA/237 (cover sheet) (April 2007)

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US2007/021015

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed.
 - ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of:
 - a. type of material
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material
 - ☐ on paper
 - ☐ in electronic form
 - c. time of filing/furnishing
 - ☐ contained in the international application as filed
 - ☐ filed together with the international application in electronic form
 - ☐ furnished subsequently to this Authority for the purposes of search
4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US2007/021015

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has, within the applicable time limit:
- ☐ paid additional fees
 - ☐ paid additional fees under protest and, where applicable, the protest fee
 - ☐ paid additional fees under protest but the applicable protest fee was not paid
 - ☒ not paid additional fees

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

- ☐ complied with
- ☒ not complied with for the following reasons:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claims 1-14, drawn to a self-drilling screw apparatus comprising a drive mechanism including a gear disposed between the first and second screw members for driving first and second screw members from a gear box.

Group II, claims 15-17, drawn to a staple for joining facets comprising a second rotatable segment having a plurality of bone piercing elements disposed on serrated surfaces.

Group III, claims 18-21, drawn to a stapling apparatus comprising a pair of grip handles disposed at a first end of a cylinder.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical feature of Group I, a self-drilling screw apparatus comprising a drive mechanism including a gear disposed between the first and second screw members for driving first and second screw members from a gear box, is not present in Groups II and/or III; the special technical feature of Group II, a staple for joining facets comprising a second rotatable segment having a plurality of bone piercing elements disposed on serrated surfaces, is not present in Groups I and/or III; the special technical feature of Group III, a stapling apparatus comprising a pair of grip handles disposed at a first end of a cylinder, is not present in Groups I and/or II.

Since none of the special technical features of the Group I, Group II or Group III inventions is found in more than one of the inventions, unity of invention is lacking.

4. Consequently, this opinion has been established in respect of the following parts of the international application:

- ☐ all parts
- ☒ the parts relating to claims Nos. 1-14

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US2007/021015

Box No. V	Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
1. Statement			
Novelty (N)	Claims	8-14	YES
	Claims	1-7	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-14	NO
Industrial applicability (IA)	Claims	1-14	YES
	Claims	None	NO
2. Citations and explanations:			
<p>Claims 1-7 lack novelty under PCT Article 33(2) as being anticipated by Ogilvie et al.</p> <p>Regarding claim 1, Ogilvie et al. disclose a self-drilling screw apparatus, which comprises: a gear box (Assembly of Fig. 5); a first screw member (Fig. 4, first screw on right side) having a tapered end (Fig. 4, item 32) and a threaded body (Fig. 4, item 31 and 33) disposed within the gear box (Fig. 4); a second screw member (Fig. 4, third screw from right side) having a tapered end (Fig. 4, item 32) and a threaded body (Fig. 4, item 31 and 33) disposed within the gear box (Fig. 4), the second screw member being axially offset from the first screw member (Fig. 4); and a drive mechanism (Assembly of Fig. 5), including a gear (Fig. 5, item 33 and 40) disposed between the first and second screw members (Fig. 5), for driving the first and second screw members from the gear box (The insert body is provided with a drive mechanism which will drive the retaining screws upon rotation of the drive mechanism. This drive mechanism comprises drive gears having a drive connection accessible from the exterior of the insert body after the insert has been placed into the void. A drive wrench is coupled to the drive connection and moved to rotate the drive gears, which will rotate the self-tapping, bone penetrating retaining screws so that they will be driven outwardly from the opposite end surfaces of the implanted insert body, col. 2, lines 13-23).</p> <p>Regarding claim 2, Ogilvie et al. disclose that as applied to claim 1 wherein the gear box includes an aperture (Fig. 1, item 45; Fig. 4, item 46) which provides access to a wormed drive screw (Fig. 5, item 40-21; Fig. 6 and Fig. 5).</p> <p>Regarding claim 3, Ogilvie et al. disclose that as applied to claim 1 wherein the drive mechanism wherein the gear is a spur gear (Fig. 5, item 33) which is driven by a wormed drive screw (Fig. 5, item 40-42) and which rotates the first and second screw members (The insert body is provided with a drive mechanism which will drive the retaining screws upon rotation of the drive mechanism. This drive mechanism comprises drive gears having a drive connection accessible from the exterior of the insert body after the insert has been placed into the void. A drive wrench is coupled to the drive connection and moved to rotate the drive gears, which will rotate the self-tapping, bone penetrating retaining screws so that they will be driven outwardly from the opposite end surfaces of the implanted insert body, col. 2, lines 13-23).</p> <p>Regarding claim 4, Ogilvie et al. disclose that as applied to claim 3 wherein the wormed drive screw includes an accessible head (Fig. 6, item 57 and 58) that is rotated in order to drive the first and second screw members from the gear box (Fig. 5; The insert body is provided with a drive mechanism which will drive the retaining screws upon rotation of the drive mechanism. This drive mechanism comprises drive gears having a drive connection accessible from the exterior of the insert body after the insert has been placed into the void. A drive wrench is coupled to the drive connection and moved to rotate the drive gears, which will rotate the self-tapping, bone penetrating retaining screws so that they will be driven outwardly from the opposite end surfaces of the implanted insert body, col. 2, lines 13-23).</p> <p>Regarding claim 5, Ogilvie et al. disclose that as applied to claim 3 wherein the first and second screw members include internal threading (Fig. 4, item 26B and 26C) and spindles (Fig. 4, item 30A; the screw shanks 30A are positioned in the interior threads of the bores 25 and 26 and the screw threads clear the thread sections 25C and 26C, col. 5, lines 41-43).</p> <p>Regarding claim 6, Ogilvie et al. disclose that as applied to claim 3 wherein the wormed drive screw includes a spindle (Fig. 5, item 54).</p> <p>Regarding claim 7, Ogilvie et al. disclose that as applied to claim 4 wherein the accessible head is rotated by a screw driver (The opposite ends of the worm shaft 40 are provided with internal polygonal openings indicated at 57 and 58, respectively, to receive suitable drive key wrenches, (such as Allen wrenches for a hex-shaped socket) for rotating the worm shafts from the exterior of the insert body 20, col. 4, lines 61-66).</p> <p>Claims 8 and 11 lack an inventive step under PCT Article 33(3) as being obvious over Ogilvie et al.</p> <p>Regarding claim 8, Ogilvie et al. disclose that as applied to claim 1. Ogilvie et al. does not teach further including: at least a second gear box; a third screw member having a tapered end and a threaded body disposed within the second gear box; a fourth screw member having a tapered end and a threaded body disposed within the second gear box, the fourth screw member being axially offset from the third screw member; and a second drive mechanism, including a gear disposed between the third and fourth screw members, for driving the third and fourth screw members from the second gear box. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use at least a second gear box; a third screw member having a tapered end and a threaded body disposed within the second gear box; a fourth screw member having a tapered end and a threaded body disposed within the second gear box, the fourth screw member being axially offset from the third screw member; and a second drive mechanism, including a gear disposed between the third and fourth screw members, for driving the third and fourth screw members from the second gear box for the purpose of providing extra support in the spine, since a mere duplication of essential working parts of device involves only routine skill in the art.</p> <p>(Continued in Supplemental Box)</p>			

Form PCT/ISA/237 (Box No. V) (April 2007)

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US2007/021015

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

Box V

Regarding claim 11, Ogilvie et al. disclose that as applied to claim 8. Ogilvie et al. does not teach further including: at least a third gear box; a fifth screw member having a tapered end and a threaded body disposed within the third gear box; a sixth screw member having a tapered end and a threaded body disposed within the third gear box, the sixth screw member being axially offset from the fifth screw member; and a third drive mechanism, including a gear disposed between the fifth and sixth screw members for driving the fifth and sixth screw members from the third gear box. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use at least a third gear box; a fifth screw member having a tapered end and a threaded body disposed within the third gear box; a sixth screw member having a tapered end and a threaded body disposed within the third gear box, the sixth screw member being axially offset from the fifth screw member; and a third drive mechanism, including a gear disposed between the fifth and sixth screw members for driving the fifth and sixth screw members from the third gear box for the purpose of providing extra support in the spine, since a mere duplication of essential working parts of device involves only routine skill in the art.

Claim 9 lacks an inventive step under PCT Article 33(3) as being obvious over Ogilvie et al. in view of Magerl et al.

Regarding claim 9, Ogilvie et al. disclose that as applied to claim 8. Ogilvie et al. do not teach which further includes a plate for joining the first and second gear boxes together. Magerl et al. teach a plate (Fig. 1, item 5) for joining the first and second devices together (Fig. 1, item 5 joins leftmost item 3 to rightmost item 3). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the plate as taught by Magerl et al. with the invention of Ogilvie et al. for the purpose of joining two of the implants together.

Claim 10 lacks an inventive step under PCT Article 33(3) as being obvious over Ogilvie et al. in view of Magerl et al. in further view of Orbay et al.

Regarding claim 10, Ogilvie et al. and Magerl et al. disclose that as applied to claim 9. Neither Ogilvie et al. or Magerl et al. teach wherein the plate includes screw caps. Orbay et al. teach screw caps (paragraph [0012]). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the screw caps as taught by Orbay et al. with the invention of Ogilvie et al. for the purpose of preventing the screw from backing out.

Claims 12-14 lack an inventive step under PCT Article 33(3) as being obvious over Ogilvie et al. in view of Shattuck et al.

Regarding claim 12, Ogilvie et al. disclose that as applied to claim 11. Ogilvie et al. do not teach wherein the gear boxes are aligned in a predetermined pattern and a first enclosure is disposed above the gear boxes and a second enclosure is disposed below the gear boxes. Shattuck et al. teach wherein the boxes are aligned in a predetermined pattern (Fig. 1 and Fig. 12 show the boxes aligned in a circular pattern) and a first enclosure (Fig. 1, item 28 on the right side of item 2) is disposed above the boxes (Fig. 1) and a second enclosure (Fig. 1, item 28 on the right side of item 2) is disposed below the boxes (Fig. 1). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the enclosure as taught by Shattuck et al. with the invention of Ogilvie et al. for the purpose of maintaining an aligned orientation for the gear boxes.

Regarding claim 13, Ogilvie et al. and Shattuck et al. disclose that as applied to claim 12. Neither Ogilvie et al. or Shattuck et al. teach wherein the gear boxes are aligned in a triangular pattern. It would have been obvious to one of ordinary skill in the art at the time the invention was made to align the gear boxes in a triangular pattern for the purpose of allowing evenly distributed pressure for motion, since a change in shape of an element involves only routine skill in the art.

Regarding claim 14, Ogilvie et al. and Shattuck et al. disclose that as applied to claim 13. Ogilvie et al. do not teach wherein the first and second enclosures include slots for bone fusion material. Shattuck et al. teach wherein the first and second enclosures include slots (Fig. 4, slotted channel surrounded by item 28, 25 and 31). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the slots as taught by Shattuck et al. with the invention of Ogilvie et al. for the purpose of allowing bone fusion/growth.

Claims 1-14 meets the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

NOTES TO FORM PCT/ISA/220 (continued)

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers, claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
2. [Where originally there were 15 claims and after amendment of all claims there are 11]:
"Claims 1 to 15 replaced by amended claims 1 to 11."
3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
4. [Where various kinds of amendments are made]:
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under Article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international application is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments and any accompanying statement, under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the time of filing the amendments (and any statement) with the International Bureau, also file with the International Preliminary Examining Authority a copy of such amendments (and of any statement) and, where required, a translation of such amendments for the procedure before that Authority (see Rules 55.3(a) and 62.2, first sentence). For further information, see the Notes to the demand form (PCT/IPEA/401).

If a demand for international preliminary examination is made, the written opinion of the International Searching Authority will, except in certain cases where the International Preliminary Examining Authority did not act as International Searching Authority and where it has notified the International Bureau under Rule 66.1bis(b), be considered to be a written opinion of the International Preliminary Examining Authority. If a demand is made, the applicant may submit to the International Preliminary Examining Authority a reply to the written opinion together, where appropriate, with amendments before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later (Rule 43bis.1(c)).

Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see the *PCT Applicant's Guide*, Volume II.

Electronic Patent Application Fee Transmittal				
Application Number:		13210168		
Filing Date:		15-Aug-2011		
Title of Invention:		BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION		
First Named Inventor/Applicant Name:		Ahmnon D. MOSKOWITZ		
Filer:		John Jeremy Dresch/Linda Logan		
Attorney Docket Number:		3003/0105PUS7		
Filed as Small Entity				
Utility under 35 USC 111(a) Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Submission- Information Disclosure Stmt	2806	1	90	90
Total in USD (\$)				90

Electronic Acknowledgement Receipt	
EFS ID:	19974970
Application Number:	13210168
International Application Number:	
Confirmation Number:	1609
Title of Invention:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION
First Named Inventor/Applicant Name:	Ahmnon D. MOSKOWITZ
Customer Number:	87409
Filer:	John Jeremy Dresch/Linda Logan
Filer Authorized By:	John Jeremy Dresch
Attorney Docket Number:	3003/0105PUS7
Receipt Date:	28-AUG-2014
Filing Date:	15-AUG-2011
Time Stamp:	18:37:31
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$ 90
RAM confirmation Number	5220
Deposit Account	505364
Authorized User	DRESCH, JOHN J
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)	

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)	3003-0105PUS7_IDS.pdf	615001	no	10
			6a21dcd30d0342e78eb8f97d92f2dc0567f02faa		
Warnings:					
Information:					
2	Foreign Reference	WO_2004_093749_A1_Foreign_Reference.pdf	1788022	no	35
			3d83276bfa8fc706aff4322be8003f33b42b3957		
Warnings:					
Information:					
3	Foreign Reference	WO_2006_091503_A1_Foreign_Reference.pdf	823935	no	20
			680120e1d2a57ce90f70408a25eefdf50a20500b7		
Warnings:					
Information:					
4	Non Patent Literature	NPL1.pdf	924775	no	8
			c7b960e8f3edeb42dd78f53c6d0a708ce8167784e		
Warnings:					
Information:					
5	Non Patent Literature	NPL2.pdf	906864	no	8
			21fb7a90e3c048ed1d6986c361c349a942c04ff		
Warnings:					
Information:					
6	Non Patent Literature	NPL3.pdf	817229	no	10
			48546a5180dd3f19fa1cd6cf972878d6103450e4		
Warnings:					
Information:					
7	Non Patent Literature	NPL4.pdf	1031397	no	10
			c0821d6792b1d13903fa6d52675799cae5d6b678		
Warnings:					
Information:					
8	Other Reference-Patent/App/Search documents	PCT_US2007_005005_ISR.pdf	756965	no	11
			9c0b0cbf2896b04ff4dd683c3fc62677c11aaf65f		
Warnings:					
Information:					

9	Other Reference-Patent/App/Search documents	PCT_US2007_021013_ISR.pdf	621579 b408b4d7df33a6408ec604ef24875418fca8dfed	no	11
Warnings:					
Information:					
10	Other Reference-Patent/App/Search documents	PCT_US2007_021015_ISR.pdf	679958 4a461a4ea93f45fa5b0b52df1aa0826a8ea51e5c	no	12
Warnings:					
Information:					
11	Fee Worksheet (SB06)	fee-info.pdf	30797 a18d1b02d8a6f058b280bfff00ed6cc587181879d	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			8996522		
<p>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.</p> <p><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.</p> <p><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.</p> <p><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.</p>					

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Ahmnon D. MOSKOWITZ, et al.
Application Number: 13/210,168
Filing Date: 08/15/2011
Group Art Unit: 3733
Examiner: Pedro PHILOGENE
Confirmation No.: 1609
Title: BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY
SCREWS AND POSTERIOR CERVICAL AND LUMBAR
INTERARTICULATING JOINT CALIBRATED STAPLING
DEVICES FOR SPINAL FUSION

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT A

Dear Sir:

This Amendment is responsive to the Office Action dated June 10, 2014, having a due date of December 10, 2014, and is accompanied by a petition and fee for a three month extension of time.

Please charge Deposit Account No. 505364 for any deficiency or overpayment.

Please amend the application as follows:

Amendments to the Claims, as reflected in the listing of claims, begin on page 2 of this paper;
and

Remarks begin on page 11 of this paper.

IN THE CLAIMS:

Please amend the claims as follows. This listing of the claims will replace all prior versions, and listings, of claims in the application:

1-25. (Canceled)

26-85. (Canceled)

86. (New) A universal, intervertebral combination internal screw guide and fixation apparatus configured to be inserted into a disc space between a first vertebral body and a second vertebral body and to provide fusion of the first vertebral body to the second vertebral body via biological bone fusion and screw fusion, the apparatus comprising:

an intervertebral cage including:

a top wall, a bottom wall, and two sidewalls defining an open space capable of receiving bone filling for the biological bone fusion; and

an internal screw guide having an entry opening and an exit opening, the entry opening formed at least partially in a top surface of the top wall and the exit opening formed at least partially in a bottom surface of the top wall and at least partially in a side surface of the top wall.

87. (New) The apparatus of claim 86, wherein an internal surface of the internal screw guide extends continuously from the entry opening to the exit opening.

88. (New) The apparatus of claim 86, wherein the internal screw guide extends through an entire depth of the top wall from the top surface to the bottom surface and exiting at least partially into the open space.

89. (New) The apparatus of claim 86, wherein the internal screw guide permits only a predetermined angled trajectory of a screw member through the intervertebral cage.

90. (New) The apparatus of claim 86, wherein the internal screw guide has a 25 degree angulation.

91. (New) The apparatus of claim 86, wherein the top wall has a thickness extending from the top surface of the top wall to the bottom surface of the top wall in a direction of a depth of the intervertebral cage, a height of the intervertebral cage extending in a direction perpendicular to the depth, and

wherein an axis of the internal screw guide extends to a greater extent in the direction of the depth of the intervertebral cage than in a direction of a height of the intervertebral cage in order to facilitate multi-level fusion of adjacent vertebral bodies with multiple intervertebral cages.

92. (New) The apparatus of claim 86, wherein the top wall of the intervertebral cage has a thickness that is greater than a thickness of each of the sidewalls.

93. (New) The apparatus of claim 86, wherein at least one of the two sidewalls includes a hole configured to allow placement of bone filling into the open space of the intervertebral cage for the biological bone fusion.

94. (New) The apparatus of claim 86, wherein the intervertebral cages includes indentations formed on surfaces of the two sidewalls and on opposite ends of the intervertebral cage for receiving ends of prongs of an implantation tool.

95. (New) The apparatus of claim 86, wherein a surface of each of the two sidewalls includes a plurality of ridges.

96. (New) The apparatus of claim 86, wherein the intervertebral cage is configured to receive a plate for securing a second intervertebral cage thereto.

97. (New) The apparatus of claim 96, wherein the intervertebral cage comprises:

a screw insert configured to receive the plate for securing the second intervertebral cage thereto.

98. (New) The apparatus of claim 86, wherein the intervertebral cage is a cervical intervertebral cage configured to fit into a cervical disc space.

99. (New) The apparatus of claim 86, wherein the intervertebral cage is a lumbar intervertebral cage configured to fit into a lumbar disc space.

100. (New) The apparatus of claim 86, wherein the intervertebral cage is a posterior lumbar intervertebral cage configured to fit into a lumbar disc space.

101. (New) The apparatus of claim 86, wherein the intervertebral cage capable of one of posterior lumbar intervertebral placement, anterior lumbar intervertebral placement, thoracic intervertebral placement, and anterior cervical intervertebral placement.

102. (New) The apparatus of claim 86, wherein the intervertebral cage further comprises:

a second internal screw guide having a second entry opening and a second exit opening, the second entry opening formed at least partially in the top surface of the top wall and the second exit opening formed at least partially in the bottom surface of the top wall and at least partially in a second side surface of the top wall.

103. (New) The apparatus of claim 102, wherein each of the internal screw guide and the second internal screw guide is angled to orient a first screw member and a second screw bi-directionally in opposite directions.

104. (New) The apparatus of claim 103, wherein the internal screw guide is configured to orient the first screw member rostrally and the second internal screw guide is configured to orient the second screw member caudally.

105. (New) The apparatus of claim 102, wherein the internal screw guide and the second internal screw guide are at an angulation with respect to the top surface of the top wall.

106. (New) The apparatus of claim 102, wherein each of the internal screw guide and the second internal screw guide permits only a 25 degree angulation of a first screw member and the second screw member.

107. (New) The apparatus of claim 102, wherein the internal screw guide and the second internal screw guide are aligned along a longitudinal axis of the top wall of the intervertebral cage.

108. (New) The apparatus of claim 102, wherein the internal screw guide and the second internal screw guide are symmetrically disposed on each side of a center point of the intervertebral cage along a longitudinal axis of the top wall of the intervertebral cage.

109. (New) The apparatus of claim 102, wherein the internal screw guide and the second internal screw guide are offset in opposite directions with respect to a center line of a longitudinal extent of the top wall.

110. (New) The apparatus of claim 109, wherein a part of the internal screw guide overlaps a part of the second internal screw guide along the longitudinal extent of the top wall.

111. (New) The apparatus of claim 102, wherein the entry opening of the internal screw guide and the second entry opening of the second internal screw guide are arranged diagonally on the top surface of the top wall.

112. (New) The apparatus of claim 102, wherein the top wall has four quadrants delineated by a first axis and a second axis each lying in a plane of the top wall, and the first axis is at a right angle with respect to the second axis,

wherein the four quadrants include a first quadrant, a second quadrant, a third quadrant, and a fourth quadrant,

wherein the first quadrant and the fourth quadrant are opposed to the second quadrant and the third quadrant with respect to the first axis, and the first quadrant and the second quadrant are opposed to the third quadrant and the fourth quadrant with respect to the second axis,

wherein the first quadrant is diagonally opposed to the third quadrant, and the second quadrant is diagonally opposed to the fourth quadrant, and

wherein a majority of an area of the entry opening of the internal screw guide is in the first quadrant and a majority of an area of the second entry opening of the second internal screw guide is in the third quadrant.

113. (New) The apparatus of claim 102, wherein the top wall has four quadrants delineated by a first axis and a second axis each lying in a plane of the first wall, and the first axis is at a right angle with respect to the second axis,

wherein the four quadrants include a first quadrant, a second quadrant, a third quadrant, and a fourth quadrant,

wherein the first quadrant and the fourth quadrant are opposed to the second quadrant and the third quadrant with respect to the first axis, and the first quadrant and the second quadrant are opposed to the third quadrant and the fourth quadrant with respect to the second axis,

wherein the first quadrant is diagonally opposed to the third quadrant, and the second quadrant is diagonally opposed to the fourth quadrant, and

wherein a center of the entry opening of the internal screw guide is in the first quadrant and a center of the second entry opening of the second internal screw guide is in the third quadrant.

114. (New) The apparatus of claim 102, wherein the top wall includes a first corner and a second corner, the first corner being arranged at an opposite side of the top wall and an opposite end of the top wall with respect to the second corner, and

wherein the internal screw guide and the second internal screw guide are diagonally arranged along a direction extending from the first corner of the top wall to the second corner of the top wall.

115. (New) The apparatus of claim 102, wherein the intervertebral cage further comprises:

a third internal screw guide having a third entry opening and a third exit opening, the third entry opening formed at least partially in the top surface of the top wall and the third exit opening formed at least partially in the bottom surface of the top wall and at least partially in the side surface of the top wall.

116. (New) The apparatus of claim 115, wherein the intervertebral cage further comprises:

a fourth internal screw guide having a fourth entry opening and a fourth exit opening, the fourth entry opening formed at least partially in the top surface of the top wall and the fourth exit opening formed at least partially in the bottom surface of the top wall and at least partially in the second side surface of the top wall.

117. (New) The apparatus of claim 116, wherein the internal screw guide and the fourth internal screw guide are oriented rostrally and the second internal screw guide and the third internal screw guide are oriented caudally.

118. (New) The apparatus of claim 116, wherein the second internal screw guide and the third internal screw guide are disposed between the internal screw guide and the fourth internal screw guide along a longitudinal length of the top wall of the intervertebral cage.

119. (New) The apparatus of claim 116, wherein each of the internal screw guide, the second internal screw guide, the third internal screw guide, and the fourth internal screw guide has a 25 degree angulation.

120. (New) The apparatus of claim 86, further comprising:

a second intervertebral cage including:

a top wall, a bottom wall, and two sidewalls defining an open space capable of receiving bone filling for biological bone fusion, and

an internal screw guide having an entry opening and an exit opening, the entry opening of the second intervertebral cage formed at least partially in a top surface of the top wall of the second intervertebral cage and the exit opening formed at least partially in a bottom surface of the top wall of the second intervertebral cage and at least partially in a side surface of the top wall of the second intervertebral cage; and

an attachment member coupling the intervertebral cage to the second intervertebral cage.

121. (New) The apparatus of claim 120, wherein the attachment member includes a supplemental cage defining one or more open spaces capable of receiving the intervertebral cage and the second intervertebral cage, and

wherein the intervertebral cage and the second intervertebral cage are secured to the supplemental cage.

122. (New) The apparatus of claim 120, wherein the attachment member includes a plate.

123. (New) The apparatus of claim 102, wherein the intervertebral cage is devoid of any other internal screw guides other than the first internal screw guide and a second internal screw guide.

124. (New) A zero-profile, intervertebral cage sized and configured to be inserted into a disc space between adjacent vertebral bodies and to provide fusion of the adjacent vertebral bodies via biological bone fusion and screw fusion,

the intervertebral cage comprising:

a top wall;

a bottom wall opposite the top wall;

a first sidewall;

a second sidewall opposite the first sidewall, each of the first sidewall and the second sidewall having a surface configured to contact one of the adjacent vertebral bodies when the intervertebral cage is inserted into the disc space,

wherein at least the first sidewall and the second sidewall bound an open space capable of receiving bone filling for the biological bone fusion,

wherein the top wall includes a top surface and a bottom surface opposite the top surface, the top surface configured to have a zero-profile with respect to the adjacent vertebral bodies when the intervertebral cage is inserted into the disc space, and the bottom surface facing the open space; and

an internal screw trajectory guide for guiding a trajectory of a screw through the intervertebral cage, the internal screw trajectory guide having an entry opening and an exit opening, the entry opening formed at least partially in the top surface of the top wall, and the exit opening formed at least partially in a bottom surface of the top wall and at least partially in a side surface of the top wall.

125. (New) The apparatus of claim 86, wherein the exit opening is formed at least partially in a surface of one of the two sidewalls.

126. (New) A universal, intervertebral combination internal screw guide and fixation apparatus configured to be inserted into a disc space between a first vertebral body and a second vertebral body and to provide fusion of the first vertebral body to the second vertebral body via biological bone fusion and screw fusion, the apparatus comprising:

an intervertebral cage including:

a top wall, a bottom wall, and two sidewalls defining an open space capable of receiving bone filling for the biological bone fusion; and

an internal screw guide having an entry opening and an exit opening, the entry opening formed at least partially in a top surface of the top wall,

the exit opening formed at least partially in a bottom surface of the top wall, and

the exit opening formed at least partially in at least one of:

a side surface of the top wall; and

a surface of one of the two sidewalls.

127. (New) The apparatus of claim 126, wherein the exit opening is formed partially in the side surface of the top wall.

128. (New) The apparatus of claim 126, wherein the exit opening is formed partially in the surface of the one of the two sidewalls.

129. (New) The apparatus of claim 126, wherein the exit opening is formed partially in the side surface of the top wall and partially in the surface of the one of the two sidewalls.

130. (New) The apparatus of claim 86, wherein the entry opening is formed substantially in the top surface of the top wall.

131. (New) The apparatus of claim 86, wherein the entry opening is formed entirely in the top surface of the top wall.

132. (New) The apparatus of claim 121, wherein the supplemental cage surrounds a perimeter of the intervertebral cage and the second intervertebral cage.

133. (New) The apparatus of claim 86, wherein the internal screw guide includes:
a counterbore formed at least partially in the top surface of the top wall for
accommodating a screw head of a screw member; and

an internal bore configured to continuously guide a body of the screw member through the internal screw guide into the open space and into the first vertebral body, wherein the internal bore includes a bore entry opening formed in a lower surface of the counterbore, the bore entry opening formed entirely between all edges of the top surface of the top wall when viewed from a direction perpendicular to a plane of the top surface, and a bore exit opening formed partially in the bottom surface of the top wall and partially in the side surface of the top wall.

134. (New) The apparatus of claim 133, wherein the internal bore is coaxial with the counterbore.

REMARKS

Claims 86-134 are pending in the application. This Amendment cancels claims 26-85 and adds new claims 86-134. This Amendment does not add new matter. Claims 86, 124, and 126 are independent.

The Provisional Double Patenting Rejection

Claims 26 – 85 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1 - 31 of copending U.S. Application No. 12/471,340. Claims 26 – 85 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1 - 88 of copending U.S. Application No. 13/418,323. Claims 26 – 85 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1 - 31 of copending U.S. Application No. 13/401,829. Claims 26 – 85 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1 - 88 of copending U.S. Application No. 13/418,335. Claims 26 – 85 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 26 - 92 of copending U.S. Application No. 13/210,162. Claims 26 – 85 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 26 - 82 of copending U.S. Application No. 13/210,150. Claims 26 – 85 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 26 - 83 of copending U.S. Application No. 13/210,157. Claims 26 – 85 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 26 - 93 of copending U.S. Application No. 13/108,982. Claims 26 – 85 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 - 31 of U.S. Patent No. 7,972,363.

Applicants respectfully traverse these rejections.

Applicants respectfully submit that new claims 86-134 of the present application are patentably distinct from the claims of the copending applications. Applicants note that while the claims may recite one or more common features, this is not enough to support an obviousness-type double patenting rejection.

Applicants note that the claims may be subject to further amendments during prosecution, which features should serve to further distinguish the claims of the present application from the claims of the co-pending applications.

With regard to the provisional obviousness-type double patenting rejections, Applicants respectfully submit that the conflicting claims have not in fact been patented, and therefore, also may be subject to further amendments during prosecution, which features may serve to further distinguish the claims of the present application from the claims of the co-pending applications.

For these reasons, Applicants respectfully reserve the right to file a terminal disclaimer in compliance with 37 C.F.R. § 1.321(c) or 1.321(d) as such time as the claims of the present application are allowable. Applicants respectfully request withdrawal of these rejections.

The Lin Reference in view of the Bagga et al. Reference

The Office Action rejects claims 26 – 85 under 35 U.S.C. § 103(a) as allegedly being unpatentable over the Lin reference (U.S. Patent No. 6,629,998) in view of the in view of the Bagga et al. reference (U.S. Patent No. 7,238,203).

Applicants respectfully traverse this rejection.

This Amendment cancels claims 26-92 and adds new claims 93-141.

None of the Lin reference and the Bagga et al. reference, either alone or in combination, discloses or suggests the features of independent claim 93, including the intervertebral cage universal, intervertebral combination internal screw guide and fixation apparatus configured to be inserted into a disc space between a first vertebral body and a second vertebral body and to provide fusion of the first vertebral body to the second vertebral body via biological bone fusion and screw fusion, the apparatus comprising an intervertebral cage including a top wall, a bottom wall, and two sidewalls defining an open space capable of receiving bone filling for the biological bone fusion; and an internal screw guide having an entry opening and an exit opening, the entry opening formed at least partially in a top surface of the top wall and the exit opening formed at least partially in a bottom surface of the top wall and at least partially in a side surface of the top wall. These features are illustrated at, for example, paragraphs [0064]; [0065]; [0066]; [0068]; [0069]; and FIGS. 1A-2G.

These features are important for providing shallow angles of the screws into the vertebral bodies, thereby avoiding interference with screws of other adjacent implantation devices and

enabling multiple level fusion. Additionally, by providing the entry opening formed at least partially in a top surface of the top wall and the exit opening formed at least partially in a bottom surface of the top wall and at least partially in a side surface of the top wall, the present invention can provide biological bone fusion of not only the cage to the bone, but also biological fusion of the screws to cage, thereby preventing backing out of the screws and providing a permanent implantation of the apparatus.

In stark contrast to the claimed invention, the Lin reference does not disclose or even mention an intervertebral cage having an open space therein capable of receiving bone filling for the biological bone fusion. Instead, the Lin reference simply discloses openings 121 being configured to receive a screw 200.

Even assuming arguendo that the opening 121 illustrated in FIG. 8 of the Lin reference would be considered to be capable of receiving bone, as alleged at page 7 of the Office Action, the Lin reference does not disclose or even mention that an exit opening is formed at least partially in a bottom surface of the top wall and at least partially in a side surface of the top wall, as recited in claim 104. Instead, as clearly shown in FIGS. 1-7 and explicitly described at col. 3, lines 7-9, the Lin reference discloses that the exit opening or outlet 121 of the hole 111 is formed only in an outer wall (contact surface 120) of the cage. Thus, the outlet of the hole 111 of the Lin reference is not formed at least partially in a bottom surface of the top wall and at least partially in a side surface of the top wall, as claimed.

Moreover, as clearly shown in FIG. 8 and explicitly described at col. 3, lines 31-32, the Lin reference discloses that each of the holes 111 has “an 8-shaped outlet on the contact surface,” which is an outer wall of the device. Emphasis added Applicants. Thus, the 8-shaped outlet 121 of the hole 111 of the Lin reference is not formed at least partially in a bottom surface of the top wall and at least partially in a side surface of the top wall, as claimed.

For these reasons, none of the Lin reference and the Bagga et al. reference, either alone or in combination, discloses or suggests the features of independent claim 93.

Applicants respectfully request withdrawal of this rejection.

The New Claims

This Amendment adds new claims 86-134. This Amendment does not add new matter. These features are illustrated at, for example, paragraphs [0064]-[0069]; and FIGS. 1A-2G, 3C, 4C, 5C, 6B, 6D, etc.

The Lin reference does not disclose or suggest the features of claims 86-134 for the reasons set forth above. The dependent claims are patentable over the applied reference by virtue of their respective dependency from each of the independent claims, as well as for the additional features recited therein.

For example, the Lin reference does not disclose or suggest the features of claim 133 wherein the internal screw guide includes a counterbore formed at least partially in the top surface of the top wall for accommodating a screw head of a screw member; and an internal bore configured to continuously guide a body of the screw member through the internal screw guide into the open space and into the first vertebral body, wherein the internal bore includes a bore entry opening formed in a lower surface of the counterbore, the bore entry opening formed entirely between all edges of the top surface of the top wall when viewed from a direction perpendicular to a plane of the top surface, and a bore exit opening formed partially in the bottom surface of the top wall and partially in the side surface of the top wall.

These features are important for eliminating the need for an external screw guide to the cage, and instead, providing an internal screw guide in the cage that guides a screw trajectory into the vertebral body at a predetermined shallow angle that avoids interference with screws of other adjacent implantation devices and enables multiple level fusion, while at the same time eliminating a need for the surgeon to remove a part of the bone from the vertebral body to insert the screw.

Applicants respectfully request allowance of these claims.

CONCLUSION

In view of the above, entry of the present Amendment and allowance of Claims 86-134 are respectfully requested. If the Examiner has any questions regarding this amendment, the Examiner is requested to contact the undersigned.

Respectfully Submitted,

/ John J. Dresch /
John J. Dresch
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Reg. No. 46,672

December 10, 2014

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PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)		Docket Number (Optional) 3003/0105PUS7																														
Application Number 13/210,168	Filed 08/15/2011																															
For <small>BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION</small>																																
Art Unit 3733	Examiner Pedro Philogene																															
<p>This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above-identified application.</p> <p>The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):</p> <table style="width: 100%; border-collapse: collapse;"><thead><tr><th></th><th style="text-align: center;"><u>Fee</u></th><th style="text-align: center;"><u>Small Entity Fee</u></th><th style="text-align: center;"><u>Micro Entity Fee</u></th><th></th></tr></thead><tbody><tr><td>☐ One month (37 CFR 1.17(a)(1))</td><td style="text-align: center;">\$200</td><td style="text-align: center;">\$100</td><td style="text-align: center;">\$50</td><td>\$ _____</td></tr><tr><td>☐ Two months (37 CFR 1.17(a)(2))</td><td style="text-align: center;">\$600</td><td style="text-align: center;">\$300</td><td style="text-align: center;">\$150</td><td>\$ _____</td></tr><tr><td>☒ Three months (37 CFR 1.17(a)(3))</td><td style="text-align: center;">\$1,400</td><td style="text-align: center;">\$700</td><td style="text-align: center;">\$350</td><td>\$ 700.00</td></tr><tr><td>☐ Four months (37 CFR 1.17(a)(4))</td><td style="text-align: center;">\$2,200</td><td style="text-align: center;">\$1,100</td><td style="text-align: center;">\$550</td><td>\$ _____</td></tr><tr><td>☐ Five months (37 CFR 1.17(a)(5))</td><td style="text-align: center;">\$3,000</td><td style="text-align: center;">\$1,500</td><td style="text-align: center;">\$750</td><td>\$ _____</td></tr></tbody></table> <p>☐ Applicant asserts small entity status. See 37 CFR 1.27.</p> <p>☐ Applicant certifies micro entity status. See 37 CFR 1.29. Form PTO/SB/15A or B or equivalent must either be enclosed or have been submitted previously.</p> <p>☐ A check in the amount of the fee is enclosed.</p> <p>☐ Payment by credit card. Form PTO-2038 is attached.</p> <p>☐ The Director has already been authorized to charge fees in this application to a Deposit Account.</p> <p>☒ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number <u>505364</u>.</p> <p>☒ Payment made via EFS-Web.</p> <p>WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.</p> <p>I am the</p> <p>☐ applicant/inventor.</p> <p>☐ assignee of record of the entire interest. See 37 CFR 3.71. 37 CFR 3.73(b) statement is enclosed (Form PTO/SB/96).</p> <p>☒ attorney or agent of record. Registration number <u>46,672</u>.</p> <p>☐ attorney or agent acting under 37 CFR 1.34. Registration number _____.</p> <p><u>/John J. Dresch/</u> <u>December 10, 2014</u></p> <p style="text-align: center;">Signature Date</p> <p><u>John J. Dresch</u> <u>571.333.0930</u></p> <p style="text-align: center;">Typed or printed name Telephone Number</p> <p>NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. Submit multiple forms if more than one signature is required, see below*.</p> <p>☒ * Total of <u>1</u> forms are submitted.</p>				<u>Fee</u>	<u>Small Entity Fee</u>	<u>Micro Entity Fee</u>		☐ One month (37 CFR 1.17(a)(1))	\$200	\$100	\$50	\$ _____	☐ Two months (37 CFR 1.17(a)(2))	\$600	\$300	\$150	\$ _____	☒ Three months (37 CFR 1.17(a)(3))	\$1,400	\$700	\$350	\$ 700.00	☐ Four months (37 CFR 1.17(a)(4))	\$2,200	\$1,100	\$550	\$ _____	☐ Five months (37 CFR 1.17(a)(5))	\$3,000	\$1,500	\$750	\$ _____
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☐ Two months (37 CFR 1.17(a)(2))	\$600	\$300	\$150	\$ _____																												
☒ Three months (37 CFR 1.17(a)(3))	\$1,400	\$700	\$350	\$ 700.00																												
☐ Four months (37 CFR 1.17(a)(4))	\$2,200	\$1,100	\$550	\$ _____																												
☐ Five months (37 CFR 1.17(a)(5))	\$3,000	\$1,500	\$750	\$ _____																												

This collection of information is required by 37 CFR 1.136(a). The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 6 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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

Privacy Act Statement

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

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

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Patent Application Fee Transmittal				
Application Number:		13210168		
Filing Date:		15-Aug-2011		
Title of Invention:		BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION		
First Named Inventor/Applicant Name:		Ahmnon D. MOSKOWITZ		
Filer:		John Jeremy Dresch		
Attorney Docket Number:		3003/0105PUS7		
Filed as Small Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension - 3 months with \$0 paid	2253	1	700	700
Miscellaneous:				
Total in USD (\$)				700

Electronic Acknowledgement Receipt	
EFS ID:	20927905
Application Number:	13210168
International Application Number:	
Confirmation Number:	1609
Title of Invention:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION
First Named Inventor/Applicant Name:	Ahmnon D. MOSKOWITZ
Customer Number:	87409
Filer:	John Jeremy Dresch
Filer Authorized By:	
Attorney Docket Number:	3003/0105PUS7
Receipt Date:	10-DEC-2014
Filing Date:	15-AUG-2011
Time Stamp:	21:54:53
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$700
RAM confirmation Number	7990
Deposit Account	505364
Authorized User	DRESCH, JOHN J
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	
Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)	

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Amendment/Req. Reconsideration-After Non-Final Reject	30030105PUS7_Amendment_20141210_rff.pdf	126046	no	15
			6896b123478e67db5a16b917e75c820a38dd3ca8		
Warnings:					
Information:					
2	Extension of Time	30030105PUS7_EOT_20141210_readyforfiling.pdf	187915	no	2
			1ee9ff21c9795a67d3e9099c694d7be7b635da5c2		
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	31152	no	2
			2c2f3ba112c6a6c5e4e3af3eb06351d7ffa9cbf0		
Warnings:					
Information:					
Total Files Size (in bytes):			345113		
<p>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.</p> <p><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.</p> <p><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.</p> <p><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.</p>					

Electronic Acknowledgement Receipt	
EFS ID:	20927905
Application Number:	13210168
International Application Number:	
Confirmation Number:	1609
Title of Invention:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION
First Named Inventor/Applicant Name:	Ahmnon D. MOSKOWITZ
Customer Number:	87409
Filer:	John Jeremy Dresch
Filer Authorized By:	
Attorney Docket Number:	3003/0105PUS7
Receipt Date:	10-DEC-2014
Filing Date:	15-AUG-2011
Time Stamp:	21:54:53
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$700
RAM confirmation Number	7990
Deposit Account	505364
Authorized User	DRESCH, JOHN J
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	
Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)	

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Amendment/Req. Reconsideration-After Non-Final Reject	30030105PUS7_Amendment_20141210_rff.pdf	126046	no	15
			6896b123478e67db5a16b917e75c820a38dd3ca8		
Warnings:					
Information:					
2	Extension of Time	30030105PUS7_EOT_20141210_readyforfiling.pdf	187915	no	2
			1ee9ff21c9795a67d3e9099c694d7be7b635da5c2		
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	31152	no	2
			2c2f3ba112c6a6c5e4e3af3eb06351d7ffa9cbf0		
Warnings:					
Information:					
Total Files Size (in bytes):			345113		
<p>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.</p> <p><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.</p> <p><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.</p> <p><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.</p>					

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

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 13/210,168	Filing Date 08/15/2011	☐ To be Mailed
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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), (j), 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 \$ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X \$ =	
☐ 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))				
			TOTAL	

* If the difference in column 1 is less than zero, enter "0" in column 2.

