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May 10, 2018

Attorney Docket No.: 46440-0009013

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

Presented for filing is a new continuation patent application for prioritized examination of:

Inventor(s): AHMNON D. MOSKOWITZ, PABLO A. VALDIVIA Y. ALVARADO, MOSHEH T. MOSKOWITZ AND NATHAN C. MOSKOWITZ

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

Enclosed are the following papers, including those required to receive a filing date under 37 CFR 1.53(b):

	Pages
Specification	27
Claims	2
Abstract	1
Drawing(s)	28

Enclosures:

— Application Data Sheet, 10 pages.
— Power of Attorney, 2 pages.
— Certification and Request for Prioritized Examination (Track I), 1 page

The applicant claims small entity status under 37 CFR 1.27.

Basic Filing Fee	$75
Search Fee	$330
Examination Fee	$380

MEDTRONIC EXHIBIT 1050
Medtronic, Inc. v. Moskowitz Family LLC
IPR2026-00163

Publication fee			$0
Track I processing fee			$70
Track I prioritized examination fee			$2000
Total Claims 10	over 20	**0 x $50**	$0
Independent Claims 2	over 3	**0 x $230**	$0
Fee for Multiple Dependent claims			$0
Application size fee for each 50 pages over 100 Total Sheets: 58x .75 - 100/50 = 0x			$0
Surcharge for late filing fee, search fee, examination fee or oath or declaration			$80
Total Filing fee			$2935

The total filing fee is being paid concurrently on the Electronic Filing System (EFS) by deposit account authorization. Apply any other required fees or any credits to Deposit Account No. 06-1050, referencing the attorney docket number shown above.

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If this application is considered to be incomplete, or if a telephone conference would otherwise be helpful, call the undersigned at (612) 337-2538.

Send all correspondence to:

26191
Customer Number

Respectfully submitted,

/Stuart A. Nelson/

Stuart A. Nelson

Registration No. 63,947

Enclosures
SWN/aur
61682742.doc

TRANSMITTAL FOR POWER OF ATTORNEY TO ONE OR MORE REGISTERED PRACTITIONERS

Application Number	To Be Assigned
Filing Date	Herewith
First Named Inventor	Ahmnon D. Moskowitz
Title	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION
Art Unit	Unknown
Examiner Name	Unknown
Attorney Docket Number	46440-0009013

SIGNATURE of Applicant or Patent Practitioner

Signature	/Stuart A. Nelson/	Date (Optional)	5/10/2018
Name	Stuart A. Nelson	Registration Number	63,947
Title (if Applicant is a juristic entity)			
Applicant Name (if Applicant is a juristic entity)			

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

☐ *Total of _____ forms are submitted.

61682678.doc

POWER OF ATTORNEY BY APPLICANT

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

Application Number	Filing Date

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☒ I hereby appoint the Patent Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter, which may be an application filed after the date of this power of attorney, or identified above:

26191

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☐ I hereby appoint Practitioner(s) named in the attached list as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the patent application referenced in the attached transmittal letter, which may be an application filed after the date of this power of attorney, or identified above.

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OR

Firm or Individual Name					
Address					
City		State		Zip	
Country					
Telephone		Email			

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

Moskowitz Family LLC

☐ Inventor or Joint Inventor (title not required below)

☐ Legal Representative of a Deceased or Legally Incapacitated Inventor (title not required below)

☒ Assignee or Person to Whom the Inventor is Under an Obligation to Assign (provide signer's title if applicant is a juristic entity)

☐ Person Who Otherwise Shows Sufficient Proprietary Interest (e.g., a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document) (provide signer's title if applicant is a juristic entity)

SIGNATURE of Applicant for Patent

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

Signature	Nathan C. Moskowitz	Date (Optional)	9/17/16
Name	Nathan C. Moskowitz		
Title	Manager, Moskowitz Family LLC		

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

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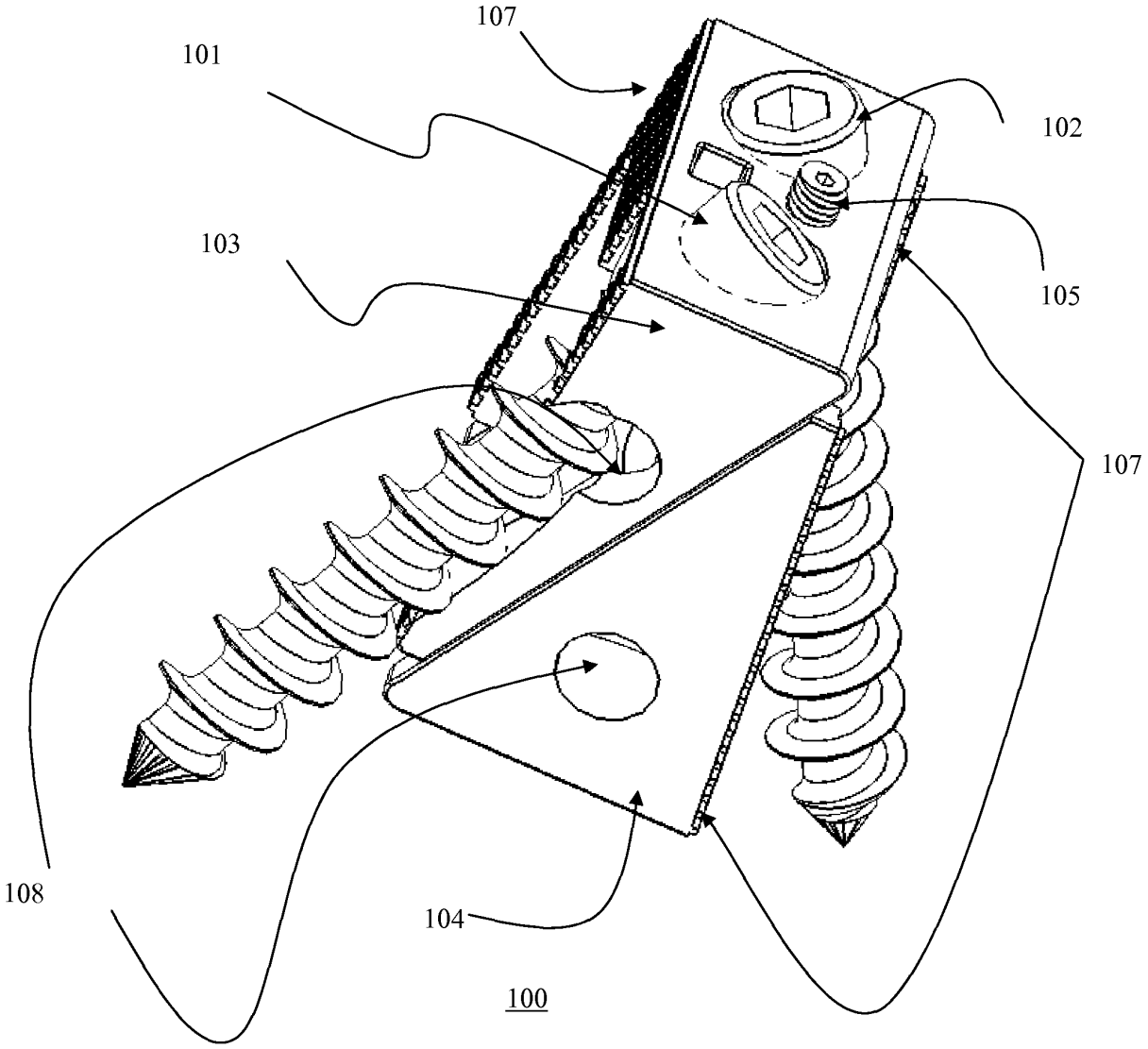


Fig. 1A

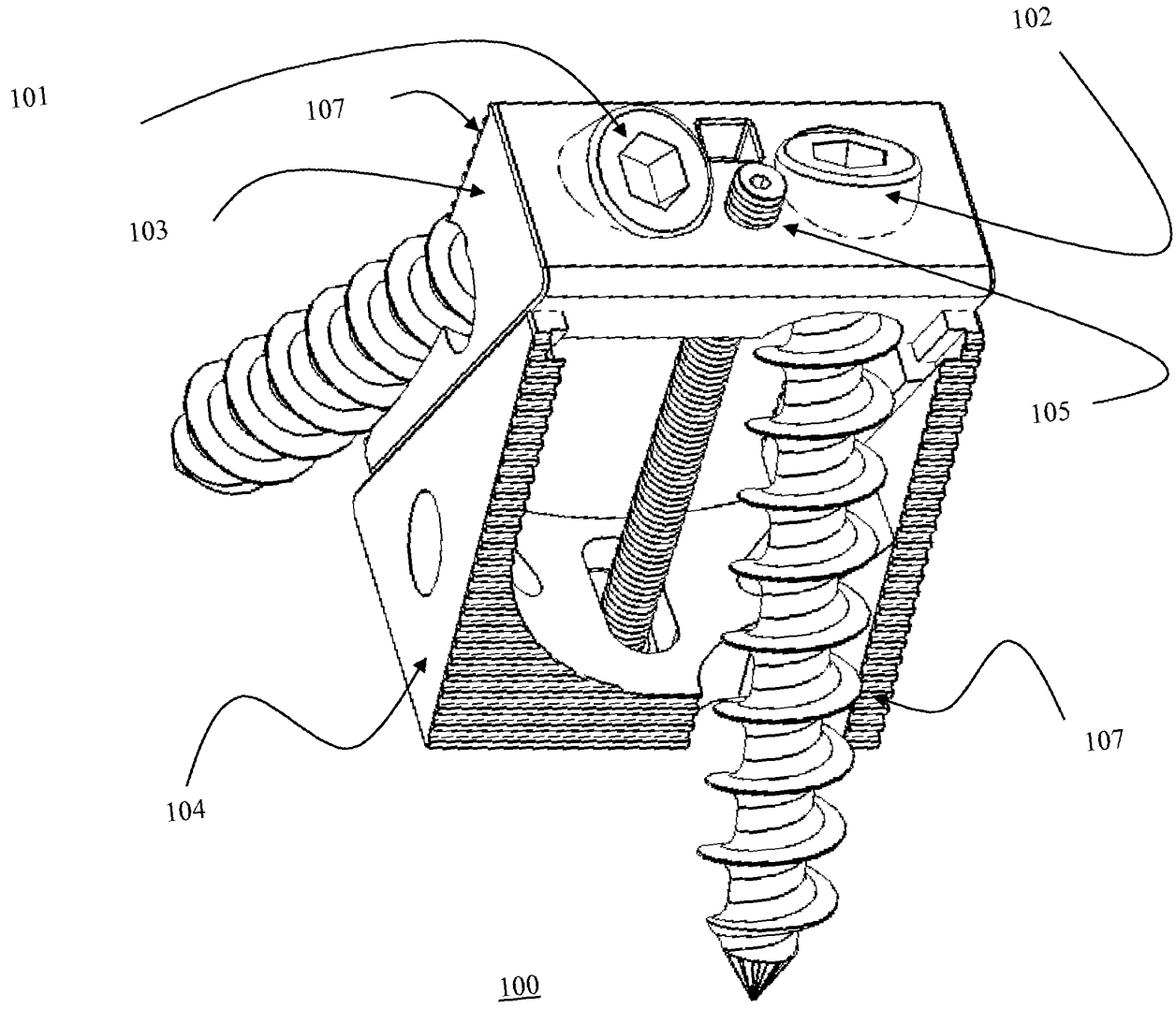


Fig. 1B

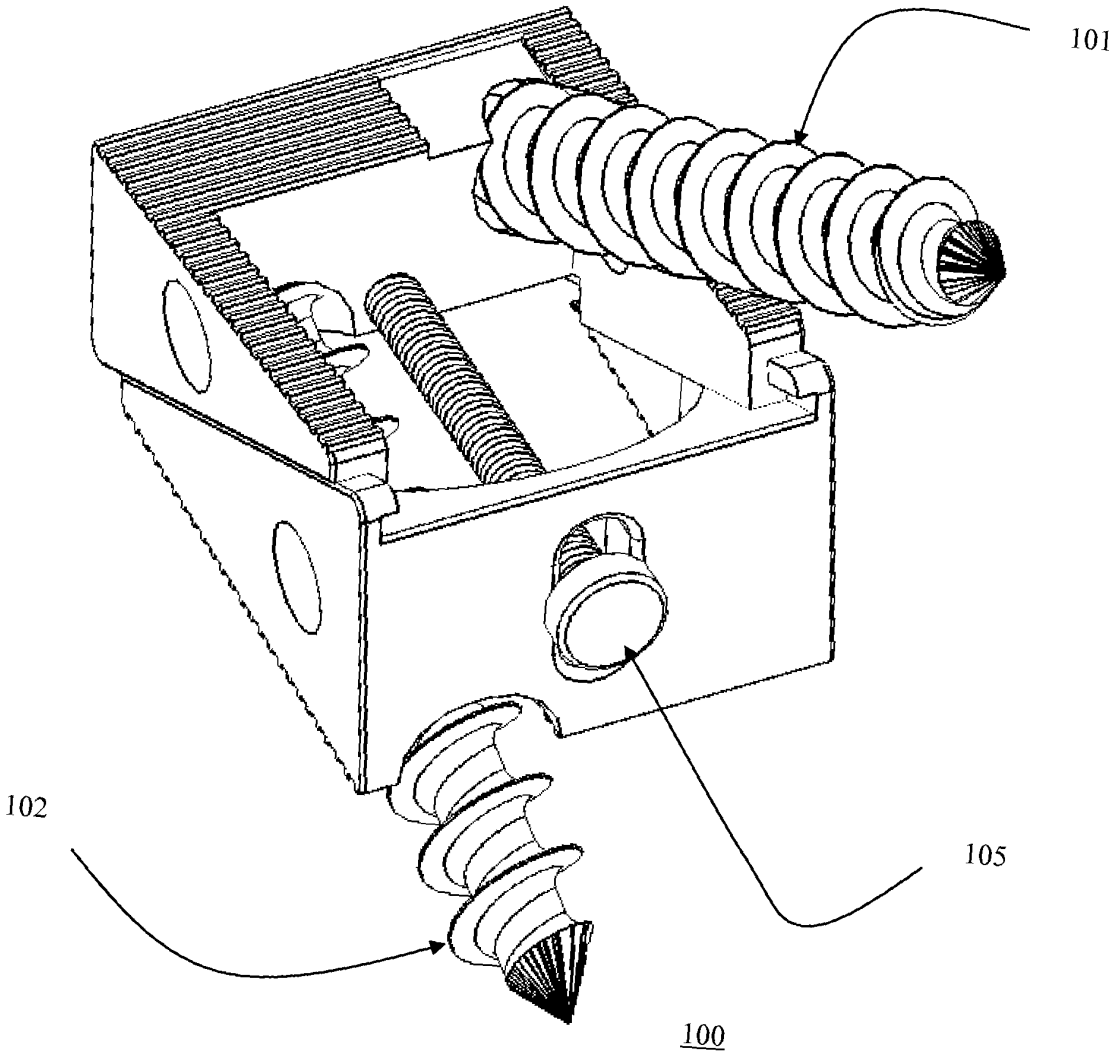


Fig. 1C

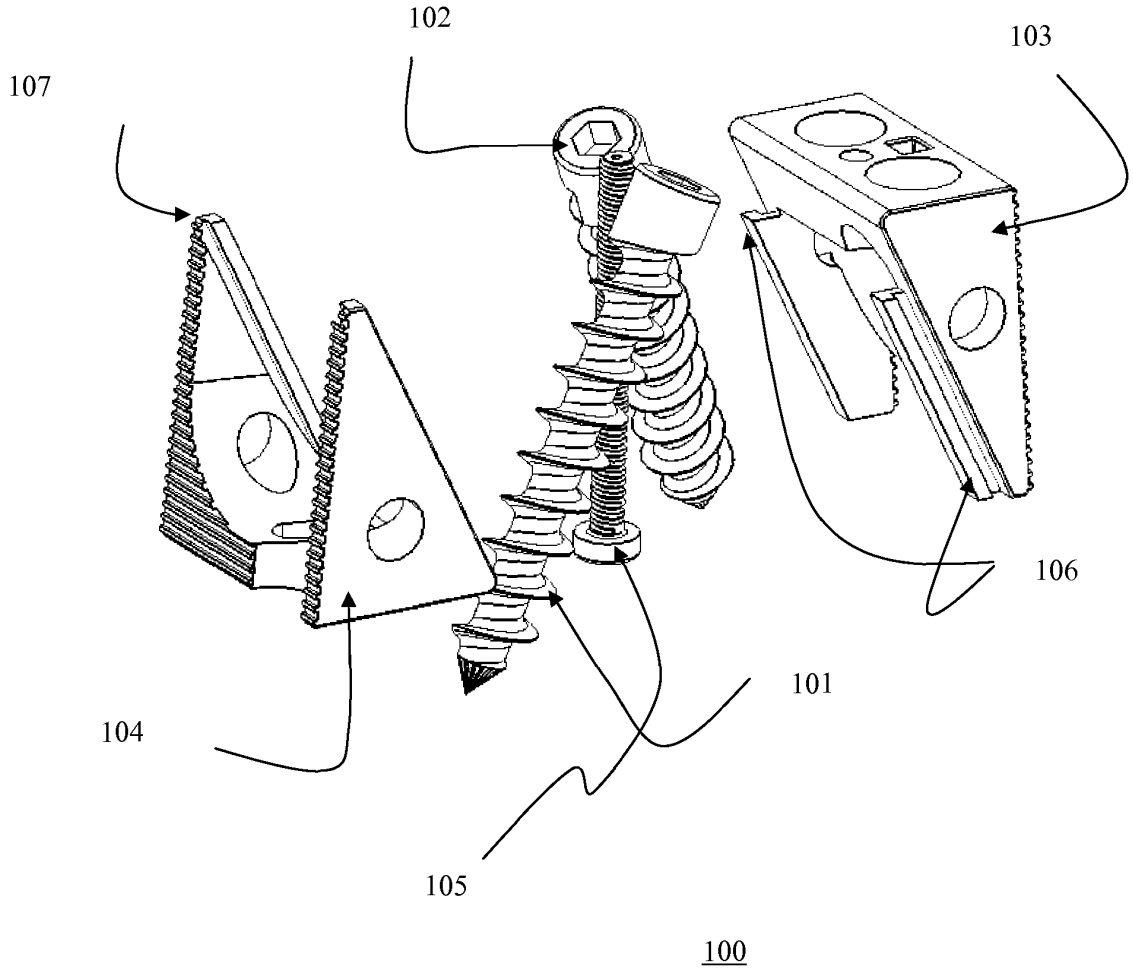


Fig. 1D