APPLICATION AS AMENDED – PART II

(Column 1) (Column 2) (Column 3)

AMENDMENT	12/10/2014	CLAIMS REMAINING AFTER AMENDMENT	MINUS	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)
	Total (37 CFR 1.16(i))	* 49	Minus	** 60	= 0	x \$40 =	0
	Independent (37 CFR 1.16(h))	* 3	Minus	***3	= 0	x \$210 =	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	MINUS	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)
	Total (37 CFR 1.16(i))	*	Minus	**	X \$ =	
	Independent (37 CFR 1.16(h))	*	Minus	***	X \$ =	
	☐ 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.

** 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 number found in the appropriate box in column 1.

LIE
/Kelley Dantzler/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/210,168	08/15/2011	Ahmnnon D. MOSKOWITZ	3003/0105PUS7	1609

87409	7590	02/10/2015
Dresch IP Law, PLLC P.O. Box 650903 Potomac Falls, VA 20165		

EXAMINER	
PHILOGENE, PEDRO	

ART UNIT	PAPER NUMBER
3733	

NOTIFICATION DATE	DELIVERY MODE
02/10/2015	ELECTRONIC

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

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

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@dreschiplaw.com
jdresch@dreschiplaw.com
linda.logan@dreschiplaw.com

Office Action Summary	Application No. 13/210,168	Applicant(s) MOSKOWITZ ET AL.	
	Examiner PEDRO PHILOGENE	Art Unit 3733	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/10/14.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 86-134 is/are pending in the application.
5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 86-134 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) ☒ Notice of References Cited (PTO-892) | 3) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
Paper No(s)/Mail Date <u>8/28/14</u> . | 4) ☐ Other: ____. |

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

Double Patenting

A rejection based on double patenting of the “same invention” type finds its support in the language of 35 U.S.C. 101 which states that “whoever invents or discovers any new and useful process... may obtain a patent therefor...” (Emphasis added). Thus, the term “same invention,” in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the claims that are directed to the same invention so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 86-134 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 84-132 of copending Application No. 13/210157. This is a provisional statutory double patenting rejection since the claims directed to the same invention have not in fact been patented.

Claims 86-134 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 93-141 of copending Application No. 13/210162. This is a provisional statutory double patenting rejection since the claims directed to the same invention have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of pre-AIA 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 86-134 are rejected under pre-AIA 35 U.S.C. 102(e) as being clearly anticipated by Waugh et al. (2008/0249575).

Response to Amendment

Applicant's arguments with respect to claims 26-85 have been considered but are moot because the arguments do not apply to any of the references being used in the current rejection.

Conclusion

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

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PEDRO PHILOGENE whose telephone number is (571)272-4716. The examiner can normally be reached on Monday to Friday 8:00 AM to 4:30 PM.

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

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

Application/Control Number: 13/210,168
Art Unit: 3733

Page 5

/PEDRO PHILOGENE/
Primary Examiner, Art Unit 3733
February 4, 2015

Notice of References Cited	Application/Control No. 13/210,168	Applicant(s)/Patent Under Reexamination MOSKOWITZ ET AL.	
	Examiner PEDRO PHILOGENE	Art Unit 3733	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-2008/0249575	10-2008	Waugh et al.	606/305
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	498	(intervertebral or vertebral or spine or spinal) & (implant or cage or prosthesis or spacer) & screw near guide	US-PGPUB; USPAT	OR	ON	2015/02/04 11:56
L2	1	"20130018468"	US-PGPUB; USPAT	OR	OFF	2015/02/04 11:57
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L4	160	1 AND ((A61B17/0642 OR A61B17/7064 OR A61B17/809 OR A61B17/86 OR A61B17/8894 OR A61B2017/0641 OR A61B2017/0648 OR A61B2017/922 OR A61F2002/2835 OR A61F2002/30133 OR A61F2002/30387 OR A61F2002/30448 OR A61F2002/30507 OR A61F2002/3055 OR A61F2002/30579 OR A61F2002/30604 OR A61F2002/30772 OR A61F2002/30878 OR A61F2002/4475 OR A61F2002/448 OR A61F2002/4627 OR A61F2002/4681 OR A61F2002/4687 OR A61F2220/0025 OR A61F2220/005 OR A61F2230/0015 OR A61F2250/0007 OR A61F2/4465 OR A61F2/447 OR A61F2/4611).CPC. OR (623/17.11-17.16).CCLS. OR (A61F2/44).IPCR.)	US-PGPUB; USPAT	OR	OFF	2015/02/04 11:58
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L8	1	("7942903").PN.	USPAT; USOCR	OR	OFF	2015/02/04 12:32

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Search Notes 	Application/Control No. 13210168	Applicant(s)/Patent Under Reexamination MOSKOWITZ ET AL.
	Examiner PEDRO PHILOGENE	Art Unit 3733

CPC- SEARCHED		
Symbol	Date	Examiner
A61B17/0642, A61B17/809, A61B17/8894, A61F2/4465, A61F2/447, A61F2/4611, A61B17/7064	2/4/2015	/P.P./
A61F2250/0007, A61B17/86, A61B2017/0641, A61B2017/0648, A61B2017/922, A61F2002/2835, A61F2002/30133, A61F2002/30387, A61F2002/30448, A61F2002/30507		
A61F2002/3055, A61F2002/30579, A61F2002/30604, A61F2002/30772, A61F2002/30878, A61F2002/4475, A61F2002/448, A61F2002/4627, A61F2002/4681, A61F2220/0025, A61F2220/005, A61F2230/0015		

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
623	17.11-17.16	2/4/2015	/P.P./
606	300-305,246, 99, 144, 151, 251, 266		
227	181.1		

SEARCH NOTES		
Search Notes	Date	Examiner
EAST search enclosed	2/4/2015	/P.P./

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

	/PEDRO PHILOGENE/ Primary Examiner.Art Unit 3733
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Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)

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

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		13210168
	Filing Date		2011-08-15
	First Named Inventor	Ahmnon D. MOSKOWITZ et al.	
	Art Unit	3733	
	Examiner Name	Pedro PHILOGENE	
	Attorney Docket Number	3003/0105PUS7	

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Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5123926		1992-06-23	Pisharodi	
	2	5514180		1996-05-07	Heggeness et al.	
	3	6368350		2002-04-09	Erickson et al.	
	4	6419704		2002-07-16	Ferree	
	5	6458159		2002-10-01	Thalgott	
	6	6527804		2003-03-04	Gauchet et al.	
	7	6533818		2003-03-18	Weber et al.	
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	Art Unit	3733
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	Attorney Docket Number	3003/0105PUS7

	9	6582468		2003-06-24	Gauchet	
	10	6719794		2004-04-13	Gerber	
	11	6733532		2004-05-11	Gauchet et al.	
	12	6764491		2004-07-20	Frey et al.	
	13	6770094		2004-08-03	Fehling et al.	
	14	6572653		2003-06-03	Simonson	
	15	5782832		1998-07-21	Larsen et al.	
	16	6641614		2003-11-04	Wagner et al.	
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	18	6375682		2002-04-23	Fleischmann et al.	
	19	6723126		2004-04-20	Berry	

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	20	5667472		1997-09-07	Finn et al.	
	21	6955671		2005-10-18	Uchikubo	
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	23	6904308		2005-06-07	Frisch et al.	
	24	7097615		2006-08-29	Banik et al.	
	25	7030904		2006-04-18	Adair et al.	
	26	4997432	A	1991-03-05	Keller	
	27	5960522		1999-10-05	Boe	
	28	5660188		1997-08-26	Groiso	
	29	4960420		1990-10-02	Goble et al.	
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	31	4554914		1985-11-26	Kapp et al.	
	32	6953477		2005-10-11	BERRY, Bret	
	33	4599086		1986-07-08	DOTY, James R.	
	34	5062850		1991-11-05	MACMILLAN et al.	
	35	5290312	A	1994-03-01	KOJIMOTO et al.	
	36	5865848		1999-02-02	Baker, Gregg S.	
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	Art Unit	3733		
	Examiner Name	Pedro PHILOGENE		
	Attorney Docket Number	3003/0105PUS7		

	42	4904261		1990-02-27	Dove et al.	
	43	7875076		2011-01-25	Mathieu et al.	
	44	7232464		2007-06-19	Mathieu et al.	
	45	7846207		2010-12-07	Lechmann et al.	
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	47	7887591		2011-02-15	Aebi et al.	
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	49	7442299		2008-10-28	Lee et al.	

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	1	20040088054		2004-05-06	Berry	

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	2	20050273170		2005-12-08	Navarro et al.	
	3	20040177531		2004-09-16	DiBenedetto et al.	
	4	20050278026	AI	2005-12-15	Gordon, et al.	
	5	20050216084	AI	2005-09-29	Fleischmann	
	6	20050027362	AI	2005-02-03	Williams et al.	
	7	20050049590	AI	2005-03-03	Alleyne et al.	
	8	20040254644	AI	2004-12-16	Taylor	
	9	20020143338	AI	2002-10-03	ORBAY et al.	
	10	20050177235	AI	2005-08-11	BAYNHAM et al.	
	11	20020068977	AI	2002-06-06	JACKSON	
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		13210168	
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	Examiner Name	Pedro PHILOGENE		
	Attorney Docket Number	3003/0105PUS7		

	13	20100305704		2010-12-02	Messerli et al.	
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	1	2004093749	WO	A1	2004-11-04	MAGERL et al.		☐
	2	2006091503	WO	A1	2006-08-31	SHATTUCK et al.		☐

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	1	Vincent C. TRAYNELIS, "Prosthetics and Biologics: The Wave of the Future," CLINICAL NEUROSURGERY, Volume 50, Proceedings of the Congress of Neurological Surgeons, Philadelphia, PA 2002, Chapter 9, pages 207-219.						☐
	2	E.K. WAI et al., "Disk Replacement Arthroplasties: Can The Success of Hip and Knee Replacements be Repeated in the Spine?," Seminars in Spine Surgery, Vol. 15, No. 4 (December) 2003, pp 473-482.						☐
	3	Richard D. GUYER et al., "Intervertebral Disc Prostheses," SPINE JOURNAL, Volume 28, Number 15S, Supp. To 8/1/03, pages S15-S23.						☐
	4	DIETER GROB et al., "Clinical Experience With the Dynesys Semirigid Fixation System for the Lumbar Spine," SPINE, Vol. 30, No. 3, 2005, pp. 324-331.						☐

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5	International Search Report (ISR) and Written Opinion of the International Searching Authority, 03 December 2007, International Application No. PCT/US 07/05005.	☐
6	International Search Report (ISR) and Written Opinion of the International Searching Authority, 21 May 2008, International Application No. PCT/US2007/021015	☐
7	International Search Report (ISR) and Written Opinion of the International Searching Authority, 09 July 2008, International Application No. PCT/US2007021013	☐

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Examiner Signature	/Pedro Philogene/	Date Considered	02/04/2015
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	Examiner Name	Pedro PHILOGENE
	Attorney Docket Number	3003/0105PUS7

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).

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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	/John J. Dresch/	Date (YYYY-MM-DD)	2014-08-28
Name/Print	John J. Dresch	Registration Number	46,672

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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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /P.P./

<p align="center"><i>Index of Claims</i></p> 	Application/Control No. 13210168	Applicant(s)/Patent Under Reexamination MOSKOWITZ ET AL.
	Examiner PEDRO PHILOGENE	Art Unit 3733

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
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☐ Claims renumbered in the same order as presented by applicant										☐ CPA										☐ T.D.										☐ R.1.47									
CLAIM			DATE																																				
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<p align="center"><i>Index of Claims</i></p> 	Application/Control No. 13210168	Applicant(s)/Patent Under Reexamination MOSKOWITZ ET AL.
	Examiner PEDRO PHILOGENE	Art Unit 3733

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

☐ Claims renumbered in the same order as presented by applicant											☐ CPA											☐ T.D.											☐ R.1.47										
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CLAIM		DATE								
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	134	✓								

Doc code: RCEX

Doc description: Request for Continued Examination (RCE)

PTO/SB/30EFS (07-09)

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

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

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

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

Application Number	13/210,168	Filing Date	2011-08-15	Docket Number (if applicable)	3003/0105PUS7	Art Unit	3733
First Named Inventor	Ahmnon D. Moskowitz et al.			Examiner Name	Pedro Philogene		

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

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

SUBMISSION REQUIRED UNDER 37 CFR 1.114

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

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

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

☐ Other _____

☒ Enclosed

☒ Amendment/Reply

☐ Information Disclosure Statement (IDS)

☐ Affidavit(s)/ Declaration(s)

☒ Other
Petition for Extension of Time

MISCELLANEOUS

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

☐ Other _____

FEES

The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.

☒ The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to Deposit Account No 505364

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

☒ Patent Practitioner Signature

☐ Applicant Signature

Doc code: RCEX

Doc description: Request for Continued Examination (RCE)

PTO/SB/30EFS (07-09)

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

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

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

Signature of Registered U.S. Patent Practitioner			
Signature	/John J. Dresch/	Date (YYYY-MM-DD)	2015-08-10
Name	John J. Dresch	Registration Number	46672

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450.

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

Privacy Act Statement

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

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

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
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.

PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)		Docket Number (Optional) 3003/0105PUS7		
Application Number 13/210,168	Filed 08/15/2011			
For BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION				
Art Unit 3733	Examiner Pedro Philogene			
This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above-identified application. The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):				
	<u>Fee</u>	<u>Small Entity Fee</u>	<u>Micro Entity Fee</u>	
☐ One month (37 CFR 1.17(a)(1))	\$200	\$100	\$50	\$ _____
☐ Two months (37 CFR 1.17(a)(2))	\$600	\$300	\$150	\$ _____
☒ Three months (37 CFR 1.17(a)(3))	\$1,400	\$700	\$350	\$ 700.00
☐ Four months (37 CFR 1.17(a)(4))	\$2,200	\$1,100	\$550	\$ _____
☐ Five months (37 CFR 1.17(a)(5))	\$3,000	\$1,500	\$750	\$ _____
☒ Applicant asserts small entity status. See 37 CFR 1.27.				
☐ Applicant certifies micro entity status. See 37 CFR 1.29. Form PTO/SB/15A or B or equivalent must either be enclosed or have been submitted previously.				
☐ A check in the amount of the fee is enclosed.				
☐ Payment by credit card. Form PTO-2038 is attached.				
☐ The Director has already been authorized to charge fees in this application to a Deposit Account.				
☒ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number <u>505364</u> .				
☒ Payment made via EFS-Web.				
WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.				
I am the				
☐ applicant/inventor.				
☐ assignee of record of the entire interest. See 37 CFR 3.71. 37 CFR 3.73(b) statement is enclosed (Form PTO/SB/96).				
☒ attorney or agent of record. Registration number <u>46,672</u> .				
☐ attorney or agent acting under 37 CFR 1.34. Registration number _____.				
/John J. Dresch/		August 10, 2015		
Signature		Date		
John J. Dresch		571.333.0930		
Typed or printed name		Telephone Number		
NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. Submit multiple forms if more than one signature is required, see below*.				
☒ * Total of <u>1</u> forms are submitted.				

This collection of information is required by 37 CFR 1.136(a). The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 6 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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

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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 disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Ahmnon D. MOSKOWITZ, et al.
Application Number: 13/210,168
Filing Date: 08/15/2011
Group Art Unit: 3733
Examiner: Pedro PHILOGENE
Confirmation No.: 1609
Title: BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY
SCREWS AND POSTERIOR CERVICAL AND LUMBAR
INTERARTICULATING JOINT CALIBRATED STAPLING
DEVICES FOR SPINAL FUSION

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT B

Dear Sir:

This Amendment is responsive to the Final Office Action dated February 10, 2015, having a due date of August 10, 2015, and accompanies an excess claim fee for one (1) excess total claim and a Request for Continued Examination.

Please charge Deposit Account No. 505364 for any deficiency or overpayment.

Please amend the application as follows:

Amendments to the Claims, as reflected in the listing of claims, begin on page 2 of this paper;
and

Remarks begin on page 12 of this paper.

IN THE CLAIMS:

Please amend the claims as follows. This listing of the claims will replace all prior versions, and listings, of claims in the application:

1-25. (Canceled)

26-85. (Canceled)

86. (Previously presented) A universal, intervertebral combination internal screw guide and fixation apparatus configured to be inserted into a disc space between a first vertebral body and a second vertebral body and to provide fusion of the first vertebral body to the second vertebral body via biological bone fusion and screw fusion, the apparatus comprising:

an intervertebral cage including:

a top wall, a bottom wall, and two sidewalls defining an open space capable of receiving bone filling for the biological bone fusion; and

an internal screw guide having an entry opening and an exit opening, the entry opening formed at least partially in a top surface of the top wall and the exit opening formed at least partially in a bottom surface of the top wall and at least partially in a side surface of the top wall.

87. (Previously presented) The apparatus of claim 86, wherein an internal surface of the internal screw guide extends continuously from the entry opening to the exit opening.

88. (Previously presented) The apparatus of claim 86, wherein the internal screw guide extends through an entire depth of the top wall from the top surface to the bottom surface and exiting at least partially into the open space.

89. (Previously presented) The apparatus of claim 86, wherein the internal screw guide permits only a predetermined angled trajectory of a screw member through the intervertebral cage.

90. (Previously presented) The apparatus of claim 86, wherein the internal screw guide has a 25 degree angulation.

91. (Previously presented) The apparatus of claim 86, wherein the top wall has a thickness extending from the top surface of the top wall to the bottom surface of the top wall in a direction of a depth of the intervertebral cage, a height of the intervertebral cage extending in a direction perpendicular to the depth, and

wherein an axis of the internal screw guide extends to a greater extent in the direction of the depth of the intervertebral cage than in a direction of a height of the intervertebral cage in order to facilitate multi-level fusion of adjacent vertebral bodies with multiple intervertebral cages.

92. (Previously presented) The apparatus of claim 86, wherein the top wall of the intervertebral cage has a thickness that is greater than a thickness of each of the sidewalls.

93. (Previously presented) The apparatus of claim 86, wherein at least one of the two sidewalls includes a hole configured to allow placement of bone filling into the open space of the intervertebral cage for the biological bone fusion.

94. (Previously presented) The apparatus of claim 86, wherein the intervertebral cages includes indentations formed on surfaces of the two sidewalls and on opposite ends of the intervertebral cage for receiving ends of prongs of an implantation tool.

95. (Previously presented) The apparatus of claim 86, wherein a surface of each of the two sidewalls includes a plurality of ridges.

96. (Previously presented) The apparatus of claim 86, wherein the intervertebral cage is configured to receive a plate for securing a second intervertebral cage thereto.

97. (Previously presented) The apparatus of claim 96, wherein the intervertebral cage comprises:

a screw insert configured to receive the plate for securing the second intervertebral cage thereto.

98. (Previously presented) The apparatus of claim 86, wherein the intervertebral cage is a cervical intervertebral cage configured to fit into a cervical disc space.

99. (Previously presented) The apparatus of claim 86, wherein the intervertebral cage is a lumbar intervertebral cage configured to fit into a lumbar disc space.

100. (Previously presented) The apparatus of claim 86, wherein the intervertebral cage is a posterior lumbar intervertebral cage configured to fit into a lumbar disc space.

101. (Previously presented) The apparatus of claim 86, wherein the intervertebral cage capable of one of posterior lumbar intervertebral placement, anterior lumbar intervertebral placement, thoracic intervertebral placement, and anterior cervical intervertebral placement.

102. (Previously presented) The apparatus of claim 86, wherein the intervertebral cage further comprises:

a second internal screw guide having a second entry opening and a second exit opening, the second entry opening formed at least partially in the top surface of the top wall and the second exit opening formed at least partially in the bottom surface of the top wall and at least partially in a second side surface of the top wall.

103. (Previously presented) The apparatus of claim 102, wherein each of the internal screw guide and the second internal screw guide is angled to orient a first screw member and a second screw bi-directionally in opposite directions.

104. (Previously presented) The apparatus of claim 103, wherein the internal screw guide is configured to orient the first screw member rostrally and the second internal screw guide is configured to orient the second screw member caudally.

105. (Previously presented) The apparatus of claim 102, wherein the internal screw guide and the second internal screw guide are at an angulation with respect to the top surface of the top wall.

106. (Previously presented) The apparatus of claim 102, wherein each of the internal screw guide and the second internal screw guide permits only a 25 degree angulation of a first screw member and the second screw member.

107. (Previously presented) The apparatus of claim 102, wherein the internal screw guide and the second internal screw guide are aligned along a longitudinal axis of the top wall of the intervertebral cage.

108. (Previously presented) The apparatus of claim 102, wherein the internal screw guide and the second internal screw guide are symmetrically disposed on each side of a center point of the intervertebral cage along a longitudinal axis of the top wall of the intervertebral cage.

109. (Previously presented) The apparatus of claim 102, wherein the internal screw guide and the second internal screw guide are offset in opposite directions with respect to a center line of a longitudinal extent of the top wall.

110. (Previously presented) The apparatus of claim 109, wherein a part of the internal screw guide overlaps a part of the second internal screw guide along the longitudinal extent of the top wall.

111. (Previously presented) The apparatus of claim 102, wherein the entry opening of the internal screw guide and the second entry opening of the second internal screw guide are arranged diagonally on the top surface of the top wall.

112. (Previously presented) The apparatus of claim 102, wherein the top wall has four quadrants delineated by a first axis and a second axis each lying in a plane of the top wall, and the first axis is at a right angle with respect to the second axis,

wherein the four quadrants include a first quadrant, a second quadrant, a third quadrant, and a fourth quadrant,

wherein the first quadrant and the fourth quadrant are opposed to the second quadrant and the third quadrant with respect to the first axis, and the first quadrant and the second quadrant are opposed to the third quadrant and the fourth quadrant with respect to the second axis,

wherein the first quadrant is diagonally opposed to the third quadrant, and the second quadrant is diagonally opposed to the fourth quadrant, and

wherein a majority of an area of the entry opening of the internal screw guide is in the first quadrant and a majority of an area of the second entry opening of the second internal screw guide is in the third quadrant.

113. (Previously presented) The apparatus of claim 102, wherein the top wall has four quadrants delineated by a first axis and a second axis each lying in a plane of the first wall, and the first axis is at a right angle with respect to the second axis,

wherein the four quadrants include a first quadrant, a second quadrant, a third quadrant, and a fourth quadrant,

wherein the first quadrant and the fourth quadrant are opposed to the second quadrant and the third quadrant with respect to the first axis, and the first quadrant and the second quadrant are opposed to the third quadrant and the fourth quadrant with respect to the second axis,

wherein the first quadrant is diagonally opposed to the third quadrant, and the second quadrant is diagonally opposed to the fourth quadrant, and

wherein a center of the entry opening of the internal screw guide is in the first quadrant and a center of the second entry opening of the second internal screw guide is in the third quadrant.

114. (Previously presented) The apparatus of claim 102, wherein the top wall includes a first corner and a second corner, the first corner being arranged at an opposite side of the top wall and an opposite end of the top wall with respect to the second corner, and

wherein the internal screw guide and the second internal screw guide are diagonally arranged along a direction extending from the first corner of the top wall to the second corner of the top wall.

115. (Previously presented) The apparatus of claim 102, wherein the intervertebral cage further comprises:

a third internal screw guide having a third entry opening and a third exit opening, the third entry opening formed at least partially in the top surface of the top wall and the third exit opening formed at least partially in the bottom surface of the top wall and at least partially in the side surface of the top wall.

116. (Previously presented) The apparatus of claim 115, wherein the intervertebral cage further comprises:

a fourth internal screw guide having a fourth entry opening and a fourth exit opening, the fourth entry opening formed at least partially in the top surface of the top wall and the fourth exit opening formed at least partially in the bottom surface of the top wall and at least partially in the second side surface of the top wall.

117. (Previously presented) The apparatus of claim 116, wherein the internal screw guide and the fourth internal screw guide are oriented rostrally and the second internal screw guide and the third internal screw guide are oriented caudally.

118. (Previously presented) The apparatus of claim 116, wherein the second internal screw guide and the third internal screw guide are disposed between the internal screw guide and the fourth internal screw guide along a longitudinal length of the top wall of the intervertebral cage.

119. (Previously presented) The apparatus of claim 116, wherein each of the internal screw guide, the second internal screw guide, the third internal screw guide, and the fourth internal screw guide has a 25 degree angulation.

120. (Previously presented) The apparatus of claim 86, further comprising:

a second intervertebral cage including:

a top wall, a bottom wall, and two sidewalls defining an open space capable of receiving bone filling for biological bone fusion, and

an internal screw guide having an entry opening and an exit opening, the entry opening of the second intervertebral cage formed at least partially in a top surface of the top wall of the second intervertebral cage and the exit opening formed at least partially in a bottom surface of the top wall of the second intervertebral cage and at least partially in a side surface of the top wall of the second intervertebral cage; and

an attachment member coupling the intervertebral cage to the second intervertebral cage.

121. (Previously presented) The apparatus of claim 120, wherein the attachment member includes a supplemental cage defining one or more open spaces capable of receiving the intervertebral cage and the second intervertebral cage, and

wherein the intervertebral cage and the second intervertebral cage are secured to the supplemental cage.

122. (Previously presented) The apparatus of claim 120, wherein the attachment member includes a plate.

123. (Previously presented) The apparatus of claim 102, wherein the intervertebral cage is devoid of any other internal screw guides other than the first internal screw guide and a second internal screw guide.

124. (Previously presented) A zero-profile, intervertebral cage sized and configured to be inserted into a disc space between adjacent vertebral bodies and to provide fusion of the adjacent vertebral bodies via biological bone fusion and screw fusion,

the intervertebral cage comprising:

- a top wall;

- a bottom wall opposite the top wall;

- a first sidewall;

- a second sidewall opposite the first sidewall, each of the first sidewall and the second sidewall having a surface configured to contact one of the adjacent vertebral bodies when the intervertebral cage is inserted into the disc space,

- wherein at least the first sidewall and the second sidewall bound an open space capable of receiving bone filling for the biological bone fusion,

- wherein the top wall includes a top surface and a bottom surface opposite the top surface, the top surface configured to have a zero-profile with respect to the adjacent vertebral bodies when the intervertebral cage is inserted into the disc space, and the bottom surface facing the open space; and

- an internal screw trajectory guide for guiding a trajectory of a screw through the intervertebral cage, the internal screw trajectory guide having an entry opening and an exit opening, the entry opening formed at least partially in the top surface of the top wall, and the exit opening formed at least partially in a bottom surface of the top wall and at least partially in a side surface of the top wall.

125. (Previously presented) The apparatus of claim 86, wherein the exit opening is formed at least partially in a surface of one of the two sidewalls.

126. (Previously presented) A universal, intervertebral combination internal screw guide and fixation apparatus configured to be inserted into a disc space between a first vertebral body and a second vertebral body and to provide fusion of the first vertebral body to the second vertebral body via biological bone fusion and screw fusion, the apparatus comprising:

- an intervertebral cage including:

- a top wall, a bottom wall, and two sidewalls defining an open space capable of receiving bone filling for the biological bone fusion; and

- an internal screw guide having an entry opening and an exit opening, the entry opening formed at least partially in a top surface of the top wall,

the exit opening formed at least partially in a bottom surface of the top wall, and
the exit opening formed at least partially in at least one of:

- a side surface of the top wall; and
- a surface of one of the two sidewalls.

127. (Previously presented) The apparatus of claim 126, wherein the exit opening is formed partially in the side surface of the top wall.

128. (Previously presented) The apparatus of claim 126, wherein the exit opening is formed partially in the surface of the one of the two sidewalls.

129. (Previously presented) The apparatus of claim 126, wherein the exit opening is formed partially in the side surface of the top wall and partially in the surface of the one of the two sidewalls.

130. (Previously presented) The apparatus of claim 86, wherein the entry opening is formed substantially in the top surface of the top wall.

131. (Previously presented) The apparatus of claim 86, wherein the entry opening is formed entirely in the top surface of the top wall.

132. (Previously presented) The apparatus of claim 121, wherein the supplemental cage surrounds a perimeter of the intervertebral cage and the second intervertebral cage.

133. (Previously presented) The apparatus of claim 86, wherein the internal screw guide includes:

- a counterbore formed at least partially in the top surface of the top wall for accommodating a screw head of a screw member; and
- an internal bore configured to continuously guide a body of the screw member through the internal screw guide into the open space and into the first vertebral body, wherein the internal bore includes a bore entry opening formed in a lower surface of the counterbore, the bore entry

opening formed entirely between all edges of the top surface of the top wall when viewed from a direction perpendicular to a plane of the top surface, and a bore exit opening formed partially in the bottom surface of the top wall and partially in the side surface of the top wall.

134. (Previously presented) The apparatus of claim 133, wherein the internal bore is coaxial with the counterbore.

135. (New) The apparatus of claim 86, wherein the internal screw guide has an internal bore with the entry opening and the exit opening, and the entry opening of the internal bore is formed only in the top surface of the top wall and the exit opening is formed at least partially in the bottom surface of the top wall and at least partially in the side surface of the top wall,

wherein the internal screw guide further comprises a counterbore formed at least partially in the top surface of the top wall for accommodating a screw head of a screw member,

wherein the entry opening of the internal bore is formed in a lower surface of the counterbore, and

wherein the entry opening of the internal bore is formed entirely between all edges of the top surface of the top wall when viewed from a direction perpendicular to a plane of the top surface.

REMARKS

Claims 86-135 are pending in the application. This Amendment adds new claim 135. Claims 86, 124, and 126 are independent. No new matter is added.

New claim 135 is added to provide more varied protection for the present invention and to raise a new issue for the Examiner's consideration, thereby to preclude a first-Action final rejection after the filing of the RCE. The features of claim 135 and the combination of claims 86 and 135 have not been presented earlier.

The Provisional Double Patenting Rejection

Claims 86-134 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 84-132 of copending Application No. 13/210,157. Claims 86-134 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 93-141 of copending Application No. 13/210,162.

Applicants respectfully traverse these rejections.

Applicants respectfully submit that claims 86-134 of the present application are patentably distinct from the claims of the copending applications. Applicants note that the claims may be subject to further amendments during prosecution, which features should serve to further distinguish the claims of the present application from the claims of the co-pending applications.

With regard to the provisional obviousness-type double patenting rejections, Applicants respectfully submit that the conflicting claims have not in fact been patented, and therefore, also may be subject to further amendments during prosecution, which features may serve to further distinguish the claims of the present application from the claims of the co-pending applications.

For these reasons, Applicants respectfully reserve the right to file a terminal disclaimer in compliance with 37 C.F.R. § 1.321(c) or 1.321(d) as such time as the claims of the present application are allowable. Applicants respectfully request withdrawal of these rejections.

The Prior Art Rejection

The Office Action rejects claims 86-134 under 35 U.S.C. §102(e) as allegedly being anticipated by the Waugh et al. reference (U.S. Publication No. 2008/0249575).

Applicants respectfully traverse this rejection.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. [...] The identical invention must be shown in as complete detail as is contained in the ... claim." M.P.E.P. § 2131.

The Waugh et al. reference does not disclose or suggest the unique combination of features of new claim 133 including an internal screw guide having an internal bore with an entry opening and an exit opening, the entry opening of the internal bore formed only in a top surface of the top wall and the exit opening formed at least partially in a bottom surface of the top wall and at least partially in a side surface of the top wall.

The Waugh et al. reference discloses several embodiments, none of which discloses each and every element of the claims. For example, in the embodiments illustrated in FIGS. 1-8, which angle the screws at a steep angle with respect to the sidewalls, each of the entry opening and exit opening of the internal bore of the screw holes is formed in two surfaces. Particularly, the entry opening of the bore is formed partially in the top surface and partially in the side surface of the top wall of the cage, and the exit opening of the bore similarly is formed partially in the bottom surface and partially in the side surface of the top wall of the cage. As a result, a surgeon will need to remove bone from the adjacent vertebral bodies in order to insert the screw into the cage and vertebral bodies.

In the embodiments illustrated in FIG. 9-14, which angle the screws at a shallow angle with respect to the sidewalls, each of the entry opening and exit opening of the internal bore of the screw holes is formed in only one surface. See, e.g., FIG. 9. Particularly, the entry opening of the bore is formed only in the top surface of the top wall of the cage, and the exit opening of the bore is formed only in the bottom surface of the top wall of the cage. In other words, depending on the intended angle of the screws, the Waugh et al. reference discloses either entering through two surfaces and exiting through two surfaces if the screw hole is it be angled at a steep angle with respect to the sidewalls, or entering through a single surface and exiting through a single surface if the screw hole is to be angled at a shallow angle with respect to the sidewalls. Hence, none of the embodiments of the Waugh et al. reference discloses each and every element of the claims.

In stark contrast to the arrangements in the applied references, the claimed invention provides a unique combination in which an internal screw guide has an internal bore with an

entry opening and an exit opening, the entry opening of the internal bore is formed only in a top surface of the top wall, while the exit opening is formed at least partially in a bottom surface of the top wall and at least partially in a side surface of the top wall. In this way, the present invention provides a unique arrangement having an internal screw guide in the cage that guides a screw trajectory into the vertebral body at a predetermined shallow angle that avoids interference with screws of other adjacent implantation devices and enables multiple level fusion, and at the same time eliminates a need for the surgeon to remove a part of the bone from the vertebral body to insert the screw. The present invention also eliminates the need to use an external screw guide.

Applicants respectfully request withdrawal of this rejection.

The New Claim

As mentioned above, this Amendment adds new claim 135. This Amendment does not add new matter. None of the applied references discloses or suggests the subject matter defined by claims 135 for at least the same reasons as independent claim 86, as well as for the additional features recited therein.

Applicants respectfully request allowance of these claims.

CONCLUSION

In view of the above, Applicants respectfully request entry of the present Amendment and allowance of Claims 86-135. Applicants invite the Examiner to contact the undersigned if the Examiner has any questions regarding this amendment. Applicants petition for an extension of time if required for entry of this Amendment.

Please charge Deposit Account No. 505364 for any deficiency or overpayment.

Respectfully Submitted,

/ John J. Dresch /
John J. Dresch
Attorney for Applicant(s)
Reg. No. 46,672

August 10, 2015

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Electronic Patent Application Fee Transmittal				
Application Number:		13210168		
Filing Date:		15-Aug-2011		
Title of Invention:		BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION		
First Named Inventor/Applicant Name:		Ahmnon D. MOSKOWITZ		
Filer:		John Jeremy Dresch/Linda Logan		
Attorney Docket Number:		3003/0105PUS7		
Filed as Small Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Claims in excess of 20	2202	1	40	40
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension-of-Time:				
Extension - 3 months with \$0 paid	2253	1	700	700
Miscellaneous:				
Request for Continued Examination	2801	1	600	600
Total in USD (\$)				1340

Electronic Acknowledgement Receipt

EFS ID:	23158164
Application Number:	13210168
International Application Number:	
Confirmation Number:	1609
Title of Invention:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION
First Named Inventor/Applicant Name:	Ahmnon D. MOSKOWITZ
Customer Number:	87409
Filer:	John Jeremy Dresch/Linda Logan
Filer Authorized By:	John Jeremy Dresch
Attorney Docket Number:	3003/0105PUS7
Receipt Date:	10-AUG-2015
Filing Date:	15-AUG-2011
Time Stamp:	11:08:25
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$ 1340
RAM confirmation Number	8797
Deposit Account	505364
Authorized User	DRESCH, JOHN J
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Request for Continued Examination (RCE)	30030105PUS7_RCE_readyforfiling.pdf	697648	no	3
			c305343a2de7f4fb5934c91a85ca0d1fb2fb35c9		
Warnings:					
Information:					
2	Extension of Time	30030105PUS7_Petition_EOT_readyforfiling.pdf	188232	no	2
			8fef28fb64dd2efa6be18453b1993646b5479cbb		
Warnings:					
Information:					
3		30030105PUS7_Amendment_B_readyforfiling.pdf	124678	yes	15
			e5fef2865bc21666e29183b460fc514fd342fd1		
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Amendment Submitted/Entered with Filing of CPA/RCE		1	1	
	Claims		2	11	
	Applicant Arguments/Remarks Made in an Amendment		12	15	
Warnings:					
Information:					
4	Fee Worksheet (SB06)	fee-info.pdf	34494	no	2
			7cd1682feb8b9adf60375be86458b15eba061b45		
Warnings:					
Information:					
Total Files Size (in bytes):			1045052		

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.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

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

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 13/210,168	Filing Date 08/15/2011	☐ To be Mailed
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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), (j), 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 \$ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X \$ =	
☐ 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	08/10/2015	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)
	Total (37 CFR 1.16(i))	* 50	Minus	** 60	= 0	x \$40 =	0
	Independent (37 CFR 1.16(h))	* 3	Minus	*** 3	= 0	x \$210 =	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 \$ =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X \$ =	
	☐ 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.

** 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 number found in the appropriate box in column 1.

LIE
/CHERYL CLARK/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/210,168	08/15/2011	Ahmnnon D. MOSKOWITZ	3003/0105PUS7	1609
87409	7590	10/30/2015		
Dresch IP Law, PLLC P.O. Box 650903 Potomac Falls, VA 20165			EXAMINER PHILOGENE, PEDRO	
			ART UNIT 3733	PAPER NUMBER
			NOTIFICATION DATE 10/30/2015	DELIVERY MODE ELECTRONIC

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

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

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@dreschiplaw.com
jdresch@dreschiplaw.com
linda.logan@dreschiplaw.com

Office Action Summary	Application No. 13/210,168	Applicant(s) MOSKOWITZ ET AL.	
	Examiner PEDRO PHILOGENE	Art Unit 3733	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/10/15.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 86-135 is/are pending in the application.
5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 86-135 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) ☒ Notice of References Cited (PTO-892) | 3) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
Paper No(s)/Mail Date ____. | 4) ☐ Other: ____. |

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

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/10/15 has been entered.

Double Patenting

A rejection based on double patenting of the “same invention” type finds its support in the language of 35 U.S.C. 101 which states that “whoever invents or discovers any new and useful process... may obtain a patent therefor...” (Emphasis added). Thus, the term “same invention,” in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the claims that are directed to the same invention so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 86-135 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 93-141 of copending Application No. 13/210,162. This is a provisional statutory double patenting rejection since the claims directed to the same invention have not in fact been patented.

Claims 86-135 provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 84-133 of copending Application No. 13/210,157. This is a provisional statutory double patenting rejection since the claims directed to the same invention have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of pre-AIA 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 86-134 are rejected under pre-AIA 35 U.S.C. 102(e) as being clearly anticipated by Waugh et al. (2008/0249575).

Claim Rejections - 35 USC § 103

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

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

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

Claim 135 is rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Waugh et al (2008/0249575) in view of Johnson (2009/0080997).

It is noted that Waugh does not teach wherein the internal screw guide has an internal bore with the entry opening and the exit opening, and the entry opening of the internal bore is formed only in the top surface of the top wall and the exit opening is formed at least partially in the bottom surface of the top wall and at least partially in the side surface of the top wall, wherein the internal screw guide further comprises a counterbore formed at least partially in the top surface of the top wall for accommodating a screw head of a screw member, wherein the entry opening of the internal bore is formed in a lower surface of the counterbore, and wherein the entry opening of the internal bore is formed entirely between all edges of the top wall when viewed from a direction perpendicular to a plane of the top surface, as claimed by applicant. However, in similar art, Johnson provides the evidences of the use of a vertebral implant wherein the internal screw guide has an internal bore with the entry opening and the exit opening, as best seen in FIG.1, and the entry opening of the internal bore is formed only in the top surface of the top wall, as best seen in FIG.1, and the exit opening is formed at least partially in the bottom surface of the top wall and at least partially in the side surface of the top wall, as best seen in FIGS.1-4 and as set forth in para[0026], wherein the internal screw guide further comprises a counterbore formed at least partially in the top surface of the top wall for accommodating a screw head of a screw member, as best seen in FIGS.1-4, wherein the entry opening of the

internal bore is formed in a lower surface of the counterbore, and wherein the entry opening of the internal bore is formed entirely between all edges of the top wall when viewed from a direction perpendicular to a plane of the top surface, as best seen in FIG.1, for allowing the screw to be secure to the appropriate vertebral body.

Therefore, given the teaching of Johnson, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Waugh, as taught by Johnson, by incorporating the features of the implant of Johnson in the device of Waugh for allowing the screw to be secured to the appropriate vertebral body.