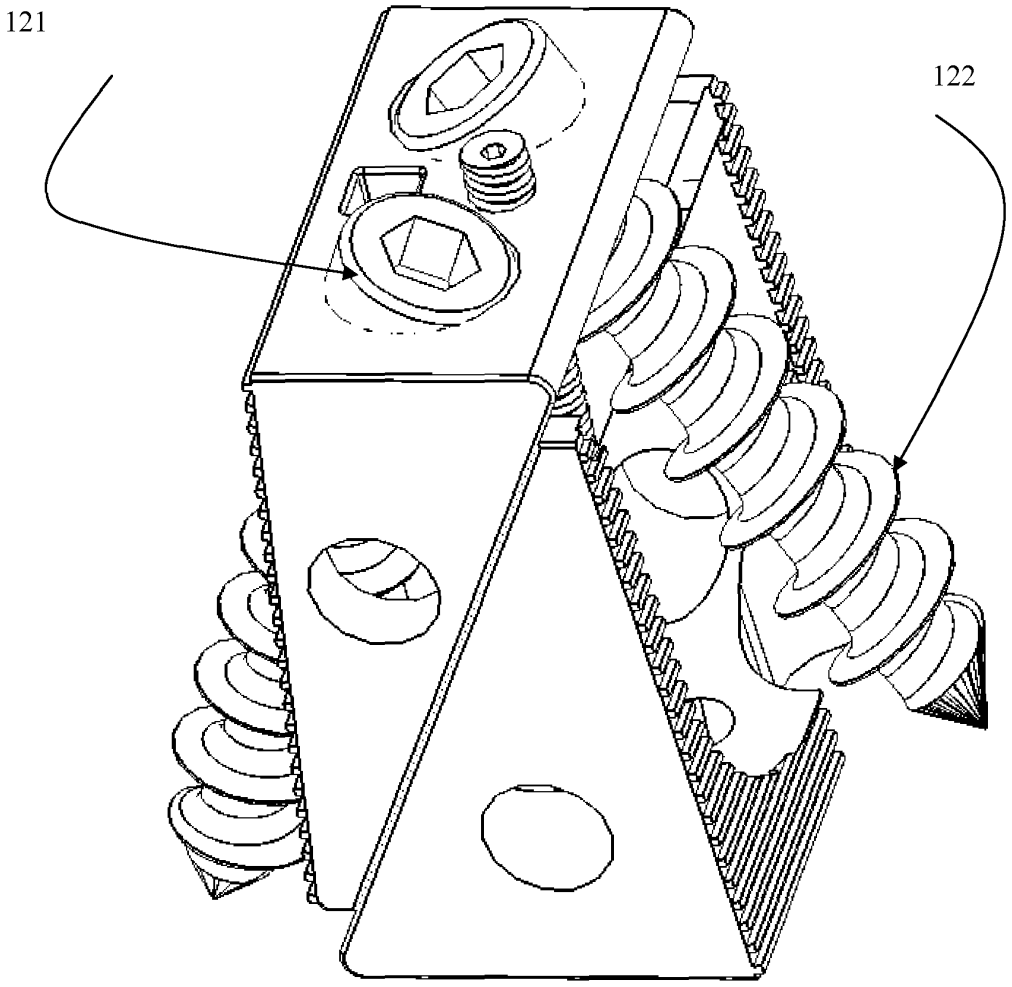


Fig. 1E

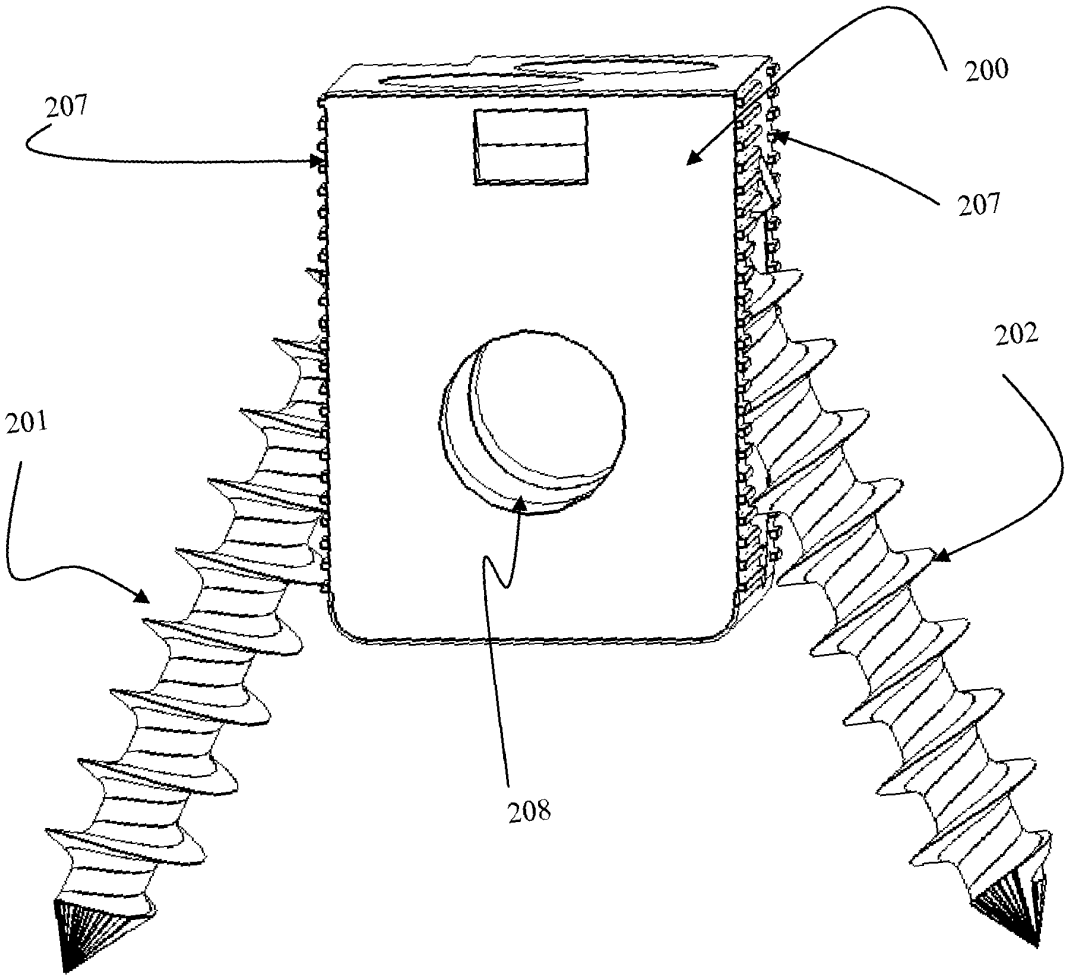


Fig. 2A

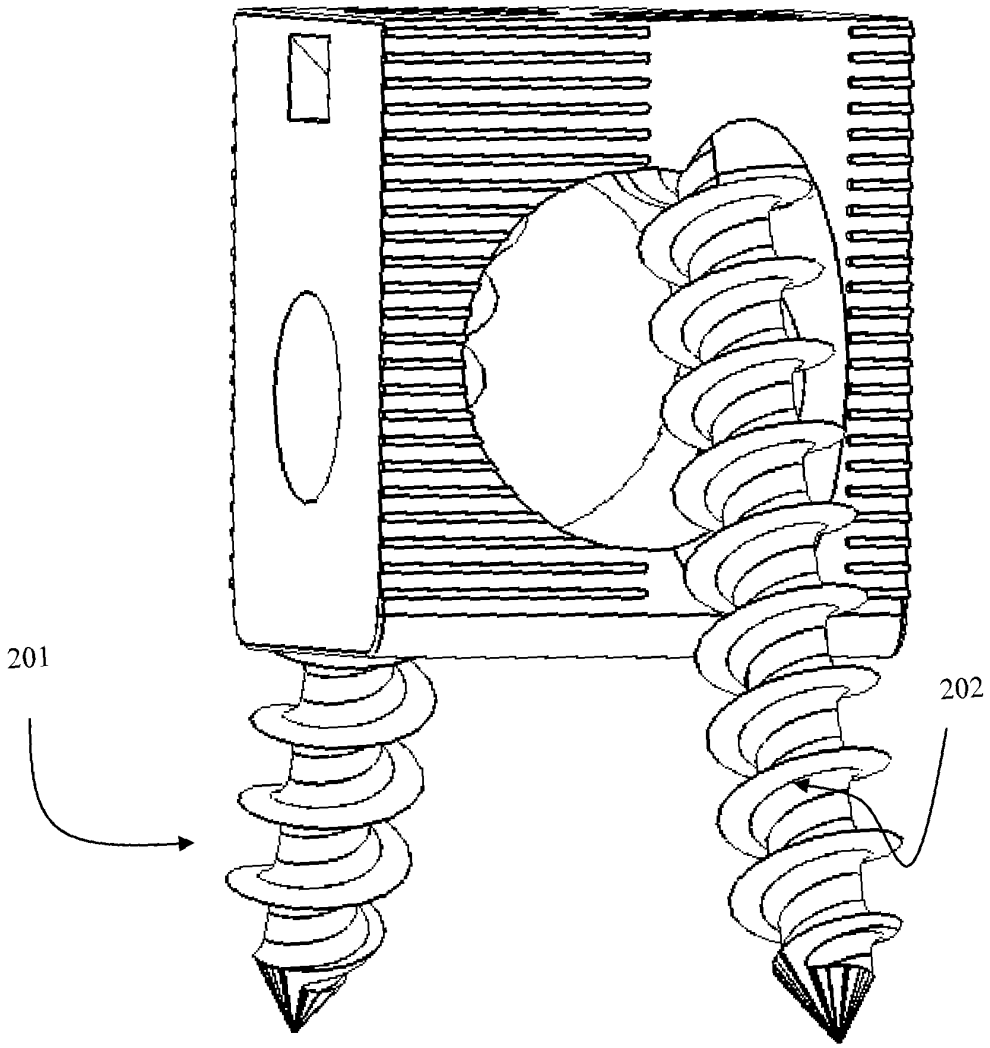


Fig. 2B

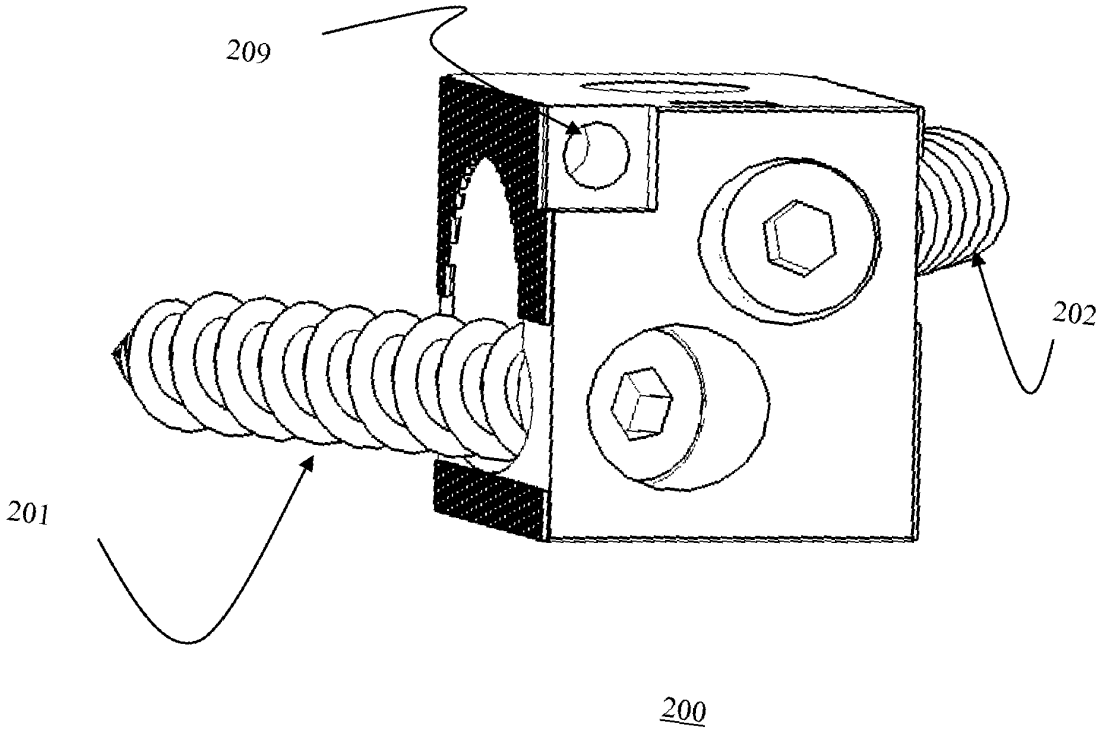


Fig. 2C

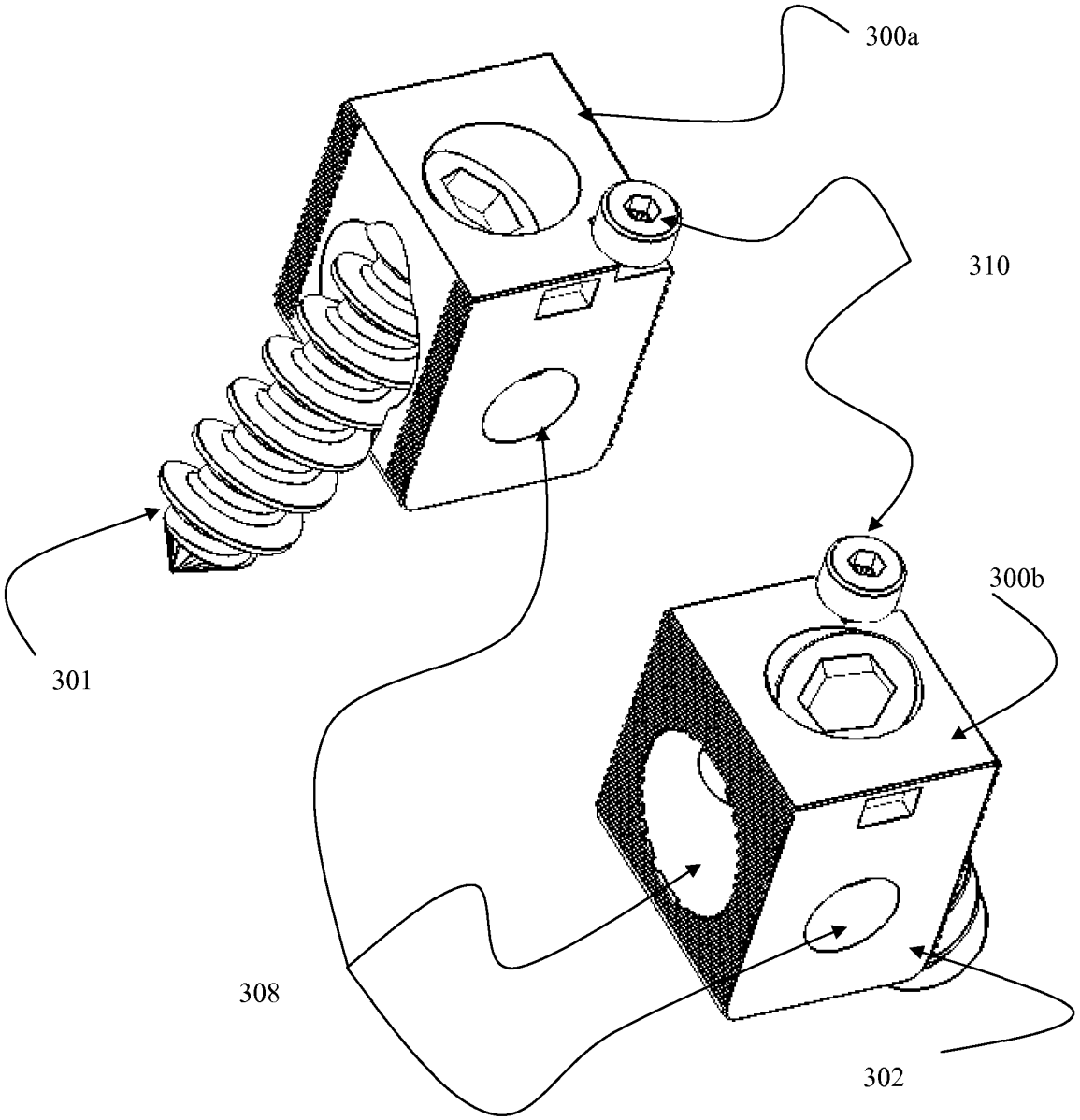


Fig. 3

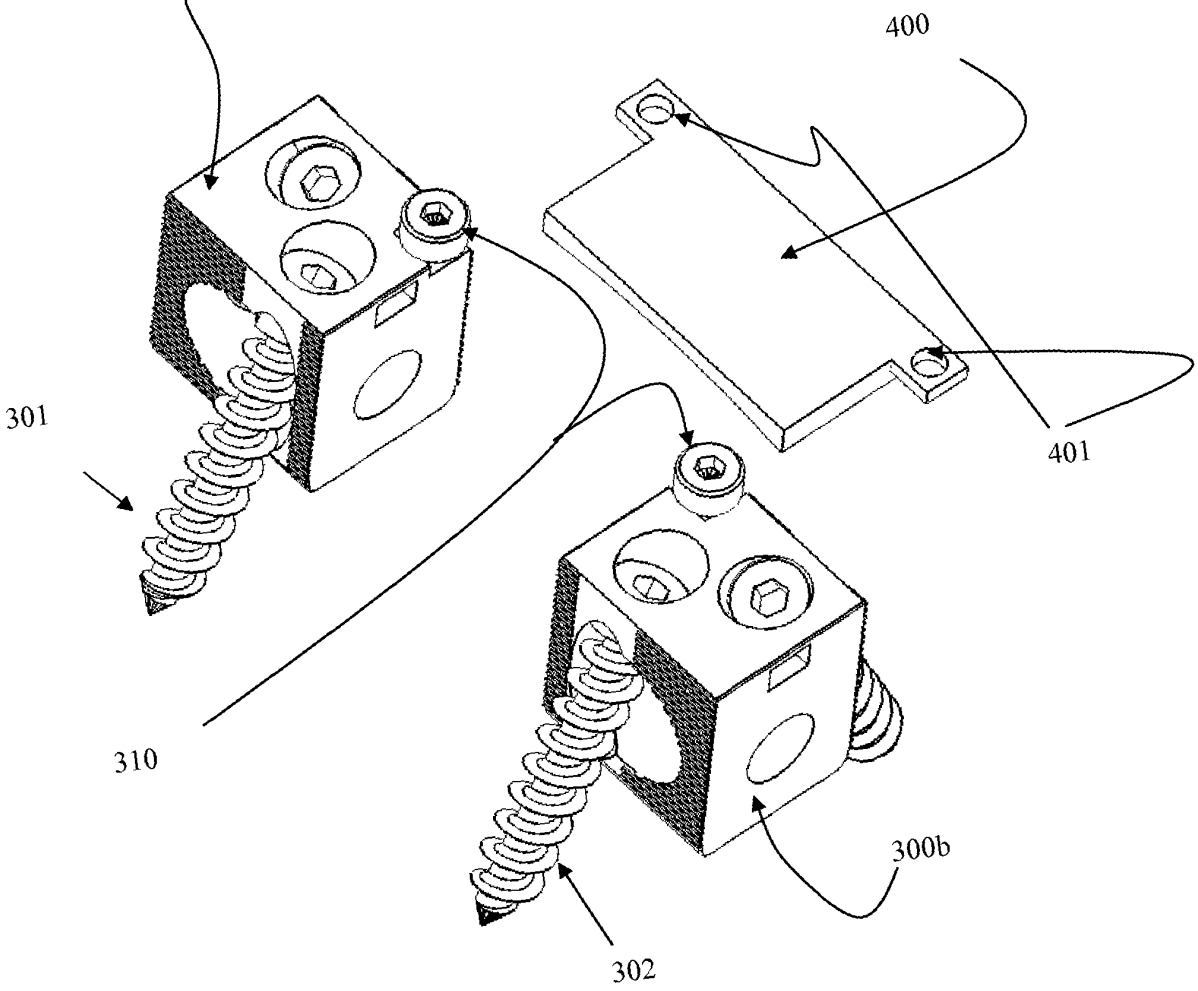


Fig. 4A

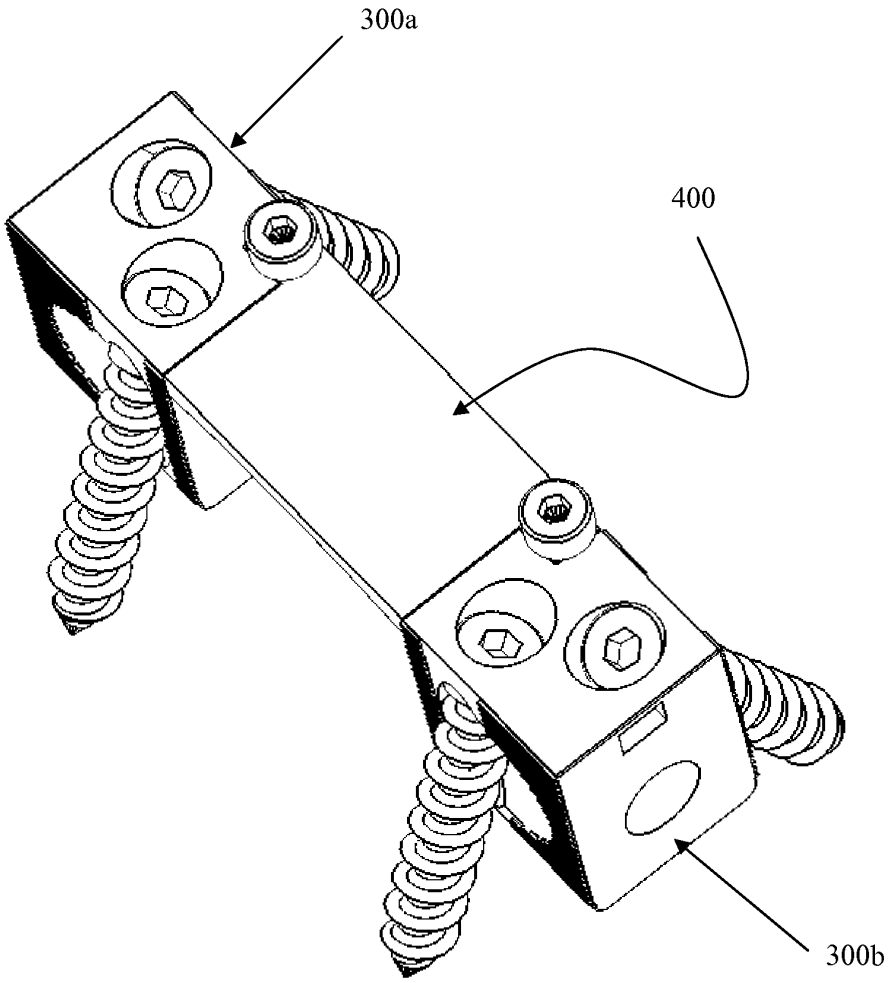


Fig. 4B