Response to Amendment

Applicant's arguments filed 8/10/15 have been fully considered but they are not persuasive. As to the Double Patenting rejection, although applicant stated that the claims of the present application may be subject to further amendments during prosecution, applicant did not state which features should serve to further distinguish the claims of the present application from the claims of the co-pending applications, applicant did not amend any of the claims in the present application. Furthermore, applicant argues that Waugh, all fails to teach the features in newly presented dependent claim 135, the examiner agrees. However, Johnson discloses a vertebral implant with all the limitations, as claimed in new claim 135. Furthermore, applicant stated that each of the entry opening and exit opening of the internal bore of the screw holes is formed in two surfaces; however, in at least claim 86, applicant is only claiming that the screw hole is formed at least partially in a top surface of the top wall. The screw

Art Unit: 3733

hole of Waugh is partially formed in the top surface. Therefore, combining Johnson with Waugh, to arrive at applicant's claimed invention would have been obvious to one of ordinary skill in the art. See rejection above.

Conclusion

A shortened statutory period for reply to this action is set to expire THREE MONTHS from the mailing date of this action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PEDRO PHILOGENE whose telephone number is (571)272-4716. The examiner can normally be reached on Monday to Friday 8:00 AM to 4:30 PM.

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

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

/PEDRO PHILOGENE/
Primary Examiner, Art Unit 3733
October 27, 2015

Notice of References Cited	Application/Control No. 13/210,168	Applicant(s)/Patent Under Reexamination MOSKOWITZ ET AL.	
	Examiner PEDRO PHILOGENE	Art Unit 3733	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-2008/0249575 A1	10-2008	Waugh; Lindsey G.	A61F2/447	606/305
*	B	US-2009/0080997 A1	03-2009	Johnson; Jeffrey	A61B17/8047	411/347
	C	US-				
	D	US-				
	E	US-				
	F	US-				
	G	US-				
	H	US-				
	I	US-				
	J	US-				
	K	US-				
	L	US-				
	M	US-				

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

<i>Index of Claims</i> 	Application/Control No. 13210168	Applicant(s)/Patent Under Reexamination MOSKOWITZ ET AL.
	Examiner PEDRO PHILOGENE	Art Unit 3733

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

☐ Claims renumbered in the same order as presented by applicant				☐ CPA		☐ T.D.		☐ R.1.47	
CLAIM		DATE							
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<i>Index of Claims</i> 	Application/Control No. 13210168	Applicant(s)/Patent Under Reexamination MOSKOWITZ ET AL.
	Examiner PEDRO PHILOGENE	Art Unit 3733

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

☐ Claims renumbered in the same order as presented by applicant				☐ CPA		☐ T.D.		☐ R.1.47	
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<i>Index of Claims</i> 	Application/Control No. 13210168	Applicant(s)/Patent Under Reexamination MOSKOWITZ ET AL.
	Examiner PEDRO PHILOGENE	Art Unit 3733

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

☐ Claims renumbered in the same order as presented by applicant				☐ CPA		☐ T.D.		☐ R.1.47	
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	106	✓	✓						
	107	✓	✓						
	108	✓	✓						

<i>Index of Claims</i> 	Application/Control No. 13210168	Applicant(s)/Patent Under Reexamination MOSKOWITZ ET AL.
	Examiner PEDRO PHILOGENE	Art Unit 3733

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

☐ Claims renumbered in the same order as presented by applicant				☐ CPA		☐ T.D.		☐ R.1.47	
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	131	✓	✓						
	132	✓	✓						
	133	✓	✓						
	134	✓	✓						
	135		✓						

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	607	(intervertebral or vertebral or spinal or spine) & (implant or cage or prosthesis or spacer) & screw near guide	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2015/10/27 10:40
L2	0	"20130018468"	USPAT	OR	OFF	2015/10/27 10:41
L3	1	"20130018468"	US-PGPUB; USPAT	OR	OFF	2015/10/27 10:41
L4	1	3 AND ((A61B17/0642 OR A61B17/7064 OR A61B17/809 OR A61B17/86 OR A61B17/8894 OR A61B2017/00407 OR A61B2017/0641 OR A61B2017/0648 OR A61B2017/922 OR A61F2002/2835 OR A61F2002/30133 OR A61F2002/30387 OR A61F2002/30448 OR A61F2002/30507 OR A61F2002/3055 OR A61F2002/30579 OR A61F2002/30604 OR A61F2002/30772 OR A61F2002/30878 OR A61F2002/4475 OR A61F2002/448 OR A61F2002/4627 OR A61F2002/4681 OR A61F2002/4687 OR A61F2220/0025 OR A61F2220/005 OR A61F2230/0015 OR A61F2250/0007 OR A61F2/4465 OR A61F2/447 OR A61F2/4611).CPC. OR (623/17.11-17.16).CCLS. OR (A61F2/44).IPCR.)	US-PGPUB; USPAT	OR	OFF	2015/10/27 10:42
L5	1	"20130018469"	US-PGPUB; USPAT	OR	OFF	2015/10/27 10:44
L6	1	5 AND ((A61B17/0642 OR A61B17/7064 OR A61B17/809 OR A61B17/86 OR A61B17/8894 OR A61B2017/00407 OR A61B2017/0641 OR A61B2017/0648 OR A61B2017/922 OR A61F2002/2835 OR A61F2002/30133 OR A61F2002/30387 OR A61F2002/30448 OR A61F2002/30507 OR A61F2002/3055 OR A61F2002/30579 OR A61F2002/30604 OR A61F2002/30772 OR A61F2002/30878 OR A61F2002/4475 OR A61F2002/448 OR A61F2002/4627 OR A61F2002/4681 OR A61F2002/4687 OR A61F2220/0025 OR A61F2220/005 OR A61F2230/0015 OR A61F2250/0007 OR A61F2/4465 OR A61F2/447 OR A61F2/4611).CPC. OR (623/17.11-17.16).CCLS. OR (A61F2/44).IPCR.)	US-PGPUB; USPAT	OR	OFF	2015/10/27 10:44
L7	180	1 AND ((A61B17/0642 OR A61B17/7064 OR A61B17/809 OR A61B17/86 OR A61B17/8894 OR A61B2017/00407 OR A61B2017/0641 OR A61B2017/0648 OR	US-PGPUB; USPAT	OR	OFF	2015/10/27 10:45

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10/ 27/ 2015 10:48:51 AM

Search Notes 	Application/Control No. 13210168	Applicant(s)/Patent Under Reexamination MOSKOWITZ ET AL.
	Examiner PEDRO PHILOGENE	Art Unit 3733

CPC- SEARCHED		
Symbol	Date	Examiner
A61B17/0642, A61B17/809, A61B17/8894, A61F2/4465, A61F2/447, A61F2/4611, A61B17/7064	10/27/2015	/P.P./
A61F2250/0007, A61B17/86, A61B2017/0641, A61B2017/0648, A61B2017/922, A61F2002/2835, A61F2002/30133, A61F2002/30387, A61F2002/30448, A61F2002/30507		
A61F2002/3055, A61F2002/30579, A61F2002/30604, A61F2002/30772, A61F2002/30878, A61F2002/4475, A61F2002/448, A61F2002/4627, A61F2002/4681, A61F2220/0025, A61F2220/005, A61F2230/0015		

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
623	17.11-17.16	10/27/2015	/P.P./
606	300-305,246, 99, 144, 151, 251, 266		
227	181.1		

SEARCH NOTES		
Search Notes	Date	Examiner
EAST search enclosed	10/27/2015	/P.P./

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

	/PEDRO PHILOGENE/ Primary Examiner.Art Unit 3733
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UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Ahmnon D. MOSKOWITZ, et al.
Application Number: 13/210,168
Filing Date: 08/15/2011
Group Art Unit: 3733
Examiner: Pedro PHILOGENE
Confirmation No.: 1609
Title: BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY
SCREWS AND POSTERIOR CERVICAL AND LUMBAR
INTERARTICULATING JOINT CALIBRATED STAPLING
DEVICES FOR SPINAL FUSION

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE C

Dear Sir:

This Amendment is responsive to the Office Action dated October 30, 2015, having a due date of March 30, 2016, and accompanies an extension of time fee.

Please charge Deposit Account No. 505364 for any deficiency or overpayment.

Please amend the application as follows:

Remarks begin on page 2 of this paper.

REMARKS

Claims 86-135 are pending in the application. Claims 86, 124, and 126 are independent. This Amendment does not add new matter.

The Provisional Double Patenting Rejection

Claims 86-135 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 93-141 of copending Application No. 13/210,162. Claims 86-135 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 84-133 of copending Application No. 13/210,157.

Applicants respectfully traverse these rejections.

Applicants respectfully submit that claims 86-135 of the present application are patentably distinct from the claims of the copending applications. Applicants note that the claims may be subject to further amendments during prosecution, which features should serve to further distinguish the claims of the present application from the claims of the co-pending applications.

With regard to the provisional obviousness-type double patenting rejections, Applicants respectfully submit that the conflicting claims have not in fact been patented, and therefore, also may be subject to further amendments during prosecution, which features may serve to further distinguish the claims of the present application from the claims of the co-pending applications.

For these reasons, Applicants respectfully reserve the right to file a terminal disclaimer in compliance with 37 C.F.R. § 1.321(c) or 1.321(d) as such time as the claims of the present application are allowable. Applicants respectfully request withdrawal of these rejections.

The Waugh et al. Reference

The Office Action rejects claims 86-134 under 35 U.S.C. §102(e) as allegedly being anticipated by the Waugh et al. reference (U.S. Publication No. 2008/0249575).

Applicants respectfully traverse this rejection.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. [...] The identical invention must be shown in as complete detail as is contained in the ... claim." M.P.E.P. § 2131.

The Waugh et al. reference does not disclose or suggest the unique combination of features of at least claim 133 including an internal screw guide having an internal bore with an entry opening and an exit opening, the entry opening of the internal bore formed only in a top surface of the top wall and the exit opening formed at least partially in a bottom surface of the top wall and at least partially in a side surface of the top wall.

The Waugh et al. reference discloses several embodiments, none of which discloses each and every element of the claims. For example, in the embodiments illustrated in FIGS. 1-8, which angle the screws at a steep angle with respect to the sidewalls, each of the entry opening and exit opening of the internal bore of the screw holes is formed in two surfaces. Particularly, the entry opening of the bore is formed partially in the top surface and partially in the side surface of the top wall of the cage, and the exit opening of the bore similarly is formed partially in the bottom surface and partially in the side surface of the top wall of the cage. As a result, a surgeon will need to remove bone from the adjacent vertebral bodies in order to insert the screw into the cage and vertebral bodies.

In the embodiments illustrated in FIG. 9-14, which angle the screws at a shallow angle with respect to the sidewalls, each of the entry opening and exit opening of the internal bore of the screw holes is formed in only one surface. See, e.g., FIG. 9. Particularly, the entry opening of the bore is formed only in the top surface of the top wall of the cage, and the exit opening of the bore is formed only in the bottom surface of the top wall of the cage. In other words, depending on the intended angle of the screws, the Waugh et al. reference discloses either entering through two surfaces and exiting through two surfaces if the screw hole is it be angled at a steep angle with respect to the sidewalls, or entering through a single surface and exiting through a single surface if the screw hole is to be angled at a shallow angle with respect to the sidewalls. Hence, none of the embodiments of the Waugh et al. reference discloses each and every element of the claims.

In stark contrast to the arrangements in the applied references, the claimed invention provides a unique combination in which an internal screw guide has an internal bore with an entry opening and an exit opening, the entry opening of the internal bore is formed only in a top surface of the top wall, while the exit opening is formed at least partially in a bottom surface of the top wall and at least partially in a side surface of the top wall, as recited in claim 133. In this way, the present invention provides a unique arrangement having an internal screw guide in the

cage that guides a screw trajectory into the vertebral body at a predetermined shallow angle that avoids interference with screws of other adjacent implantation devices and enables multiple level fusion, and at the same time eliminates a need for the surgeon to remove a part of the bone from the vertebral body to insert the screw. The present invention also eliminates the need to use an external screw guide.

Applicants respectfully request withdrawal of this rejection.

The Waugh et al. Reference in view of the Johnson Reference

The Office Action rejects claim 135 under 35 U.S.C. § 103(a) as allegedly being unpatentable over the Waugh et al. reference (U.S. Publication No. 2008/0249575) in view of the Johnson reference (U.S. Publication No. 2009/0080997).

Applicants respectfully traverse this rejection.

Applicants respectfully submit that the Johnson reference is not available as prior art to the present application, and therefore, this rejection should be withdrawn.

The Office Action relies on the Johnson et al reference for allegedly disclosing “*Johnson provides the evidences of the use of a vertebral implant wherein the internal screw guide has an internal bore with the entry opening and the exit opening, as best seen in FIG. 1, and the entry opening of the internal bore is formed only in the top surface of the top wall, as best seen in FIG. 1, and the exit opening is formed at least partially in the bottom surface of the top wall and at least partially in the side surface of the top wall, as best seen in FIGS. 1-4 and as set forth in para [0026], wherein the internal screw guide further comprises a counterbore formed at least partially in the top surface of the top wall for accommodating a screw head of a screw member, as best seen in FIGS. 1-4, wherein the entry opening of the internal bore is formed in a lower surface of the counterbore, and wherein the entry opening of the internal bore is formed entirely between all edges of the top wall when viewed from a direction perpendicular to a plane of the top surface, as best seen in FIG. 1, for allowing the screw to be secure to the appropriate vertebral body.*” Emphasis added Applicants.

However, Applicants respectfully submit that the subject matter of claim 135 including:

“*wherein the internal screw guide has an internal bore with the entry opening and the exit opening, and the entry opening of the internal bore is formed only in the*

top surface of the top wall and the exit opening is formed at least partially in the bottom surface of the top wall and at least partially in the side surface of the top wall, wherein the internal screw guide further comprises a counterbore formed at least partially in the top surface of the top wall for accommodating a screw head of a screw member, wherein the entry opening of the internal bore is formed in a lower surface of the counterbore, and wherein the entry opening of the internal bore is formed entirely between all edges of the top surface of the top wall when viewed from a direction perpendicular to a plane of the top surface. ”

is entitled to at least a priority date of **August 21, 2007**, based on U.S. Application Serial No. 11/842,855, (now U.S. Patent No. 7,942,903), as evidenced by Figures 2A, 2B, and 2C of the parent ‘855 application, which correspond to FIGS. 2A, 2B, and 2C of the present application. These features also are disclosed, for example, at paragraph [0064] of the original specification of U.S. Application Serial No. 11/842,855.

Particularly, this application is a Pre-AIA Continuation Application, for which priority is claimed under 35 U.S.C. § 120 to Application Serial No. 11/842,855, filed on **August 21, 2007** (now U.S. Patent No. 7,942,903, issued May 17, 2011). The priority date of **August 21, 2007**, for the above-referenced subject matter of the claimed invention, clearly antedates the earliest effective filing date of the Johnson et al. reference (based on the earliest foreign priority application filed on **September 24, 2007**). Therefore, the Johnson et al. reference is not available as prior art for the teachings of the features recited by independent claim 135.

For these reasons, Applicants respectfully submit that the Johnson et al. reference is not available as prior art to the present application for these features of the claimed invention.

Applicants respectfully request withdrawal of this rejection.

CONCLUSION

In view of the above, Applicants respectfully request entry of the present Amendment and allowance of Claims 86-135. Applicants invite the Examiner to contact the undersigned if the Examiner has any questions regarding this amendment. Applicants petition for an extension of time if required for entry of this Amendment.

Please charge Deposit Account No. 505364 for any deficiency or overpayment.

Respectfully Submitted,

/ John J. Dresch /
John J. Dresch
Attorney for Applicant(s)
Reg. No. 46,672

March 30, 2016

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Fax: 1.703.485.0278
jdresch@dreschiplaw.com
***** Customer No. 87409 *****

PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)		Docket Number (Optional) 3003/0105PUS7																																		
Application Number 13/210,168	Filed 08/15/2011																																			
For BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION																																				
Art Unit 3733	Examiner Pedro Philogene																																			
<p>This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above-identified application.</p> <p>The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):</p> <table style="width: 100%; border-collapse: collapse;"><thead><tr><th></th><th style="text-align: center;"><u>Fee</u></th><th style="text-align: center;"><u>Small Entity Fee</u></th><th style="text-align: center;"><u>Micro Entity Fee</u></th><th></th></tr></thead><tbody><tr><td>☐ One month (37 CFR 1.17(a)(1))</td><td style="text-align: right;">\$200</td><td style="text-align: right;">\$100</td><td style="text-align: right;">\$50</td><td>\$ _____</td></tr><tr><td>☒ Two months (37 CFR 1.17(a)(2))</td><td style="text-align: right;">\$600</td><td style="text-align: right;">\$300</td><td style="text-align: right;">\$150</td><td>\$ <u>300.00</u></td></tr><tr><td>☐ Three months (37 CFR 1.17(a)(3))</td><td style="text-align: right;">\$1,400</td><td style="text-align: right;">\$700</td><td style="text-align: right;">\$350</td><td>\$ _____</td></tr><tr><td>☐ Four months (37 CFR 1.17(a)(4))</td><td style="text-align: right;">\$2,200</td><td style="text-align: right;">\$1,100</td><td style="text-align: right;">\$550</td><td>\$ _____</td></tr><tr><td>☐ Five months (37 CFR 1.17(a)(5))</td><td style="text-align: right;">\$3,000</td><td style="text-align: right;">\$1,500</td><td style="text-align: right;">\$750</td><td>\$ _____</td></tr></tbody></table> <p>☒ Applicant asserts small entity status. See 37 CFR 1.27.</p> <p>☐ Applicant certifies micro entity status. See 37 CFR 1.29. Form PTO/SB/15A or B or equivalent must either be enclosed or have been submitted previously.</p> <p>☐ A check in the amount of the fee is enclosed.</p> <p>☐ Payment by credit card. Form PTO-2038 is attached.</p> <p>☐ The Director has already been authorized to charge fees in this application to a Deposit Account.</p> <p>☒ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number <u>505364</u>.</p> <p>☒ Payment made via EFS-Web.</p> <p>WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.</p> <p>I am the</p> <p>☐ applicant/inventor.</p> <p>☐ assignee of record of the entire interest. See 37 CFR 3.71. 37 CFR 3.73(b) statement is enclosed (Form PTO/SB/96).</p> <p>☒ attorney or agent of record. Registration number <u>46,672</u>.</p> <p>☐ attorney or agent acting under 37 CFR 1.34. Registration number _____.</p> <table style="width: 100%; border-collapse: collapse;"><tr><td style="width: 50%; padding: 5px;"><u>/John J. Dresch/</u> Signature</td><td style="width: 50%; padding: 5px;"><u>March 30, 2016</u> Date</td></tr><tr><td style="padding: 5px;"><u>John J. Dresch</u> Typed or printed name</td><td style="padding: 5px;"><u>571.333.0930</u> Telephone Number</td></tr></table> <p>NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. Submit multiple forms if more than one signature is required, see below*.</p> <p>☒ * Total of <u>1</u> forms are submitted.</p>				<u>Fee</u>	<u>Small Entity Fee</u>	<u>Micro Entity Fee</u>		☐ One month (37 CFR 1.17(a)(1))	\$200	\$100	\$50	\$ _____	☒ Two months (37 CFR 1.17(a)(2))	\$600	\$300	\$150	\$ <u>300.00</u>	☐ Three months (37 CFR 1.17(a)(3))	\$1,400	\$700	\$350	\$ _____	☐ Four months (37 CFR 1.17(a)(4))	\$2,200	\$1,100	\$550	\$ _____	☐ Five months (37 CFR 1.17(a)(5))	\$3,000	\$1,500	\$750	\$ _____	<u>/John J. Dresch/</u> Signature	<u>March 30, 2016</u> Date	<u>John J. Dresch</u> Typed or printed name	<u>571.333.0930</u> Telephone Number
	<u>Fee</u>	<u>Small Entity Fee</u>	<u>Micro Entity Fee</u>																																	
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<u>John J. Dresch</u> Typed or printed name	<u>571.333.0930</u> Telephone Number																																			

This collection of information is required by 37 CFR 1.136(a). The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 6 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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

Privacy Act Statement

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

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

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Patent Application Fee Transmittal				
Application Number:		13210168		
Filing Date:		15-Aug-2011		
Title of Invention:		BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION		
First Named Inventor/Applicant Name:		Ahmnon D. MOSKOWITZ		
Filer:		John Jeremy Dresch		
Attorney Docket Number:		3003/0105PUS7		
Filed as Small Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension - 2 months with \$0 paid	2252	1	300	300
Miscellaneous:				
Total in USD (\$)				300

Electronic Acknowledgement Receipt	
EFS ID:	25353603
Application Number:	13210168
International Application Number:	
Confirmation Number:	1609
Title of Invention:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION
First Named Inventor/Applicant Name:	Ahmnon D. MOSKOWITZ
Customer Number:	87409
Filer:	John Jeremy Dresch
Filer Authorized By:	
Attorney Docket Number:	3003/0105PUS7
Receipt Date:	30-MAR-2016
Filing Date:	15-AUG-2011
Time Stamp:	22:48:47
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$ 300
RAM confirmation Number	9863
Deposit Account	505364
Authorized User	DRESCH, JOHN J
<p>The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:</p> <p>Charge any Additional Fees required under 37 CFR 1.16 (National application filing, search, and examination fees)</p> <p>Charge any Additional Fees required under 37 CFR 1.17 (Patent application and reexamination processing fees)</p>	

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Amendment/Req. Reconsideration-After Non-Final Reject	30030105PUS7_Amend_C_readyforfiling.pdf	148714	no	6
			bab5a9e3bce273f2d01e4b4548e9785b1a080910		
Warnings:					
Information:					
2	Extension of Time	30030105PUS7_Petition_EOT_readyforfiling.pdf	188847	no	2
			5421c26a35da6ff6cde97d7fa390cfd52b1b26		
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	31114	no	2
			7a79ba16ccd345787f8dd4088332ba47812a401b		
Warnings:					
Information:					
Total Files Size (in bytes):			368675		
<p>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.</p> <p><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.</p> <p><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.</p> <p><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.</p>					



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/210,168	08/15/2011	Ahmnnon D. MOSKOWITZ	3003/0105PUS7	1609

87409	7590	05/10/2016
Dresch IP Law, PLLC P.O. Box 650903 Potomac Falls, VA 20165		

EXAMINER	
PHILOGENE, PEDRO	

ART UNIT	PAPER NUMBER
3733	

NOTIFICATION DATE	DELIVERY MODE
05/10/2016	ELECTRONIC

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

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

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@dreschiplaw.com
jdresch@dreschiplaw.com
linda.logan@dreschiplaw.com

Office Action Summary	Application No. 13/210,168	Applicant(s) MOSKOWITZ ET AL.	
	Examiner PEDRO PHILOGENE	Art Unit 3733	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/30/16.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 86-135 is/are pending in the application.
5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 86-135 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) ☒ Notice of References Cited (PTO-892) | 3) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
Paper No(s)/Mail Date ____. | 4) ☐ Other: ____. |

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

Double Patenting

A rejection based on double patenting of the “same invention” type finds its support in the language of 35 U.S.C. 101 which states that “whoever invents or discovers any new and useful process... may obtain a patent therefor...” (Emphasis added). Thus, the term “same invention,” in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the claims that are directed to the same invention so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 86-135 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 93-141 of copending Application No. 13/210,162. This is a provisional statutory double patenting rejection since the claims directed to the same invention have not in fact been patented.

Claims 86-135 provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 84-133 of copending Application No. 13/210,157. This is a provisional statutory double patenting rejection since the claims directed to the same invention have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of pre-AIA 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 86-134 are rejected under pre-AIA 35 U.S.C. 102(e) as being clearly anticipated by *Waugh et al.* (2008/0249575).

Allowable Subject Matter

Claim 135 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Amendment

Applicant's arguments filed 3/30/16 have been fully considered but they are not persuasive. As to the Double Patenting rejection, although applicant stated that the claims of the present application may be subject to further amendments during prosecution, applicant did not state which features should serve to further distinguish the claims of the present application from the claims of the co-pending applications, applicant did not amend any of the claims in the present application. Furthermore, applicant argues that *Waugh* fails to teach all the features in newly presented

dependent claim 135, and that Johnson is not prior art to the application, since the application antedates the earliest effective filing date of Johnson, the examiner agrees.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PEDRO PHILOGENE whose telephone number is (571)272-4716. The examiner can normally be reached on Monday to Friday 8:00 AM to 4:30 PM.

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

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

/PEDRO PHILOGENE/
Primary Examiner, Art Unit 3733
May 4, 2016

Notice of References Cited	Application/Control No. 13/210,168	Applicant(s)/Patent Under Reexamination MOSKOWITZ ET AL.	
	Examiner PEDRO PHILOGENE	Art Unit 3733	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-2008/0249575 A1	10-2008	Waugh; Lindsey G.	A61F2/447	606/305
	B	US-				
	C	US-				
	D	US-				
	E	US-				
	F	US-				
	G	US-				
	H	US-				
	I	US-				
	J	US-				
	K	US-				
	L	US-				
	M	US-				

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Search Notes 	Application/Control No. 13210168	Applicant(s)/Patent Under Reexamination MOSKOWITZ ET AL.
	Examiner PEDRO PHILOGENE	Art Unit 3733

CPC- SEARCHED		
Symbol	Date	Examiner
A61B17/0642, A61B17/809, A61B17/8894, A61F2/4465, A61F2/447, A61F2/4611, A61B17/7064	5/4/2016	/P.P./
A61F2250/0007, A61B17/86, A61B2017/0641, A61B2017/0648, A61B2017/922, A61F2002/2835, A61F2002/30133, A61F2002/30387, A61F2002/30448, A61F2002/30507		
A61F2002/3055, A61F2002/30579, A61F2002/30604, A61F2002/30772, A61F2002/30878, A61F2002/4475, A61F2002/448, A61F2002/4627, A61F2002/4681, A61F2220/0025, A61F2220/005, A61F2230/0015		

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
623	17.11-17.16	5/4/2016	/P.P./
606	300-305,246, 99, 144, 151, 251, 266		
227	181.1		

SEARCH NOTES		
Search Notes	Date	Examiner
EAST search enclosed	5/4/2016	/P.P./

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

	/PEDRO PHILOGENE/ Primary Examiner.Art Unit 3733
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EAST Search History**EAST Search History (Prior Art)**

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	1	"20090080997"	US-PGPUB; USPAT	OR	ON	2016/05/04 10:07
L2	338	411/347	US-PGPUB; USPAT	OR	OFF	2016/05/04 10:09
L3	1	"20130018469"	US-PGPUB; USPAT	OR	OFF	2016/05/04 10:27
L4	1150	A61B17/0642.cpc.	US-PGPUB; USPAT	OR	OFF	2016/05/04 10:30
L5	653	A61B17/809.cpc.	US-PGPUB; USPAT	OR	OFF	2016/05/04 10:35
L6	161	A61B17/8894.cpc.	US-PGPUB; USPAT	OR	OFF	2016/05/04 10:39
L7	966	A61B17/7064.cpc.	US-PGPUB; USPAT	OR	OFF	2016/05/04 10:40
L8	1645	A61F2/4465.cpc.	US-PGPUB; USPAT	OR	OFF	2016/05/04 10:45
L9	2051	A61F2/447.cpc.	US-PGPUB; USPAT	OR	OFF	2016/05/04 10:56
L10	5556	A61F2/4611.cpc.	US-PGPUB; USPAT	OR	OFF	2016/05/04 11:11

5/ 4/ 2016 11:19:15 AM

<p align="center">Index of Claims</p> 	<p>Application/Control No.</p> <p>13210168</p>	<p>Applicant(s)/Patent Under Reexamination</p> <p>MOSKOWITZ ET AL.</p>
	<p>Examiner</p> <p>PEDRO PHILOGENE</p>	<p>Art Unit</p> <p>3733</p>

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

☐ Claims renumbered in the same order as presented by applicant						☐ CPA		☐ T.D.		☐ R.1.47	
CLAIM		DATE									
Final	Original	02/04/2015	10/27/2015	05/04/2016							
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	2	-	-	-							
	3	-	-	-							
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<i>Index of Claims</i> 	Application/Control No. 13210168	Applicant(s)/Patent Under Reexamination MOSKOWITZ ET AL.
	Examiner PEDRO PHILOGENE	Art Unit 3733

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
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CLAIM		DATE									
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	71	-	-	-							
	72	-	-	-							

<i>Index of Claims</i> 	Application/Control No. 13210168	Applicant(s)/Patent Under Reexamination MOSKOWITZ ET AL.
	Examiner PEDRO PHILOGENE	Art Unit 3733

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	103	✓	✓	✓							
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	105	✓	✓	✓							
	106	✓	✓	✓							
	107	✓	✓	✓							
	108	✓	✓	✓							

<i>Index of Claims</i> 	Application/Control No. 13210168	Applicant(s)/Patent Under Reexamination MOSKOWITZ ET AL.
	Examiner PEDRO PHILOGENE	Art Unit 3733

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CLAIM		DATE													
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	135		✓	✓											

Doc code: RCEX

Doc description: Request for Continued Examination (RCE)

PTO/SB/30EFS (07-09)

Approved for use through 07/31/2012. OMB 0851-0031

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

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

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

Application Number	13/210,168	Filing Date	2011-08-15	Docket Number (if applicable)	3003/0105PUS7	Art Unit	3733
First Named Inventor	Ahmnon D. Moskowitz et al.			Examiner Name	Pedro Philogene		

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

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

SUBMISSION REQUIRED UNDER 37 CFR 1.114

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

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

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

☐ Other _____

☒ Enclosed

☒ Amendment/Reply

☒ Information Disclosure Statement (IDS)

☐ Affidavit(s)/ Declaration(s)

☒ Other Petition for Extension of Time

MISCELLANEOUS

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

☐ Other _____

FEES

The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.

☒ The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to Deposit Account No 505364

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

☒ Patent Practitioner Signature
 Applicant Signature

Doc code: RCEX

Doc description: Request for Continued Examination (RCE)

PTO/SB/30EFS (07-09)

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

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

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

Signature of Registered U.S. Patent Practitioner			
Signature	John J. Dresch/	Date (YYYY-MM-DD)	2016-11-10
Name	John J. Dresch	Registration Number	46672

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450.

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

Privacy Act Statement

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

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

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
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.

PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)		Docket Number (Optional) 3003/0105PUS7																																		
Application Number 13/210,168	Filed 08/15/2011																																			
For BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION																																				
Art Unit 3733	Examiner Pedro Philogene																																			
<p>This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above-identified application.</p> <p>The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):</p> <table style="width: 100%; border-collapse: collapse;"><thead><tr><th></th><th style="text-align: center;"><u>Fee</u></th><th style="text-align: center;"><u>Small Entity Fee</u></th><th style="text-align: center;"><u>Micro Entity Fee</u></th><th></th></tr></thead><tbody><tr><td>☐ One month (37 CFR 1.17(a)(1))</td><td style="text-align: center;">\$200</td><td style="text-align: center;">\$100</td><td style="text-align: center;">\$50</td><td>\$ _____</td></tr><tr><td>☐ Two months (37 CFR 1.17(a)(2))</td><td style="text-align: center;">\$600</td><td style="text-align: center;">\$300</td><td style="text-align: center;">\$150</td><td>\$ _____</td></tr><tr><td>☒ Three months (37 CFR 1.17(a)(3))</td><td style="text-align: center;">\$1,400</td><td style="text-align: center;">\$700</td><td style="text-align: center;">\$350</td><td>\$ <u>700.00</u></td></tr><tr><td>☐ Four months (37 CFR 1.17(a)(4))</td><td style="text-align: center;">\$2,200</td><td style="text-align: center;">\$1,100</td><td style="text-align: center;">\$550</td><td>\$ _____</td></tr><tr><td>☐ Five months (37 CFR 1.17(a)(5))</td><td style="text-align: center;">\$3,000</td><td style="text-align: center;">\$1,500</td><td style="text-align: center;">\$750</td><td>\$ _____</td></tr></tbody></table> <p>☒ Applicant asserts small entity status. See 37 CFR 1.27.</p> <p>☐ Applicant certifies micro entity status. See 37 CFR 1.29. Form PTO/SB/15A or B or equivalent must either be enclosed or have been submitted previously.</p> <p>☐ A check in the amount of the fee is enclosed.</p> <p>☐ Payment by credit card. Form PTO-2038 is attached.</p> <p>☐ The Director has already been authorized to charge fees in this application to a Deposit Account.</p> <p>☒ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number <u>505364</u>.</p> <p>☒ Payment made via EFS-Web.</p> <p>WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.</p> <p>I am the</p> <p>☐ applicant/inventor.</p> <p>☐ assignee of record of the entire interest. See 37 CFR 3.71. 37 CFR 3.73(b) statement is enclosed (Form PTO/SB/96).</p> <p>☒ attorney or agent of record. Registration number <u>46,672</u>.</p> <p>☐ attorney or agent acting under 37 CFR 1.34. Registration number _____.</p> <table style="width: 100%; border-collapse: collapse;"><tr><td style="width: 50%; padding: 5px;"><u>/John J. Dresch/</u> Signature</td><td style="width: 50%; padding: 5px;"><u>November 10, 2016</u> Date</td></tr><tr><td style="padding: 5px;"><u>John J. Dresch</u> Typed or printed name</td><td style="padding: 5px;"><u>571.333.0930</u> Telephone Number</td></tr></table> <p>NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. Submit multiple forms if more than one signature is required, see below*.</p> <p>☒ * Total of <u>1</u> forms are submitted.</p>				<u>Fee</u>	<u>Small Entity Fee</u>	<u>Micro Entity Fee</u>		☐ One month (37 CFR 1.17(a)(1))	\$200	\$100	\$50	\$ _____	☐ Two months (37 CFR 1.17(a)(2))	\$600	\$300	\$150	\$ _____	☒ Three months (37 CFR 1.17(a)(3))	\$1,400	\$700	\$350	\$ <u>700.00</u>	☐ Four months (37 CFR 1.17(a)(4))	\$2,200	\$1,100	\$550	\$ _____	☐ Five months (37 CFR 1.17(a)(5))	\$3,000	\$1,500	\$750	\$ _____	<u>/John J. Dresch/</u> Signature	<u>November 10, 2016</u> Date	<u>John J. Dresch</u> Typed or printed name	<u>571.333.0930</u> Telephone Number
	<u>Fee</u>	<u>Small Entity Fee</u>	<u>Micro Entity Fee</u>																																	
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Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)

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

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

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	13210168
	Filing Date	2011-08-15
	First Named Inventor	MOSKOWITZ et al.
	Art Unit	3733
	Examiner Name	PHILOGENE, PEDRO
	Attorney Docket Number	3003/0105PUS7

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	7238203		2007-07-03	BAGGA, CHARANPREET et al.	
	2	6342074		2002-01-29	SIMPSON, NATHAN S.	
	3	7232464		2007-06-19	MATHIEU, CLAUDE et al.	
	4	7442209		2008-10-28	MICHELSON GARY K	
	5	8790405		2014-07-29	BIEDERMANN, LUTZ et al.	
	6	8268000		2012-09-18	WAUGH, LINDSEY G. et al.	
	7	7985255		2011-07-26	BRAY, ROBERT S. et al.	
	8	6962606		2005-11-08	MICHELSON, GARY KARLIN	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	13210168
	Filing Date	2011-08-15
	First Named Inventor	MOSKOWITZ et al.
	Art Unit	3733
	Examiner Name	PHILOGENE, PEDRO
	Attorney Docket Number	3003/0105PUS7

	9	7135043		2006-11-14	NAKAHARA, SHINNOSUKE et al.	
	10	4904261		1990-02-27	DOVE, JOHN 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
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	1	2727003	FR		1996-05-24	TISSERAND, PHILIPPE		×

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

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	13210168
	Filing Date	2011-08-15
	First Named Inventor	MOSKOWITZ et al.
	Art Unit	3733
	Examiner Name	PHILOGENE, PEDRO
	Attorney Docket Number	3003/0105PUS7

EXAMINER SIGNATURE			
Examiner Signature			Date Considered
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	13210168
	Filing Date	2011-08-15
	First Named Inventor	MOSKOWITZ et al.
	Art Unit	3733
	Examiner Name	PHILOGENE, PEDRO
	Attorney Docket Number	3003/0105PUS7

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

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

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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	/John J. Dresch/	Date (YYYY-MM-DD)	2016-11-10
Name/Print	John J. Dresch	Registration Number	46,672

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(11) N° de publication :
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2 727 003

(21) N° d'enregistrement national :

94 14067

(51) Int Cl⁶ : A 61 F 2/44, A 61 B 17/70

(12)

DEMANDE DE BREVET D'INVENTION

A1

(22) Date de dépôt : 18.11.94.

(30) Priorité :

(43) Date de la mise à disposition du public de la
demande : 24.05.96 Bulletin 96/21.

(56) Liste des documents cités dans le rapport de
recherche préliminaire : *Se reporter à la fin du
présent fascicule.*

(60) Références à d'autres documents nationaux
apparentés :

(71) Demandeur(s) : EUROS SA SOCIETE ANONYME —
FR.

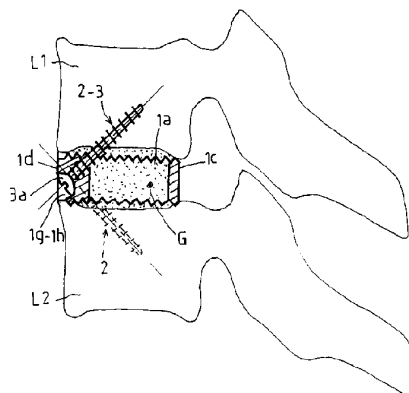
(72) Inventeur(s) : TISSERAND PHILIPPE.

(73) Titulaire(s) :

(74) Mandataire : CABINET LAURENT ET CHARRAS.

(54) DISPOSITIF DE STABILISATION ANTERIEURE DU RACHIS LOMBO-SACRE.

(57) Le dispositif comprend un élément (1) apte à maintenir l'écartement entre les corps vertébraux (L1) (L2) du rachis lombaire tout en étant agencé pour recevoir des greffons spongieux et permettre leur fusion intersomatique, ledit élément (1) présentant des trous orientés (1g) (1h) pour le passage d'organes de fixation (2) et (3) coopérant avec les corps vertébraux sus et sous jacents.



FR 2 727 003 - A1



Dispositif de stabilisation antérieure du rachis lombo-sacré

5 L'invention se rattache au secteur technique des implants rachidiens.

Le problème que se propose de résoudre l'invention, est de stabiliser les vertèbres lombaires et la charnière lombo-sacrée, par voie antérieure.

10 Pour assurer une telle stabilisation, il est connu d'utiliser des implants sous forme de plateaux, destinés à être insérés entre les corps vertébraux. Le plateau n'est pas fixé mais est simplement impacté entre les deux corps vertébraux. Le plateau peut être conformé pour recevoir un greffon. Cette solution n'est cependant pas satisfaisante, étant donné qu'il
15 peut y avoir des risques d'expulsion du greffon, en cas d'instabilité et de déplacement du plateau, qui n'est pas fixé.

L'invention s'est fixée pour but de remédier à ces inconvénients, de manière simple, sûre, efficace et rationnelle.
20

Le problème que se propose de résoudre l'invention, est d'apporter une stabilité des vertèbres lombaires concernées, au moyen d'un ensemble prothétique, en évitant tout risque d'expulsion de cet ensemble prothétique, et en tenant compte du fait qu'au niveau lombaire, il
25 peut y avoir des risques vasculaires, étant donné que les vertèbres sont relativement proches des vaisseaux.

Pour résoudre un tel problème, il a été conçu et mis au point un dispositif de stabilisation antérieure du rachis lombo-sacré, qui comprend un élément apte à maintenir l'écartement entre les corps
30 vertébraux du rachis lombaire tout en étant agencé pour recevoir des

greffons spongieux et permettre leur fusion intersomatique, ledit élément présentant des trous orientés pour le passage et l'intégration d'organes de fixation coopérant avec les corps vertébraux sus et sous jacents.

- 5 Pour résoudre le problème posé d'intégrer les organes de fixation et pour permettre auxdits organes d'être implantés dans l'os cortico-spongieux des corps vertébraux, les trous constituent des chambrages internes formés à partir de la face antérieure de l'élément, l'un des chambrages étant dirigés vers le bas tandis que l'autre est dirigé vers le
- 10 haut, en étant orienté l'un par rapport à l'autre, selon un angle d'environ 90°.

- Pour résoudre le problème posé d'éviter l'écrasement, tout en ayant pour objectif de permettre la fusion intersomatique des greffons,
- 15 l'élément est constitué par une structure volumétrique creuse de forme générale rectangulaire profilée pour correspondre à l'anatomie des corps vertébraux concernés. L'élément présente un bord postérieur concave en arrière et un bord antérieur arrondi pour épouser la face antérieure du corps vertébral.

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Pour résoudre le problème posé de respecter la lordose lombo-sacrée, la hauteur de la face antérieure est supérieure à la hauteur de la face postérieure pour respecter la lordose lombo-sacrée.

- Les faces supérieure et inférieure de l'élément sont crantées
- 25 pour faciliter la stabilité primaire.

L'invention est exposée, ci-après plus en détail à l'aide des dessins annexés, dans lesquels :

30

La figure 1 est une vue en perspective du dispositif selon

l'invention.

La figure 2 est une vue en plan du dispositif.

La figure 3 est une vue en coupe montrant la fixation du dispositif entre deux plateaux des vertèbres lombaires.

5

Comme le montre la figure 1, le dispositif comprend un élément (1) apte à maintenir l'écartement entre deux corps vertébraux (L1) et (L2) de la partie lombaire du rachis, y compris de la charnière lombo-sacrée. Cet élément (1) est agencé pour recevoir des greffons spongieux (G) et permettre leur fusion intersomatique. Les greffons sont
10 avantageusement prélevés sur la crête iliaque ou dans l'extrémité supérieure du tibia.