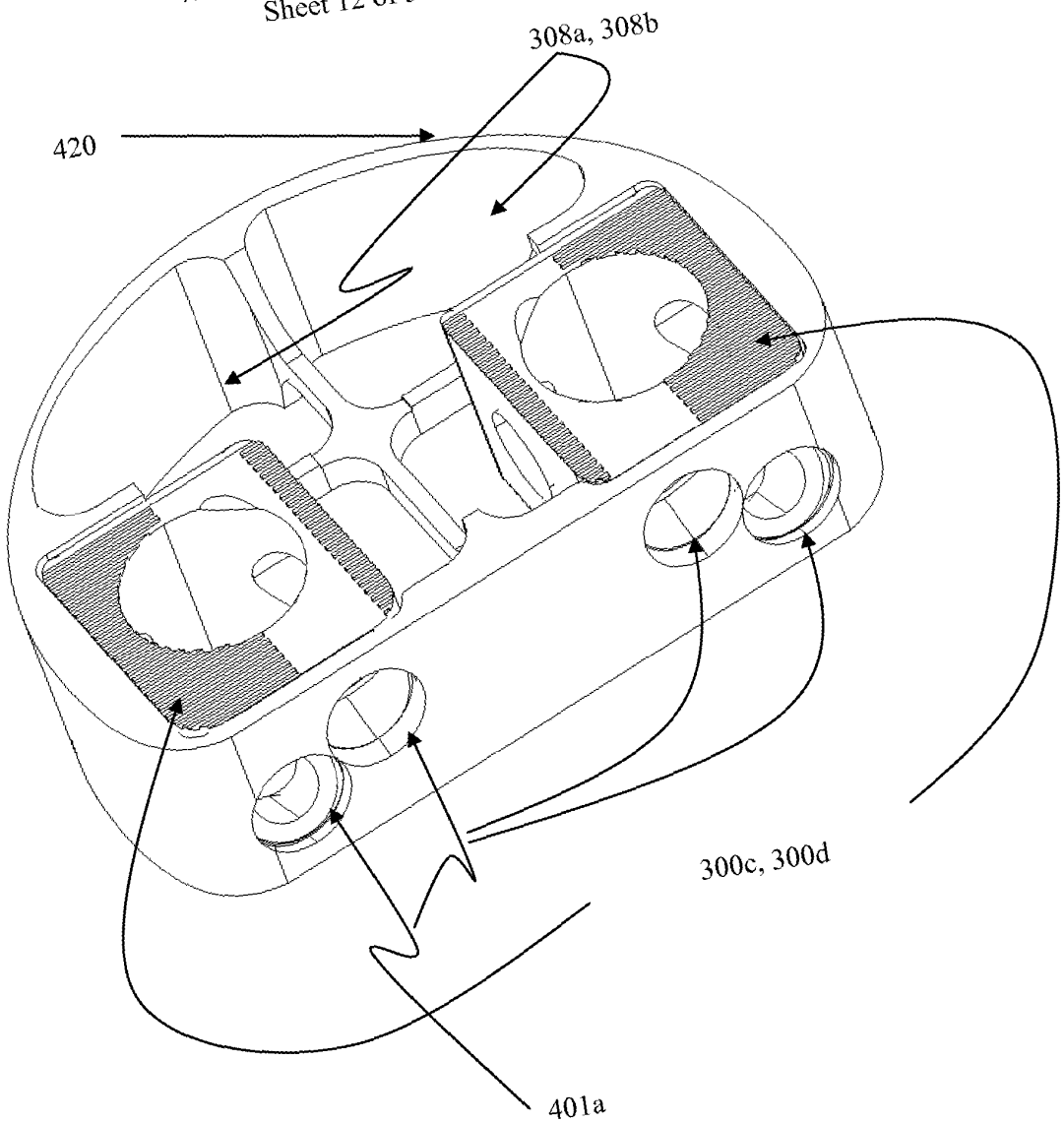


FIG. 4C

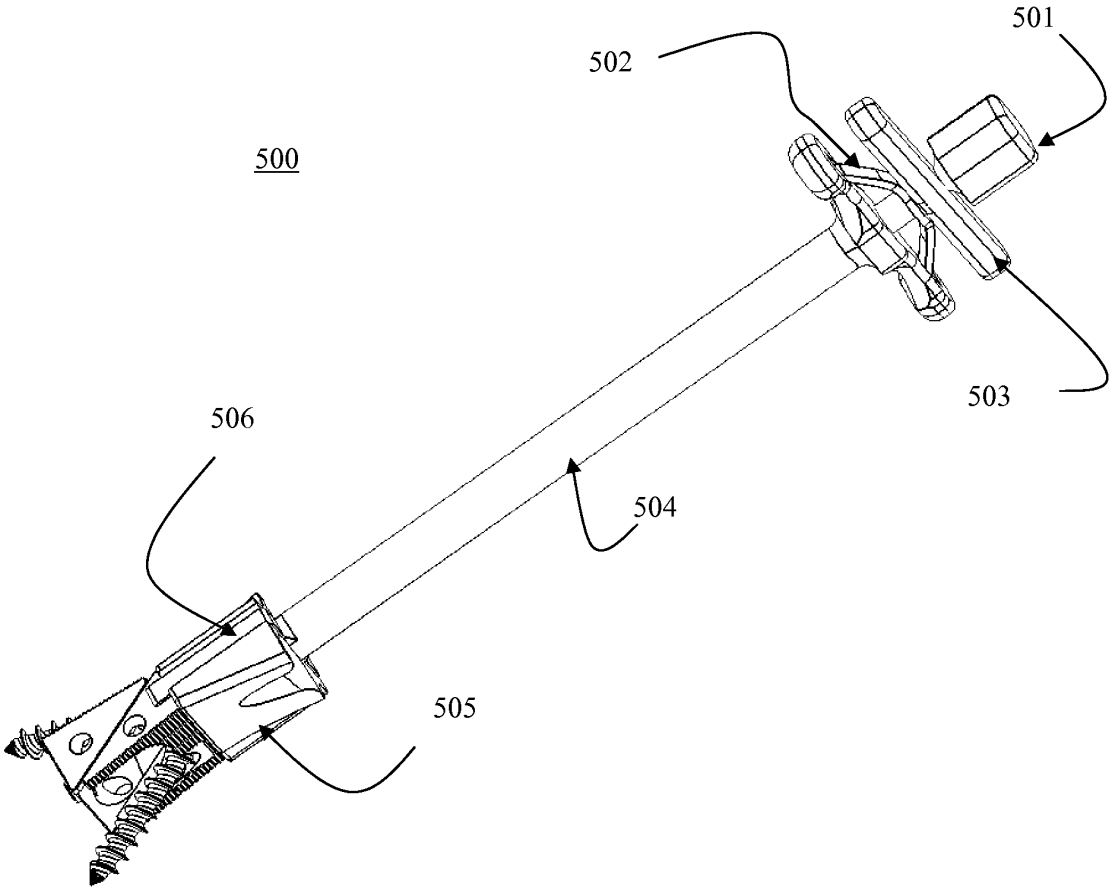


Fig. 5A

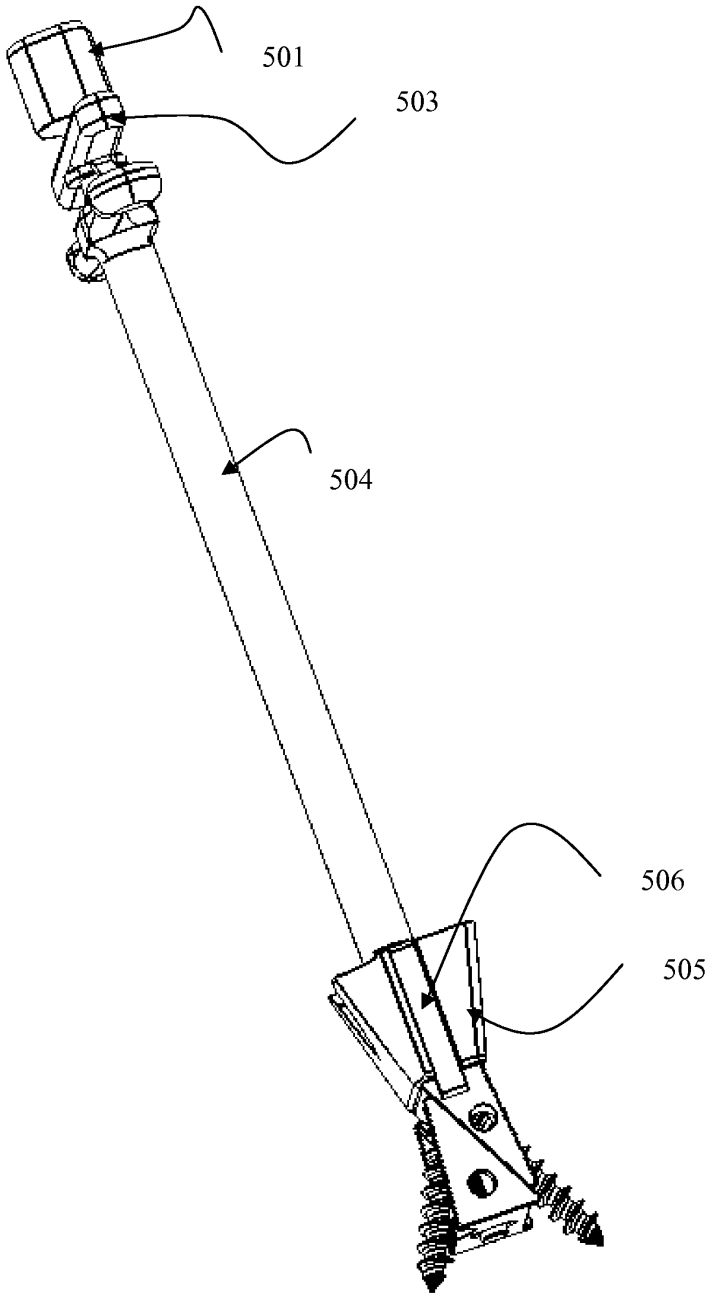


Fig. 5B

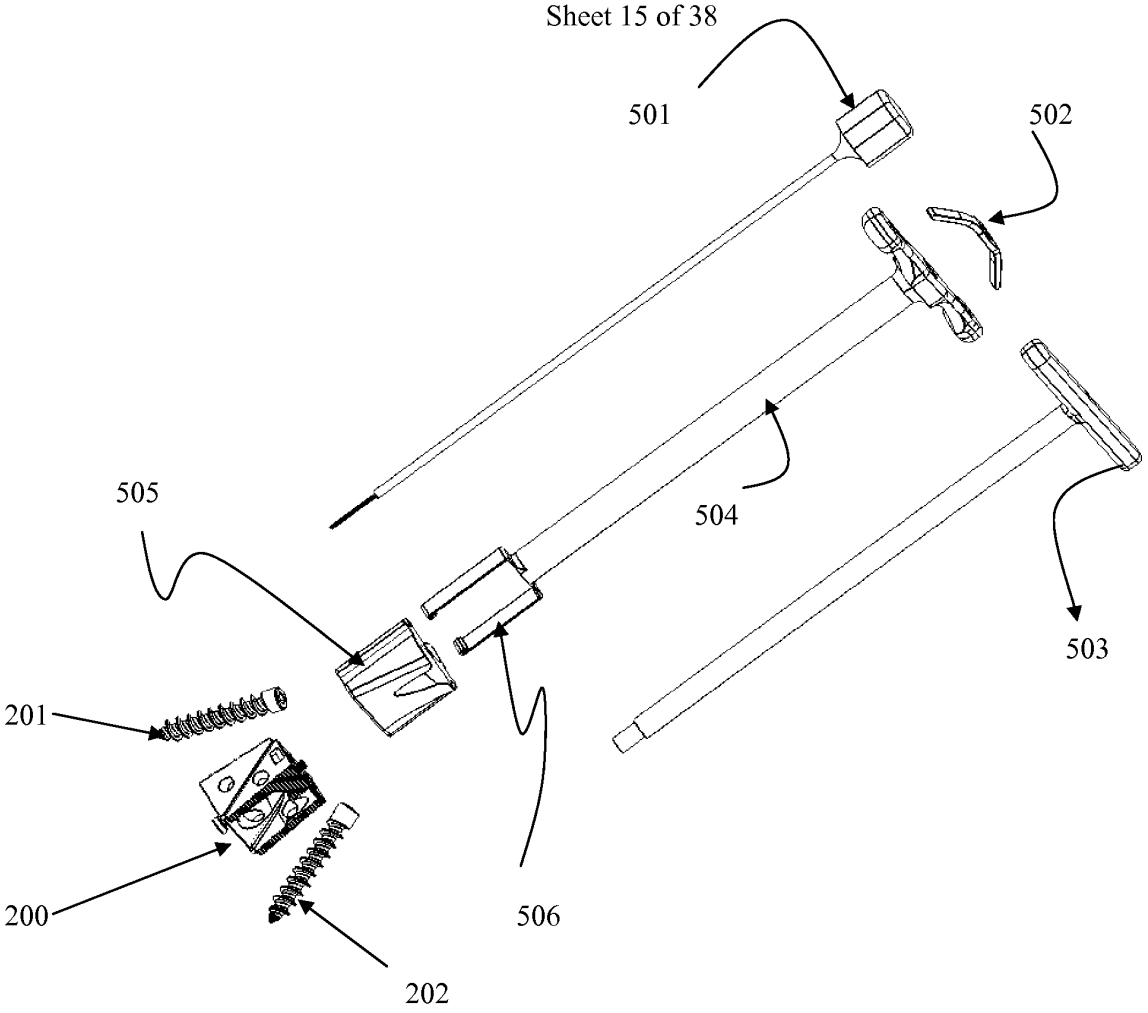