15 L'élément (1) est constitué par une structure volumétrique creuse de forme générale rectangulaire profilée, pour correspondre à l'anatomie des corps vertébraux (L1) (L2). Notamment, l'élément (1) présente un bord postérieur (1c) concave en arrière et un bord antérieur arrondi (1d). La hauteur de la face antérieure est supérieure à la hauteur
20 de la face postérieure.

En outre, l'élément (1) présente deux ouvertures débouchantes et séparées (1a) (1b), recevant chacune les greffons spongieux. On n'exclut pas de pratiquer dans l'épaisseur de l'élément (1),
25 une seule ouverture débouchante, ou plus de deux ouvertures.

Suivant une caractéristique importante de l'invention, l'élément (1) présente des trous orientés (1g) (1h), pour le passage et l'intégration d'organes de fixation (2) et (3), coopérant avec les corps
30 vertébraux (L1) et (L2) sus et sous jacents audit élément (1). Comme le

montre notamment la figure 3, les trous (1g) et (1h) constituent des chambrages internes établis à partir de la face antérieure (1d), à proximité des bords transversaux de l'élément (1). Le chambrage (1g) est orienté vers le haut, tandis que le chambrage (1h) est orienté vers le bas. Les deux
5 chambrages (1g) et (1h) sont décalés angulairement d'environ 90°.

En conséquence, après introduction des vis (2) et (3), l'une d'entre elles (2) sera dirigée vers le bas, tandis que l'autre (3) sera dirigée vers le haut. A noter que ces vis sont orientées d'un angle de très sensiblement 45°, pour s'implanter dans l'os cortico-spongieux, des corps
10 vertébraux (L1) (L2).

Les têtes (2a) et (3a) des vis (2) et (3) sont noyées dans le chambrage, en appui dans le fond de ce dernier, et ne débordent pas de la face antérieure (1d).

15 Les faces supérieure (1i) et inférieure (1j) sont crantées pour faciliter la stabilité primaire. L'élément (1) est exécuté en titane ou polymère renforcé de fibre de carbone.

A noter que l'élément (1) est réalisé selon essentiellement
20 trois tailles, à savoir :

- une petite taille correspondant à une largeur de l'ordre de 20mm et à une longueur de l'ordre de 30mm,
- une taille moyenne correspondant à une largeur de l'ordre de 25mm et à une longueur de l'ordre de 35mm,
- 25 - une grande taille correspondant à une largeur de l'ordre de 30mm et à une longueur de l'ordre de 40mm.

A noter également que l'on distingue deux types d'éléments (1), selon qu'il concerne l'étage lombo-sacré L5-S1 ou les étages
30 supérieures. A l'étage lombo-sacré, on utilise un élément dont l'obliquité

est plus accentuée, c'est-à-dire dont la hauteur de la face antérieure est nettement supérieure à celle de la face postérieure.

Trois types d'implants sont disponibles pour l'étage L5-S1, dont les hauteurs antérieures sont respectivement de 10mm, 12mm et 14mm, tandis que les hauteurs postérieures 8mm, 10mm et 12mm. Pour les étages supérieurs L4, L5 et suivants, les hauteurs antérieure sont respectivement de 9mm, 11mm et 13mm, tandis que les hauteurs postérieures sont de 8mm, 10mm et 12mm.

On indique ci-après, le mode opératoire de mise en place du dispositif selon l'invention.

Après ablation du disque intervertébral réalisée par une voie antérieure, la distraction vertébrale permet de récupérer la hauteur intervertébrale souhaitée. Cette distraction peut être réalisée par une traction appliquée sur le crâne et est permise par la résection la plus large possible de tout le tissu discal jusqu'au niveau du ligament vertébral postérieur qui peut être également réséqué. Un distracteur intersomatique peut compléter l'espacement intervertébral, la hauteur de l'élément (1) étant calculée d'après des fantômes et après essai de la bonne taille de l'élément. L'élément (1) est rempli de greffons spongieux et est disposé dans l'espace intervertébral considéré (L1) (L2) par exemple. L'élément (1) est ensuite solidarisé aux vertèbres sus et sous jacentes au moyen des vis (2) et (3), qui coopèrent dans l'os cortico-spongieux des corps vertébraux.

Un contrôle radioscopique per-opératoire est nécessaire pour s'assurer de la bonne position du dispositif.

Ce dispositif est particulièrement bien adapté pour stabiliser un segment mobile du rachis lombaire ou lombosacré et s'adresse essentiellement soit à la charnière lombosacrée soit aux vertèbres sus-

jaçentes, notamment au niveau des espaces L3-L4 et L4-L5.

Les avantages ressortent bien de la description, en particulier
5 on souligne et on rappelle que l'emploi des vis d'ostéosynthèse permet
une stabilisation primaire, et permet d'éviter toute mobilisation des greffons
spongieux, pendant le délai nécessaire à la repousse osseuse.

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REVENDEICATIONS

- 5 -1- Dispositif de stabilisation antérieure du rachis lombosacré, caractérisé en ce qu'il comprend un élément (1) apte à maintenir l'écartement entre les corps vertébraux (L1) (L2) du rachis lombaire tout en étant agencé pour recevoir des greffons spongieux et permettre leur fusion intersomatique, ledit élément (1) présentant des trous orientés (1g) (1h) pour le passage d'organes de fixation (2) et (3) coopérant avec les corps vertébraux sus et sous jacents.
- 10 -2-Dispositif selon la revendication 1, caractérisé en ce que les trous (1g) (1h) constituent des chambrages internes formés à partir de la face antérieure (1d) de l'élément (1), l'un des chambrages étant dirigé vers le bas tandis que l'autre est dirigé vers le haut, en étant orientés l'un par
- 15 rapport à l'autre, selon un angle d'environ 90°.
- 20 -3- Dispositif selon la revendication 1, caractérisé en ce que l'élément (1) est constitué par une structure volumétrique creuse de forme générale rectangulaire profilée pour correspondre à l'anatomie des corps vertébraux concernés.
- 25 -4- Dispositif selon la revendication 1, caractérisé en ce que l'élément présente un bord postérieur (1c) concave en arrière et un bord antérieur arrondi (1d) pour épouser la face antérieure du corps vertébral.
- 30 -5- Dispositif selon la revendication 1, caractérisé en ce que la hauteur de la face antérieure (1d) est supérieure à la hauteur de la face postérieure (1c) pour respecter la lordose lombosacrée.
- 30 -6- Dispositif selon la revendication 1, caractérisé en ce que les faces

supérieure (1i) et inférieure (1j) de l'élément (1) sont crantées pour faciliter la stabilité primaire.

5 -7- Dispositif selon la revendication 1, caractérisé en ce que l'élément (1) présente deux ouvertures débouchantes séparées (1a) (1b) pour recevoir les greffons spongieux.

10 -8- Dispositif selon la revendication 1, caractérisé en ce que l'élément (1) est réalisé en titane ou en polymère renforcé en fibres de carbone.

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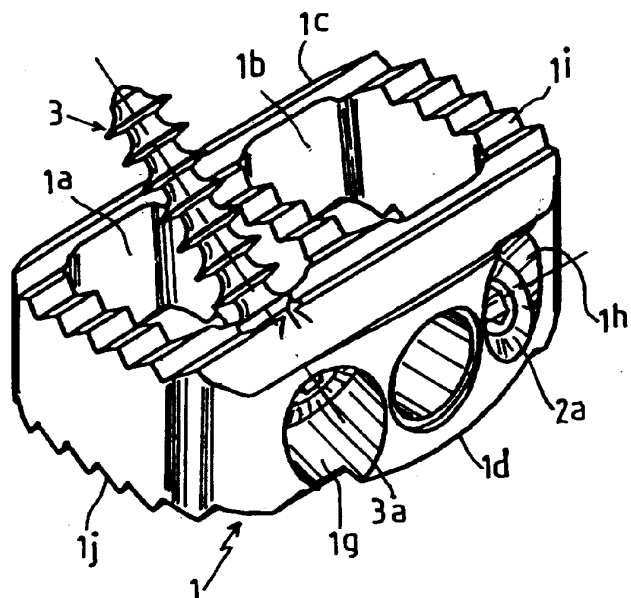


FIG. 1

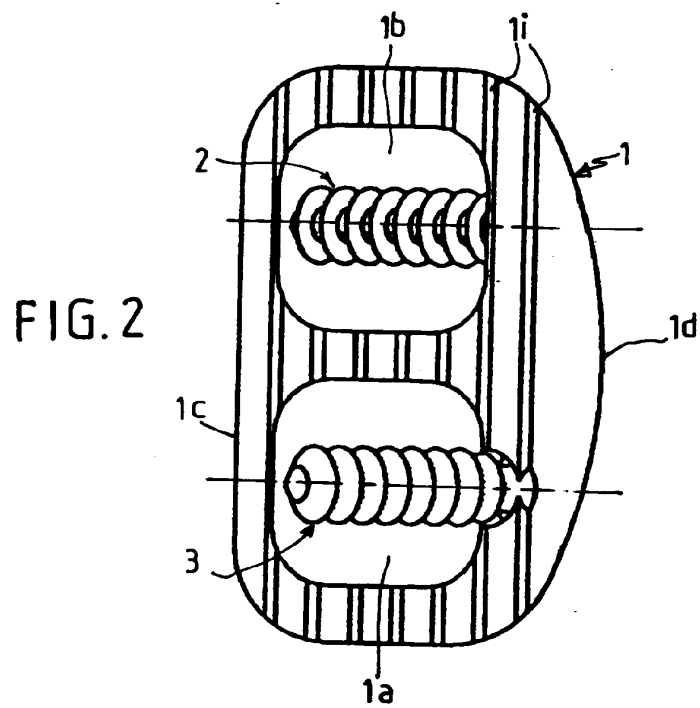
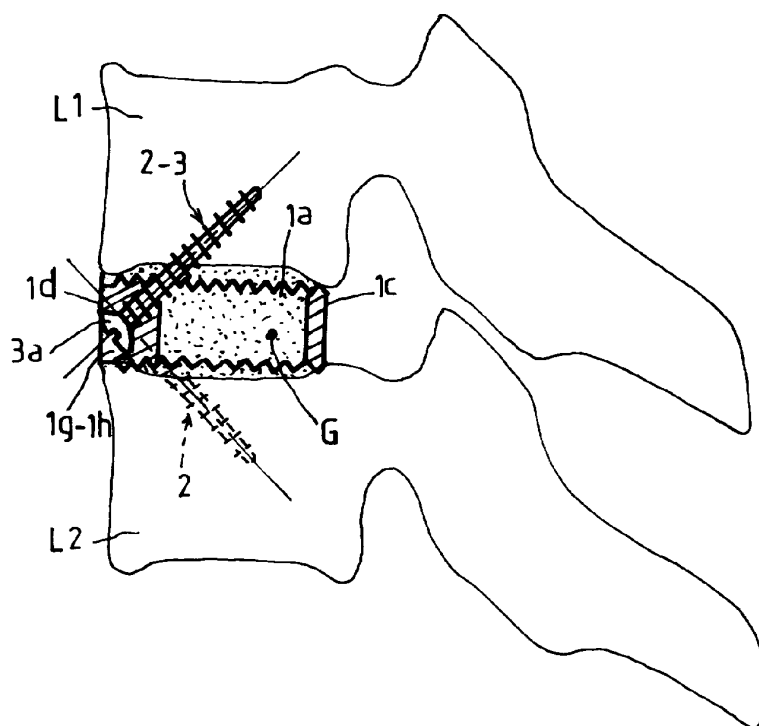


FIG. 2

2/2

FIG. 3



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**RAPPORT DE RECHERCHE
PRELIMINAIRE**

établi sur la base des dernières revendications
déposées avant le commencement de la recherche

2727003

N° d'enregistrement
national

FA 507769
FR 9414067

DOCUMENTS CONSIDERES COMME PERTINENTS		Revendications concernées de la demande examinée
Catégorie	Citation du document avec indication, en cas de besoin, des parties pertinentes	
X	WO-A-94 18913 (HENDERSON FRASER C ;HENDERSON REBECCA SASSCER (US); NEWMAN JOHN W) 1 Septembre 1994 * page 8, alinéa 1 - page 9, alinéa 1; figures * * abrégé *	1,3
Y	---	5-7
A	---	2
Y	FR-A-2 703 580 (ROBERT GILLES) 14 Octobre 1994 * abrégé; revendication 6; figures *	5-7
A	---	1,3,8
A	WO-A-94 05235 (BRANTIGAN JOHN W) 17 Mars 1994 * abrégé; figures *	1,3,6-8
A	EP-A-0 298 233 (SULZER AG) 11 Janvier 1989 * colonne 2, ligne 14 - ligne 17; revendications; figures * * abrégé *	1,4,5,8
A	US-A-5 180 381 (AUST GILBERT M ET AL) 19 Janvier 1993 * abrégé; figure 2 * -----	1,2
		DOMAINES TECHNIQUES RECHERCHES (Int.CL.6)
		A61F A61B
Date d'achèvement de la recherche		Examinateur
19 Juillet 1995		Neumann, E
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1
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19. FRENCH REPUBLIC

NATIONAL INSTITUTE OF
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PARIS

12.

APPLICATION FOR PATENT

11. **Publication No.:**
(to be used only for
ordering copies)

2 727 003

21. **National Registration No.:**

94 14067

51. Int Cl⁶: A 61 F 2/44, A 61 B 17/70

A1

22. **Date of filing:** 11.18.94

30. **Priority:**

43. **Date application made available to the public:**
05.24.96 Bulletin 96/21

56. **List of documents cited in the initial search
report:** *Please see the end of this specification.*

60. **References to other related national docu-
ments:**

71. **Applicant(s):** EUROS SA SOCIETE ANONYME –
FR

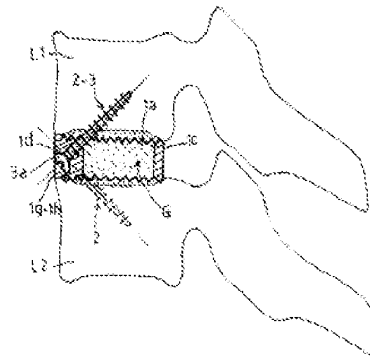
72. **Inventor(s):** TISSERAND PHILIPPE

73. **Holder(s):**

74. **Attorney:** LAURENT AND CHARRAS LAW
OFFICE

54. **DEVICE FOR ANTERIOR STABILIZATION OF THE LUMBOSACRAL SPINE**

57. The device comprises an element (1) suitable for maintaining the separation between the vertebral bodies (L1) (L2) of the lumbar spine while being arranged to receive cancellous grafts and to enable their interbody fusion, said element (1) having oriented holes (1g) (1h) for the passage of fasteners (2) and (3) cooperating with the superjacent and subjacent vertebral bodies.



FR 2 727 003 – A1



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Device for anterior stabilization of the lumbosacral spine

The invention relates to the technical area of spinal implants

5 The problem the invention proposes to resolve is of stabilizing the lumbar vertebrae and the lumbosacral hinge by the anterior approach.

 To ensure such stabilization, it is known to use implants in the form of plates, intended to be inserted between the vertebral bodies. The plate is not fixed but is simply impacted between the two vertebral bodies. The plate can be adapted to receive a graft. However, this solution is unsatisfactory because of the risk of expulsion of the graft in the event of instability and movement of the plate, which is not fixed.

10

 The purpose of the invention is to remedy these disadvantages in a way that is simple, safe, effective and rational.

15

 The problem that the invention proposes to resolve is to contribute stability to the lumbar vertebrae concerned, by means of a prosthetic assembly, while avoiding any risk of expulsion of said prosthetic assembly, and by taking into account the fact that in the lumbar area there can be vascular risks because of the vertebrae being relatively close to the vessels.

20

 To resolve this problem, and anterior stabilization device for the lumbosacral spine has been designed and developed, which comprises an element capable of maintaining the separation between the vertebral bodies of the lumbar spine while being adapted to receive cancellous grafts and

25

allowing their interbody fusion, said element having holes oriented for the passage and integration of fasteners cooperating with the superjacent and subjacent vertebral bodies.

5 To resolve the problem posed of integrating the fasteners and enabling said fasteners to be implanted in the cortical-cancellous bone of the vertebral bodies, the holes consist of internal recesses formed from the anterior face of the element, one of said recesses being directed downwards while the other is directed upwards, and being oriented at an angle of about 90° with respect to each
10 other.

 To resolve the problem posed of preventing crushing, while having the objective of allowing the interbody fusion of the grafts, the element consists of a hollow volumetric generally rectangular structure, shaped to correspond to the
15 anatomy of the vertebral bodies concerned. The element has a concave posterior edge at the back and a rounded anterior edge to fit snugly with the anterior face of the vertebral body.

 To resolve the problem posed of complying with the lumbosacral lordosis,
20 the height of the anterior face is greater than the height of the posterior face in order to comply with the lumbosacral lordosis.

 The upper and lower faces of the element are notched to facilitate primary stability.

25 The invention is explained in more detail with reference to the appended drawings, in which:

Figure 1 is a view in perspective of the device according to the invention.

Figure 2 is a plan view of the device.

Figure 3 is a cross-section view showing the attachment of the device between two plates of the lumbar vertebrae.

5

As shown in figure 1, the device comprises an element (1) capable of maintaining the separation between two vertebral bodies (L1) and (L2) of the lumbar part of the spine, including the lumbosacral hinge. Said element (1) is arranged to receive cancellous grafts (G) and to allow their interbody fusion. The grafts are advantageously taken from the iliac crest or the upper end of the tibia.

10

The element (1) consists of a hollow volumetric generally rectangular structure, shaped to correspond to the anatomy of the vertebral bodies (L1) (L2). In particular, the element (1) has a concave posterior edge (1c) at the back and a rounded anterior edge (1d). The height of the anterior face is greater than the height of the posterior face.

15

Furthermore, the element (1) has two separate through-openings (1a) (1b), each receiving cancellous grafts. It is also possible to produce a single through-opening in the thickness of the element (1), or more than two openings.

20

According to one important characteristic of the invention, the element (1) has oriented holes (1g) (1h) for the passage and integration of fasteners (2) and (3), cooperating with the superjacent and subjacent vertebral bodies (L1) and (L2) at said element (1). As shown particularly in

25

figure 3, the holes (1g) and (1h) consist of internal recesses made from the anterior face (1d), near the transverse edges of the element (1). The recess (1g) is oriented upwards, while the recess (1h) is oriented downwards. The two recesses (1g) and (1h) are angularly offset by about 90°.

Consequently, after insertion of the screws (2) and (3), one of them (2) will be directed downwards, while the other (3) will be directed upwards. It should be noted that said screws are oriented at an angle of very substantially 45°, in order to be implanted in the cortical-cancellous bone of the vertebral bodies (L1) (L2).

The heads (2a) and (3a) of the screws (2) and (3) are embedded in the recess, pressed against the bottom thereof, and do not extend beyond the anterior face (1d).

The upper face (1i) and lower face (1j) are notched to facilitate primary stability. The element (1) is made of titanium or polymer reinforced with carbon fiber.

It should be noted that the element (1) is produced in essentially three sizes, namely:

- a small size with a width of around 20 mm and a length of around 30 mm,
- a medium size with a width of around 25 mm and a length of around 35 mm,
- a large size with a width of around 30 mm and a length of around 40 mm.

It should also be noted that a distinction is made between two types of elements (1), depending on whether it involves the lumbosacral level L5-S1 or the higher levels. At the lumbosacral level, an element is used the

obliquity of which is more accentuated, i.e. the height of the anterior face is clearly greater than that of the posterior face.

Three types of implants are available for the L5-S1 level, the anterior heights of which are respectively 10 mm, 12 mm and 14 mm, while the posterior heights are 8 mm, 10 mm and 12 mm. For the higher levels, L4, L5 and above, the anterior heights are respectively 9 mm, 11 mm and 13 mm, while the posterior heights are 8 mm, 10 mm and 12 mm.

The following is a description of the installation of the device according to the invention.

After ablation of the intervertebral disc via an anterior approach, vertebral distraction enables the desired intervertebral height to be regained. Said distraction can be accomplished by means of traction applied to the cranium and is made possible by the broadest possible resection of all the disk tissue all the way to the posterior vertebral ligament, which can also be resected. An interbody distracter completes the intervertebral spacing, the height of the element (1) having been calculated according to the echo images and after trial of the correct size of the element. The element (1) is filled with cancellous grafts and is implanted in the intervertebral space concerned, (L1) (L2) for example. The element (1) is then secured to the superjacent and subjacent vertebrae by means of screws (2) and (3), which cooperate in the cortical-cancellous bone of the vertebral bodies.

Intraoperative radiology monitoring is necessary to ensure the proper positioning of the device.

Said device is particularly well-suited for stabilizing a mobile segment of the lumbar or lumbosacral spine and essentially applies either to the lumbosacral hinge or to the superjacent vertebrae, particularly at spaces L3-L4 and L4-L5.

The advantages can be clearly seen from the description, particularly the use of osteosynthesis screws for primary stabilization, and for avoiding any movement of the cancellous grafts during the time required for bone regrowth.

CLAIMS

5 -1- Device for the anterior stabilization of the lumbosacral spine, characterized in that it comprises an element (1) suitable for maintaining the separation between the vertebral bodies (L1) (L2) of the lumbar spine while being arranged to receive cancellous grafts and to enable their interbody fusion, said element (1) having oriented holes (1g) (1h) for the passage of fasteners (2) and (3) cooperating with the superjacent and subjacent vertebral bodies.

10 -2- Device according to claim 1, characterized in that the holes (1g) (1h) consist of internal recesses formed from the anterior face (1d) of the element (1), one of said recesses being directed downwards while the other is directed upwards, and being oriented at an angle of about 90° with respect to each other.

15 -3- Device according to claim 1, characterized in that the element (1) consists of a hollow volumetric generally rectangular structure, shaped to correspond to the anatomy of the vertebral bodies concerned.

20 -4- Device according to claim 1, characterized in that the element has a concave posterior edge (1c) at the back and a rounded anterior edge (1d) to fit snugly with the anterior face of the vertebral body.

25 -5- Device according to claim 1, characterized in that the height of the anterior face (1d) is greater than the height of the posterior face (1c) in order to comply with the lumbosacral lordosis.

 -6- Device according to claim 1, characterized in that the upper face (1i)

and lower face (1j) of the element (1) are notched to facilitate primary stability.

-7- Device according to claim 1, characterized in that the element (1) has two separate through-openings (1a) (1b) to receive the cancellous grafts.

5

-8- Device according to claim 1, characterized in that the element (1) is made of titanium or polymer reinforced with carbon fibers.

1/2

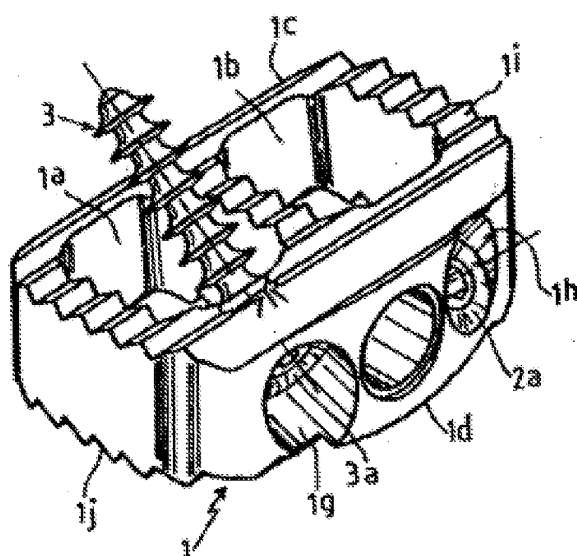


FIG. 1

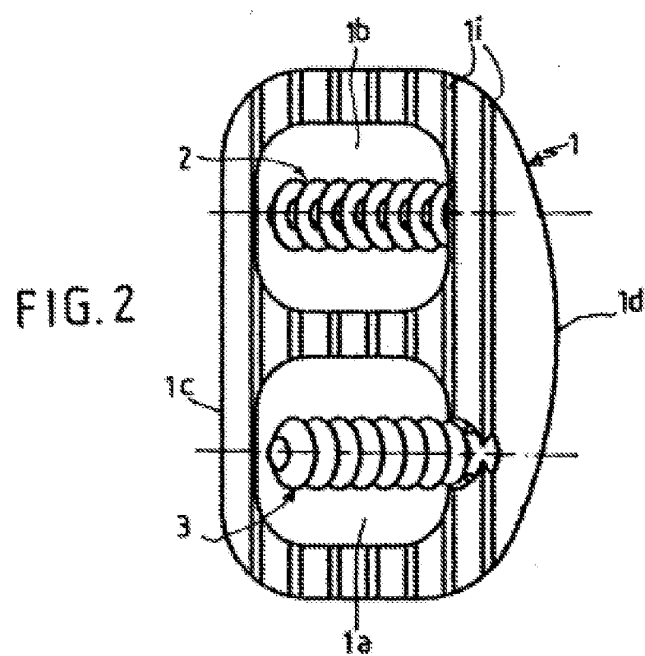


FIG. 2

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Electronic Patent Application Fee Transmittal				
Application Number:		13210168		
Filing Date:		15-Aug-2011		
Title of Invention:		BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION		
First Named Inventor/Applicant Name:		Ahmnon D. MOSKOWITZ		
Filer:		John Jeremy Dresch		
Attorney Docket Number:		3003/0105PUS7		
Filed as Small Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension - 3 months with \$0 paid	2253	1	700	700
Miscellaneous:				
RCE- 2ND AND SUBSEQUENT REQUEST	2820	1	850	850
Total in USD (\$)				1550

Electronic Acknowledgement Receipt	
EFS ID:	27481336
Application Number:	13210168
International Application Number:	
Confirmation Number:	1609
Title of Invention:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION
First Named Inventor/Applicant Name:	Ahmnon D. MOSKOWITZ
Customer Number:	87409
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Application Type:	Utility under 35 USC 111(a)

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The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: 37 CFR 1.16 (National application filing, search, and examination fees) 37 CFR 1.17 (Patent application and reexamination processing fees)	

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Amendment Submitted/Entered with Filing of CPA/RCE	30030105PUS7_Amendment_D_20161110_readyforfiling.pdf	129086	no	15
			4eddfa9255577402f8b8e29efa3348057203b972		
Warnings:					
Information:					
2	Request for Continued Examination (RCE)	30030105PUS7_RCE2_readyfor filing.pdf	697649	no	3
			89cda4944dd1a8cc90db11a00d90d8d862f0968d		
Warnings:					
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3	Extension of Time	30030105PUS7_Petition_EOT_readyforfiling_20161110.pdf	188246	no	2
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4	Information Disclosure Statement (IDS) Form (SB08)	30030105PUS7_IDS_20161110.pdf	612798	no	5
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Warnings:					
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5	Foreign Reference	FR2727003A1_Tisserand_and_Cert_Translation_A.pdf	943307	no	23
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6	Fee Worksheet (SB06)	fee-info.pdf	32770	no	2
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UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Ahmnon D. MOSKOWITZ, et al.
Application Number: 13/210,168
Filing Date: 08/15/2011
Group Art Unit: 3733
Examiner: Pedro PHILOGENE
Confirmation No.: 1609
Title: BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND
POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT
CALIBRATED STAPLING DEVICES FOR SPINAL FUSION

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

AMENDMENT D

Dear Sir:

This Amendment is responsive to the Final Office Action dated May 10, 2016, having a due date of November 10, 2016, and accompanies an extension of time, and a Request for Continued Examination.

Please charge Deposit Account No. 505364 for any deficiency or overpayment.

Please amend the application as follows:

Amendments to the Claims, as reflected in the listing of claims, begin on page 2 of this paper;
and

Remarks begin on page 12 of this paper.

IN THE CLAIMS:

Please amend the claims as follows. This listing of the claims will replace all prior versions, and listings, of claims in the application:

1-85. (Canceled)

86. (Previously presented) A universal, intervertebral combination internal screw guide and fixation apparatus configured to be inserted into a disc space between a first vertebral body and a second vertebral body and to provide fusion of the first vertebral body to the second vertebral body via biological bone fusion and screw fusion, the apparatus comprising:

an intervertebral cage including:

a top wall, a bottom wall, and two sidewalls defining an open space capable of receiving bone filling for the biological bone fusion; and

an internal screw guide having an entry opening and an exit opening, the entry opening formed at least partially in a top surface of the top wall and the exit opening formed at least partially in a bottom surface of the top wall and at least partially in a side surface of the top wall.

87. (Previously presented) The apparatus of claim 86, wherein an internal surface of the internal screw guide extends continuously from the entry opening to the exit opening.

88. (Previously presented) The apparatus of claim 86, wherein the internal screw guide extends through an entire depth of the top wall from the top surface to the bottom surface and exiting at least partially into the open space.

89. (Previously presented) The apparatus of claim 86, wherein the internal screw guide permits only a predetermined angled trajectory of a screw member through the intervertebral cage.

90. (Previously presented) The apparatus of claim 86, wherein the internal screw guide has a 25 degree angulation.

91. (Previously presented) The apparatus of claim 86, wherein the top wall has a thickness extending from the top surface of the top wall to the bottom surface of the top wall in a direction of a depth of the intervertebral cage, a height of the intervertebral cage extending in a direction perpendicular to the depth, and

wherein an axis of the internal screw guide extends to a greater extent in the direction of the depth of the intervertebral cage than in a direction of a height of the intervertebral cage in order to facilitate multi-level fusion of adjacent vertebral bodies with multiple intervertebral cages.

92. (Previously presented) The apparatus of claim 86, wherein the top wall of the intervertebral cage has a thickness that is greater than a thickness of each of the sidewalls.

93. (Previously presented) The apparatus of claim 86, wherein at least one of the two sidewalls includes a hole configured to allow placement of bone filling into the open space of the intervertebral cage for the biological bone fusion.

94. (Previously presented) The apparatus of claim 86, wherein the intervertebral cages includes indentations formed on surfaces of the two sidewalls and on opposite ends of the intervertebral cage for receiving ends of prongs of an implantation tool.

95. (Previously presented) The apparatus of claim 86, wherein a surface of each of the two sidewalls includes a plurality of ridges.

96. (Previously presented) The apparatus of claim 86, wherein the intervertebral cage is configured to receive a plate for securing a second intervertebral cage thereto.

97. (Previously presented) The apparatus of claim 96, wherein the intervertebral cage comprises:

a screw insert configured to receive the plate for securing the second intervertebral cage thereto.

98. (Previously presented) The apparatus of claim 86, wherein the intervertebral cage is a cervical intervertebral cage configured to fit into a cervical disc space.

99. (Previously presented) The apparatus of claim 86, wherein the intervertebral cage is a lumbar intervertebral cage configured to fit into a lumbar disc space.

100. (Previously presented) The apparatus of claim 86, wherein the intervertebral cage is a posterior lumbar intervertebral cage configured to fit into a lumbar disc space.

101. (Previously presented) The apparatus of claim 86, wherein the intervertebral cage capable of one of posterior lumbar intervertebral placement, anterior lumbar intervertebral placement, thoracic intervertebral placement, and anterior cervical intervertebral placement.

102. (Previously presented) The apparatus of claim 86, wherein the intervertebral cage further comprises:

a second internal screw guide having a second entry opening and a second exit opening, the second entry opening formed at least partially in the top surface of the top wall and the second exit opening formed at least partially in the bottom surface of the top wall and at least partially in a second side surface of the top wall.

103. (Previously presented) The apparatus of claim 102, wherein each of the internal screw guide and the second internal screw guide is angled to orient a first screw member and a second screw bi-directionally in opposite directions.

104. (Previously presented) The apparatus of claim 103, wherein the internal screw guide is configured to orient the first screw member rostrally and the second internal screw guide is configured to orient the second screw member caudally.

105. (Previously presented) The apparatus of claim 102, wherein the internal screw guide and the second internal screw guide are at an angulation with respect to the top surface of the top wall.

106. (Previously presented) The apparatus of claim 102, wherein each of the internal screw guide and the second internal screw guide permits only a 25 degree angulation of a first screw member and the second screw member.

107. (Previously presented) The apparatus of claim 102, wherein the internal screw guide and the second internal screw guide are aligned along a longitudinal axis of the top wall of the intervertebral cage.

108. (Previously presented) The apparatus of claim 102, wherein the internal screw guide and the second internal screw guide are symmetrically disposed on each side of a center point of the intervertebral cage along a longitudinal axis of the top wall of the intervertebral cage.

109. (Previously presented) The apparatus of claim 102, wherein the internal screw guide and the second internal screw guide are offset in opposite directions with respect to a center line of a longitudinal extent of the top wall.

110. (Previously presented) The apparatus of claim 109, wherein a part of the internal screw guide overlaps a part of the second internal screw guide along the longitudinal extent of the top wall.

111. (Previously presented) The apparatus of claim 102, wherein the entry opening of the internal screw guide and the second entry opening of the second internal screw guide are arranged diagonally on the top surface of the top wall.

112. (Previously presented) The apparatus of claim 102, wherein the top wall has four quadrants delineated by a first axis and a second axis each lying in a plane of the top wall, and the first axis is at a right angle with respect to the second axis,

wherein the four quadrants include a first quadrant, a second quadrant, a third quadrant, and a fourth quadrant,

wherein the first quadrant and the fourth quadrant are opposed to the second quadrant and the third quadrant with respect to the first axis, and the first quadrant and the second quadrant are opposed to the third quadrant and the fourth quadrant with respect to the second axis,

wherein the first quadrant is diagonally opposed to the third quadrant, and the second quadrant is diagonally opposed to the fourth quadrant, and

wherein a majority of an area of the entry opening of the internal screw guide is in the first quadrant and a majority of an area of the second entry opening of the second internal screw guide is in the third quadrant.

113. (Previously presented) The apparatus of claim 102, wherein the top wall has four quadrants delineated by a first axis and a second axis each lying in a plane of the first wall, and the first axis is at a right angle with respect to the second axis,

wherein the four quadrants include a first quadrant, a second quadrant, a third quadrant, and a fourth quadrant,

wherein the first quadrant and the fourth quadrant are opposed to the second quadrant and the third quadrant with respect to the first axis, and the first quadrant and the second quadrant are opposed to the third quadrant and the fourth quadrant with respect to the second axis,

wherein the first quadrant is diagonally opposed to the third quadrant, and the second quadrant is diagonally opposed to the fourth quadrant, and

wherein a center of the entry opening of the internal screw guide is in the first quadrant and a center of the second entry opening of the second internal screw guide is in the third quadrant.

114. (Previously presented) The apparatus of claim 102, wherein the top wall includes a first corner and a second corner, the first corner being arranged at an opposite side of the top wall and an opposite end of the top wall with respect to the second corner, and

wherein the internal screw guide and the second internal screw guide are diagonally arranged along a direction extending from the first corner of the top wall to the second corner of the top wall.

115. (Previously presented) The apparatus of claim 102, wherein the intervertebral cage further comprises:

a third internal screw guide having a third entry opening and a third exit opening, the third entry opening formed at least partially in the top surface of the top wall and the third exit opening formed at least partially in the bottom surface of the top wall and at least partially in the side surface of the top wall.

116. (Previously presented) The apparatus of claim 115, wherein the intervertebral cage further comprises:

a fourth internal screw guide having a fourth entry opening and a fourth exit opening, the fourth entry opening formed at least partially in the top surface of the top wall and the fourth exit opening formed at least partially in the bottom surface of the top wall and at least partially in the second side surface of the top wall.

117. (Previously presented) The apparatus of claim 116, wherein the internal screw guide and the fourth internal screw guide are oriented rostrally and the second internal screw guide and the third internal screw guide are oriented caudally.

118. (Previously presented) The apparatus of claim 116, wherein the second internal screw guide and the third internal screw guide are disposed between the internal screw guide and the fourth internal screw guide along a longitudinal length of the top wall of the intervertebral cage.

119. (Previously presented) The apparatus of claim 116, wherein each of the internal screw guide, the second internal screw guide, the third internal screw guide, and the fourth internal screw guide has a 25 degree angulation.

120. (Previously presented) The apparatus of claim 86, further comprising:

a second intervertebral cage including:

a top wall, a bottom wall, and two sidewalls defining an open space capable of receiving bone filling for biological bone fusion, and

an internal screw guide having an entry opening and an exit opening, the entry opening of the second intervertebral cage formed at least partially in a top surface of the top wall of the second intervertebral cage and the exit opening formed at least partially in a bottom surface of the top wall of the second intervertebral cage and at least partially in a side surface of the top wall of the second intervertebral cage; and

an attachment member coupling the intervertebral cage to the second intervertebral cage.

121. (Previously presented) The apparatus of claim 120, wherein the attachment member includes a supplemental cage defining one or more open spaces capable of receiving the intervertebral cage and the second intervertebral cage, and

wherein the intervertebral cage and the second intervertebral cage are secured to the supplemental cage.

122. (Previously presented) The apparatus of claim 120, wherein the attachment member includes a plate.

123. (Previously presented) The apparatus of claim 102, wherein the intervertebral cage is devoid of any other internal screw guides other than the first internal screw guide and a second internal screw guide.

124. (Previously presented) A zero-profile, intervertebral cage sized and configured to be inserted into a disc space between adjacent vertebral bodies and to provide fusion of the adjacent vertebral bodies via biological bone fusion and screw fusion,

the intervertebral cage comprising:

a top wall;

a bottom wall opposite the top wall;

a first sidewall;

a second sidewall opposite the first sidewall, each of the first sidewall and the second sidewall having a surface configured to contact one of the adjacent vertebral bodies when the intervertebral cage is inserted into the disc space,

wherein at least the first sidewall and the second sidewall bound an open space capable of receiving bone filling for the biological bone fusion,

wherein the top wall includes a top surface and a bottom surface opposite the top surface, the top surface configured to have a zero-profile with respect to the adjacent vertebral bodies when the intervertebral cage is inserted into the disc space, and the bottom surface facing the open space; and

an internal screw trajectory guide for guiding a trajectory of a screw through the intervertebral cage, the internal screw trajectory guide having an entry opening and an exit opening, the entry opening formed at least partially in the top surface of the top wall, and the exit opening formed at least partially in a bottom surface of the top wall and at least partially in a side surface of the top wall.

125. (Previously presented) The apparatus of claim 86, wherein the exit opening is formed at least partially in a surface of one of the two sidewalls.

126. (Previously presented) A universal, intervertebral combination internal screw guide and fixation apparatus configured to be inserted into a disc space between a first vertebral body and a second vertebral body and to provide fusion of the first vertebral body to the second vertebral body via biological bone fusion and screw fusion, the apparatus comprising:

an intervertebral cage including:

a top wall, a bottom wall, and two sidewalls defining an open space capable of receiving bone filling for the biological bone fusion; and

an internal screw guide having an entry opening and an exit opening, the entry opening formed at least partially in a top surface of the top wall,

the exit opening formed at least partially in a bottom surface of the top wall, and the exit opening formed at least partially in at least one of:

a side surface of the top wall; and

a surface of one of the two sidewalls.

127. (Previously presented) The apparatus of claim 126, wherein the exit opening is formed partially in the side surface of the top wall.

128. (Previously presented) The apparatus of claim 126, wherein the exit opening is formed partially in the surface of the one of the two sidewalls.

129. (Previously presented) The apparatus of claim 126, wherein the exit opening is formed partially in the side surface of the top wall and partially in the surface of the one of the two sidewalls.

130. (Previously presented) The apparatus of claim 86, wherein the entry opening is formed substantially in the top surface of the top wall.

131. (Previously presented) The apparatus of claim 86, wherein the entry opening is formed entirely in the top surface of the top wall.

132. (Previously presented) The apparatus of claim 121, wherein the supplemental cage surrounds a perimeter of the intervertebral cage and the second intervertebral cage.

133-134. (Canceled)

135. (Previously presented) The apparatus of claim 86, wherein the internal screw guide has an internal bore with the entry opening and the exit opening, and the entry opening of the internal bore is formed only in the top surface of the top wall and the exit opening is formed at least partially in the bottom surface of the top wall and at least partially in the side surface of the top wall,

wherein the internal screw guide further comprises a counterbore formed at least partially in the top surface of the top wall for accommodating a screw head of a screw member,

wherein the entry opening of the internal bore is formed in a lower surface of the counterbore, and

wherein the entry opening of the internal bore is formed entirely between all edges of the top surface of the top wall when viewed from a direction perpendicular to a plane of the top surface.

136. (New) The apparatus of claim 86, wherein the entry opening of the internal screw guide is formed only in the top surface of the top wall.

137. (New) The apparatus of claim 86, wherein the entry opening of the internal screw guide is formed entirely between all edges of the top surface of the top wall when viewed from a direction perpendicular to a plane of the top surface.

REMARKS

Claims 86-132 and 134-137 are pending in the application. This Amendment amends cancels claims 133 and 134 and adds new claims 136 and 137. Claims 86, 124, and 126 are independent.

This Amendment adds new claims 136 and 137 to provide more varied protection for the present invention and to raise a new issue for the Examiner's consideration, thereby to preclude a first-action final rejection after the filing of the RCE. The features of claim 136 and the combination of claims 86 and 136 have not been presented earlier. This Amendment does not add new matter. None of the applied references discloses or suggests the subject matter defined by claims 136 and 137 for at least the same reasons as independent claim 86 and similar to allowable claim 135, as well as for the additional features recited therein.

The Allowable Subject Matter

Applicants gratefully acknowledge the indication by the Office Action that claim 135 would be allowable if rewritten in independent form.

The Provisional Double Patenting Rejection

Claims 86-135 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 93-141 of copending Application No. 13/210,162. Claims 86-135 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 84-133 of copending Application No. 13/210,157.

Applicants respectfully traverse these rejections.

Applicants respectfully submit that claims 86-135 of the present application are patentably distinct from the claims of the copending applications. Applicants note that the claims may be subject to further amendments during prosecution, which features should serve to further distinguish the claims of the present application from the claims of the co-pending applications.

With regard to the provisional obviousness-type double patenting rejections, Applicants respectfully submit that the conflicting claims have not in fact been patented, and therefore, also

may be subject to further amendments during prosecution, which features may serve to further distinguish the claims of the present application from the claims of the co-pending applications.

For these reasons, Applicants respectfully reserve the right to file a terminal disclaimer in compliance with 37 C.F.R. § 1.321(c) or 1.321(d) as such time as the claims of the present application are allowable. Applicants respectfully request withdrawal of these rejections.

The Waugh et al. Reference

The Office Action rejects claims 86-134 under 35 U.S.C. §102(e) as allegedly being anticipated by the Waugh et al. reference (U.S. Publication No. 2008/0249575).

Applicants respectfully traverse this rejection.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. [...] The identical invention must be shown in as complete detail as is contained in the ... claim." M.P.E.P. § 2131.

The Waugh et al. reference does not disclose or suggest the unique combination of features of at least claim 136 including wherein the entry opening of the internal screw guide is formed only in the top surface of the top wall, or the features of claim 137 including wherein the entry opening of the internal screw guide is formed entirely between all edges of the top surface of the top wall when viewed from a direction perpendicular to a plane of the top surface.

The Waugh et al. reference discloses several embodiments, none of which discloses each and every element of the claims. For example, in the embodiments illustrated in FIGS. 1-8, which angle the screws at a steep angle with respect to the sidewalls, each of the entry opening and exit opening of the internal bore of the screw holes is formed in two surfaces. Particularly, the entry opening of the bore is formed partially in the top surface and partially in the side surface of the top wall of the cage, and the exit opening of the bore similarly is formed partially in the bottom surface and partially in the side surface of the top wall of the cage. As a result, a surgeon will need to remove bone from the adjacent vertebral bodies in order to insert the screw into the cage and vertebral bodies.

In the embodiments illustrated in FIG. 9-14, which angle the screws at a shallow angle with respect to the sidewalls, each of the entry opening and exit opening of the internal bore of the screw holes is formed in only one surface. See, e.g., FIG. 9. Particularly, the entry opening of the bore is formed only in the top surface of the top wall of the cage, and the exit opening of

the bore is formed only in the bottom surface of the top wall of the cage. In other words, depending on the intended angle of the screws, the Waugh et al. reference discloses either entering through two surfaces and exiting through two surfaces if the screw hole is to be angled at a steep angle with respect to the sidewalls, or entering through a single surface and exiting through a single surface if the screw hole is to be angled at a shallow angle with respect to the sidewalls. Hence, none of the embodiments of the Waugh et al. reference discloses each and every element of the claims.

In stark contrast to the arrangements in the applied references, the claimed invention provides a unique combination in which an internal screw guide has an internal bore with an entry opening and an exit opening, wherein the entry opening of the internal screw guide is formed only in the top surface of the top wall, as recited in claim 136, or wherein the entry opening of the internal screw guide is formed entirely between all edges of the top surface of the top wall when viewed from a direction perpendicular to a plane of the top surface, as recited in claim 137. In this way, the present invention provides a unique arrangement having an internal screw guide in the cage that guides a screw trajectory into the vertebral body at a predetermined shallow angle that avoids interference with screws of other adjacent implantation devices and enables multiple level fusion, and at the same time eliminates a need for the surgeon to remove a part of the bone from the vertebral body to insert the screw. The present invention also eliminates the need to use an external screw guide.

Applicants respectfully request withdrawal of this rejection.

CONCLUSION

In view of the above, Applicants respectfully request entry of the present Amendment and allowance of the claims. Applicants invite the Examiner to contact the undersigned if the Examiner has any questions regarding this amendment. Applicants petition for an extension of time if required for entry of this Amendment.

Please charge Deposit Account No. 505364 for any deficiency or overpayment.

Respectfully Submitted,

/ John J. Dresch /
John J. Dresch
Attorney for Applicant(s)
Reg. No. 46,672

November 10, 2016

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***** Customer No. 87409 *****

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

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 13/210,168	Filing Date 08/15/2011	☐ To be Mailed
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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), (j), 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 \$ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X \$ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	

APPLICATION AS AMENDED – PART II

(Column 1) (Column 2) (Column 3)

AMENDMENT	11/10/2016	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)
	Total (37 CFR 1.16(i))	* 50	Minus	** 60	= 0	x \$40 =	0
	Independent (37 CFR 1.16(h))	* 3	Minus	*** 3	= 0	x \$210 =	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 \$ =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X \$ =	
	☐ 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.

** 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 number found in the appropriate box in column 1.

LIE
/RUTH LLOYD/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/210,168	08/15/2011	Ahmnnon D. MOSKOWITZ	3003/0105PUS7	1609

87409 7590 01/26/2017
Dresch IP Law, PLLC
P.O. Box 650903
Potomac Falls, VA 20165

EXAMINER

PHILOGENE, PEDRO

ART UNIT	PAPER NUMBER
----------	--------------

3733

NOTIFICATION DATE	DELIVERY MODE
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01/26/2017

ELECTRONIC

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

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

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@dreschiplaw.com
jdresch@dreschiplaw.com
linda.logan@dreschiplaw.com

Office Action Summary	Application No. 13/210,168	Applicant(s) MOSKOWITZ ET AL.	
	Examiner PEDRO PHILOGENE	Art Unit 3733	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/10/16.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 86-132 and 135-137 is/are pending in the application.
5a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) _____ is/are allowed.
- 7) ☒ Claim(s) 86-132 and 135-137 is/are rejected.
- 8) ☐ Claim(s) _____ is/are objected to.
- 9) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) ☐ Notice of References Cited (PTO-892) | 3) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
Paper No(s)/Mail Date <u>11/10/16</u> | 4) ☐ Other: _____ |

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

Double Patenting

A rejection based on double patenting of the “same invention” type finds its support in the language of 35 U.S.C. 101 which states that “whoever invents or discovers any new and useful process... may obtain a patent therefor...” (Emphasis added). Thus, the term “same invention,” in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the claims that are directed to the same invention so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 86-132, 135-137 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 93-141 of copending Application No. 13/210,162. This is a provisional statutory double patenting rejection since the claims directed to the same invention have not in fact been patented.

Claims 86-132, 135-137 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 84-133 of copending Application No.

13/210,157. This is a provisional statutory double patenting rejection since the claims directed to the same invention have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of pre-AIA 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 86-132 are rejected under pre-AIA 35 U.S.C. 102(e) as being clearly anticipated by Waugh et al. (2008/0249575).

Allowable Subject Matter

Claims 135-137 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Amendment

Applicant's arguments filed 11/10/16 have been fully considered but they are not persuasive. As to the Double Patenting rejection, although applicant stated that the claims of the present application may be subject to further amendments during prosecution, applicant did not state which features should serve to further distinguish the claims of the present application from the claims of the co-pending applications, applicant did not amend any of the claims in the present application. Furthermore,

applicant argues that Waugh fails to teach all the features in newly presented dependent claims 135-137, the examiner agrees.

Conclusion

A shortened statutory period for reply to this action is set to expire THREE MONTHS from the mailing date of this action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PEDRO PHILOGENE whose telephone number is (571)272-4716. The examiner can normally be reached on Monday to Friday 8:00 AM to 4:30 PM.

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

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

Application/Control Number: 13/210,168
Art Unit: 3733

Page 5

/PEDRO PHILOGENE/
Primary Examiner, Art Unit 3733
January 22, 2017

Doc code: IDS

Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)

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

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

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	13210168
	Filing Date	2011-08-15
	First Named Inventor	MOSKOWITZ et al.
	Art Unit	3733
	Examiner Name	PHILOGENE, PEDRO
	Attorney Docket Number	3003/0105PUS7

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	7238203		2007-07-03	BAGGA, CHARANPREET et al.	
	2	6342074		2002-01-29	SIMPSON, NATHAN S.	
	3	7232464		2007-06-19	MATHIEU, CLAUDE et al.	
	4	7442209		2008-10-28	MICHELSON GARY K	
	5	8790405		2014-07-29	BIEDERMANN, LUTZ et al.	
	6	8268000		2012-09-18	WAUGH, LINDSEY G. et al.	
	7	7985255		2011-07-26	BRAY, ROBERT S. et al.	
	8	6962606		2005-11-08	MICHELSON, GARY KARLIN	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	13210168
	Filing Date	2011-08-15
	First Named Inventor	MOSKOWITZ et al.
	Art Unit	3733
	Examiner Name	PHILOGENE, PEDRO
	Attorney Docket Number	3003/0105PUS7

	9	7135043		2006-11-14	NAKAHARA, SHINNOSUKE et al.	
	10	4904261		1990-02-27	DOVE, JOHN et al.	

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	1	2727003	FR		1996-05-24	TISSERAND, PHILIPPE		×

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	13210168
	Filing Date	2011-08-15
	First Named Inventor	MOSKOWITZ et al.
	Art Unit	3733
	Examiner Name	PHILOGENE, PEDRO
	Attorney Docket Number	3003/0105PUS7

EXAMINER SIGNATURE			
Examiner Signature	/PEDRO PHILOGENE/		Date Considered
01/22/2017			
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			
<small> 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. </small>			

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	13210168
	Filing Date	2011-08-15
	First Named Inventor	MOSKOWITZ et al.
	Art Unit	3733
	Examiner Name	PHILOGENE, PEDRO
	Attorney Docket Number	3003/0105PUS7

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	/John J. Dresch/	Date (YYYY-MM-DD)	2016-11-10
Name/Print	John J. Dresch	Registration Number	46,672

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.

Search Notes 	Application/Control No. 13210168	Applicant(s)/Patent Under Reexamination MOSKOWITZ ET AL.
	Examiner PEDRO PHILOGENE	Art Unit 3733

CPC- SEARCHED		
Symbol	Date	Examiner
A61B17/0642, A61B17/809, A61B17/8894, A61F2/4465, A61F2/447, A61F2/4611, A61B17/7064	1/22/2017	/P.P./
A61F2250/0007, A61B17/86, A61B2017/0641, A61B2017/0648, A61B2017/922, A61F2002/2835, A61F2002/30133, A61F2002/30387, A61F2002/30448, A61F2002/30507		
A61F2002/3055, A61F2002/30579, A61F2002/30604, A61F2002/30772, A61F2002/30878, A61F2002/4475, A61F2002/448, A61F2002/4627, A61F2002/4681, A61F2220/0025, A61F2220/005, A61F2230/0015		

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
623	17.11-17.16	1/22/2017	/P.P./
606	300-305,246, 99, 144, 151, 251, 266		
227	181.1		

SEARCH NOTES		
Search Notes	Date	Examiner
EAST search enclosed	1/22/2017	/P.P./

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

	/PEDRO PHILOGENE/ Primary Examiner.Art Unit 3733
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EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	10	("4904261" "6342074" "6962606" "7135043" "7232464" "7238203" "7442209" "7985255" "8268000" "8790405").PN.	US-PGPUB; USPAT	OR	OFF	2017/01/22 09:24

1/ 22/ 2017 9:25:21 AM

EAST Search History**EAST Search History (Prior Art)**

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L2	353	411/347	US-PGPUB; USPAT	OR	OFF	2017/01/22 08:42
L3	1	"20130018469"	US-PGPUB; USPAT	OR	OFF	2017/01/22 08:42
L4	1235	A61B17/0642.cpc.	US-PGPUB; USPAT	OR	OFF	2017/01/22 08:43
L5	703	A61B17/809.cpc.	US-PGPUB; USPAT	OR	OFF	2017/01/22 08:46
L6	173	A61B17/8894.cpc.	US-PGPUB; USPAT	OR	OFF	2017/01/22 08:47
L7	1022	A61B17/7064.cpc.	US-PGPUB; USPAT	OR	OFF	2017/01/22 08:48
L8	1857	A61F2/4465.cpc.	US-PGPUB; USPAT	OR	OFF	2017/01/22 08:49
L9	2347	A61F2/447.cpc.	US-PGPUB; USPAT	OR	OFF	2017/01/22 08:52
L10	5995	A61F2/4611.cpc.	US-PGPUB; USPAT	OR	OFF	2017/01/22 09:04

1/22/2017 9:05:19 AM

<p align="center"><i>Index of Claims</i></p> 	<p>Application/Control No.</p> <p>13210168</p>	<p>Applicant(s)/Patent Under Reexamination</p> <p>MOSKOWITZ ET AL.</p>
	<p>Examiner</p> <p>PEDRO PHILOGENE</p>	<p>Art Unit</p> <p>3733</p>

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

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47									
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<i>Index of Claims</i> 	Application/Control No. 13210168	Applicant(s)/Patent Under Reexamination MOSKOWITZ ET AL.
	Examiner PEDRO PHILOGENE	Art Unit 3733

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

☐ Claims renumbered in the same order as presented by applicant						☐ CPA		☐ T.D.		☐ R.1.47	
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	Examiner PEDRO PHILOGENE	Art Unit 3733

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
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☐ Claims renumbered in the same order as presented by applicant										☐ CPA		☐ T.D.		☐ R.1.47	
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	107	✓	✓	✓	✓										
	108	✓	✓	✓	✓										

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	Examiner PEDRO PHILOGENE	Art Unit 3733

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

☐ Claims renumbered in the same order as presented by applicant		☐ CPA		☐ T.D.		☐ R.1.47			
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	136				✓				
	137				✓				

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Ahmnon D. MOSKOWITZ, et al.
Application Number: 13/210,168
Filing Date: 08/15/2011
Group Art Unit: 3733
Examiner: Pedro PHILOGENE
Confirmation No.: 1609
Title: BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND
POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT
CALIBRATED STAPLING DEVICES FOR SPINAL FUSION

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT

Dear Sir:

This Amendment is responsive to the Office Action dated January 26, 2017, having a due date of May 26, 2017, and accompanies excess claims fees for two (2) excess independent claims and an extension of time fee.

Please charge Deposit Account No. 505364 for any deficiency or overpayment.

Please amend the application as follows:

Amendments to the Claims, as reflected in the listing of claims, begin on page 2 of this paper; and

Remarks begin on page 13 of this paper.

IN THE CLAIMS:

Please amend the claims as follows. This listing of the claims will replace all prior versions, and listings, of claims in the application:

1-85. (Canceled)

86. (Currently amended) A universal, intervertebral combination internal screw guide and fixation apparatus configured to be inserted into a disc space between a first vertebral body and a second vertebral body and to provide fusion of the first vertebral body to the second vertebral body via biological bone fusion and screw fusion, the apparatus comprising:

an intervertebral cage including:

a top wall, a bottom wall, and two sidewalls defining an open space capable of receiving bone filling for the biological bone fusion; and

an internal screw guide having an entry opening and an exit opening, the entry opening formed at least partially in a top surface of the top wall and the exit opening formed at least partially in a bottom surface of the top wall and at least partially in a side surface of the top wall,

wherein the entry opening of the internal screw guide is formed entirely between all edges of the top surface of the top wall when viewed from a direction perpendicular to a plane of the top surface.

87. (Previously presented) The apparatus of claim 86, wherein an internal surface of the internal screw guide extends continuously from the entry opening to the exit opening.

88. (Previously presented) The apparatus of claim 86, wherein the internal screw guide extends through an entire depth of the top wall from the top surface to the bottom surface and exiting at least partially into the open space.

89. (Previously presented) The apparatus of claim 86, wherein the internal screw guide permits only a predetermined angled trajectory of a screw member through the intervertebral cage.

90. (Previously presented) The apparatus of claim 86, wherein the internal screw guide has a 25 degree angulation.

91. (Previously presented) The apparatus of claim 86, wherein the top wall has a thickness extending from the top surface of the top wall to the bottom surface of the top wall in a direction of a depth of the intervertebral cage, a height of the intervertebral cage extending in a direction perpendicular to the depth, and

wherein an axis of the internal screw guide extends to a greater extent in the direction of the depth of the intervertebral cage than in a direction of a height of the intervertebral cage in order to facilitate multi-level fusion of adjacent vertebral bodies with multiple intervertebral cages.

92. (Previously presented) The apparatus of claim 86, wherein the top wall of the intervertebral cage has a thickness that is greater than a thickness of each of the sidewalls.

93. (Previously presented) The apparatus of claim 86, wherein at least one of the two sidewalls includes a hole configured to allow placement of bone filling into the open space of the intervertebral cage for the biological bone fusion.

94. (Previously presented) The apparatus of claim 86, wherein the intervertebral cages includes indentations formed on surfaces of the two sidewalls and on opposite ends of the intervertebral cage for receiving ends of prongs of an implantation tool.

95. (Previously presented) The apparatus of claim 86, wherein a surface of each of the two sidewalls includes a plurality of ridges.

96. (Previously presented) The apparatus of claim 86, wherein the intervertebral cage is configured to receive a plate for securing a second intervertebral cage thereto.

97. (Previously presented) The apparatus of claim 96, wherein the intervertebral cage comprises:

a screw insert configured to receive the plate for securing the second intervertebral cage thereto.

98. (Previously presented) The apparatus of claim 86, wherein the intervertebral cage is a cervical intervertebral cage configured to fit into a cervical disc space.

99. (Previously presented) The apparatus of claim 86, wherein the intervertebral cage is a lumbar intervertebral cage configured to fit into a lumbar disc space.

100. (Previously presented) The apparatus of claim 86, wherein the intervertebral cage is a posterior lumbar intervertebral cage configured to fit into a lumbar disc space.

101. (Previously presented) The apparatus of claim 86, wherein the intervertebral cage capable of one of posterior lumbar intervertebral placement, anterior lumbar intervertebral placement, thoracic intervertebral placement, and anterior cervical intervertebral placement.

102. (Previously presented) The apparatus of claim 86, wherein the intervertebral cage further comprises:

a second internal screw guide having a second entry opening and a second exit opening, the second entry opening formed at least partially in the top surface of the top wall and the second exit opening formed at least partially in the bottom surface of the top wall and at least partially in a second side surface of the top wall.

103. (Previously presented) The apparatus of claim 102, wherein each of the internal screw guide and the second internal screw guide is angled to orient a first screw member and a second screw bi-directionally in opposite directions.

104. (Previously presented) The apparatus of claim 103, wherein the internal screw guide is configured to orient the first screw member rostrally and the second internal screw guide is configured to orient the second screw member caudally.

105. (Previously presented) The apparatus of claim 102, wherein the internal screw guide and the second internal screw guide are at an angulation with respect to the top surface of the top wall.

106. (Previously presented) The apparatus of claim 102, wherein each of the internal screw guide and the second internal screw guide permits only a 25 degree angulation of a first screw member and the second screw member.

107. (Previously presented) The apparatus of claim 102, wherein the internal screw guide and the second internal screw guide are aligned along a longitudinal axis of the top wall of the intervertebral cage.

108. (Previously presented) The apparatus of claim 102, wherein the internal screw guide and the second internal screw guide are symmetrically disposed on each side of a center point of the intervertebral cage along a longitudinal axis of the top wall of the intervertebral cage.

109. (Previously presented) The apparatus of claim 102, wherein the internal screw guide and the second internal screw guide are offset in opposite directions with respect to a center line of a longitudinal extent of the top wall.

110. (Previously presented) The apparatus of claim 109, wherein a part of the internal screw guide overlaps a part of the second internal screw guide along the longitudinal extent of the top wall.

111. (Previously presented) The apparatus of claim 102, wherein the entry opening of the internal screw guide and the second entry opening of the second internal screw guide are arranged diagonally on the top surface of the top wall.

112. (Previously presented) The apparatus of claim 102, wherein the top wall has four quadrants delineated by a first axis and a second axis each lying in a plane of the top wall, and the first axis is at a right angle with respect to the second axis,

wherein the four quadrants include a first quadrant, a second quadrant, a third quadrant, and a fourth quadrant,

wherein the first quadrant and the fourth quadrant are opposed to the second quadrant and the third quadrant with respect to the first axis, and the first quadrant and the second quadrant are opposed to the third quadrant and the fourth quadrant with respect to the second axis,

wherein the first quadrant is diagonally opposed to the third quadrant, and the second quadrant is diagonally opposed to the fourth quadrant, and

wherein a majority of an area of the entry opening of the internal screw guide is in the first quadrant and a majority of an area of the second entry opening of the second internal screw guide is in the third quadrant.

113. (Previously presented) The apparatus of claim 102, wherein the top wall has four quadrants delineated by a first axis and a second axis each lying in a plane of the first wall, and the first axis is at a right angle with respect to the second axis,

wherein the four quadrants include a first quadrant, a second quadrant, a third quadrant, and a fourth quadrant,

wherein the first quadrant and the fourth quadrant are opposed to the second quadrant and the third quadrant with respect to the first axis, and the first quadrant and the second quadrant are opposed to the third quadrant and the fourth quadrant with respect to the second axis,

wherein the first quadrant is diagonally opposed to the third quadrant, and the second quadrant is diagonally opposed to the fourth quadrant, and

wherein a center of the entry opening of the internal screw guide is in the first quadrant and a center of the second entry opening of the second internal screw guide is in the third quadrant.

114. (Previously presented) The apparatus of claim 102, wherein the top wall includes a first corner and a second corner, the first corner being arranged at an opposite side of the top wall and an opposite end of the top wall with respect to the second corner, and

wherein the internal screw guide and the second internal screw guide are diagonally arranged along a direction extending from the first corner of the top wall to the second corner of the top wall.

115. (Previously presented) The apparatus of claim 102, wherein the intervertebral cage further comprises:

a third internal screw guide having a third entry opening and a third exit opening, the third entry opening formed at least partially in the top surface of the top wall and the third exit opening formed at least partially in the bottom surface of the top wall and at least partially in the side surface of the top wall.

116. (Previously presented) The apparatus of claim 115, wherein the intervertebral cage further comprises:

a fourth internal screw guide having a fourth entry opening and a fourth exit opening, the fourth entry opening formed at least partially in the top surface of the top wall and the fourth exit opening formed at least partially in the bottom surface of the top wall and at least partially in the second side surface of the top wall.

117. (Previously presented) The apparatus of claim 116, wherein the internal screw guide and the fourth internal screw guide are oriented rostrally and the second internal screw guide and the third internal screw guide are oriented caudally.

118. (Previously presented) The apparatus of claim 116, wherein the second internal screw guide and the third internal screw guide are disposed between the internal screw guide and the fourth internal screw guide along a longitudinal length of the top wall of the intervertebral cage.

119. (Previously presented) The apparatus of claim 116, wherein each of the internal screw guide, the second internal screw guide, the third internal screw guide, and the fourth internal screw guide has a 25 degree angulation.

120. (Previously presented) The apparatus of claim 86, further comprising:

a second intervertebral cage including:

a top wall, a bottom wall, and two sidewalls defining an open space capable of receiving bone filling for biological bone fusion, and

an internal screw guide having an entry opening and an exit opening, the entry opening of the second intervertebral cage formed at least partially in a top surface of the top wall of the second intervertebral cage and the exit opening formed at least partially in a bottom surface of the top wall of the second intervertebral cage and at least partially in a side surface of the top wall of the second intervertebral cage; and

an attachment member coupling the intervertebral cage to the second intervertebral cage.

121. (Previously presented) The apparatus of claim 120, wherein the attachment member includes a supplemental cage defining one or more open spaces capable of receiving the intervertebral cage and the second intervertebral cage, and

wherein the intervertebral cage and the second intervertebral cage are secured to the supplemental cage.

122. (Previously presented) The apparatus of claim 120, wherein the attachment member includes a plate.

123. (Previously presented) The apparatus of claim 102, wherein the intervertebral cage is devoid of any other internal screw guides other than the first internal screw guide and a second internal screw guide.

124. (Currently amended) A zero-profile, intervertebral cage sized and configured to be inserted into a disc space between adjacent vertebral bodies and to provide fusion of the adjacent vertebral bodies via biological bone fusion and screw fusion,

the intervertebral cage comprising:

a top wall;

a bottom wall opposite the top wall;

a first sidewall;

a second sidewall opposite the first sidewall, each of the first sidewall and the second sidewall having a surface configured to contact one of the adjacent vertebral bodies when the intervertebral cage is inserted into the disc space,

wherein at least the first sidewall and the second sidewall bound an open space capable of receiving bone filling for the biological bone fusion,

wherein the top wall includes a top surface and a bottom surface opposite the top surface, the top surface configured to have a zero-profile with respect to the adjacent vertebral bodies when the intervertebral cage is inserted into the disc space, and the bottom surface facing the open space; and

an internal screw trajectory guide for guiding a trajectory of a screw through the intervertebral cage, the internal screw trajectory guide having an entry opening and an exit opening, the entry opening formed at least partially in the top surface of the top wall, and the exit opening formed at least partially in a bottom surface of the top wall and at least partially in a side surface of the top wall,

wherein the entry opening of the internal screw guide is formed entirely between all edges of the top surface of the top wall when viewed from a direction perpendicular to a plane of the top surface.

125. (Previously presented) The apparatus of claim 86, wherein the exit opening is formed at least partially in a surface of one of the two sidewalls.

126. (Currently amended) A universal, intervertebral combination internal screw guide and fixation apparatus configured to be inserted into a disc space between a first vertebral body and a second vertebral body and to provide fusion of the first vertebral body to the second vertebral body via biological bone fusion and screw fusion, the apparatus comprising:

an intervertebral cage including:

a top wall, a bottom wall, and two sidewalls defining an open space capable of receiving bone filling for the biological bone fusion; and
an internal screw guide having an entry opening and an exit opening, the entry opening formed at least partially in a top surface of the top wall,
the exit opening formed at least partially in a bottom surface of the top wall, and
the exit opening formed at least partially in at least one of:
a side surface of the top wall; and
a surface of one of the two sidewalls,
wherein the entry opening of the internal screw guide is formed entirely between all edges of the top surface of the top wall when viewed from a direction perpendicular to a plane of the top surface.

127. (Previously presented) The apparatus of claim 126, wherein the exit opening is formed partially in the side surface of the top wall.

128. (Previously presented) The apparatus of claim 126, wherein the exit opening is formed partially in the surface of the one of the two sidewalls.

129. (Previously presented) The apparatus of claim 126, wherein the exit opening is formed partially in the side surface of the top wall and partially in the surface of the one of the two sidewalls.

130. (Previously presented) The apparatus of claim 86, wherein the entry opening is formed substantially in the top surface of the top wall.

131. (Previously presented) The apparatus of claim 86, wherein the entry opening is formed entirely in the top surface of the top wall.

132. (Previously presented) The apparatus of claim 121, wherein the supplemental cage surrounds a perimeter of the intervertebral cage and the second intervertebral cage.

133-134. (Canceled)

135. (Currently amended) A universal, intervertebral combination internal screw guide and fixation apparatus configured to be inserted into a disc space between a first vertebral body and a second vertebral body and to provide fusion of the first vertebral body to the second vertebral body via biological bone fusion and screw fusion, the apparatus comprising:

an intervertebral cage including:

a top wall, a bottom wall, and two sidewalls defining an open space capable of receiving bone filling for the biological bone fusion; and

an internal screw guide having an entry opening and an exit opening, the entry opening formed at least partially in a top surface of the top wall and the exit opening formed at least partially in a bottom surface of the top wall and at least partially in a side surface of the top wall,

~~The apparatus of claim 86,~~

wherein the internal screw guide has an internal bore with an [[the]] entry opening and an [[the]] exit opening, and the entry opening of the internal bore is formed only in the top surface of the top wall and the exit opening is formed at least partially in the bottom surface of the top wall and at least partially in the side surface of the top wall,

wherein the internal screw guide further comprises a counterbore formed at least partially through ~~in~~ the top surface of the top wall for accommodating a screw head of a screw member,

wherein the entry opening of the internal bore is formed in a lower surface of the counterbore, and

wherein the entry opening of the internal bore is positioned ~~formed~~ entirely between all edges of the top surface of the top wall when viewed from a direction perpendicular to a plane of the top surface.

136. (Currently amended) A universal, intervertebral combination internal screw guide and fixation apparatus configured to be inserted into a disc space between a first vertebral body and a second vertebral body and to provide fusion of the first vertebral body to the second vertebral body via biological bone fusion and screw fusion, the apparatus comprising:

an intervertebral cage including:

a top wall, a bottom wall, and two sidewalls defining an open space capable of receiving bone filling for the biological bone fusion; and

an internal screw guide having an entry opening and an exit opening, the entry opening formed at least partially in a top surface of the top wall and the exit opening formed at least partially in a bottom surface of the top wall and at least partially in a side surface of the top wall,

~~The apparatus of claim 86,~~

wherein the entry opening of the internal screw guide is formed only in the top surface of the top wall.

137. (Canceled)

138. (New) The apparatus of claim 126,

wherein the internal screw guide has an internal bore with an entry opening and an exit opening, and the entry opening of the internal bore is formed only in the top surface of the top wall and the exit opening is formed at least partially in the bottom surface of the top wall and at least partially in the side surface of the top wall,

wherein the internal screw guide further comprises a counterbore formed at least partially through the top surface of the top wall for accommodating a screw head of a screw member,

wherein the entry opening of the internal bore is formed in a lower surface of the counterbore, and

wherein the entry opening of the internal bore is positioned entirely between all edges of the top surface of the top wall when viewed from a direction perpendicular to a plane of the top surface.

REMARKS

Claims 86-132, 134-136, and 138 are pending in the application. This Amendment amends claims 86, 124, 126, 135, and 136, cancels claim 137, and adds new claim 138. Claims 86, 124, 126, 135, and 136 are independent. This Amendment does not add new matter.

The Allowable Subject Matter

Applicants gratefully acknowledge the indication by the Office Action that claims 135-137 would be allowable if rewritten in independent form. This Amendment rewrites claims 135 and 136 in independent form.

This Amendment also incorporates the features of allowable claim 137 into independent claims 86, 124, and 126, respectively, thereby placing all of the claims in condition for allowance.

This Amendment also adds new claim 138, which recites the same features as allowable claim 136 and depends from independent claim 126.

The Provisional Double Patenting Rejection

Claims 86-132 and 135-137 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 93-141 of copending Application No. 13/210,162 and claims 84-133 of copending Application No. 13/210,157.

Applicants respectfully traverse these rejections.

Applicants respectfully submit that claims 86-132 and 135-137 of the present application are patentably distinct from the claims of the copending applications. Applicants note that the claims may be subject to further amendments during prosecution, which features should serve to further distinguish the claims of the present application from the claims of the co-pending applications.

With regard to the provisional obviousness-type double patenting rejections, Applicants respectfully submit that the conflicting claims have not in fact been patented, and therefore, also may be subject to further amendments during prosecution, which features may serve to further distinguish the claims of the present application from the claims of the co-pending applications.

For these reasons, Applicants respectfully reserve the right to file a terminal disclaimer in compliance with 37 C.F.R. § 1.321(c) or 1.321(d) as such time as the claims of the present application are allowable. Applicants respectfully request withdrawal of these rejections.

The Waugh et al. Reference

The Office Action rejects claims 86-132 under 35 U.S.C. §102(e) as allegedly being anticipated by the Waugh et al. reference (U.S. Publication No. 2008/0249575).

This Amendment amends the independent claims to incorporate features of allowable claim 37, thereby placing all of the claims in condition for allowance.

Applicants respectfully request withdrawal of this rejection.

CONCLUSION

In view of the above, Applicants respectfully request entry of the present Amendment and allowance of the claims. Applicants invite the Examiner to contact the undersigned if the Examiner has any questions regarding this amendment. Applicants petition for an extension of time if required for entry of this Amendment.

Please charge Deposit Account No. 505364 for any deficiency or overpayment.

Respectfully Submitted,

/ John J. Dresch /
John J. Dresch
Attorney for Applicant(s)
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May 26, 2017

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Electronic Patent Application Fee Transmittal				
Application Number:		13210168		
Filing Date:		15-Aug-2011		
Title of Invention:		BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION		
First Named Inventor/Applicant Name:		Ahmnon D. MOSKOWITZ		
Filer:		John Jeremy Dresch		
Attorney Docket Number:		3003/0105PUS7		
Filed as Small Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
INDEPENDENT CLAIMS IN EXCESS OF 3	2201	2	210	420
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension-of-Time:				
Extension - 1 month with \$0 paid	2251	1	100	100
Miscellaneous:				
Total in USD (\$)				520

Electronic Acknowledgement Receipt	
EFS ID:	29331811
Application Number:	13210168
International Application Number:	
Confirmation Number:	1609
Title of Invention:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION
First Named Inventor/Applicant Name:	Ahmnon D. MOSKOWITZ
Customer Number:	87409
Filer:	John Jeremy Dresch
Filer Authorized By:	
Attorney Docket Number:	3003/0105PUS7
Receipt Date:	26-MAY-2017
Filing Date:	15-AUG-2011
Time Stamp:	22:54:31
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	\$ 520
RAM confirmation Number	053017INTEFSW22560100
Deposit Account	505364
Authorized User	John Dresch
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: 37 CFR 1.16 (National application filing, search, and examination fees) 37 CFR 1.17 (Patent application and reexamination processing fees)	

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Extension of Time	30030105PUS7_Petition_EOT_readyforfiling_20170526.pdf	188837	no	2
			6b0a3ef3ed1823fcff3a168a3b725896809e557f		
Warnings:					
Information:					
2	Amendment/Req. Reconsideration-After Non-Final Reject	30030105PUS7_Amend_20170526_readyforfiling.pdf	127522	no	14
			af4c072916b3ae17f431dd327bc56f9b5b889b29		
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	32803	no	2
			091211cddbbaa97d9369bc5905ae1e245a8ff1f8d		
Warnings:					
Information:					
Total Files Size (in bytes):			349162		
<p>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.</p> <p><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.</p> <p><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.</p> <p><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.</p>					

PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)		Docket Number (Optional) 3003/0105PUS7																														
Application Number 13/210,168	Filed 08/15/2011																															
For BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION																																
Art Unit 3733	Examiner Pedro Philogene																															
<p>This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above-identified application.</p> <p>The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):</p> <table style="width: 100%; border-collapse: collapse;"><thead><tr><th></th><th style="text-align: center;"><u>Fee</u></th><th style="text-align: center;"><u>Small Entity Fee</u></th><th style="text-align: center;"><u>Micro Entity Fee</u></th><th></th></tr></thead><tbody><tr><td>☒ One month (37 CFR 1.17(a)(1))</td><td style="text-align: right;">\$200</td><td style="text-align: right;">\$100</td><td style="text-align: right;">\$50</td><td style="text-align: right;">\$ <u>100.00</u></td></tr><tr><td>☐ Two months (37 CFR 1.17(a)(2))</td><td style="text-align: right;">\$600</td><td style="text-align: right;">\$300</td><td style="text-align: right;">\$150</td><td style="text-align: right;">\$ _____</td></tr><tr><td>☐ Three months (37 CFR 1.17(a)(3))</td><td style="text-align: right;">\$1,400</td><td style="text-align: right;">\$700</td><td style="text-align: right;">\$350</td><td style="text-align: right;">\$ _____</td></tr><tr><td>☐ Four months (37 CFR 1.17(a)(4))</td><td style="text-align: right;">\$2,200</td><td style="text-align: right;">\$1,100</td><td style="text-align: right;">\$550</td><td style="text-align: right;">\$ _____</td></tr><tr><td>☐ Five months (37 CFR 1.17(a)(5))</td><td style="text-align: right;">\$3,000</td><td style="text-align: right;">\$1,500</td><td style="text-align: right;">\$750</td><td style="text-align: right;">\$ _____</td></tr></tbody></table> <p>☒ Applicant asserts small entity status. See 37 CFR 1.27.</p> <p>☐ Applicant certifies micro entity status. See 37 CFR 1.29. Form PTO/SB/15A or B or equivalent must either be enclosed or have been submitted previously.</p> <p>☐ A check in the amount of the fee is enclosed.</p> <p>☐ Payment by credit card. Form PTO-2038 is attached.</p> <p>☐ The Director has already been authorized to charge fees in this application to a Deposit Account.</p> <p>☒ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number <u>505364</u>.</p> <p>☒ Payment made via EFS-Web.</p> <p>WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.</p> <p>I am the</p> <p>☐ applicant/inventor.</p> <p>☐ assignee of record of the entire interest. See 37 CFR 3.71. 37 CFR 3.73(b) statement is enclosed (Form PTO/SB/96).</p> <p>☒ attorney or agent of record. Registration number <u>46,672</u>.</p> <p>☐ attorney or agent acting under 37 CFR 1.34. Registration number _____.</p> <p><u>/John J. Dresch/</u> <u>May 26, 2017</u></p> <p style="text-align: center;">Signature Date</p> <p><u>John J. Dresch</u> <u>571.333.0930</u></p> <p style="text-align: center;">Typed or printed name Telephone Number</p> <p>NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. Submit multiple forms if more than one signature is required, see below*.</p> <p>☒ * Total of <u>1</u> forms are submitted.</p>				<u>Fee</u>	<u>Small Entity Fee</u>	<u>Micro Entity Fee</u>		☒ One month (37 CFR 1.17(a)(1))	\$200	\$100	\$50	\$ <u>100.00</u>	☐ Two months (37 CFR 1.17(a)(2))	\$600	\$300	\$150	\$ _____	☐ Three months (37 CFR 1.17(a)(3))	\$1,400	\$700	\$350	\$ _____	☐ Four months (37 CFR 1.17(a)(4))	\$2,200	\$1,100	\$550	\$ _____	☐ Five months (37 CFR 1.17(a)(5))	\$3,000	\$1,500	\$750	\$ _____
	<u>Fee</u>	<u>Small Entity Fee</u>	<u>Micro Entity Fee</u>																													
☒ One month (37 CFR 1.17(a)(1))	\$200	\$100	\$50	\$ <u>100.00</u>																												
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☐ Five months (37 CFR 1.17(a)(5))	\$3,000	\$1,500	\$750	\$ _____																												

This collection of information is required by 37 CFR 1.136(a). The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 6 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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

Privacy Act Statement

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

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

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/210,168	08/15/2011	Ahmnnon D. MOSKOWITZ	3003/0105PUS7	1609

87409 7590 07/03/2017
Dresch IP Law, PLLC
P.O. Box 650903
Potomac Falls, VA 20165

EXAMINER

PHILOGENE, PEDRO

ART UNIT	PAPER NUMBER
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3733

NOTIFICATION DATE	DELIVERY MODE
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07/03/2017

ELECTRONIC

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

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

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@dreschiplaw.com
jdresch@dreschiplaw.com
linda.logan@dreschiplaw.com

Office Action Summary	Application No. 13/210,168	Applicant(s) MOSKOWITZ ET AL.	
	Examiner PEDRO PHILOGENE	Art Unit 3733	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5/26/17.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 86-132, 135, 136 and 138 is/are pending in the application.
5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 86-132, 135-136, 138 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) ☒ Notice of References Cited (PTO-892) | 3) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
Paper No(s)/Mail Date ____. | 4) ☐ Other: ____. |

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

Claim Rejections - 35 USC § 112

The following is a quotation of 35 U.S.C. 112(b):

(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 86-132, 135-136, 138 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.

In claims 86, 135, 136, applicant is claiming that the entry opening is formed at least partially in a top surface of the top wall and also only on the top surface of the top wall which renders the claim ambiguous and indefinite.

The following is a quotation of the first paragraph of 35 U.S.C. 112(a):

(a) IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

The following is a quotation of the first paragraph of pre-AIA 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 86-132, 135-136, 138 rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant fails to teach that the entry opening is formed at least partially in a top surface of the top wall and the entry opening is formed only in the top surface of the top wall.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP §§ 706.02(l)(1) - 706.02(l)(3) for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 86-132, 135-136, 138 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 93-141 of copending Application No. 13/210162. Although the claims at issue are not identical, they are not patentably distinct from each other because it is clear that all the elements of claims of

the application are to be found in claims of the copending application. The difference between claims of the application and claims of the copending application lies in the fact that the copending application claims include any more elements and are thus much more specific. Thus the invention of claims of the copending application is in effect a “species” of the “generic” invention of claims of the application. It has been held that the generic invention is “anticipated” by the “species”. See *in re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claims of the application are anticipated by claims of the copending application, they are not patentably distinct.

This is a provisional nonstatutory double patenting rejection because the patentably indistinct claims have not in fact been patented.

Claims 86-132, 135-136, 138 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 84-133 of copending Application No. 13/210157. Although the claims at issue are not identical, they are not patentably distinct from each other because it is clear that all the elements of claims of the application are to be found in claims of the copending application. The difference between claims of the application and claims of the copending application lies in the fact that the copending application claims include any more elements and are thus much more specific. Thus the invention of claims of the copending application is in effect a “species” of the “generic” invention of claims of the application. It has been held that the generic invention is “anticipated” by the “species”. See *in re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claims of the application are anticipated by claims of the copending application, they are not patentably distinct.

This is a provisional nonstatutory double patenting rejection because the patentably indistinct claims have not in fact been patented.

Claim Rejections - 35 USC § 103

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

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

Claims 86-132, 135-136, 138 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Waugh et al (2008/0249575) in view of Messerli et al. (2010/0305704).