Fig. 5C

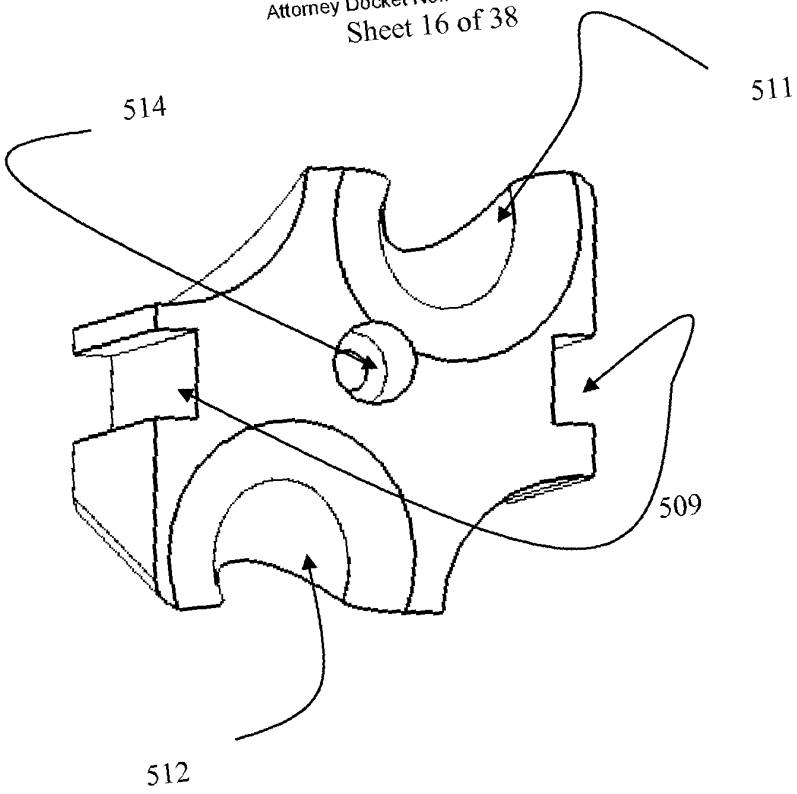


Fig. 5D

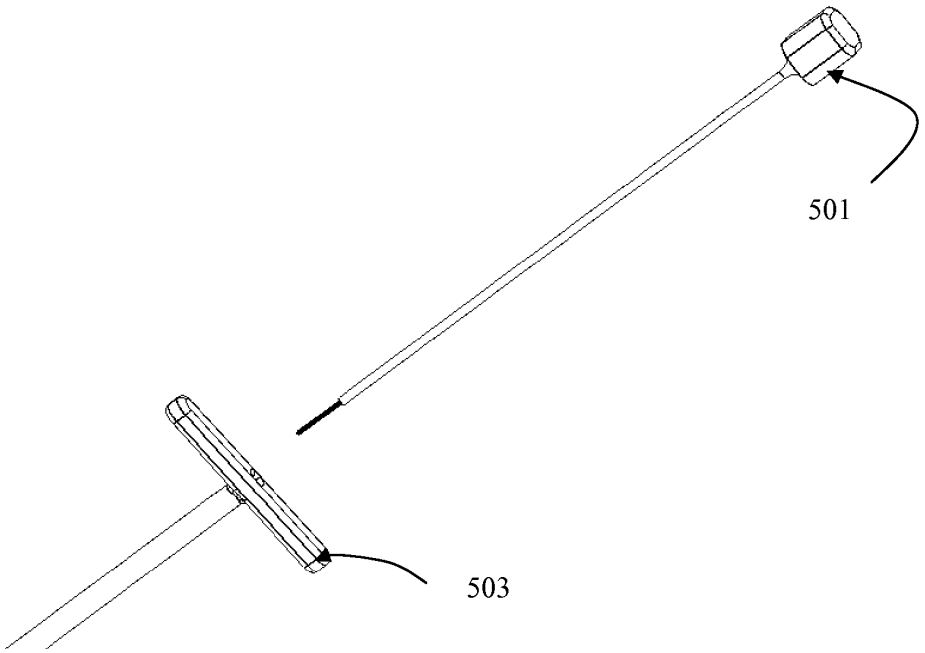


Fig. 5E

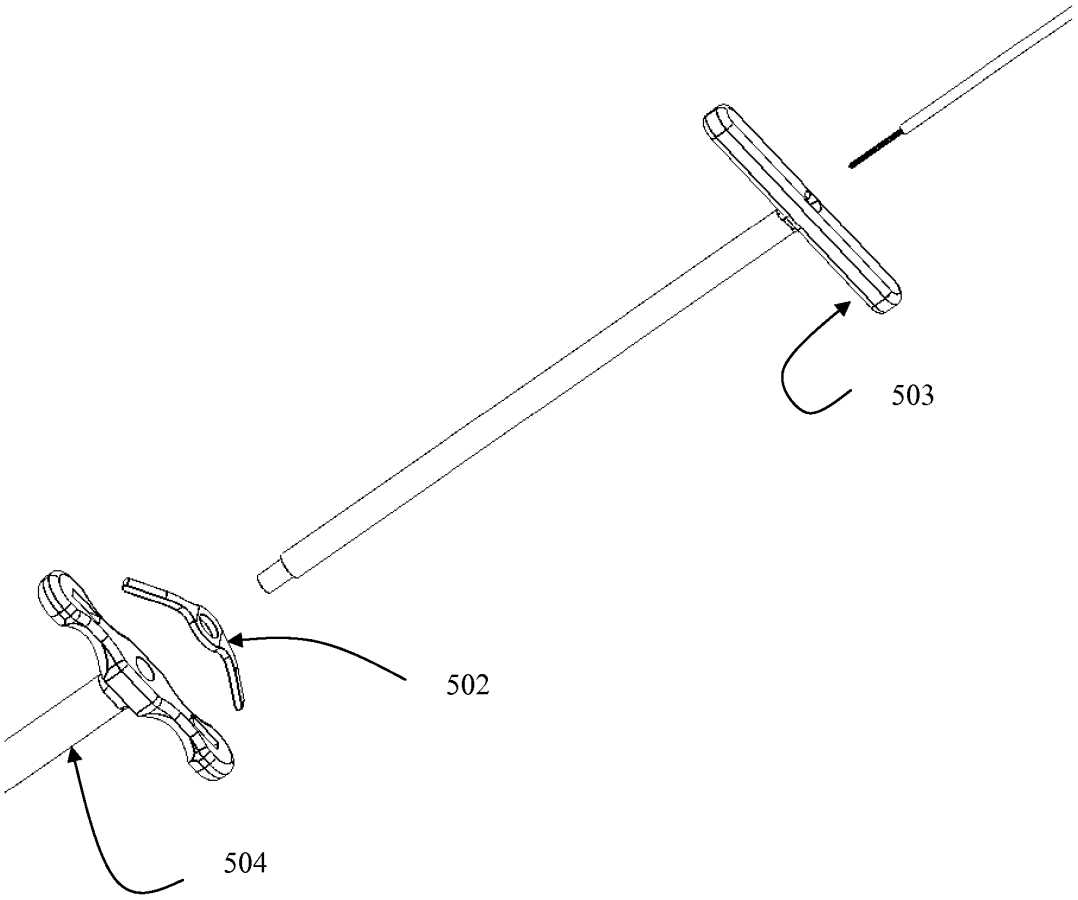


Fig. 5F