It is noted that Waugh teaches all the limitations, as set forth in previous rejections, except that Waugh does not teach wherein the internal screw guide has an internal bore with the entry opening and the exit opening, and the entry opening of the internal bore is formed only in the top surface of the top wall and the exit opening is formed at least partially in the bottom surface of the top wall and at least partially in the side surface of the top wall, wherein the internal screw guide further comprises a counterbore formed at least partially in the top surface of the top wall for accommodating a screw head of a screw member, wherein the entry opening of the internal bore is formed in a lower surface of the counterbore, and wherein the entry opening of the internal bore is formed entirely between all edges of the top wall when viewed from a direction perpendicular to a plane of the top surface, as claimed by

applicant. However, in similar art, Messerli provides the evidences of the use of a vertebral implant wherein the internal screw guide has an internal bore with the entry opening and the exit opening, as best seen in FIGS., and the entry opening of the internal bore is formed only in the top surface of the top wall, as best seen in FIGS., and the exit opening is formed at least partially in the bottom surface of the top wall and at least partially in the side surface of the top wall, as best seen in FIGS., wherein the internal screw guide further comprises a counterbore formed at least partially in the top surface of the top wall for accommodating a screw head of a screw member, as best seen in FIGS., wherein the entry opening of the internal bore is formed in a lower surface of the counterbore, and wherein the entry opening of the internal bore is formed entirely between all edges of the top wall when viewed from a direction perpendicular to a plane of the top surface, as best seen in FIGS., for allowing the screw to be secure to the appropriate vertebral body.

Therefore, given the teaching of Messerli, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Waugh, as taught by Messerli, by incorporating the features of the implant of Johnson in the device of Waugh for allowing the screw to be secured to the appropriate vertebral body.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the entry opening

partially on the top wall must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Response to Amendment

First, the examiner would like to apologize for indicating allowable subject matter in the last office action. An update search reveals the reference to Messerli et al which is being used herein to reject the claims. See rejection above.

Furthermore, applicant's arguments filed 5/26/17 have been fully considered but they are not persuasive. As to the Double Patenting rejection, although applicant stated that the claims of the present application may be subject to further amendments during prosecution, applicant did not state which features should serve to further distinguish the claims of the present application from the claims of the co-pending application. However, Messerli discloses a vertebral implant with all the limitations, as claimed in the newly amended claims. Furthermore, applicant stated that each of the entry opening and exit opening of the internal bore of the screw holes is formed in two surfaces; however, applicant is only claiming that the screw hole is formed at least partially in a top surface of the top wall. The screw hole of Waugh is partially formed in the top surface. Therefore, combining Messerli with Waugh, to arrive at applicant's claimed invention would have been obvious to one of ordinary skill in the art. See rejection above.

Conclusion

A shortened statutory period for reply to this action is set to expire THREE MONTHS from the mailing date of this action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PEDRO PHILOGENE whose telephone number is (571)272-4716. The examiner can normally be reached on Monday to Friday 8:00 AM to 4:30 PM.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an

interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

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

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

/PEDRO PHILOGENE/
Primary Examiner, Art Unit 3733
June 27, 2017

Notice of References Cited	Application/Control No. 13/210,168	Applicant(s)/Patent Under Reexamination MOSKOWITZ ET AL.	
	Examiner PEDRO PHILOGENE	Art Unit 3733	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-2008/0249575 A1	10-2008	Waugh; Lindsey G.	A61F2/447	606/305
*	B	US-2010/0305704 A1	12-2010	Messerli; Dominique	A61F2/442	623/17.16
	C	US-				
	D	US-				
	E	US-				
	F	US-				
	G	US-				
	H	US-				
	I	US-				
	J	US-				
	K	US-				
	L	US-				
	M	US-				

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	6234	A61F2/4611.cpc.	US-PGPUB; USPAT	OR	OFF	2017/06/27 09:32
L2	1273	A61B17/0642.cpc.	US-PGPUB; USPAT	OR	OFF	2017/06/27 09:51
L3	1097	A61B17/7064.cpc.	US-PGPUB; USPAT	OR	OFF	2017/06/27 10:13
L4	2	"20080249575"	US-PGPUB; USPAT	OR	OFF	2017/06/27 10:27
L5	59	("20020022843" "20020099376" "20020151899" "20020169508" "20030078583" "20040015169" "20040030338" "20050071006" "20050177236" "20050192577" "20050216081" "20060085071" "4904261" "5397364" "5578034" "5643265" "5876402" "5888223" "5931838" "6235059" "6258089" "6261291" "6331179" "6342074" "6468311" "6533786" "6579290" "6592586" "6602255" "6613091" "6629998" "7001389" "7025769" "7033394" "7794482" "7909859").PN. OR ("8425607").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2017/06/27 10:28

6/ 27/ 2017 10:31:32 AM

Search Notes 	Application/Control No. 13210168	Applicant(s)/Patent Under Reexamination MOSKOWITZ ET AL.
	Examiner PEDRO PHILOGENE	Art Unit 3733

CPC- SEARCHED		
Symbol	Date	Examiner
A61B17/0642, A61B17/809, A61B17/8894, A61F2/4465, A61F2/447, A61F2/4611, A61B17/7064	6/27/2017	/P.P./
A61F2250/0007, A61B17/86, A61B2017/0641, A61B2017/0648, A61B2017/922, A61F2002/2835, A61F2002/30133, A61F2002/30387, A61F2002/30448, A61F2002/30507		
A61F2002/3055, A61F2002/30579, A61F2002/30604, A61F2002/30772, A61F2002/30878, A61F2002/4475, A61F2002/448, A61F2002/4627, A61F2002/4681, A61F2220/0025, A61F2220/005, A61F2230/0015		

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
623	17.11-17.16	6/27/2017	/P.P./
606	300-305,246, 99, 144, 151, 251, 266		
227	181.1		

SEARCH NOTES		
Search Notes	Date	Examiner
EAST search enclosed	6/27/2017	/P.P./

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

	/PEDRO PHILOGENE/ Primary Examiner.Art Unit 3733
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<i>Index of Claims</i> 	Application/Control No. 13210168	Applicant(s)/Patent Under Reexamination MOSKOWITZ ET AL.
	Examiner PEDRO PHILOGENE	Art Unit 3733

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

☐ Claims renumbered in the same order as presented by applicant								☐ CPA		☐ T.D.		☐ R.1.47	
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<i>Index of Claims</i> 	Application/Control No. 13210168	Applicant(s)/Patent Under Reexamination MOSKOWITZ ET AL.
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✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
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☐ Claims renumbered in the same order as presented by applicant								☐ CPA		☐ T.D.		☐ R.1.47	
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✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
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☐ Claims renumbered in the same order as presented by applicant								☐ CPA		☐ T.D.		☐ R.1.47	
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<i>Index of Claims</i> 	Application/Control No. 13210168	Applicant(s)/Patent Under Reexamination MOSKOWITZ ET AL.
	Examiner PEDRO PHILOGENE	Art Unit 3733

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

☐ Claims renumbered in the same order as presented by applicant		☐ CPA		☐ T.D.		☐ R.1.47			
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	136				✓	✓			
	137				✓	-			
	138					✓			

STATEMENT UNDER 37 CFR 3.73(b)Applicant/Patent Owner: Moskowitz et al.Application No./Patent No.: 13/210,168 Filed/Issue Date: 8/15/2011

Entitled: BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION

Nathan C. Moskowitz
(Name of Assignee)An Individual
(Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that it is:

1. ☒ the assignee of the entire right, title, and interest; or
2. ☐ an assignee of less than the entire right, title and interest.
The extent (by, percentage) of its ownership interest is _____ %
3. ☐ the assignee of an undivided interest in the entirety of (a complete assignment from one of the joint inventors was made)

in the patent application/patent identified above by virtue of either:

- 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 (035557, 039331 and 039331), Frame (0312, 0648 and 0867), or for which a copy thereof is attached.

OR

- B. ☐ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as shown below:

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.
3. 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.

- ☒ As required by 37 CFR 3.73(b)(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, if the assignment is to be recorded in the records of the USPTO. See MPEP 302.8]

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

_____ /Michael T. Hawkins/ Signature	_____ July 20, 2017 Date
_____ Michael T. Hawkins, 57,867 Printed or Typed Name	_____ (612) 335-5070 Telephone Number
_____ Attorney for Assignee Title	

POWER OF ATTORNEY TO PROSECUTE APPLICATIONS BEFORE THE USPTO

I hereby revoke all previous powers of attorney given in the application identified in the attached statement under 37 CFR 3.73(b).

I hereby appoint:

☒ Practitioners associated with the Customer Number: 26191
OR

☐ Practitioner(s) named below (if more than ten patent practitioners are to be named, then a customer number must be used):

Name	Registration Number	Name	Registration Number

as attorney(s) or agent(s) to represent the undersigned before the United States Patent and Trademark Office (USPTO) in connection with any and all patent applications assigned only to the undersigned according to the USPTO assignment records or assignment documents attached to this form in accordance with 37 CFR 3.73(b).

Please change the correspondence address for the application identified in the attached statement under 37 CFR 3.73(b) to:

☒ The address associated with Customer Number: 26191
OR

☐ Firm or Individual Name	Fish & Richardson P.C.		
Address	P.O. Box 1022		
City	Minneapolis	State	Zip
	MN		55440-1022
Country	United States		
Telephone			Email

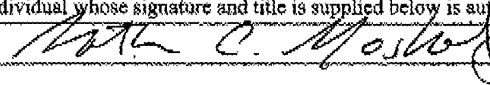
Assignee Name and Address:

Nathan C. Moskowitz
212 N Adams St
Rockville, MD 20850

A copy of this form, together with a statement under 37 CFR 3.73(b) (Form PTO/SB/96 or equivalent) is required to be filed in each application in which this form is used. The statement under 37 CFR 3.73(b) may be completed by one of the practitioners appointed in this form if the appointed practitioner is authorized to act on behalf of the assignee, and must identify the application in which this Power of Attorney is to be filed.

SIGNATURE of Assignee of Record

The individual whose signature and title is supplied below is authorized to act on behalf of the assignee

Signature		Date	7/20/17
Name	Nathan C. Moskowitz	Telephone	
Title			

This collection of information is required by 37 CFR 1.31, 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:	29845761
Application Number:	13210168
International Application Number:	
Confirmation Number:	1609
Title of Invention:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION
First Named Inventor/Applicant Name:	Ahmnon D. MOSKOWITZ
Customer Number:	87409
Filer:	Michael T. Hawkins/Abby Remer
Filer Authorized By:	Michael T. Hawkins
Attorney Docket Number:	3003/0105PUS7
Receipt Date:	20-JUL-2017
Filing Date:	15-AUG-2011
Time Stamp:	16:24:12
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment		no			
File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Power of Attorney	POA.pdf	420977	no	2
			603993760ac819d67f87afa9298a4c97a154701d		
Warnings:					

Information:	
Total Files Size (in bytes):	420977
<p>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.</p> <p><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.</p> <p><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.</p> <p><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.</p>	



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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
13/210,168	08/15/2011	Ahmnnon D. MOSKOWITZ	45335-0009007

CONFIRMATION NO. 1609

POA ACCEPTANCE LETTER

26191
FISH & RICHARDSON P.C. (TC)
PO BOX 1022
MINNEAPOLIS, MN 55440-1022



OC000000093057713

Date Mailed: 07/27/2017

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 07/20/2017.

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.

/sibrahim/



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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
13/210,168	08/15/2011	Ahmnnon D. MOSKOWITZ	3003/0105PUS7

87409
Dresch IP Law, PLLC
P.O. Box 650903
Potomac Falls, VA 20165

CONFIRMATION NO. 1609
POWER OF ATTORNEY NOTICE



OC000000093057676

Date Mailed: 07/27/2017

NOTICE REGARDING CHANGE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 07/20/2017.

- The Power of Attorney to you in this application has been revoked by the assignee who has intervened as provided by 37 CFR 3.71. Future correspondence will be mailed to the new address of record(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.

/sibrahim/

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor : Ahmnon D. Moskowitz Art Unit : 3733
Serial No. : 13/210,168 Examiner : Pedro Philogene
Filed : August 15, 2011 Conf. No. : 1609
Title : BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY
SCREWS AND POSTERIOR CERVICAL AND LUMBAR
INTERARTICULATING JOINT CALIBRATED STAPLING
DEVICES FOR SPINAL FUSION

MAIL STOP AMENDMENT

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

INFORMATION DISCLOSURE STATEMENT

Please consider the references listed on the enclosed PTO-1449 Form. Cited U.S. patents and patent application publications will be provided on request.

This statement is being filed after a first action on the merits, but before receipt of a final action or a notice of allowance. A late submission fee in the amount of \$90, specified by 37 CFR §1.17(p), is being paid with this statement.

Apply any necessary charges or credits to deposit account 06-1050, referencing the above attorney docket number.

Please contact the undersigned if there are any questions regarding this statement.

Respectfully submitted,

Date: 9/20/2017

/Stuart A. Nelson/
Stuart A. Nelson
Reg. No. 63,947

Customer Number
Fish & Richardson P.C.
Telephone: (612) 337-2538
Facsimile: (877) 769-7945

61565074.doc

Substitute Disclosure Form U.S. Department of Commerce Patent and Trademark Office Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))	Attorney Docket No. 45335-0009007	Application No. 13/210,168
	Applicant Ahmnnon D. Moskowitz et al.	
	Filing Date August 15, 2011	Group Art Unit 3733

U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	1.	7862616	1/4/2011	Lechmann et al.			
	2.	8403986	3/26/2013	Michelson			
	3.	8328872	12/11/2012	Duffield et al.			
	4.	5005749	4/9/1991	Aranyi			
	5.	5413583	5/9/1995	Wohlers			
	6.	5454819	10/3/1995	Knoepfner			
	7.	5951574	9/14/1999	Stefanchik et al.			
	8.	7615059	11/10/2009	Watschke et al.			
	9.	6613055	9/2/2003	Di Emidio			
	10.	8034060	10/11/2011	Keren et al.			
	11.	4064881	12/27/1977	Meredith			
	12.	5713912	2/3/1998	Porter			
	13.	5976136	11/2/1999	Bailey et al.			
	14.	6852117	2/8/2005	Orlowski			
	15.	5916224	6/29/1999	Esplin			
	16.	7727246	6/1/2010	Sixto et al.			
	17.	5968054	10/19/1999	Yeatts et al.			
	18.	20100145460	6/10/2010	McDonough et al.			
	19.	20090105831	4/23/2009	Jones et al.			
	20.	8,353,913	Jan-13	Moskowitz et al.			
	21.	8,029,512	Oct-11	Paltzer			
	22.	7776093	Aug-10	Wolek			
	23.	7628816	Dec-09	Mageri et al.			
	24.	8425607	Apr-13	Waugh et al.			
	25.	8105367	1/31/2012	Austin et al.			
	26.	8273127	9/25/2012	Jones et al.			

Examiner Signature	Date Considered
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

Substitute Disclosure Form

Substitute Disclosure Form U.S. Department of Commerce Patent and Trademark Office Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))	Attorney Docket No. 45335-0009007	Application No. 13/210,168
	Applicant Ahmnnon D. Moskowitz et al.	
	Filing Date August 15, 2011	Group Art Unit 3733

U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	27.	2360942	10/24/1944	Ellerstein et al.			
	28.	7704279	4/27/2010	Moskowitz et al.			
	29.	7803162	9/28/2010	Marnay et al.			
	30.	7942903	5/17/2011	Moskowitz et al.			
	31.	8114162	2/14/2012	Bradley			
	32.	8137405	3/20/2012	Kostuik et al.			
	33.	8167949	5/1/2012	Tyber et al.			
	34.	8414651	4/9/2013	Tyber et al.			
	35.	8540774	9/24/2013	Kucenzi et al.			
	36.	8419797	4/6/2013	Biedermann et al.			
	37.	8613761	12/24/2013	Lindermann et al.			
	38.	20080183293	7/31/2008	Parry et al.			
	39.	20040220571	11/4/2004	Assaker et al.			
	40.	20030130737	7/10/2003	McGahan et al.			
	41.	20070250167	10/25/2007	Bray et al.			
	42.	20070276498	11/29/2007	Aebi et al.			
	43.	20080249569	10/9/2008	Waugh et al.			
	44.	20080249625	10/9/2008	Waugh et al.			
	45.	20080281425	11/13/2008	Thalgott et al.			
	46.	20090030520	1/29/2009	Biedermann et al.			
	47.	20090182430	7/16/2009	Tyber et al.			
	48.	20090210062	8/20/2009	Thalgott et al.			
	49.	20060155285	7/13/2006	Anderson et al.			
	50.	20090105830	4/23/2009	Jones et al.			
	51.	20120271423	10/25/2012	Wallenstein et al.			
	52.	20120277870	11/1/2012	Wolters et al.			

Examiner Signature	Date Considered
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

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Substitute Disclosure Form U.S. Department of Commerce Patent and Trademark Office Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))	Attorney Docket No. 45335-0009007	Application No. 13/210,168
	Applicant Ahmnon D. Moskowitz et al.	
	Filing Date August 15, 2011	Group Art Unit 3733

U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	53.	20120323330	12/20/2012	Kucenzi et al.			
	54.	20130060339	3/7/2013	Duffield et al.			
	55.	20040193272	9/30/2004	Zubok et al.			
	56.	20090187218	7/23/2009	Schaffhausen et al.			
	57.	8728165	5/20/2014	Parry et al.			
	58.	6235034	5/22/2001	Bray			
	59.	6224602	5/1/2001	Hayes			
	60.	6890355	5/10/2005	Michelson			
	61.	6322562	11/27/2001	Wolter			
	62.	20080281424	11/13/2008	Parry et al.			
	63.	6454807	9/24/2002	Jackson			
	64.	6716247	4/6/2004	Michelson			
	65.	20040186569	9/23/2004	Berry			
	66.	7776047	8/17/2010	Fanger et al.			
	67.	20040186482	9/23/2004	Kolb et al.			
	68.	7758617	Jul-10	Lott et al.			
	69.	8328851	Dec-12	Curran			
	70.	8882813	11/11/2014	Jones et al.			
	71.	20050256576	11/17/2005	Moskowitz et al.			
	72.	20050261769	11/24/2005	Moskowitz et al.			
	73.	20070198089	8/23/2007	Moskowitz et al.			
	74.	20110288646	11/24/2011	Moskowitz et al.			
	75.	20070167678	7/19/2007	Moskowitz et al.			
	76.	20130173002	7/4/2013	Moskowitz et al.			
	77.	20060241621	10/26/2006	Moskowitz et al.			
	78.	20090112271	4/30/2009	Moskowitz et al.			

Examiner Signature	Date Considered
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

Substitute Disclosure Form

Substitute Disclosure Form	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No. 45335-0009007	Application No. 13/210,168
Information Disclosure Statement by Applicant (Use several sheets if necessary)		Applicant Ahmnon D. Moskowitz et al.	
		Filing Date August 15, 2011	Group Art Unit 3733

(37 CFR §1.98(b))

U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	79.	20110208312	8/25/2011	Moskowitz et al.			
	80.	20070250172	10/25/2007	Moskowitz et al.			
	81.	20110178600	7/21/2011	Moskowitz et al.			
	82.	20170252178	9/7/2017	Moskowitz et al.			
	83.	20070049943	3/1/2007	Moskowitz et al.			
	84.	20100324606	12/23/2010	Moskowitz et al.			
	85.	20150105824	4/16/2015	Moskowitz et al.			
	86.	20080033440	2/7/2008	Moskowitz et al.			
	87.	20110295327	12/1/2011	Moskowitz et al.			
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	89.	20130053962	2/28/2013	Moskowitz et al.			
	90.	20130018468	1/17/2013	Moskowitz et al.			
	91.	20130023991	1/24/2013	Moskowitz et al.			
	92.	20130018469	1/17/2013	Moskowitz et al.			
	93.	20130282017	10/24/2013	Moskowitz et al.			
	94.	20160374830	12/29/2016	Moskowitz et al.			
	95.	20080177307	7/24/2008	Moskowitz et al.			
	96.	20120010714	1/12/2012	Moskowitz et al.			
	97.	20090234455	9/17/2009	Moskowitz et al.			
	98.	20150025637	1/22/2015	Moskowitz et al.			
	99.	20110137349	6/9/2011	Moskowitz et al.			
	100.	20090224023	9/10/2009	Moskowitz et al.			
	101.	20110125269	5/26/2011	Moskowitz et al.			
	102.	20110319935	12/29/2011	Moskowitz et al.			
	103.	20150148847	5/28/2015	Moskowitz et al.			
	104.	20110307011	12/15/2011	Moskowitz et al.			

Examiner Signature	Date Considered
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

Substitute Disclosure Form

Substitute Disclosure Form U.S. Department of Commerce Patent and Trademark Office Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))	Attorney Docket No. 45335-0009007	Application No. 13/210,168
	Applicant Ahmnnon D. Moskowitz et al.	
	Filing Date August 15, 2011	Group Art Unit 3733

U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	105.	20120330419	12/27/2012	Moskowitz et al.			
	106.	20140249629	9/4/2014	Moskowitz et al.			
	107.	20130023992	1/24/2013	Moskowitz et al.			
	108.	20130018470	1/17/2013	Moskowitz et al.			

Foreign Patent Documents or Published Foreign Patent Applications								
Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document

Examiner Signature	Date Considered
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Substitute Disclosure Form

Electronic Patent Application Fee Transmittal				
Application Number:		13210168		
Filing Date:		15-Aug-2011		
Title of Invention:		BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION		
First Named Inventor/Applicant Name:		Ahmnon D. MOSKOWITZ		
Filer:		Stuart A. Nelson/Melissa Andersen		
Attorney Docket Number:		45335-0009007		
Filed as Small Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
SUBMISSION- INFORMATION DISCLOSURE STMT	2806	1	90	90
Total in USD (\$)				90

Electronic Acknowledgement Receipt	
EFS ID:	30426255
Application Number:	13210168
International Application Number:	
Confirmation Number:	1609
Title of Invention:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION
First Named Inventor/Applicant Name:	Ahmnon D. MOSKOWITZ
Customer Number:	26191
Filer:	Stuart A. Nelson/Melissa Andersen
Filer Authorized By:	Stuart A. Nelson
Attorney Docket Number:	45335-0009007
Receipt Date:	20-SEP-2017
Filing Date:	15-AUG-2011
Time Stamp:	17:33:06
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	\$90
RAM confirmation Number	092117INTEFSW00004748061050
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	Transmittal.pdf	72001	no	1
			0d5b3f2296d13ebe4db2771fd87093006bf9dca		
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
2	Information Disclosure Statement (IDS) Form (SB08)	PTO-1449.pdf	144194	no	5
			c8490841c41a51e077f617128872d4b0dd71a48a		
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
3	Fee Worksheet (SB06)	fee-info.pdf	30887	no	2
			5931508e49facda0742a3f6a4d371e90ac8b03f9		
Warnings:					
Information:					
Total Files Size (in bytes):			247082		
<p>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.</p> <p><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.</p> <p><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.</p> <p><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.</p>					

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor : Ahmnon D. Moskowitz Art Unit : 3733
Serial No. : 13/210,168 Examiner : Pedro Philogene
Filed : August 15, 2011 Conf. No. : 1609
Title : BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY
SCREWS AND POSTERIOR CERVICAL AND LUMBAR
INTERARTICULATING JOINT CALIBRATED STAPLING
DEVICES FOR SPINAL FUSION

Mail Stop Amendment

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

REPLY TO ACTION OF JULY 3, 2017

Please consider the following reply.

List of claims (replacing prior versions).

1-85. (Canceled)

86. (Currently Amended) ~~A universal, intervertebral combination internal screw guide and fixation apparatus configured to be inserted into a disc space between a first vertebral body and a second vertebral body and~~ A system to provide fusion of ~~[[the]]~~ a first vertebral body to ~~[[the]]~~ a second vertebral body via biological bone fusion and screw fusion, the ~~apparatus~~ system comprising:

an intervertebral cage comprising a top portion and a bottom portion with the top portion operably connected to the bottom portion, wherein the top portion and the bottom portion combine to form including: a top wall, a bottom wall, a first sidewall and a second sidewall, wherein the top wall is formed at least partially by the top portion and wherein the first sidewall, the second sidewall, and the bottom wall are formed at least partially by the bottom portion, and wherein the intervertebral cage defines: and two sidewalls defining an open space capable of receiving bone filling for the biological bone fusion; and

at least one open space capable of receiving bone filling for biological bone fusion.

[[an]] a first internal screw guide having [[an]] a first entry opening and [[an]] a first exit opening, the first entry opening formed at least partially in a top surface of the top portion at the top wall and the first exit opening formed at least partially in a bottom surface of the top portion at the top wall and at least partially in a first side surface of the top portion at the top wall,

a second internal screw guide having a second entry opening and a second exit opening, the second entry opening formed at least partially in the top surface of the top portion at the top wall and the second exit opening formed at least partially in the bottom surface of the top portion at the top wall and at least

partially in a second side surface of the top portion at the top wall, wherein the first internal screw guide and the second internal screw guide are angled to orient screw members bi-directionally,

an indentation extending into the top surface of the top portion between the first internal screw guide and the second internal screw guide at an angle that is substantially perpendicular to the top surface, wherein the indentation is defined by first and second parallel indentation sides and third and fourth parallel indentation sides that are perpendicular to the first and second parallel indentation sides, and wherein the indentation is positioned along a centerline axis of the intervertebral cage that bisects the top surface, and

a circular top hole extending into the top surface of the top portion between the first internal screw guide and the second internal screw guide at an angle that is substantially perpendicular to the top surface, wherein the circular top hole is positioned along the centerline axis of the intervertebral cage that bisects the top surface;

a first screw having a first screw head and a first threaded body that is sized and configured to be inserted through the first internal screw guide at a first angle so the first screw extends at least partially into the open space and at least partially next to the open space;

a second screw having a second screw head and a second threaded body that is sized and configured to be inserted through the second internal screw guide at a second angle different than the first angle; and

a tool configured for manipulating and inserting the intervertebral cage into a disc space between the first vertebral body and the second vertebral body to provide fusion of the first vertebral body to the second vertebral body via biological bone fusion and screw fusion, the tool comprising:

an elongate shaft;

a handle at a proximal end of the elongate shaft;

at least one projection extending distally away from a distal end of the elongate shaft sized and configured to engage the intervertebral cage; and

a screw guide defining a first screw trajectory guide and a second screw trajectory guide for controlling a direction of the first screw and the second screw that are inserted into the first internal screw guide and the second internal screw guide of the intervertebral cage, wherein the projection extends distally past the first and second screw trajectory guides, and wherein when the projection is engaged with the intervertebral cage the first and second screw trajectory guides of the tool are aligned with the first and second internal screw guides of the intervertebral cage.

~~wherein the entry opening of the internal screw guide is formed entirely between all edges of the top surface of the top wall when viewed from a direction perpendicular to a plane of the top surface.~~

87. (Currently Amended) The ~~apparatus~~ system of claim 86, wherein an internal surface of the internal screw guide extends continuously from the entry opening to the exit opening.

88. (Currently Amended) The ~~apparatus~~ system of claim 86, wherein the internal screw guide extends through an entire depth of the top wall from the top surface to the bottom surface and exiting at least partially into the open space.

89. (Currently Amended) The ~~apparatus~~ system of claim 86, wherein the internal screw guide permits only a predetermined angled trajectory of a screw member through the intervertebral cage.

90. (Currently Amended) The ~~apparatus~~ system of claim 86, wherein the internal screw guide has a 25 degree angulation.

91. (Currently Amended) The ~~apparatus~~ system of claim 86, wherein the top wall has a thickness extending from the top surface of the top wall to the bottom surface of the top wall in a direction of a depth of the intervertebral cage, a height of the intervertebral cage

extending in a direction perpendicular to the depth, and

wherein an axis of the internal screw guide extends to a greater extent in the direction of the depth of the intervertebral cage than in a direction of a height of the intervertebral cage in order to facilitate multi-level fusion of adjacent vertebral bodies with multiple intervertebral cages.

92. (Currently Amended) The ~~apparatus~~ system of claim 86, wherein the top wall of the intervertebral cage has a thickness that is greater than a thickness of each of the sidewalls.

93. (Currently Amended) The ~~apparatus~~ system of claim 86, wherein ~~at least one of the two sidewalls includes a hole~~ the first and second side holes are configured to allow placement of bone filling into the open space of the intervertebral cage for the biological bone fusion.

94. (Currently Amended) The ~~apparatus~~ system of claim 86, wherein the intervertebral cages includes indentations formed on surfaces of the two sidewalls and on opposite ends of the intervertebral cage for receiving ends of prongs of an implantation tool.

95. (Currently Amended) The ~~apparatus~~ system of claim 86, wherein a surface of each of the two sidewalls includes a plurality of ridges.

96-97. (Cancelled)

98. (Currently Amended) The ~~apparatus~~ system of claim 86, wherein the intervertebral cage is a cervical intervertebral cage configured to fit into a cervical disc space.

99. (Currently Amended) The ~~apparatus~~ system of claim 86, wherein the intervertebral cage is a lumbar intervertebral cage configured to fit into a lumbar disc space.

100. (Currently Amended) The ~~apparatus~~ system of claim 86, wherein the intervertebral cage is a posterior lumbar intervertebral cage configured to fit into a lumbar disc space.

101. (Currently Amended) The ~~apparatus~~ system of claim 86, wherein the intervertebral cage capable of one of posterior lumbar intervertebral placement, anterior lumbar intervertebral placement, thoracic intervertebral placement, and anterior cervical intervertebral placement.

102-105. (Cancelled)

106. (Currently Amended) The ~~apparatus~~ system of claim [[102]] 86, wherein each of the internal screw guide and the second internal screw guide permits only a 25 degree angulation of a first screw member and the second screw member.

107. (Currently Amended) The ~~apparatus~~ system of claim [[102]] 86, wherein the internal screw guide and the second internal screw guide are aligned along a longitudinal axis of the top wall of the intervertebral cage.

108. (Currently Amended) The ~~apparatus~~ system of claim [[102]] 86, wherein the first internal screw guide and the second internal screw guide are symmetrically disposed on each side of a center point of the intervertebral cage along a longitudinal axis of the top wall of the intervertebral cage.

109. (Currently Amended) The ~~apparatus~~ system of claim [[102]] 86, wherein the first internal screw guide and the second internal screw guide are offset in opposite directions with respect to a center line of a longitudinal extent of the top wall.

110. (Currently Amended) The ~~apparatus~~ system of claim 109, wherein a part of the

first internal screw guide overlaps a part of the second internal screw guide along the longitudinal extent of the top wall.

111. (Currently Amended) The ~~apparatus~~ system of claim [[102]] 86, wherein the first entry opening of the first internal screw guide and the second entry opening of the second internal screw guide are arranged diagonally on the top surface of the top wall.

112. (Currently Amended) The ~~apparatus~~ system of claim [[102]] 86, wherein the top wall has four quadrants delineated by a first axis and a second axis each lying in a plane of the top wall, and the first axis is at a right angle with respect to the second axis,

wherein the four quadrants include a first quadrant, a second quadrant, a third quadrant, and a fourth quadrant,

wherein the first quadrant and the fourth quadrant are opposed to the second quadrant and the third quadrant with respect to the first axis, and the first quadrant and the second quadrant are opposed to the third quadrant and the fourth quadrant with respect to the second axis,

wherein the first quadrant is diagonally opposed to the third quadrant, and the second quadrant is diagonally opposed to the fourth quadrant, and

wherein a majority of an area of the first entry opening of the first internal screw guide is in the first quadrant and a majority of an area of the second entry opening of the second internal screw guide is in the third quadrant.

113. (Currently Amended) The ~~apparatus~~ system of claim [[102]] 86, wherein the top wall has four quadrants delineated by a first axis and a second axis each lying in a plane of the ~~[[first]]~~ top wall, and the first axis is at a right angle with respect to the second axis,

wherein the four quadrants include a first quadrant, a second quadrant, a third quadrant, and a fourth quadrant,

wherein the first quadrant and the fourth quadrant are opposed to the second quadrant and the third quadrant with respect to the first axis, and the first quadrant and the second quadrant are opposed to the third quadrant and the fourth quadrant with respect to the second

axis,

wherein the first quadrant is diagonally opposed to the third quadrant, and the second quadrant is diagonally opposed to the fourth quadrant, and

wherein a center of the first entry opening of the first internal screw guide is in the first quadrant and a center of the second entry opening of the second internal screw guide is in the third quadrant.

114. (Currently Amended) The ~~apparatus~~ system of claim [[102]] 86, wherein the top wall includes a first corner and a second corner, the first corner being arranged at an opposite side of the top wall and an opposite end of the top wall with respect to the second corner, and

wherein the first internal screw guide and the second internal screw guide are diagonally arranged along a direction extending from the first corner of the top wall to the second corner of the top wall.

115. (Currently Amended) The ~~apparatus~~ system of claim [[102]] 86, wherein the intervertebral cage further comprises:

a third internal screw guide having a third entry opening and a third exit opening, the third entry opening formed at least partially in the top surface of the top portion at the top wall and the third exit opening formed at least partially in the bottom surface of the top portion at the top wall and at least partially in the side surface of the top wall.

116. (Currently Amended) The ~~apparatus~~ system of claim 115, wherein the intervertebral cage further comprises:

a fourth internal screw guide having a fourth entry opening and a fourth exit opening, the fourth entry opening formed at least partially in the top surface of the top portion at the top wall and the fourth exit opening formed at least partially in the bottom surface of the top portion at the top wall and at least partially in the second side surface of the top wall.

117. (Currently Amended) The ~~apparatus~~ system of claim 116, wherein the first internal screw guide and the fourth internal screw guide are oriented rostrally and the second internal screw guide and the third internal screw guide are oriented caudally.

118. (Currently Amended) The ~~apparatus~~ system of claim 116, wherein the second internal screw guide and the third internal screw guide are disposed between the first internal screw guide and the fourth internal screw guide along a longitudinal length of the top wall of the intervertebral cage.

119. (Currently Amended) The ~~apparatus~~ system of claim 116, wherein each of the first internal screw guide, the second internal screw guide, the third internal screw guide, and the fourth internal screw guide has a 25 degree angulation.

120-130. (Cancelled)

131. (Currently Amended) The ~~apparatus~~ system of claim 86, wherein the entry opening is formed entirely in the top surface of the top wall.

132-138. (Canceled)

139. (New) The system of claim 86, wherein the circular top hole is a threaded circular hole.

140. (New) The system of claim 86, wherein the open space extends from an inner surface of the first sidewall to an inner surface of the second sidewall and extends from an inner surface of the top wall to an inner surface of the bottom wall.

141. (New) The system of claim 86, and further comprising means for facilitating integration and fusion with superior and inferior vertebral bodies.

142. (New) The system of claim 141, wherein the means is positioned at least partially on the first side surface of the top wall.

143. (New) A system to provide fusion of a first vertebral body to a second vertebral body via biological bone fusion and screw fusion, the system comprising:

- an intervertebral cage comprising a top portion and a bottom portion with the top portion operably connected to the bottom portion, wherein the top portion and the bottom portion combine to form a top wall, a bottom wall, a first sidewall and a second sidewall, wherein the top portion forms the top wall and at least part of the first and second side walls, wherein the bottom portion forms the bottom wall and at least part of the first and second side walls, and wherein the intervertebral cage defines:

- at least one open space capable of receiving bone filling for biological bone fusion,

- a first side slot on the first sidewall;

- a second side slot on the second sidewall, wherein the second side slot is positioned opposite the first side slot,

- a first internal screw guide having a first entry opening and a first exit opening, the first entry opening formed at least partially in a top surface of the top portion at the top wall and the first exit opening formed at least partially in a bottom surface of the top portion at the top wall and at least partially in a first side surface of the top portion at the top wall, and

- a second internal screw guide having a second entry opening and a second exit opening, the second entry opening formed at least partially in the top surface of the top portion at the top wall and the second exit opening formed at least partially in the bottom surface of the top portion at the top wall and at least partially in a second side surface of the top portion at the top wall, wherein the first internal screw guide and the second internal screw guide are angled to orient screw members bi-directionally; and

- a first screw having a first screw head and a first threaded body that is sized and configured to be inserted through the first internal screw guide at a first angle so the first

screw extends at least partially into the open space and at least partially next to the open space;

a second screw having a second screw head and a second threaded body that is sized and configured to be inserted through the second internal screw guide at a second angle different than the first angle; and

a tool configured for manipulating and inserting the intervertebral cage into a disc space between the first vertebral body and the second vertebral body to provide fusion of the first vertebral body to the second vertebral body via biological bone fusion and screw fusion, the tool comprising:

an elongate shaft portion; and

a screw guide defining a first screw trajectory guide and a second screw trajectory guide for controlling a direction of insertion of the first screw and the second screw as they are inserted into the first internal screw guide and the second internal screw guide of the intervertebral cage, wherein when the tool is engaged with the intervertebral cage the first and second screw trajectory guides of the tool are aligned with the first and second internal screw guides of the intervertebral cage.

144. (New) The system of claim 143, wherein the elongate shaft has a handle at a proximal end and has the screw guide at a distal end.

145. (New) The system of claim 143, wherein the open space extends from an inner surface of the first sidewall to an inner surface of the second sidewall and extends from an inner surface of the top wall to an inner surface of the bottom wall.

146. (New) The system of claim 143, and further comprising means for facilitating integration and fusion with superior and inferior vertebral bodies.

147. (New) The system of claim 146, wherein the means is positioned at least partially on the first side surface of the top wall.

148. (New) The system of claim 146, wherein the tool comprises at least one projection extending distally away from a distal end of the elongate shaft sized and that is configured to engage the intervertebral cage, wherein when the projection is engaged with the intervertebral cage the first and second screw trajectory guides of the tool are aligned with the first and second internal screw guides of the intervertebral cage.

149. (New) A system to provide fusion of a first vertebral body to a second vertebral body via biological bone fusion and screw fusion, the system comprising:

- an intervertebral cage comprising a top portion and a bottom portion with the top portion operably connected to the bottom portion, wherein the top portion and the bottom portion combine to form a top wall, a bottom wall, a first sidewall and a second sidewall, wherein the top portion forms the top wall and at least part of the first and second side walls, wherein the bottom portion forms the bottom wall and at least part of the first and second side walls, and wherein the intervertebral cage defines:

- at least one open space capable of receiving bone filling for biological bone fusion,

- a first side slot on the first sidewall;

- a second side slot on the second sidewall, wherein the second side slot is positioned opposite the first side slot,

- a first internal screw guide having a first entry opening and a first exit opening, the first entry opening formed at least partially in a top surface of the top portion at the top wall and the first exit opening formed at least partially in a bottom surface of the top portion at the top wall and at least partially in a first side surface of the top portion at the top wall,

- a second internal screw guide having a second entry opening and a second exit opening, the second entry opening formed at least partially in the top surface of the top portion at the top wall and the second exit opening formed at least partially in the bottom surface of the top portion at the top wall and at least partially in a second side surface of the top portion at the top wall, wherein the

first internal screw guide and the second internal screw guide are angled to orient screw members bi-directionally, and

at least one indentation in the top surface of the top portion of the top wall positioned between the first internal screw guide and the second internal screw guide;

a first screw having a first screw head and a first threaded body that is sized and configured to be inserted through the first internal screw guide at a first angle so the first screw extends at least partially into the open space and at least partially next to the open space;

a second screw having a second screw head and a second threaded body that is sized and configured to be inserted through the second internal screw guide at a second angle different than the first angle so the second screw extends at least partially into the open space and at least partially next to the open space; and

a tool configured for manipulating and inserting the intervertebral cage into a disc space between the first vertebral body and the second vertebral body to provide fusion of the first vertebral body to the second vertebral body via biological bone fusion and screw fusion, the tool comprising first and second gripper prongs at a distal end of the tool wherein the first gripper prong opposes the second gripper prong and is sized and configured to grip and hold the intervertebral cage while inserting the intervertebral cage, wherein the distal end of the tool is shaped to expose the first and second internal screw guides enough to allow a tool to screw the first and second screws in the first and second internal screw guides while the tool is holding the intervertebral cage.

150. (New) The system of claim 149, wherein the open space extends from an inner surface of the first sidewall to an inner surface of the second sidewall and extends from an inner surface of the top wall to an inner surface of the bottom wall.

151. (New) The system of claim 149, and further comprising means for facilitating integration and fusion with superior and inferior vertebral bodies.

152. (New) The system of claim 149, wherein the at least one indentation in the top surface comprises first and second indentations in the top surface of the top portion of the top wall positioned between the first internal screw guide and the second internal screw guide.

153. (New) The system of claim 152, wherein the first indentation comprises a threaded circular hole and the second indentation is substantially square shaped.

154. (New) The system of claim 152, wherein the first and second indentations are both positioned along the centerline axis that bisects the top surface.

155. (New) The system of claim 149, wherein the top portion is configured to engage the bottom portion with part of the top portion extending into the first and second slots.

156. (New) The system of claim 149, wherein the intervertebral cage further comprises means for engaging the top portion to the bottom portion.

157. (New) The system of claim 143, wherein the intervertebral cage further comprises means for engaging the top portion to the bottom portion.

158. (New) The system of claim 86, wherein the intervertebral cage further comprises means for engaging the top portion to the bottom portion.