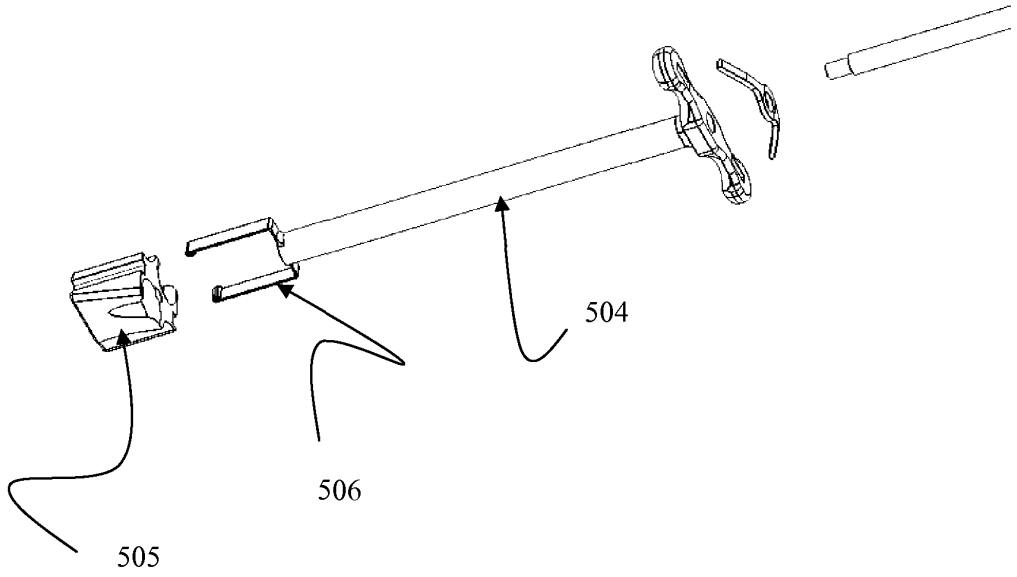


Fig. 5G

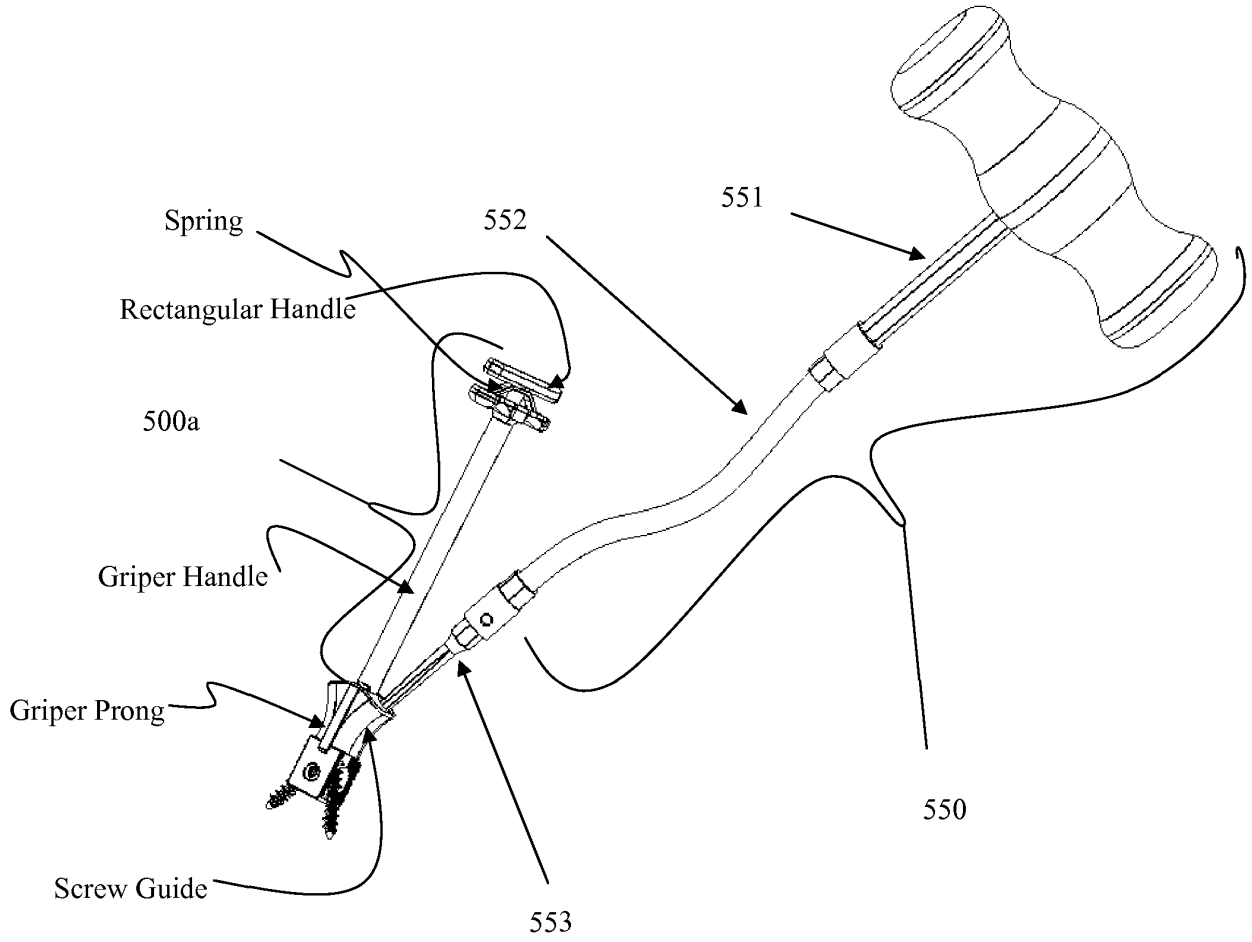

Spring
552
551
Rectangular Handle
500a
Griper Handle
Griper Prong
Screw Guide
553
550