159. (New) A system to provide fusion of a first vertebral body to a second vertebral body via biological bone fusion and screw fusion, the system comprising:
an intervertebral cage comprising a top portion and a bottom portion with the top portion operably connected to the bottom portion, wherein the top portion and the bottom portion combine to form a top wall, a bottom wall, a first sidewall and a second sidewall, wherein the top wall is formed at least partially by the top portion and wherein the first sidewall, the second sidewall, and the bottom wall are formed at least partially by the bottom portion, and wherein the intervertebral cage defines:

at least one open space capable of receiving bone filling for biological bone fusion,

a first side hole extending through the first sidewall of the bottom portion;

a second side hole extending through the second sidewall of the bottom portion, wherein the second side hole is positioned opposite the first side hole and wherein the first and second side holes are positioned nearer a bottom of the intervertebral cage than a top of the intervertebral cage,

a first internal screw guide having a first entry opening and a first exit opening, the first entry opening formed at least partially in a top surface of the top portion at the top wall and the first exit opening formed at least partially in a bottom surface of the top portion at the top wall and at least partially in a first side surface of the top portion at the top wall,

a second internal screw guide having a second entry opening and a second exit opening, the second entry opening formed at least partially in the top surface of the top portion at the top wall and the second exit opening formed at least partially in the bottom surface of the top portion at the top wall and at least partially in a second side surface of the top portion at the top wall, wherein the first internal screw guide and the second internal screw guide are angled to orient screw members bi-directionally, and

a top hole extending into the top surface of the top portion between the first internal screw guide and the second internal screw guide at an angle that is substantially perpendicular to the top surface, wherein the top hole is smaller than the first and second internal screw guides and is positioned along a centerline axis of the intervertebral cage that bisects the top surface;

a first screw having a first screw head and a first threaded body that is sized and configured to be inserted through the first internal screw guide;

a second screw having a second screw head and a second threaded body that is sized and configured to be inserted through the second internal screw guide; and

a tool configured for manipulating and inserting the intervertebral cage into a disc space between the first vertebral body and the second vertebral body to provide fusion of

the first vertebral body to the second vertebral body via biological bone fusion and screw fusion, the tool comprising:

- an elongate shaft;
- a handle at a proximal end of the elongate shaft;
- at least one projection extending distally away from a distal end of the elongate shaft sized and configured to engage the intervertebral cage; and
- a screw guide defining a first screw trajectory guide and a second screw trajectory guide for controlling a direction of the first screw and the second screw that are inserted into the first internal screw guide and the second internal screw guide of the intervertebral cage, wherein the projection extends distally past the first and second screw trajectory guides, and wherein when the projection is engaged with the intervertebral cage the first and second screw trajectory guides of the tool are aligned with the first and second internal screw guides of the intervertebral cage.

160. (New) The system of claim 159, wherein the intervertebral cage further comprises means for engaging the top portion to the bottom portion and wherein the system further comprises means for facilitating integration and fusion with superior and inferior vertebral bodies.

First Named Inventor : Ahmnon D. Moskowitz
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REMARKS

Claims 86-132, 135, 136, and 138 are pending, with claims 86, 124, 126, 135, and 136 being independent. With this amendment, claims 86-95, 98-101, 106-119, and 131 are amended, claims 96-97, 102-105, 120-130, 132, 135-136 and 138 are canceled, and claims 139-160 are new.

Claim Rejections – 35 USC § 112

Claims 86-132, 135-136, 138 were rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention. Without agreeing with the merits of the rejection but to move prosecution forward, claim 86 has been amended to remove the identified ambiguous language and claims 135 and 136 have been cancelled. Accordingly, the Applicant respectfully requests that this rejection be withdrawn.

Double Patenting

Claims 86-132, 135-136, 138 were provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 93-141 of copending Application No. 13/210162. Claims 86-132, 135-136, 138 were provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 84-133 of copending Application No. 13/210157. Without agreeing with the merits of the rejection, applicant reserves the right to file a terminal disclaimer once the claims are otherwise deemed allowable only if the double patenting rejection remains at that time. For example, the claims of the present application have been amended with features not claimed in Application No. 13/210162 and Application No. 13/210157.

Claim Rejections – 35 USC § 103

Claims 86-132, 135-136, 138 were rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over U.S. Publication No. 2008/0249575 (Waugh) in view of U.S. Publication No.

2010/0305704 (Messerli). Without agreeing with the merits of the rejection but to move prosecution forward, claim 86 has been amended and claims 135 and 136 have been cancelled.

As amended, claim 86 includes claim elements not taught or obvious over the cited references. For example, claim 86 has been amended to require a system including an intervertebral cage and a tool for manipulating and inserting the intervertebral cage each having specific structure not taught in the cited references, let alone taught in the particular combination and orientations claimed. Accordingly, claim 86 and all claims depending therefrom are patentable over the cited references for at least this reason.

New claims 139-160 also require systems that include an intervertebral cage and a tool for manipulating and inserting the intervertebral cage and also have particular structural limitations that are not taught in the cited references, let alone taught in the particular combination and orientations claimed. Accordingly, claims 139-160 are also patentable over the cited references.

Drawings

The drawings were objected to under 37 CFR 1.83(a) for failing to show every feature claimed. Applicant understands that this objection relates to the language identified as ambiguous in the rejection under § 112. Claim 86 has been amended to remove the alleged ambiguity, and accordingly, Applicant believes that this obviates the objection to the drawings.

As amended, claim 86 now requires “the first entry opening formed at least partially in a top surface of the top portion at the top wall.” Figure 1A shows one example of a first entry opening formed at least partially in a top surface of the top portion of the top wall. Figures 2A-4C also show examples of entry openings formed at least partially in a top surface. Accordingly, the Applicant respectfully requests that this objection be withdrawn.

Request for Reconsideration

The Applicant respectfully requests prompt consideration and a Notice of Allowance. In the event that no Notice of Allowance will be provided in the next communication, Applicant requests that the Examiner telephone the undersigned attorney (612-337-2538) prior to the next communication so that prosecution on the merits may be expedited. It is believed that all of the

First Named Inventor : Ahmnon D. Moskowitz
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pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendments herein do not signify concession of unpatentability of any claims prior to this amendment. Applicant hereby specifically reserves the right to prosecute the previously presented subject matter in a continuing application. Also, Applicant expressly reserves the right to prosecute claims of different or broader scope in a continuing application. The Patent Office should infer no (i) adoption of a position with respect to patentability, (ii) change in the Applicant's position with respect to any claim or subject matter of the invention, or (iii) acquiescence in any way to any position taken by the Office Action, based on the amendments made herein.

Any fees for excess claims and extension of time are being paid with this reply on the Electronic Filing System. Apply those fees and any other necessary charges or credits to Deposit Account 06-1050, referencing the above attorney docket number.

Respectfully submitted,

Date: 10/27/2017

/Stuart A. Nelson/

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61546926.doc

Electronic Patent Application Fee Transmittal				
Application Number:		13210168		
Filing Date:		15-Aug-2011		
Title of Invention:		BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION		
First Named Inventor/Applicant Name:		Ahmnon D. MOSKOWITZ		
Filer:		Stuart A. Nelson/Amanda Petersen		
Attorney Docket Number:		45335-0009007		
Filed as Small Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension - 1 month with \$0 paid	2251	1	100	100
Miscellaneous:				
Total in USD (\$)				100

Electronic Acknowledgement Receipt	
EFS ID:	30787468
Application Number:	13210168
International Application Number:	
Confirmation Number:	1609
Title of Invention:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION
First Named Inventor/Applicant Name:	Ahmnon D. MOSKOWITZ
Customer Number:	26191
Filer:	Stuart A. Nelson/Amanda Petersen
Filer Authorized By:	Stuart A. Nelson
Attorney Docket Number:	45335-0009007
Receipt Date:	27-OCT-2017
Filing Date:	15-AUG-2011
Time Stamp:	16:34:51
Application Type:	Utility under 35 USC 111(a)

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Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		Response.pdf	130285	yes	19
			25135028f8f5e69df4e1dc2eea1d83aff9dbea7f		
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Amendment/Req. Reconsideration-After Non-Final Reject		1	1	
	Claims		2	16	
	Applicant Arguments/Remarks Made in an Amendment		17	19	
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	31249	no	2
			3d2724680abaf108e7b8327245cd986d4b8fbd01		
Warnings:					
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Total Files Size (in bytes):			161534		

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

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

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor :	Ahmnon D. Moskowitz	Art Unit :	3733
Serial No. :	13/210,168	Examiner :	Pedro Philogene
Filed :	August 15, 2011	Conf. No. :	1609
Title :	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION		

Mail Stop Amendment

Commissioner for Patents
P.O. Box 1450
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REPLY TO ACTION OF JULY 3, 2017

Please consider the following reply.

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 13/210,168	Filing Date 08/15/2011	☐ To be Mailed
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ENTITY: ☐ LARGE ☒ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	RATE (\$)	FEE (\$)
☒ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	165
☐ SEARCH FEE (37 CFR 1.16(k), (j), 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 \$ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X \$ =	
☐ 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))				
			TOTAL	165

* If the difference in column 1 is less than zero, enter "0" in column 2.

APPLICATION AS AMENDED – PART II

AMENDMENT	(Column 1)	(Column 2)	(Column 3)	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)
	10/27/2017	CLAIMS REMAINING AFTER AMENDMENT					
	Total (37 CFR 1.16(i))	* 51	Minus	** 60	= 0	x \$40 =	0
	Independent (37 CFR 1.16(h))	* 4	Minus	***5	= 0	x \$210 =	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

AMENDMENT	(Column 1)	(Column 2)	(Column 3)	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)
		CLAIMS REMAINING AFTER AMENDMENT					
	Total (37 CFR 1.16(i))	*	Minus	**	=	X \$ =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X \$ =	
	☐ 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.

** 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 number found in the appropriate box in column 1.

LIE
GLORIA J. TRAMMELL

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/210,168	08/15/2011	Ahmnnon D. MOSKOWITZ	45335-0009007	1609

26191 7590 12/04/2017
FISH & RICHARDSON P.C. (TC)
PO BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER

PHILOGENE, PEDRO

ART UNIT	PAPER NUMBER
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3733

NOTIFICATION DATE	DELIVERY MODE
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12/04/2017

ELECTRONIC

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

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

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No. 13/210,168	Applicant(s) MOSKOWITZ ET AL.	
	Examiner PEDRO PHILOGENE	Art Unit 3733	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/27/17.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 86-95,98-101,106-119,131 and 139-160 is/are pending in the application.
5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 86-95,98-101,106-119,131 and 139-160 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) ☐ Notice of References Cited (PTO-892) | 3) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
Paper No(s)/Mail Date <u>9/20/17</u> . | 4) ☐ Other: ____. |

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

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP §§ 706.02(l)(1) -

706.02(l)(3) for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 86-95, 98-101, 106-119, 131, 139-160 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 93-141 of copending Application No. 13/210162. Although the claims at issue are not identical, they are not patentably distinct from each other because it is clear that all the elements of claims of the application are to be found in claims of the copending application. The difference between claims of the application and claims of the copending application lies in the fact that the copending application claims include any more elements and are thus much more specific. Thus the invention of claims of the copending application is in effect a "species" of the "generic" invention of claims of claims of the application. It has been held that the generic invention is "anticipated" by the "species". See in re

Goodman, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claims of the application are anticipated by claims of the copending application, they are not patentably distinct.

This is a provisional nonstatutory double patenting rejection because the patentably indistinct claims have not in fact been patented.

Claims 86-95, 98-101, 106-119, 131, 139-160 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 84-133 of copending Application No. 13/210157. Although the claims at issue are not identical, they are not patentably distinct from each other because it is clear that all the elements of claims of the application are to be found in claims of the copending application. The difference between claims of the application and claims of the copending application lies in the fact that the copending application claims include any more elements and are thus much more specific. Thus the invention of claims of the copending application is in effect a “species” of the “generic” invention of claims of the application. It has been held that the generic invention is “anticipated” by the “species”. See in re Goodman, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claims of the application are anticipated by claims of the copending application, they are not patentably distinct.

This is a provisional nonstatutory double patenting rejection because the patentably indistinct claims have not in fact been patented.

Response to Amendment

Applicant's arguments, see remarks, filed 10/27/17, with respect to claims 86-132, 135, 136, 138 have been fully considered and are persuasive. The art rejection of

the claims has been withdrawn. However, the double patenting rejection is still maintained. See rejection above.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PEDRO PHILOGENE whose telephone number is (571)272-4716. The examiner can normally be reached on Monday to Friday 8:00 AM to 4:30 PM.

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

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

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

/PEDRO PHILOGENE/
Primary Examiner, Art Unit 3733
November 29, 2017

Search Notes 	Application/Control No. 13210168	Applicant(s)/Patent Under Reexamination MOSKOWITZ ET AL.
	Examiner PEDRO PHILOGENE	Art Unit 3733

CPC- SEARCHED		
Symbol	Date	Examiner
A61B17/0642, A61B17/809, A61B17/8894, A61F2/4465, A61F2/447, A61F2/4611, A61B17/7064	11/29/2017	/P.P./
A61F2250/0007, A61B17/86, A61B2017/0641, A61B2017/0648, A61B2017/922, A61F2002/2835, A61F2002/30133, A61F2002/30387, A61F2002/30448, A61F2002/30507		
A61F2002/3055, A61F2002/30579, A61F2002/30604, A61F2002/30772, A61F2002/30878, A61F2002/4475, A61F2002/448, A61F2002/4627, A61F2002/4681, A61F2220/0025, A61F2220/005, A61F2230/0015		

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
623	17.11-17.16	11/29/2017	/P.P./
606	300-305,246, 99, 144, 151, 251, 266		
227	181.1		

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

SEARCH NOTES		
Search Notes	Date	Examiner
EAST search enclosed	11/29/2017	/P.P./

INTERFERENCE SEARCH

	/PEDRO PHILOGENE/ Primary Examiner.Art Unit 3733
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US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

	/PEDRO PHILOGENE/ Primary Examiner.Art Unit 3733
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<i>Index of Claims</i> 	Application/Control No. 13210168	Applicant(s)/Patent Under Reexamination MOSKOWITZ ET AL.
	Examiner PEDRO PHILOGENE	Art Unit 3733

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

☐ Claims renumbered in the same order as presented by applicant										☐ CPA		☐ T.D.		☐ R.1.47	
CLAIM		DATE													
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<i>Index of Claims</i> 	Application/Control No. 13210168	Applicant(s)/Patent Under Reexamination MOSKOWITZ ET AL.
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CLAIM		DATE													
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	108	✓	✓	✓	✓	✓	✓								

<i>Index of Claims</i> 	Application/Control No. 13210168	Applicant(s)/Patent Under Reexamination MOSKOWITZ ET AL.
	Examiner PEDRO PHILOGENE	Art Unit 3733

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
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☐ Claims renumbered in the same order as presented by applicant										☐ CPA		☐ T.D.		☐ R.1.47	
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	138					✓	-								
	139						✓								
	130						✓								
	141						✓								
	142						✓								
	143						✓								
	144						✓								

<i>Index of Claims</i> 	Application/Control No. 13210168	Applicant(s)/Patent Under Reexamination MOSKOWITZ ET AL.
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CLAIM		DATE							
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	146						✓		
	147						✓		
	148						✓		
	149						✓		
	150						✓		
	151						✓		
	152						✓		
	153						✓		
	154						✓		
	155						✓		
	156						✓		
	157						✓		
	158						✓		
	159						✓		
	160						✓		

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	2	"20080249575"	US-PGPUB; USPAT	OR	OFF	2017/11/29 09:47
L2	1	"20100305704"	US-PGPUB; USPAT	OR	OFF	2017/11/29 09:48
L3	15	(insertor or inserter or insertion near device) same screw near guide & intervertebral near (cage or implant or spacer or disc)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2017/11/29 09:54
L4	129	("20050177245" "20050187552" "20050283152" "20060079961" "20060085071" "20060122703" "20060200166" "20060206208" "20060282165" "20070233253" "20070270965" "20080082173" "20080177307" "20080249569" "20080249575" "20080281425" "20080306596" "20080312742" "20090088849" "20090099659" "20090105831" "20090157186" "20090182430" "20090210062" "20090210063" "20090224023" "20090234455" "20090259256" "20090270991" "20100049324" "20100057206" "20100125334" "20100145460" "20100185288" "20100204739" "20100249935" "4463753" "4599086" "4743256" "4790303" "4892545" "4904261" "5002576" "5062850" "5397364" "5405391" "5534031" "5549612" "5616144" "5713899" "5843082" "5861041" "5876456" "5876457" "5893889" "5951558" "6099531" "6120503" "6123705" "6136001" "6139550" "6152927" "6193721" "6214005" "6235059" "6258089" "6306139" "6306170" "6364880" "6371986" "6395030" "6423063" "6468311" "6471724" "6485517" "6540785" "6558423" "6558424" "6562073" "6576017" "6579290" "6626907" "6652525" "6669700" "6682561" "6730127" "6911045" "6916320" "6926718" "6969390" "6972019" "7001385" "7001387" "7033394" "7041135" "7063701" "7077844" "7094239" "7112222" "7137984" "7163561" "7172627" "7226482" "7232464" "7235105")	US-PGPUB; USPAT; USOCR	OR	OFF	2017/11/29 09:59

		"7255698" "7267690" "7323011" "7491237" "7621956" "7621960" "7637951" "7637954").PN. OR ("7651497" "7662185" "7776093" "7846207" "7914554" "8048075" "D623750").PN. OR ("8840668").URPN.				
L5	23	(insertor or inserter or insertion near device) same screw near guide & (intervertebral or vertebral or spine or spinal) & (cage or implant or spacer or disc or prosthesis)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2017/11/29 10:11
L6	154	(insertor or inserter or insertion near device) & screw near guide & (intervertebral or vertebral or spine or spinal) & (cage or implant or spacer or disc or prosthesis)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2017/11/29 10:12
L7	1	"20130018468"	US-PGPUB; USPAT	OR	OFF	2017/11/29 10:13
L8	1	7 AND ((A61B17/0642 OR A61B17/7064 OR A61B17/809 OR A61B17/86 OR A61B17/8635 OR A61B17/8894 OR A61B17/92 OR A61B2017/00407 OR A61B2017/0641 OR A61B2017/0648 OR A61B2017/922 OR A61F2002/2835 OR A61F2002/30133 OR A61F2002/30387 OR A61F2002/30448 OR A61F2002/30507 OR A61F2002/3055 OR A61F2002/30579 OR A61F2002/30604 OR A61F2002/30772 OR A61F2002/30878 OR A61F2002/30879 OR A61F2002/30904 OR A61F2002/4475 OR A61F2002/448 OR A61F2002/4627 OR A61F2002/4681 OR A61F2002/4687 OR A61F2220/0025 OR A61F2220/005 OR A61F2230/0015 OR A61F2250/0007 OR A61F2/4465 OR A61F2/447 OR A61F2/4611).CPC. OR (623/17.11-17.16 or 606/246-279,99,96,151,144).CCLS. OR (A61F2/44).IPC.)	US-PGPUB; USPAT	OR	OFF	2017/11/29 10:14
L9	0	"20130018469"	USPAT	OR	OFF	2017/11/29 10:15
L10	1	"20130018469"	US-PGPUB; USPAT	OR	OFF	2017/11/29 10:16
L11	1	10 AND ((A61B17/0642 OR A61B17/7064 OR A61B17/809 OR A61B17/86 OR A61B17/8635 OR A61B17/8894 OR A61B17/92 OR A61B2017/00407 OR A61B2017/0641 OR A61B2017/0648 OR A61B2017/922 OR A61F2002/2835 OR A61F2002/30133 OR A61F2002/30387 OR A61F2002/30448 OR A61F2002/30507 OR A61F2002/3055 OR A61F2002/30579 OR A61F2002/30604 OR A61F2002/30772 OR A61F2002/30878 OR A61F2002/30879 OR A61F2002/30904 OR A61F2002/4475 OR A61F2002/448 OR A61F2002/4627 OR A61F2002/4681 OR A61F2002/4687 OR A61F2220/0025 OR A61F2220/005 OR A61F2230/0015 OR A61F2250/0007 OR	US-PGPUB; USPAT	OR	OFF	2017/11/29 10:18

		A61F2/4465 OR A61F2/447 OR A61F2/4611).CPC. OR (623/17.11-17.16 or 606/246-279,99,100,96,151,144).CCLS. OR (A61F2/44).IPCR.)				
L12	120	6 AND ((A61B17/0642 OR A61B17/7064 OR A61B17/809 OR A61B17/86 OR A61B17/8635 OR A61B17/8894 OR A61B17/92 OR A61B2017/00407 OR A61B2017/0641 OR A61B2017/0648 OR A61B2017/922 OR A61F2002/2835 OR A61F2002/30133 OR A61F2002/30387 OR A61F2002/30448 OR A61F2002/30507 OR A61F2002/3055 OR A61F2002/30579 OR A61F2002/30604 OR A61F2002/30772 OR A61F2002/30878 OR A61F2002/30879 OR A61F2002/30904 OR A61F2002/4475 OR A61F2002/448 OR A61F2002/4627 OR A61F2002/4681 OR A61F2002/4687 OR A61F2220/0025 OR A61F2220/005 OR A61F2230/0015 OR A61F2250/0007 OR A61F2/4465 OR A61F2/447 OR A61F2/4611).CPC. OR (623/17.11-17.16 or 606/246-279,99,100,96,151,144).CCLS. OR (A61F2/44).IPCR.)	US-PGPUB; USPAT	OR	OFF	2017/11/29 10:18

11/ 29/ 2017 10:21:27 AM

Substitute Disclosure Form U.S. Department of Commerce Patent and Trademark Office Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))	Attorney Docket No. 45335-0009007	Application No. 13/210,168
	Applicant Ahmnnon D. Moskowitz et al.	
	Filing Date August 15, 2011	Group Art Unit 3733

U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	1.	7862616	1/4/2011	Lechmann et al.			
	2.	8403986	3/26/2013	Michelson			
	3.	8328872	12/11/2012	Duffield et al.			
	4.	5005749	4/9/1991	Aranyi			
	5.	5413583	5/9/1995	Wohlers			
	6.	5454819	10/3/1995	Knoepfner			
	7.	5951574	9/14/1999	Stefanchik et al.			
	8.	7615059	11/10/2009	Watschke et al.			
	9.	6613055	9/2/2003	Di Emidio			
	10.	8034060	10/11/2011	Keren et al.			
	11.	4064881	12/27/1977	Meredith			
	12.	5713912	2/3/1998	Porter			
	13.	5976136	11/2/1999	Bailey et al.			
	14.	6852117	2/8/2005	Orlowski			
	15.	5916224	6/29/1999	Esplin			
	16.	7727246	6/1/2010	Sixto et al.			
	17.	5968054	10/19/1999	Yeatts et al.			
	18.	20100145460	6/10/2010	McDonough et al.			
	19.	20090105831	4/23/2009	Jones et al.			
	20.	8,353,913	Jan-13	Moskowitz et al.			
	21.	8,029,512	Oct-11	Paltzer			
	22.	7776093	Aug-10	Wolek			
	23.	7628816	Dec-09	Mageri et al.			
	24.	8425607	Apr-13	Waugh et al.			
	25.	8105367	1/31/2012	Austin et al.			
	26.	8273127	9/25/2012	Jones et al.			

Examiner Signature /PEDRO PHILOGENE/	Date Considered 11/29/2017
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

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	Applicant Ahmnnon D. Moskowitz et al.	
	Filing Date August 15, 2011	Group Art Unit 3733

U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	27.	2360942	10/24/1944	Ellerstein et al.			
	28.	7704279	4/27/2010	Moskowitz et al.			
	29.	7803162	9/28/2010	Marnay et al.			
	30.	7942903	5/17/2011	Moskowitz et al.			
	31.	8114162	2/14/2012	Bradley			
	32.	8137405	3/20/2012	Kostuik et al.			
	33.	8167949	5/1/2012	Tyber et al.			
	34.	8414651	4/9/2013	Tyber et al.			
	35.	8540774	9/24/2013	Kucenzi et al.			
	36.	8419797	4/6/2013	Biedermann et al.			
	37.	8613761	12/24/2013	Lindermann et al.			
	38.	20080183293	7/31/2008	Parry et al.			
	39.	20040220571	11/4/2004	Assaker et al.			
	40.	20030130737	7/10/2003	McGahan et al.			
	41.	20070250167	10/25/2007	Bray et al.			
	42.	20070276498	11/29/2007	Aebi et al.			
	43.	20080249569	10/9/2008	Waugh et al.			
	44.	20080249625	10/9/2008	Waugh et al.			
	45.	20080281425	11/13/2008	Thalgott et al.			
	46.	20090030520	1/29/2009	Biedermann et al.			
	47.	20090182430	7/16/2009	Tyber et al.			
	48.	20090210062	8/20/2009	Thalgott et al.			
	49.	20060155285	7/13/2006	Anderson et al.			
	50.	20090105830	4/23/2009	Jones et al.			
	51.	20120271423	10/25/2012	Wallenstein et al.			
	52.	20120277870	11/1/2012	Wolters et al.			

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Information Disclosure Statement by Applicant (Use several sheets if necessary)		Applicant Ahmnon D. Moskowitz et al.	
		Filing Date August 15, 2011	Group Art Unit 3733

(37 CFR §1.98(b))

U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	53.	20120323330	12/20/2012	Kucenzi et al.			
	54.	20130060339	3/7/2013	Duffield et al.			
	55.	20040193272	9/30/2004	Zubok et al.			
	56.	20090187218	7/23/2009	Schaffhausen et al.			
	57.	8728165	5/20/2014	Parry et al.			
	58.	6235034	5/22/2001	Bray			
	59.	6224602	5/1/2001	Hayes			
	60.	6890355	5/10/2005	Michelson			
	61.	6322562	11/27/2001	Wolter			
	62.	20080281424	11/13/2008	Parry et al.			
	63.	6454807	9/24/2002	Jackson			
	64.	6716247	4/6/2004	Michelson			
	65.	20040186569	9/23/2004	Berry			
	66.	7776047	8/17/2010	Fanger et al.			
	67.	20040186482	9/23/2004	Kolb et al.			
	68.	7758617	Jul-10	Lott et al.			
	69.	8328851	Dec-12	Curran			
	70.	8882813	11/11/2014	Jones et al.			
	71.	20050256576	11/17/2005	Moskowitz et al.			
	72.	20050261769	11/24/2005	Moskowitz et al.			
	73.	20070198089	8/23/2007	Moskowitz et al.			
	74.	20110288646	11/24/2011	Moskowitz et al.			
	75.	20070167678	7/19/2007	Moskowitz et al.			
	76.	20130173002	7/4/2013	Moskowitz et al.			
	77.	20060241621	10/26/2006	Moskowitz et al.			
	78.	20090112271	4/30/2009	Moskowitz et al.			

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	Applicant Ahmnnon D. Moskowitz et al.	
	Filing Date August 15, 2011	Group Art Unit 3733

U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	79.	20110208312	8/25/2011	Moskowitz et al.			
	80.	20070250172	10/25/2007	Moskowitz et al.			
	81.	20110178600	7/21/2011	Moskowitz et al.			
	82.	20170252178	9/7/2017	Moskowitz et al.			
	83.	20070049943	3/1/2007	Moskowitz et al.			
	84.	20100324606	12/23/2010	Moskowitz et al.			
	85.	20150105824	4/16/2015	Moskowitz et al.			
	86.	20080033440	2/7/2008	Moskowitz et al.			
	87.	20110295327	12/1/2011	Moskowitz et al.			
	88.	20110295371	12/1/2011	Moskowitz et al.			
	89.	20130053962	2/28/2013	Moskowitz et al.			
	90.	20130018468	1/17/2013	Moskowitz et al.			
	91.	20130023991	1/24/2013	Moskowitz et al.			
	92.	20130018469	1/17/2013	Moskowitz et al.			
	93.	20130282017	10/24/2013	Moskowitz et al.			
	94.	20160374830	12/29/2016	Moskowitz et al.			
	95.	20080177307	7/24/2008	Moskowitz et al.			
	96.	20120010714	1/12/2012	Moskowitz et al.			
	97.	20090234455	9/17/2009	Moskowitz et al.			
	98.	20150025637	1/22/2015	Moskowitz et al.			
	99.	20110137349	6/9/2011	Moskowitz et al.			
	100.	20090224023	9/10/2009	Moskowitz et al.			
	101.	20110125269	5/26/2011	Moskowitz et al.			
	102.	20110319935	12/29/2011	Moskowitz et al.			
	103.	20150148847	5/28/2015	Moskowitz et al.			
	104.	20110307011	12/15/2011	Moskowitz et al.			

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	Applicant Ahmnon D. Moskowitz et al.	
	Filing Date August 15, 2011	Group Art Unit 3733

U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	105.	20120330419	12/27/2012	Moskowitz et al.			
	106.	20140249629	9/4/2014	Moskowitz et al.			
	107.	20130023992	1/24/2013	Moskowitz et al.			
	108.	20130018470	1/17/2013	Moskowitz et al.			

Foreign Patent Documents or Published Foreign Patent Applications								
Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document

Examiner Signature /PEDRO PHILOGENE/	Date Considered 11/29/2017
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/210,168	08/15/2011	Ahmnnon D. MOSKOWITZ	45335-0009007	1609

26191 7590 12/04/2017
FISH & RICHARDSON P.C. (TC)
PO BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER

PHILOGENE, PEDRO

ART UNIT	PAPER NUMBER
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3733

NOTIFICATION DATE	DELIVERY MODE
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12/04/2017

ELECTRONIC

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

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

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No. 13/210,168	Applicant(s) MOSKOWITZ ET AL.	
	Examiner PEDRO PHILOGENE	Art Unit 3733	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/27/17.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

- 5) ☒ Claim(s) 86-95,98-101,106-119,131 and 139-160 is/are pending in the application.
5a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) _____ is/are allowed.
- 7) ☒ Claim(s) 86-95,98-101,106-119,131 and 139-160 is/are rejected.
- 8) ☐ Claim(s) _____ is/are objected to.
- 9) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) ☐ Notice of References Cited (PTO-892) | 3) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
Paper No(s)/Mail Date <u>9/20/17</u> . | 4) ☐ Other: _____ |

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

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP §§ 706.02(l)(1) -

706.02(l)(3) for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 86-95, 98-101, 106-119, 131, 139-160 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 93-141 of copending Application No. 13/210162. Although the claims at issue are not identical, they are not patentably distinct from each other because it is clear that all the elements of claims of the application are to be found in claims of the copending application. The difference between claims of the application and claims of the copending application lies in the fact that the copending application claims include any more elements and are thus much more specific. Thus the invention of claims of the copending application is in effect a "species" of the "generic" invention of claims of the application. It has been held that the generic invention is "anticipated" by the "species". See in re

Goodman, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claims of the application are anticipated by claims of the copending application, they are not patentably distinct.

This is a provisional nonstatutory double patenting rejection because the patentably indistinct claims have not in fact been patented.

Claims 86-95, 98-101, 106-119, 131, 139-160 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 84-133 of copending Application No. 13/210157. Although the claims at issue are not identical, they are not patentably distinct from each other because it is clear that all the elements of claims of the application are to be found in claims of the copending application. The difference between claims of the application and claims of the copending application lies in the fact that the copending application claims include any more elements and are thus much more specific. Thus the invention of claims of the copending application is in effect a “species” of the “generic” invention of claims of the application. It has been held that the generic invention is “anticipated” by the “species”. See in re Goodman, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claims of the application are anticipated by claims of the copending application, they are not patentably distinct.

This is a provisional nonstatutory double patenting rejection because the patentably indistinct claims have not in fact been patented.

Response to Amendment

Applicant's arguments, see remarks, filed 10/27/17, with respect to claims 86-132, 135, 136, 138 have been fully considered and are persuasive. The art rejection of

the claims has been withdrawn. However, the double patenting rejection is still maintained. See rejection above.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PEDRO PHILOGENE whose telephone number is (571)272-4716. The examiner can normally be reached on Monday to Friday 8:00 AM to 4:30 PM.

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

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

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

/PEDRO PHILOGENE/
Primary Examiner, Art Unit 3733
November 29, 2017

Search Notes 	Application/Control No. 13210168	Applicant(s)/Patent Under Reexamination MOSKOWITZ ET AL.
	Examiner PEDRO PHILOGENE	Art Unit 3733

CPC- SEARCHED		
Symbol	Date	Examiner
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CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
623	17.11-17.16	11/29/2017	/P.P./
606	300-305,246, 99, 144, 151, 251, 266		
227	181.1		

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

SEARCH NOTES		
Search Notes	Date	Examiner
EAST search enclosed	11/29/2017	/P.P./

INTERFERENCE SEARCH

	/PEDRO PHILOGENE/ Primary Examiner.Art Unit 3733
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US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

	/PEDRO PHILOGENE/ Primary Examiner.Art Unit 3733
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<i>Index of Claims</i> 	Application/Control No. 13210168	Applicant(s)/Patent Under Reexamination MOSKOWITZ ET AL.
	Examiner PEDRO PHILOGENE	Art Unit 3733

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

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	Examiner PEDRO PHILOGENE	Art Unit 3733

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	Examiner PEDRO PHILOGENE	Art Unit 3733

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

☐ Claims renumbered in the same order as presented by applicant										☐ CPA		☐ T.D.		☐ R.1.47	
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	Examiner PEDRO PHILOGENE	Art Unit 3733

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

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47									
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EAST Search History

EAST Search History (Prior Art)

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11/ 29/ 2017 10:21:27 AM

Substitute Disclosure Form U.S. Department of Commerce Patent and Trademark Office Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))	Attorney Docket No. 45335-0009007	Application No. 13/210,168
	Applicant Ahmnon D. Moskowitz et al.	
	Filing Date August 15, 2011	Group Art Unit 3733

U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
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Examiner Signature /PEDRO PHILOGENE/	Date Considered 11/29/2017
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Substitute Disclosure Form

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /P.P/

Substitute Disclosure Form U.S. Department of Commerce Patent and Trademark Office Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))	Attorney Docket No. 45335-0009007	Application No. 13/210,168
	Applicant Ahmnon D. Moskowitz et al.	
	Filing Date August 15, 2011	Group Art Unit 3733

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Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor :	Ahmnon D. Moskowitz	Art Unit :	3733
Serial No. :	13/210,168	Examiner :	Pedro Philogene
Filed :	August 15, 2011	Conf. No. :	1609

Title : BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY
SCREWS AND POSTERIOR CERVICAL AND LUMBAR
INTERARTICULATING JOINT CALIBRATED STAPLING
DEVICES FOR SPINAL FUSION

MAIL STOP AF

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

REPLY TO ACTION OF DECEMBER 4, 2017

Please consider the following reply.

List of claims (replacing prior versions).

1-85. (Canceled)

86. (Previously Presented) A system to provide fusion of a first vertebral body to a second vertebral body via biological bone fusion and screw fusion, the system comprising:

an intervertebral cage comprising a top portion and a bottom portion with the top portion operably connected to the bottom portion, wherein the top portion and the bottom portion combine to form a top wall, a bottom wall, a first sidewall and a second sidewall, wherein the top wall is formed at least partially by the top portion and wherein the first sidewall, the second sidewall, and the bottom wall are formed at least partially by the bottom portion, and wherein the intervertebral cage defines:

at least one open space capable of receiving bone filling for biological bone fusion,

a first internal screw guide having a first entry opening and a first exit opening, the first entry opening formed at least partially in a top surface of the top portion at the top wall and the first exit opening formed at least partially in a bottom surface of the top portion at the top wall and at least partially in a first side surface of the top portion at the top wall,

a second internal screw guide having a second entry opening and a second exit opening, the second entry opening formed at least partially in the top surface of the top portion at the top wall and the second exit opening formed at least partially in the bottom surface of the top portion at the top wall and at least partially in a second side surface of the top portion at the top wall, wherein the first internal screw guide and the second internal screw guide are angled to orient screw members bi-directionally,

an indentation extending into the top surface of the top portion between

the first internal screw guide and the second internal screw guide at an angle that is substantially perpendicular to the top surface, wherein the indentation is defined by first and second parallel indentation sides and third and fourth parallel indentation sides that are perpendicular to the first and second parallel indentation sides, and wherein the indentation is positioned along a centerline axis of the intervertebral cage that bisects the top surface, and

a circular top hole extending into the top surface of the top portion between the first internal screw guide and the second internal screw guide at an angle that is substantially perpendicular to the top surface, wherein the circular top hole is positioned along the centerline axis of the intervertebral cage that bisects the top surface;

a first screw having a first screw head and a first threaded body that is sized and configured to be inserted through the first internal screw guide at a first angle so the first screw extends at least partially into the open space and at least partially next to the open space;

a second screw having a second screw head and a second threaded body that is sized and configured to be inserted through the second internal screw guide at a second angle different than the first angle; and

a tool configured for manipulating and inserting the intervertebral cage into a disc space between the first vertebral body and the second vertebral body to provide fusion of the first vertebral body to the second vertebral body via biological bone fusion and screw fusion, the tool comprising:

an elongate shaft;

a handle at a proximal end of the elongate shaft;

at least one projection extending distally away from a distal end of the

elongate shaft sized and configured to engage the intervertebral cage; and

a screw guide defining a first screw trajectory guide and a second screw trajectory guide for controlling a direction of the first screw and the second screw that are inserted into the first internal screw guide and the second internal screw guide of the intervertebral cage, wherein the projection extends distally past the first and second screw trajectory guides, and wherein when

the projection is engaged with the intervertebral cage the first and second screw trajectory guides of the tool are aligned with the first and second internal screw guides of the intervertebral cage..

87. (Previously Presented) The system of claim 86, wherein an internal surface of the internal screw guide extends continuously from the entry opening to the exit opening.

88. (Previously Presented) The system of claim 86, wherein the internal screw guide extends through an entire depth of the top wall from the top surface to the bottom surface and exiting at least partially into the open space.

89. (Previously Presented) The system of claim 86, wherein the internal screw guide permits only a predetermined angled trajectory of a screw member through the intervertebral cage.

90. (Previously Presented) The system of claim 86, wherein the internal screw guide has a 25 degree angulation.

91. (Previously Presented) The system of claim 86, wherein the top wall has a thickness extending from the top surface of the top wall to the bottom surface of the top wall in a direction of a depth of the intervertebral cage, a height of the intervertebral cage extending in a direction perpendicular to the depth, and

wherein an axis of the internal screw guide extends to a greater extent in the direction of the depth of the intervertebral cage than in a direction of a height of the intervertebral cage in order to facilitate multi-level fusion of adjacent vertebral bodies with multiple intervertebral cages.

92. (Previously Presented) The system of claim 86, wherein the top wall of the intervertebral cage has a thickness that is greater than a thickness of each of the sidewalls.

93. (Previously Presented) The system of claim 86, wherein the first and second side

holes are configured to allow placement of bone filling into the open space of the intervertebral cage for the biological bone fusion.

94. (Previously Presented) The system of claim 86, wherein the intervertebral cages includes indentations formed on surfaces of the two sidewalls and on opposite ends of the intervertebral cage for receiving ends of prongs of an implantation tool.

95. (Previously Presented) The system of claim 86, wherein a surface of each of the two sidewalls includes a plurality of ridges.

96-97. (Cancelled)

98. (Previously Presented) The system of claim 86, wherein the intervertebral cage is a cervical intervertebral cage configured to fit into a cervical disc space.

99. (Previously Presented) The system of claim 86, wherein the intervertebral cage is a lumbar intervertebral cage configured to fit into a lumbar disc space.

100. (Previously Presented) The system of claim 86, wherein the intervertebral cage is a posterior lumbar intervertebral cage configured to fit into a lumbar disc space.

101. (Previously Presented) The system of claim 86, wherein the intervertebral cage capable of one of posterior lumbar intervertebral placement, anterior lumbar intervertebral placement, thoracic intervertebral placement, and anterior cervical intervertebral placement.

102-105. (Cancelled)

106. (Previously Presented) The system of claim 86, wherein each of the internal screw guide and the second internal screw guide permits only a 25 degree angulation of a first screw member and the second screw member.

107. (Previously Presented) The system of claim 86, wherein the internal screw guide and the second internal screw guide are aligned along a longitudinal axis of the top wall of the intervertebral cage.

108. (Previously Presented) The system of claim 86, wherein the first internal screw guide and the second internal screw guide are symmetrically disposed on each side of a center point of the intervertebral cage along a longitudinal axis of the top wall of the intervertebral cage.

109. (Previously Presented) The system of claim 86, wherein the first internal screw guide and the second internal screw guide are offset in opposite directions with respect to a center line of a longitudinal extent of the top wall.

110. (Previously Presented) The system of claim 109, wherein a part of the first internal screw guide overlaps a part of the second internal screw guide along the longitudinal extent of the top wall.

111. (Previously Presented) The system of claim 86, wherein the first entry opening of the first internal screw guide and the second entry opening of the second internal screw guide are arranged diagonally on the top surface of the top wall.

112. (Previously Presented) The system of claim 86, wherein the top wall has four quadrants delineated by a first axis and a second axis each lying in a plane of the top wall, and the first axis is at a right angle with respect to the second axis,

wherein the four quadrants include a first quadrant, a second quadrant, a third quadrant, and a fourth quadrant,

wherein the first quadrant and the fourth quadrant are opposed to the second quadrant and the third quadrant with respect to the first axis, and the first quadrant and the second quadrant are opposed to the third quadrant and the fourth quadrant with respect to the second

axis,

wherein the first quadrant is diagonally opposed to the third quadrant, and the second quadrant is diagonally opposed to the fourth quadrant, and

wherein a majority of an area of the first entry opening of the first internal screw guide is in the first quadrant and a majority of an area of the second entry opening of the second internal screw guide is in the third quadrant.

113. (Previously Presented) The system of claim 86, wherein the top wall has four quadrants delineated by a first axis and a second axis each lying in a plane of the top wall, and the first axis is at a right angle with respect to the second axis,

wherein the four quadrants include a first quadrant, a second quadrant, a third quadrant, and a fourth quadrant,

wherein the first quadrant and the fourth quadrant are opposed to the second quadrant and the third quadrant with respect to the first axis, and the first quadrant and the second quadrant are opposed to the third quadrant and the fourth quadrant with respect to the second axis,

wherein the first quadrant is diagonally opposed to the third quadrant, and the second quadrant is diagonally opposed to the fourth quadrant, and

wherein a center of the first entry opening of the first internal screw guide is in the first quadrant and a center of the second entry opening of the second internal screw guide is in the third quadrant.

114. (Previously Presented) The system of claim 86, wherein the top wall includes a first corner and a second corner, the first corner being arranged at an opposite side of the top wall and an opposite end of the top wall with respect to the second corner, and

wherein the first internal screw guide and the second internal screw guide are diagonally arranged along a direction extending from the first corner of the top wall to the second corner of the top wall.

115. (Previously Presented) The system of claim 86, wherein the intervertebral cage

further comprises:

a third internal screw guide having a third entry opening and a third exit opening, the third entry opening formed at least partially in the top surface of the top portion at the top wall and the third exit opening formed at least partially in the bottom surface of the top portion at the top wall and at least partially in the side surface of the top wall.

116. (Previously Presented) The system of claim 115, wherein the intervertebral cage further comprises:

a fourth internal screw guide having a fourth entry opening and a fourth exit opening, the fourth entry opening formed at least partially in the top surface of the top portion at the top wall and the fourth exit opening formed at least partially in the bottom surface of the top portion at the top wall and at least partially in the second side surface of the top wall.

117. (Previously Presented) The system of claim 116, wherein the first internal screw guide and the fourth internal screw guide are oriented rostrally and the second internal screw guide and the third internal screw guide are oriented caudally.

118. (Previously Presented) The system of claim 116, wherein the second internal screw guide and the third internal screw guide are disposed between the first internal screw guide and the fourth internal screw guide along a longitudinal length of the top wall of the intervertebral cage.

119. (Previously Presented) The system of claim 116, wherein each of the first internal screw guide, the second internal screw guide, the third internal screw guide, and the fourth internal screw guide has a 25 degree angulation.

120-130. (Cancelled)

131. (Previously Presented) The system of claim 86, wherein the entry opening is formed

entirely in the top surface of the top wall.

132-138. (Canceled)

139. (Previously Presented) The system of claim 86, wherein the circular top hole is a threaded circular hole.

140. (Previously Presented) The system of claim 86, wherein the open space extends from an inner surface of the first sidewall to an inner surface of the second sidewall and extends from an inner surface of the top wall to an inner surface of the bottom wall.

141. (Previously Presented) The system of claim 86, and further comprising means for facilitating integration and fusion with superior and inferior vertebral bodies.

142. (Previously Presented) The system of claim 141, wherein the means is positioned at least partially on the first side surface of the top wall.

143. (Previously Presented) A system to provide fusion of a first vertebral body to a second vertebral body via biological bone fusion and screw fusion, the system comprising:

- an intervertebral cage comprising a top portion and a bottom portion with the top portion operably connected to the bottom portion, wherein the top portion and the bottom portion combine to form a top wall, a bottom wall, a first sidewall and a second sidewall, wherein the top portion forms the top wall and at least part of the first and second side walls, wherein the bottom portion forms the bottom wall and at least part of the first and second side walls, and wherein the intervertebral cage defines:

- at least one open space capable of receiving bone filling for biological bone fusion,

- a first side slot on the first sidewall;

- a second side slot on the second sidewall, wherein the second side slot is positioned opposite the first side slot,

a first internal screw guide having a first entry opening and a first exit opening, the first entry opening formed at least partially in a top surface of the top portion at the top wall and the first exit opening formed at least partially in a bottom surface of the top portion at the top wall and at least partially in a first side surface of the top portion at the top wall, and

a second internal screw guide having a second entry opening and a second exit opening, the second entry opening formed at least partially in the top surface of the top portion at the top wall and the second exit opening formed at least partially in the bottom surface of the top portion at the top wall and at least partially in a second side surface of the top portion at the top wall, wherein the first internal screw guide and the second internal screw guide are angled to orient screw members bi-directionally; and

a first screw having a first screw head and a first threaded body that is sized and configured to be inserted through the first internal screw guide at a first angle so the first screw extends at least partially into the open space and at least partially next to the open space;

a second screw having a second screw head and a second threaded body that is sized and configured to be inserted through the second internal screw guide at a second angle different than the first angle; and

a tool configured for manipulating and inserting the intervertebral cage into a disc space between the first vertebral body and the second vertebral body to provide fusion of the first vertebral body to the second vertebral body via biological bone fusion and screw fusion, the tool comprising:

an elongate shaft portion; and

a screw guide defining a first screw trajectory guide and a second screw trajectory guide for controlling a direction of insertion of the first screw and the second screw as they are inserted into the first internal screw guide and the second internal screw guide of the intervertebral cage, wherein when the tool is engaged with the intervertebral cage the first and second screw trajectory guides of the tool

are aligned with the first and second internal screw guides of the intervertebral cage.

144. (Previously Presented) The system of claim 143, wherein the elongate shaft has a handle at a proximal end and has the screw guide at a distal end.

145. (Previously Presented) The system of claim 143, wherein the open space extends from an inner surface of the first sidewall to an inner surface of the second sidewall and extends from an inner surface of the top wall to an inner surface of the bottom wall.

146. (Previously Presented) The system of claim 143, and further comprising means for facilitating integration and fusion with superior and inferior vertebral bodies.

147. (Previously Presented) The system of claim 146, wherein the means is positioned at least partially on the first side surface of the top wall.

148. (Previously Presented) The system of claim 146, wherein the tool comprises at least one projection extending distally away from a distal end of the elongate shaft sized and that is configured to engage the intervertebral cage, wherein when the projection is engaged with the intervertebral cage the first and second screw trajectory guides of the tool are aligned with the first and second internal screw guides of the intervertebral cage.

149. (Previously Presented) A system to provide fusion of a first vertebral body to a second vertebral body via biological bone fusion and screw fusion, the system comprising:

an intervertebral cage comprising a top portion and a bottom portion with the top portion operably connected to the bottom portion, wherein the top portion and the bottom portion combine to form a top wall, a bottom wall, a first sidewall and a second sidewall, wherein the top portion forms the top wall and at least part of the first and second side walls, wherein the bottom portion forms the bottom wall and at least part of the first and second side walls, and wherein the intervertebral cage defines:

at least one open space capable of receiving bone filling for biological bone fusion,

a first side slot on the first sidewall;

a second side slot on the second sidewall, wherein the second side slot is positioned opposite the first side slot,

a first internal screw guide having a first entry opening and a first exit opening, the first entry opening formed at least partially in a top surface of the top portion at the top wall and the first exit opening formed at least partially in a bottom surface of the top portion at the top wall and at least partially in a first side surface of the top portion at the top wall,

a second internal screw guide having a second entry opening and a second exit opening, the second entry opening formed at least partially in the top surface of the top portion at the top wall and the second exit opening formed at least partially in the bottom surface of the top portion at the top wall and at least partially in a second side surface of the top portion at the top wall, wherein the first internal screw guide and the second internal screw guide are angled to orient screw members bi-directionally, and

at least one indentation in the top surface of the top portion of the top wall positioned between the first internal screw guide and the second internal screw guide;

a first screw having a first screw head and a first threaded body that is sized and configured to be inserted through the first internal screw guide at a first angle so the first screw extends at least partially into the open space and at least partially next to the open space;

a second screw having a second screw head and a second threaded body that is sized and configured to be inserted through the second internal screw guide at a second angle different than the first angle so the second screw extends at least partially into the open space and at least partially next to the open space; and

a tool configured for manipulating and inserting the intervertebral cage into a disc space between the first vertebral body and the second vertebral body to provide fusion of

the first vertebral body to the second vertebral body via biological bone fusion and screw fusion, the tool comprising first and second gripper prongs at a distal end of the tool wherein the first gripper prong opposes the second gripper prong and is sized and configured to grip and hold the intervertebral cage while inserting the intervertebral cage, wherein the distal end of the tool is shaped to expose the first and second internal screw guides enough to allow a tool to screw the first and second screws in the first and second internal screw guides while the tool is holding the intervertebral cage.

150. (Previously Presented) The system of claim 149, wherein the open space extends from an inner surface of the first sidewall to an inner surface of the second sidewall and extends from an inner surface of the top wall to an inner surface of the bottom wall.

151. (Previously Presented) The system of claim 149, and further comprising means for facilitating integration and fusion with superior and inferior vertebral bodies.

152. (Previously Presented) The system of claim 149, wherein the at least one indentation in the top surface comprises first and second indentations in the top surface of the top portion of the top wall positioned between the first internal screw guide and the second internal screw guide.

153. (Previously Presented) The system of claim 152, wherein the first indentation comprises a threaded circular hole and the second indentation is substantially square shaped.

154. (Previously Presented) The system of claim 152, wherein the first and second indentations are both positioned along the centerline axis that bisects the top surface.

155. (Previously Presented) The system of claim 149, wherein the top portion is configured to engage the bottom portion with part of the top portion extending into the first and second slots.

156. (Previously Presented) The system of claim 149, wherein the intervertebral cage further comprises means for engaging the top portion to the bottom portion.

157. (Previously Presented) The system of claim 143, wherein the intervertebral cage further comprises means for engaging the top portion to the bottom portion.

158. (Previously Presented) The system of claim 86, wherein the intervertebral cage further comprises means for engaging the top portion to the bottom portion.

159. (Previously Presented) A system to provide fusion of a first vertebral body to a second vertebral body via biological bone fusion and screw fusion, the system comprising:

- an intervertebral cage comprising a top portion and a bottom portion with the top portion operably connected to the bottom portion, wherein the top portion and the bottom portion combine to form a top wall, a bottom wall, a first sidewall and a second sidewall, wherein the top wall is formed at least partially by the top portion and wherein the first sidewall, the second sidewall, and the bottom wall are formed at least partially by the bottom portion, and wherein the intervertebral cage defines:

- at least one open space capable of receiving bone filling for biological bone fusion,

- a first side hole extending through the first sidewall of the bottom portion;

- a second side hole extending through the second sidewall of the bottom portion, wherein the second side hole is positioned opposite the first side hole and wherein the first and second side holes are positioned nearer a bottom of the intervertebral cage than a top of the intervertebral cage,

- a first internal screw guide having a first entry opening and a first exit opening, the first entry opening formed at least partially in a top surface of the top portion at the top wall and the first exit opening formed at least partially in a bottom surface of the top portion at the top wall and at least partially in a first side surface of the top portion at the top wall,

- a second internal screw guide having a second entry opening and a second exit opening, the second entry opening formed at least partially in the top surface of the top portion at the top wall and the second exit opening formed at least

partially in the bottom surface of the top portion at the top wall and at least partially in a second side surface of the top portion at the top wall, wherein the first internal screw guide and the second internal screw guide are angled to orient screw members bi-directionally, and

a top hole extending into the top surface of the top portion between the first internal screw guide and the second internal screw guide at an angle that is substantially perpendicular to the top surface, wherein the top hole is smaller than the first and second internal screw guides and is positioned along a centerline axis of the intervertebral cage that bisects the top surface;

a first screw having a first screw head and a first threaded body that is sized and configured to be inserted through the first internal screw guide;

a second screw having a second screw head and a second threaded body that is sized and configured to be inserted through the second internal screw guide; and

a tool configured for manipulating and inserting the intervertebral cage into a disc space between the first vertebral body and the second vertebral body to provide fusion of the first vertebral body to the second vertebral body via biological bone fusion and screw fusion, the tool comprising:

an elongate shaft;

a handle at a proximal end of the elongate shaft;

at least one projection extending distally away from a distal end of the elongate shaft sized and configured to engage the intervertebral cage; and

a screw guide defining a first screw trajectory guide and a second screw trajectory guide for controlling a direction of the first screw and the second screw that are inserted into the first internal screw guide and the second internal screw guide of the intervertebral cage, wherein the projection extends distally past the first and second screw trajectory guides, and wherein when the projection is engaged with the intervertebral cage the first and second screw trajectory guides of the tool are aligned with the first and second internal screw guides of the intervertebral cage.

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160. (Previously Presented) The system of claim 159, wherein the intervertebral cage further comprises means for engaging the top portion to the bottom portion and wherein the system further comprises means for facilitating integration and fusion with superior and inferior vertebral bodies.

161. (New) The system of claim 159, wherein the top hole is a threaded circular hole.

162. (New) The system of claim 159, wherein the first and second entry openings are formed entirely in the top surface of the top wall.

163. (New) The system of claim 143, wherein the first and second entry openings are formed entirely in the top surface of the top wall.

164. (New) The system of claim 149, wherein the first and second entry openings are formed entirely in the top surface of the top wall.

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REMARKS

Claims 86-95, 98-101, 106-119, 131, and 139-160 are pending, with claims 86, 143, 149, and 159 being independent. With this amendment, claims 161-164 are added.

Double Patenting

Claims 86-95, 98-101, 106-119, 131, 139-160 were provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 93-141 of copending Application No. 13/210,162. Claims 86-95, 98-101, 106-119, 131, 139-160 were provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 84-133 of copending Application No. 13/210,157.

Without conceding the merits of this rejection but to expedite prosecution, a terminal disclaimer is filed herewith.

New Claims

New claims 161-164 depend from independent claims 143, 149, and 159 and are allowable for at least the same reasons as for those independent claims.

Request for Reconsideration

The Applicant respectfully requests prompt consideration and a Notice of Allowance. In the event that no Notice of Allowance will be provided in the next communication, Applicant requests that the Examiner telephone the undersigned attorney (612-337-2538) prior to the next communication so that prosecution on the merits may be expedited. It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendments herein do not

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signify concession of unpatentability of any claims prior to this amendment. Applicant hereby specifically reserves the right to prosecute the previously presented subject matter in a continuing application. Also, Applicant expressly reserves the right to prosecute claims of different or broader scope in a continuing application. The Patent Office should infer no (i) adoption of a position with respect to patentability, (ii) change in the Applicant's position with respect to any claim or subject matter of the invention, or (iii) acquiescence in any way to any position taken by the Office Action, based on the amendments made herein.

Please apply any necessary charges or credits to Deposit Account 06-1050, referencing the above attorney docket number.

Respectfully submitted,

Date: 12/13/2017

/Stuart A. Nelson/

Stuart A. Nelson

Reg. No. 63,947

Customer Number
Fish & Richardson P.C.
Telephone: (612) 337-2538
Facsimile: (877) 769-7945

61603586.doc

Electronic Acknowledgement Receipt	
EFS ID:	31219731
Application Number:	13210168
International Application Number:	
Confirmation Number:	1609
Title of Invention:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION
First Named Inventor/Applicant Name:	Ahmnon D. MOSKOWITZ
Customer Number:	26191
Filer:	Stuart A. Nelson/Abby Remer
Filer Authorized By:	Stuart A. Nelson
Attorney Docket Number:	45335-0009007
Receipt Date:	13-DEC-2017
Filing Date:	15-AUG-2011
Time Stamp:	17:07:17
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no				
File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		Response.pdf	117105 cdde84de52df8df3b17df28e4b5706c7a61f4d40	yes	18

Multipart Description/PDF files in .zip description			
Document Description		Start	End
Response After Final Action		1	1
Claims		2	16
Applicant Arguments/Remarks Made in an Amendment		17	18
Warnings:			
Information:			
Total Files Size (in bytes):		117105	
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Doc Code: DIST.E.FILE Document Description: Electronic Terminal Disclaimer - Filed		PTO/SB/25 U.S. Patent and Trademark Office Department of Commerce	
Electronic Petition Request	TERMINAL DISCLAIMER TO OBTAIN A PROVISIONAL DOUBLE PATENTING REJECTION OVER A PENDING "REFERENCE" APPLICATION		
Application Number	13210168		
Filing Date	15-Aug-2011		
First Named Inventor	Ahmnon MOSKOWITZ		
Attorney Docket Number	45335-0009007		
Title of Invention	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION		
☒ Filing of terminal disclaimer does not obviate requirement for response under 37 CFR 1.111 to outstanding Office Action ☒ This electronic Terminal Disclaimer is not being used for a Joint Research Agreement.			
Owner		Percent Interest	
Nathan C. Moskowitz		100%	
The owner(s) of percent interest listed above in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of any patent granted on pending reference Application Number(s)			
13210157 filed on 08/15/2011 13210162 filed on 08/15/2011 as the term of any patent granted on said reference application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending reference application. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and any patent granted on the reference application are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns. In making the above disclaimer, the owner does not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term of any patent granted on said reference application, "as the term of any patent granted on said reference application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending reference application," in the event that any such patent granted on the pending reference application: expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321, has all claims canceled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term as shortened by any terminal disclaimer filed prior to its grant.			
☒ Terminal disclaimer fee under 37 CFR 1.20(d) is included with Electronic Terminal Disclaimer request.			

☐ I certify, in accordance with 37 CFR 1.4(d)(4), that the terminal disclaimer fee under 37 CFR 1.20(d) required for this terminal disclaimer has already been paid in the above-identified application.	
Applicant claims the following fee status: ☒ Small Entity ☐ Micro Entity ☐ Regular Undiscounted	
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.	
THIS PORTION MUST BE COMPLETED BY THE SIGNATORY OR SIGNATORIES I certify, in accordance with 37 CFR 1.4(d)(4) that I am: ☒ An attorney or agent registered to practice before the Patent and Trademark Office who is of record in this application Registration Number <u>63947</u> ☐ A sole inventor ☐ A joint inventor; I certify that I am authorized to sign this submission on behalf of all of the inventors as evidenced by the power of attorney in the application ☐ A joint inventor; all of whom are signing this request	
Signature	/Stuart A. Nelson/
Name	Stuart A. Nelson

*Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner).
 Form PTO/SB/96 may be used for making this certification. See MPEP § 324.

Electronic Patent Application Fee Transmittal				
Application Number:		13210168		
Filing Date:		15-Aug-2011		
Title of Invention:		BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION		
First Named Inventor/Applicant Name:		Ahmnon D. MOSKOWITZ		
Filer:		Stuart A. Nelson		
Attorney Docket Number:		45335-0009007		
Filed as Small Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
STATUTORY OR TERMINAL DISCLAIMER	2814	1	160	160
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				160

Doc Code: DISQ.E.FILE

Document Description: Electronic Terminal Disclaimer – Approved

Application No.: 13210168

Filing Date: 15-Aug-2011

Applicant/Patent under Reexamination: MOSKOWITZ

Electronic Terminal Disclaimer filed on December 13, 2017

☒ APPROVED

This patent is subject to a terminal disclaimer

☐ DISAPPROVED

Approved/Disapproved by: Electronic Terminal Disclaimer automatically approved by EFS-Web

U.S. Patent and Trademark Office

Electronic Acknowledgement Receipt	
EFS ID:	31220057
Application Number:	13210168
International Application Number:	
Confirmation Number:	1609
Title of Invention:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION
First Named Inventor/Applicant Name:	Ahmnon D. MOSKOWITZ
Customer Number:	26191
Filer:	Stuart A. Nelson
Filer Authorized By:	
Attorney Docket Number:	45335-0009007
Receipt Date:	13-DEC-2017
Filing Date:	15-AUG-2011
Time Stamp:	17:24:14
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	\$ 160
RAM confirmation Number	121417INTEFSW00004710061050
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Authorized User	
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File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Terminal Disclaimer-Filed (Electronic)	eTerminal-Disclaimer.pdf	36837	no	2
			cd9cd8214dfaa2ee021060447d20447dd6fc9210		
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30844	no	2
			aec0e44e14e57427cc99bb8bf3b6070e0c8c35e6		
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 13/210,168	Filing Date 08/15/2011	☐ To be Mailed
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ENTITY: ☐ LARGE ☒ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

FOR	NUMBER FILED (Column 1)	NUMBER EXTRA (Column 2)	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), (j), 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 \$ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X \$ =	
☐ 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

AMENDMENT	12/13/2017	CLAIMS REMAINING AFTER AMENDMENT	MINUS	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)
	Total (37 CFR 1.16(i))	* 55	Minus	** 60	= 0	x \$40 =	0
	Independent (37 CFR 1.16(h))	* 4	Minus	*** 5	= 0	x \$210 =	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

AMENDMENT	CLAIMS REMAINING AFTER AMENDMENT	MINUS	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)
	Total (37 CFR 1.16(i))	*	Minus	**	=	X \$ =
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X \$ =
	☐ 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.
 ** 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 number found in the appropriate box in column 1.

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This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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NOTICE OF ALLOWANCE AND FEE(S) DUE

26191 7590 01/11/2018
FISH & RICHARDSON P.C. (TC)
PO BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER

PHILOGENE, PEDRO

ART UNIT

PAPER NUMBER

3733

DATE MAILED: 01/11/2018

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/210,168	08/15/2011	Ahmnnon D. MOSKOWITZ	45335-0009007	1609

TITLE OF INVENTION: BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$480	\$0	\$0	\$480	04/11/2018

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

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26191 7590 01/11/2018
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(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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13/210,168 08/15/2011 Ahmnon D. MOSKOWITZ 45335-0009007 1609

TITLE OF INVENTION: BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
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nonprovisional SMALL \$480 \$0 \$0 \$480 04/11/2018

EXAMINER	ART UNIT	CLASS-SUBCLASS
PHIOLOGENE, PEDRO	3733	606-251000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

- (1) The names of up to 3 registered patent attorneys or agents OR, alternatively, 1 _____
- (2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2 _____
- 3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
- ☐ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☐ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)

- ☐ Applicant certifying micro entity status. See 37 CFR 1.29
- ☐ Applicant asserting small entity status. See 37 CFR 1.27
- ☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/210,168	08/15/2011	Ahmnon D. MOSKOWITZ	45335-0009007	1609

26191 7590 01/11/2018
FISH & RICHARDSON P.C. (TC)
PO BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER

PHILOGENE, PEDRO

ART UNIT	PAPER NUMBER
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3733

DATE MAILED: 01/11/2018

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. 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.

Privacy Act Statement

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

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

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 13/210,168	Applicant(s) MOSKOWITZ ET AL.	
	Examiner PEDRO PHILOGENE	Art Unit 3733	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to applicant's amendment filed 12/13/17.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are 86-95,98-101,106-119,131,139-164. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a) ☐ All b) ☐ Some *c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: ____.

Applicant has **THREE MONTHS FROM THE "MAILING DATE"** of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in **ABANDONMENT** of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ **CORRECTED DRAWINGS** (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date ____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ **DEPOSIT OF and/or INFORMATION** about the deposit of **BIOLOGICAL MATERIAL** must be submitted. Note the attached Examiner's comment regarding **REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL**.

Attachment(s)

- | | |
|--|---|
| 1. ☐ Notice of References Cited (PTO-892) | 5. ☐ Examiner's Amendment/Comment |
| 2. ☐ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date ____ | 6. ☐ Examiner's Statement of Reasons for Allowance |
| 3. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 7. ☐ Other ____. |
| 4. ☐ Interview Summary (PTO-413),
Paper No./Mail Date ____. | |

/PEDRO PHILOGENE/
Primary Examiner, Art Unit 3733

Search Notes 	Application/Control No. 13210168	Applicant(s)/Patent Under Reexamination MOSKOWITZ ET AL.
	Examiner PEDRO PHILOGENE	Art Unit 3733

CPC- SEARCHED		
Symbol	Date	Examiner
A61B17/0642, A61B17/809, A61B17/8894, A61F2/4465, A61F2/447, A61F2/4611, A61B17/7064	12/22/2017	/P.P./
A61F2250/0007, A61B17/86, A61B2017/0641, A61B2017/0648, A61B2017/922, A61F2002/2835, A61F2002/30133, A61F2002/30387, A61F2002/30448, A61F2002/30507		
A61F2002/3055, A61F2002/30579, A61F2002/30604, A61F2002/30772, A61F2002/30878, A61F2002/4475, A61F2002/448, A61F2002/4627, A61F2002/4681, A61F2220/0025, A61F2220/005, A61F2230/0015		

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
623	17.11-17.16	12/22/2017	/P.P./
606	300-305,246, 99, 144, 151, 251, 266		
227	181.1		

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

SEARCH NOTES		
Search Notes	Date	Examiner
EAST search enclosed	12/22/2017	/P.P./

INTERFERENCE SEARCH

	/PEDRO PHILOGENE/ Primary Examiner.Art Unit 3733
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US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
623	17.16	12/22/2017	/P,P./
Interference Search History Printout		12/22/2017	/P.P./

	/PEDRO PHILOGENE/ Primary Examiner.Art Unit 3733
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor :	Ahmnon D. Moskowitz	Art Unit :	3733
Serial No. :	13/210,168	Examiner :	Pedro Philogene
Filed :	August 15, 2011	Conf. No. :	1609

Title : BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY
SCREWS AND POSTERIOR CERVICAL AND LUMBAR
INTERARTICULATING JOINT CALIBRATED STAPLING
DEVICES FOR SPINAL FUSION

MAIL STOP AF

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

REPLY TO ACTION OF DECEMBER 4, 2017

Please consider the following reply.

OK TO ENTER: /P.P/

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	55	moskowitz near ahmnon.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2017/12/22 10:13
L2	81	moskowitz near mosheh.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2017/12/22 10:13
L3	80	moskowitz near nathan.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2017/12/22 10:13
L4	4	pablo near valdivia.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2017/12/22 10:14
L5	0	pablo near valdivia.in. & (insertor or inserter or insertion near device) same screw near guide & (interveertebral or vertebral or spine or spinal) & (cage or implant or spacer or disc or prosthesis)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2017/12/22 10:17
L6	2	moskowitz near ahmnon.in. & (insertor or inserter or insertion near device) same screw near guide & (interveertebral or vertebral or spine or spinal) & (cage or implant or spacer or disc or prosthesis)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2017/12/22 10:17
L7	2	moskowitz near mosheh.in. & (insertor or inserter or insertion near device) same screw near guide & (interveertebral or vertebral or spine or spinal) & (cage or implant or spacer or disc or prosthesis)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2017/12/22 10:18
L8	2	moskowitz near nathan.in. & (insertor or	US-PGPUB;	OR	ON	2017/12/22

		inserter or insertion near device) same screw near guide & (intervertebral or vertebral or spine or spinal) & (cage or implant or spacer or disc or prosthesis)	USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB			10:18
L9	2	moskowitz near nathan.in. & (inserter or inserter or insertion near device) same screw near guide & (intervertebral or vertebral or spine or spinal) & (cage or implant or spacer or disc or prosthesis)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2017/12/22 10:18
L10	23	(inserter or inserter or insertion near device) same screw near guide & (intervertebral or vertebral or spine or spinal) & (cage or implant or spacer or disc or prosthesis)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2017/12/22 10:19
L12	157	(inserter or inserter or insertion near device) & screw near guide & (intervertebral or vertebral or spine or spinal) & (cage or implant or spacer or disc or prosthesis)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2017/12/22 10:21
L13	1	"20130018468"	US-PGPUB; USPAT	OR	OFF	2017/12/22 10:21
L14	1	"20130018469"	US-PGPUB; USPAT	OR	OFF	2017/12/22 10:24
L15	1	14 AND ((A61B17/0642 OR A61B17/7064 OR A61B17/809 OR A61B17/86 OR A61B17/8635 OR A61B17/8894 OR A61B17/92 OR A61B2017/00407 OR A61B2017/0641 OR A61B2017/0648 OR A61B2017/922 OR A61F2002/2835 OR A61F2002/30133 OR A61F2002/30387 OR A61F2002/30448 OR A61F2002/30507 OR A61F2002/3055 OR A61F2002/30579 OR A61F2002/30604 OR A61F2002/30772 OR A61F2002/30878 OR A61F2002/30879 OR A61F2002/30904 OR A61F2002/4475 OR A61F2002/448 OR A61F2002/4627 OR A61F2002/4681 OR A61F2002/4687 OR A61F2220/0025 OR A61F2220/005 OR A61F2230/0015 OR A61F2250/0007 OR A61F2/4465 OR A61F2/447 OR A61F2/4611).CPC. OR (623/17.11-17.16 or 606/246-279,99,100,96,151,144).CCLS. OR (A61F2/44).IPCR.)	US-PGPUB; USPAT	OR	OFF	2017/12/22 10:26
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		A61F2002/30904 OR A61F2002/4475 OR A61F2002/448 OR A61F2002/4627 OR A61F2002/4681 OR A61F2002/4687 OR A61F2220/0025 OR A61F2220/005 OR A61F2230/0015 OR A61F2250/0007 OR A61F2/4465 OR A61F2/447 OR A61F2/4611).CPC. OR (623/17.11-17.16 or 606/246-279,99,100,96,151,144).CCLS. OR (A61F2/44).IPC.)				
L18	5961	A61F002/44.ipc.	USPAT; FPRS; EPO; JPO; DERWENT; IBM TDB	OR	OFF	2017/12/22 10:29

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L11	6	(insertor or inserter or insertion near device) same screw near guide & (intervertebral or vertebral or spine or spinal) & (cage or implant or spacer or disc or prosthesis).clm.	USPAT	OR	ON	2017/12/22 10:20
L17	4531	(623/17.16).CCLS.	US- PGPUB; USPAT	OR	OFF	2017/12/22 10:28

12/ 22/ 2017 10:29:49 AM

<i>Index of Claims</i> 	Application/Control No. 13210168	Applicant(s)/Patent Under Reexamination MOSKOWITZ ET AL.
	Examiner PEDRO PHILOGENE	Art Unit 3733

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

☐ Claims renumbered in the same order as presented by applicant											☐ CPA		☒ T.D.		☐ R.1.47	
CLAIM		DATE														
Final	Original	02/04/2015	10/27/2015	05/04/2016	01/22/2017	06/27/2017	11/29/2017	12/22/2017								
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	36	-	-	-	-	-	-	-								

<i>Index of Claims</i> 	Application/Control No. 13210168	Applicant(s)/Patent Under Reexamination MOSKOWITZ ET AL.
	Examiner PEDRO PHILOGENE	Art Unit 3733

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

☐ Claims renumbered in the same order as presented by applicant											☐ CPA											☒ T.D.											☐ R.1.47										
CLAIM		DATE																																									
Final	Original	02/04/2015	10/27/2015	05/04/2016	01/22/2017	06/27/2017	11/29/2017	12/22/2017																																			
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<i>Index of Claims</i> 	Application/Control No. 13210168	Applicant(s)/Patent Under Reexamination MOSKOWITZ ET AL.
	Examiner PEDRO PHILOGENE	Art Unit 3733

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

☐ Claims renumbered in the same order as presented by applicant											☐ CPA											☒ T.D.											☐ R.1.47										
CLAIM		DATE																																									
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17	108	✓	✓	✓	✓	✓	✓	=																																			

<i>Index of Claims</i> 	Application/Control No. 13210168	Applicant(s)/Patent Under Reexamination MOSKOWITZ ET AL.
	Examiner PEDRO PHILOGENE	Art Unit 3733

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

☐ Claims renumbered in the same order as presented by applicant											☐ CPA		☒ T.D.		☐ R.1.47	
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<i>Index of Claims</i> 	Application/Control No. 13210168	Applicant(s)/Patent Under Reexamination MOSKOWITZ ET AL.
	Examiner PEDRO PHILOGENE	Art Unit 3733

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

☐ Claims renumbered in the same order as presented by applicant											☐ CPA		☒ T.D.		☐ R.1.47	
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Issue Classification 	Application/Control No. 13210168	Applicant(s)/Patent Under Reexamination MOSKOWITZ ET AL.	
	Examiner PEDRO PHILOGENE	Art Unit 3733	

CPC						
Symbol					Type	Version
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(Assistant Examiner) _____ (Date) _____ /PEDRO PHILOGENE/ Primary Examiner.Art Unit 3733 (Primary Examiner) _____ (Date) _____						
					O.G. Print Claim(s)	O.G. Print Figure
					1	1B

Issue Classification 	Application/Control No. 13210168	Applicant(s)/Patent Under Reexamination MOSKOWITZ ET AL.
	Examiner PEDRO PHILOGENE	Art Unit 3733

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CPC Combination Sets				
Symbol	Type	Set	Ranking	Version

NONE		Total Claims Allowed:	
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(Date)			
/PEDRO PHILOGENE/ Primary Examiner.Art Unit 3733	12/22/2017	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1B

Issue Classification 	Application/Control No. 13210168	Applicant(s)/Patent Under Reexamination MOSKOWITZ ET AL.
	Examiner PEDRO PHILOGENE	Art Unit 3733

US ORIGINAL CLASSIFICATION						INTERNATIONAL CLASSIFICATION													
CLASS		SUBCLASS				CLAIMED					NON-CLAIMED								
623		17.16				A	6	1	F	2 / 44 (2006.01.01)									
CROSS REFERENCE(S)																			
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)																		

NONE		Total Claims Allowed:	
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(Assistant Examiner)	(Date)		
/PEDRO PHILOGENE/ Primary Examiner.Art Unit 3733	12/22/2017	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1B

Issue Classification 	Application/Control No. 13210168	Applicant(s)/Patent Under Reexamination MOSKOWITZ ET AL.
	Examiner PEDRO PHILOGENE	Art Unit 3733

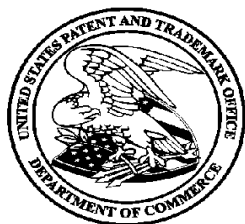
☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☒ T.D. ☐ R.1.47															
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NONE		Total Claims Allowed:	
		55	
(Assistant Examiner)	(Date)		
/PEDRO PHILOGENE/ Primary Examiner.Art Unit 3733	12/22/2017	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1B

UNITED STATES PATENT AND TRADEMARK OFFICE
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FISH & RICHARDSON P.C. (TC)
PO BOX 1022
MINNEAPOLIS, MN 55440-1022



**Courtesy Reminder for
Application Serial No: 13/210,168**

Attorney Docket No: 45335-0009007

Customer Number: 26191

Date of Electronic Notification: 01/11/2018

This is a courtesy reminder that new correspondence is available for this application. If you have not done so already, please review the correspondence. The official date of notification of the outgoing correspondence will be indicated on the form PTOL-90 accompanying the correspondence.

An email notification regarding the correspondence was sent to the following email address(es) associated with your customer number:
PATDOCTC@fr.com

To view your correspondence online or update your email addresses, please visit us anytime at <https://sportal.uspto.gov/secure/myportal/privatepair>. If you have any questions, please email the Electronic Business Center (EBC) at EBC@uspto.gov or call 1-866-217-9197.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor : Ahmnon D. Art Unit : 3733
Moskowitz Examiner : Pedro Philogene
Serial No. : 13/210,168 Confirmation No. : 1609
Filed : August 15, 2011 Notice of Allowance Date: January 11, 2018

Title : BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY
SCREWS AND POSTERIOR CERVICAL AND LUMBAR
INTERARTICULATING JOINT CALIBRATED STAPLING
DEVICES FOR SPINAL FUSION

MAIL STOP ISSUE FEE

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

REPLY TO NOTICE OF ALLOWANCE

In response to the Notice of Allowance dated January 11, 2018, enclosed is a completed Part B - Fee(s) Transmittal.

The issue fee is being paid with this reply on the Electronic Filing System. Apply those fees and any other necessary charges or credits to Deposit Account 06-1050, referencing the above attorney docket number.

Respectfully submitted,

Date: 1/19/2018

/Stuart A. Nelson/
Stuart A. Nelson
Reg. No. 63,947

Customer Number
Fish & Richardson P.C.
Telephone: (612) 766-2049
Facsimile: (877) 769-7945

61622485.doc

PART B - FEE(S) TRANSMITTAL

**Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885**

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

26191 7590 01/11/2018

FISH & RICHARDSON P.C.
P.O. BOX 1022
MINNEAPOLIS, MN 55440-1022

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/210,168	08/15/2011	Ahmnon D. Moskowitz	45335-0009007	1609

TITLE OF INVENTION: BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$500	\$0		\$500	04/11/2018

EXAMINER	ART UNIT	CLASS-SUBCLASS
PHIOGENE, PEDRO	3733	606-251000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,

1 Fish & Richardson P.C.

(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

Nathan C. Moskowitz

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Rockville, MD

Please check the appropriate assignee category or categories (will not be printed on the patent): ☒ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

☒ Issue Fee

☐ Publication Fee (No small entity discount permitted)

☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): (**Please first reapply any previously paid issue fee shown above**)

☐ A check in the amount of the fee(s) is enclosed.

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

☒ The Director is hereby authorized to charge the required fee(s), or credit any overpayment, to Deposit Account Number 06-1050.

5. **Change in Entity Status** (from status indicated above)

☐ Applicant certifying micro entity status. See 37 CFR 1.29

☐ Applicant asserting small entity status. See 37 CFR 1.27.

☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see form PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

The Director of the USPTO is requested to apply the Issue Fee and Publication Fee (if any) or to re-apply any previously paid issue fee to the application identified above.

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature /Stuart A. Nelson/

Date 1/19/2018

Typed or printed name Stuart A. Nelson

Registration No. 63,947

Electronic Patent Application Fee Transmittal				
Application Number:		13210168		
Filing Date:		15-Aug-2011		
Title of Invention:		BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION		
First Named Inventor/Applicant Name:		Ahmnon D. MOSKOWITZ		
Filer:		Stuart A. Nelson/Abby Remer		
Attorney Docket Number:		45335-0009007		
Filed as Small Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
UTILITY APPL ISSUE FEE	2501	1	480	480

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				480

Electronic Acknowledgement Receipt	
EFS ID:	31553820
Application Number:	13210168
International Application Number:	
Confirmation Number:	1609
Title of Invention:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION
First Named Inventor/Applicant Name:	Ahmnon D. MOSKOWITZ
Customer Number:	26191
Filer:	Stuart A. Nelson/Brenda Jurgens
Filer Authorized By:	Stuart A. Nelson
Attorney Docket Number:	45335-0009007
Receipt Date:	19-JAN-2018
Filing Date:	15-AUG-2011
Time Stamp:	16:05:02
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	\$480
RAM confirmation Number	012218INTEFSW00002949061050
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
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Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	31066	no	2
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Information:					
Total Files Size (in bytes):			159554		
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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/210,168	03/06/2018	9907674	45335-0009007	1609

26191 7590 02/14/2018
FISH & RICHARDSON P.C. (TC)
PO BOX 1022
MINNEAPOLIS, MN 55440-1022

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment is 329 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site <http://pair.uspto.gov> for additional applicants):

Ahmnon D. MOSKOWITZ, Rockville, MD;
Pablo A Valdivia Y ALVARADO, Cambridge, MA;
Mosheh T. MOSKOWITZ, Rockville, MD;
Nathan C. MOSKOWITZ, Rockville, MD;

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor : Ahmnon D. Moskowitz Art Unit : 3733
Patent No. : 9,907,674 Examiner : Pedro Philogene
Issue Date : March 6, 2018 Conf. No. : 1609
Serial No. : 13/210,168
Filed : August 15, 2011
Title : BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND
POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT
CALIBRATED STAPLING DEVICES FOR SPINAL FUSION

Attention Certificate of Corrections Branch
Commissioner for Patents
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REQUEST FOR CERTIFICATE OF CORRECTION

Please issue a certificate of correction in accordance with the attached form.

All errors to be corrected were made in printing by the Patent and Trademark Office, and no fee is believed to be due.

Apply any other necessary charges or credits to Deposit Account 06-1050, referencing the above attorney docket number.

Respectfully submitted,

Date: 4/17/2018

/Stuart A. Nelson/
Stuart A. Nelson
Reg. No. 63,947

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Fish & Richardson P.C.
Telephone: (612) 337-2538
Facsimile: (877) 769-7945

61666657.doc

**UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION**

Page 1 of 1

PATENT NO. : 9,907,674
APPLICATION NO.: 13/210,168
ISSUE DATE : March 6, 2018
INVENTOR(S) : Ahmnon D. Moskowitz, Pablo A. Valdivia Y. Alvarado, Mosheh T. Moskowitz and Nathan C. Moskowitz

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 13, Line 8 (Claims): In Claim 1, delete "sy stem" and insert - - system - -, therefor.

Column 15, Line 21 (Claims): In Claim 19, delete "claim 15," and insert - - claim 18, - -, therefor.

Column 16, Line 54 (Claims): In Claim 34, delete "sy stem" and insert - - system - -, therefor.

Column 18, Line 6 (Claims): In Claim 41, delete "sy stem" and insert - - system - -, therefor.

Column 19, Line 39 (Claims): In Claim 52, delete "sy stem" and insert - - system - -, therefor.

MAILING ADDRESS OF SENDER (Please do not use customer number below):

Fish & Richardson P.C.
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Electronic Acknowledgement Receipt	
EFS ID:	32370607
Application Number:	13210168
International Application Number:	
Confirmation Number:	1609
Title of Invention:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION
First Named Inventor/Applicant Name:	Ahmnon D. MOSKOWITZ
Customer Number:	26191
Filer:	Stuart A. Nelson/Abby Remer
Filer Authorized By:	Stuart A. Nelson
Attorney Docket Number:	45335-0009007
Receipt Date:	18-APR-2018
Filing Date:	15-AUG-2011
Time Stamp:	11:41:35
Application Type:	Utility under 35 USC 111(a)

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Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Request for Certificate of Correction	COC.pdf	104702	no	2
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Total Files Size (in bytes):	104702
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CERTIFICATE OF CORRECTION

PATENT NO. : 9,907,674 B2
APPLICATION NO. : 13/210168
DATED : March 6, 2018
INVENTOR(S) : Ahmnon D. Moskowitz et al.

Page 1 of 1

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In the Claims

Column 13, Line 8: In Claim 1, delete “sy stem” and insert -- system --, therefor.

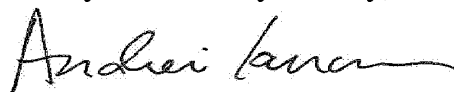
Column 15, Line 21: In Claim 19, delete “claim 15,” and insert -- claim 18, --, therefor.

Column 16, Line 54: In Claim 34, delete “sy stem” and insert -- system --, therefor.

Column 18, Line 6: In Claim 41, delete “sy stem” and insert -- system --, therefor.

Column 19, Line 39: In Claim 52, delete “sy stem” and insert -- system --, therefor.

Signed and Sealed this
Twenty-second Day of May, 2018



Andrei Iancu
Director of the United States Patent and Trademark Office