FIG. 5H

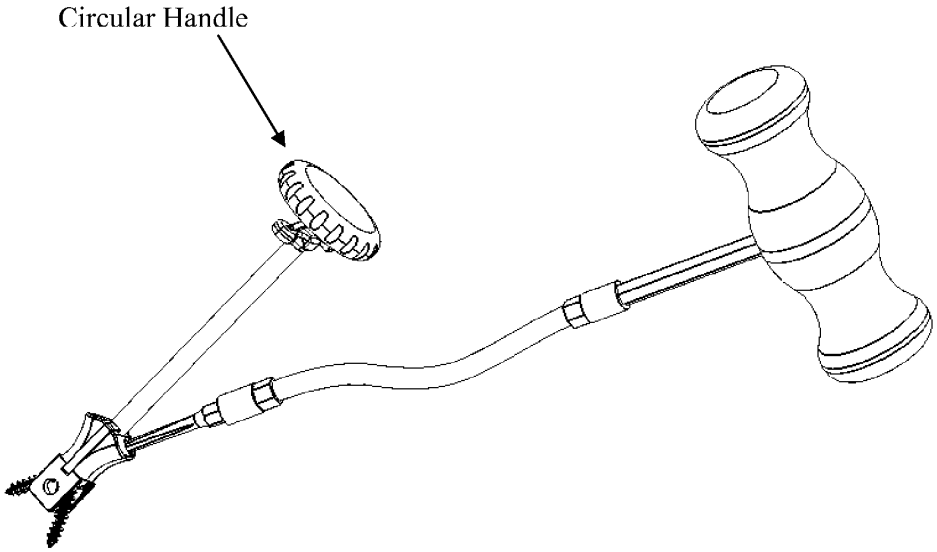


FIG. 5I

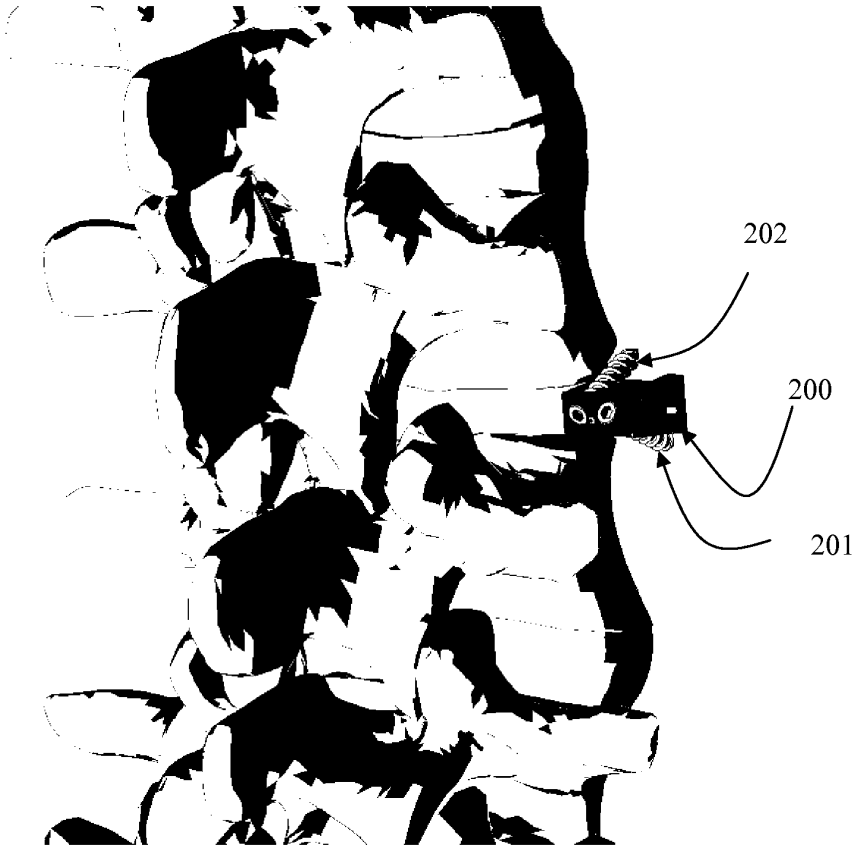


Fig. 6A

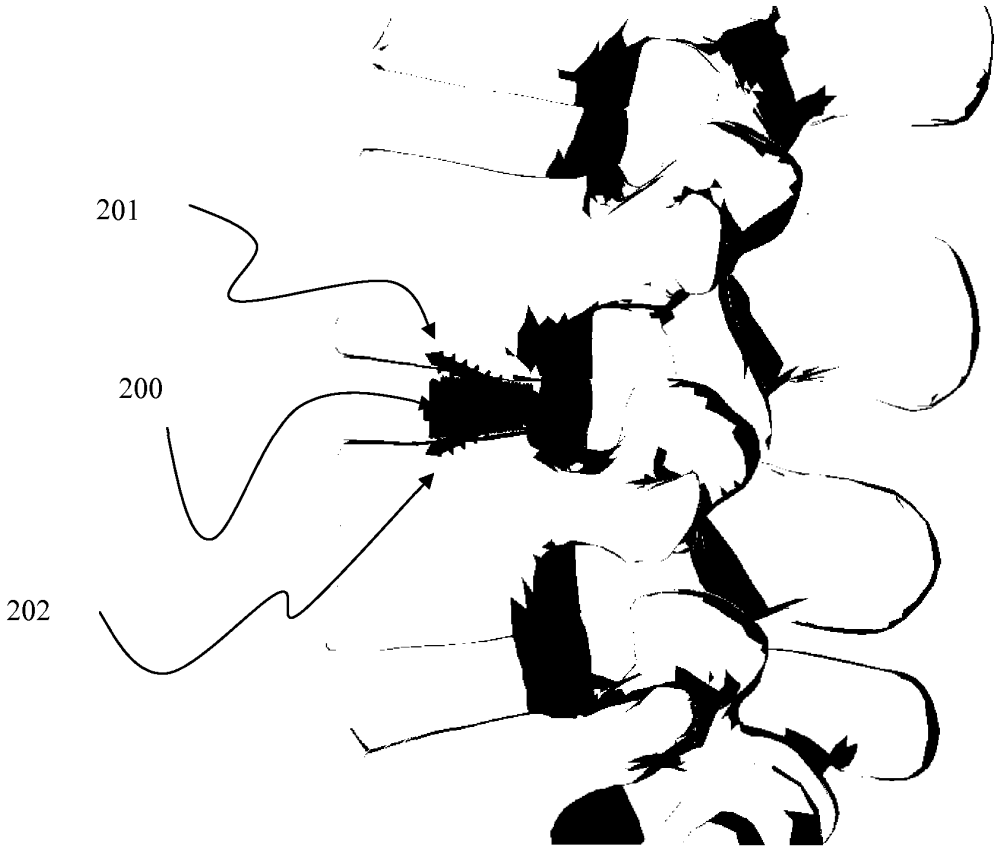


Fig. 6B

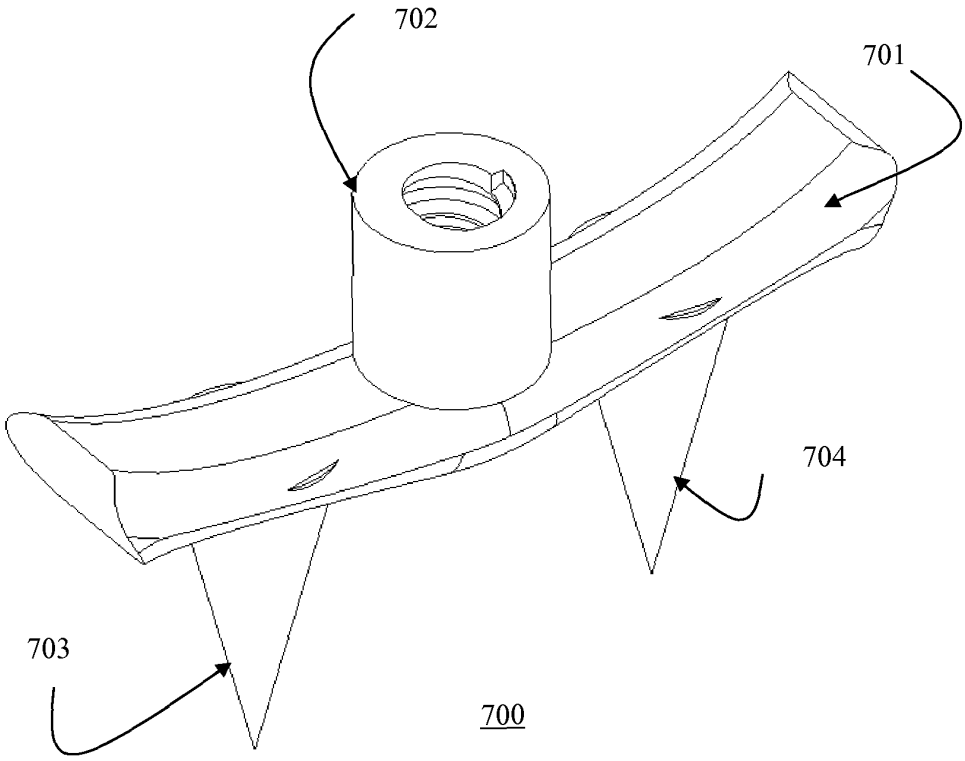
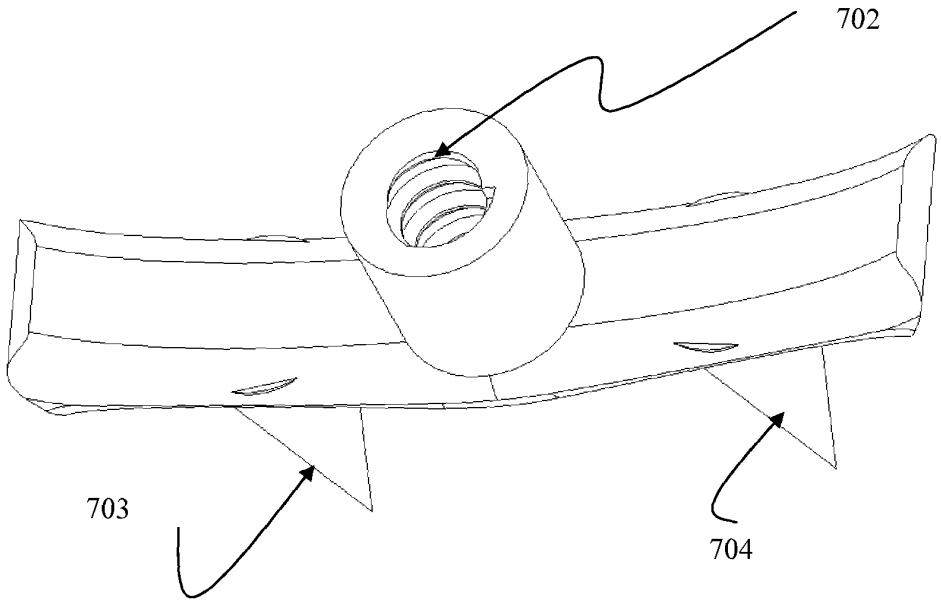


Fig. 7A



700

Fig. 7B

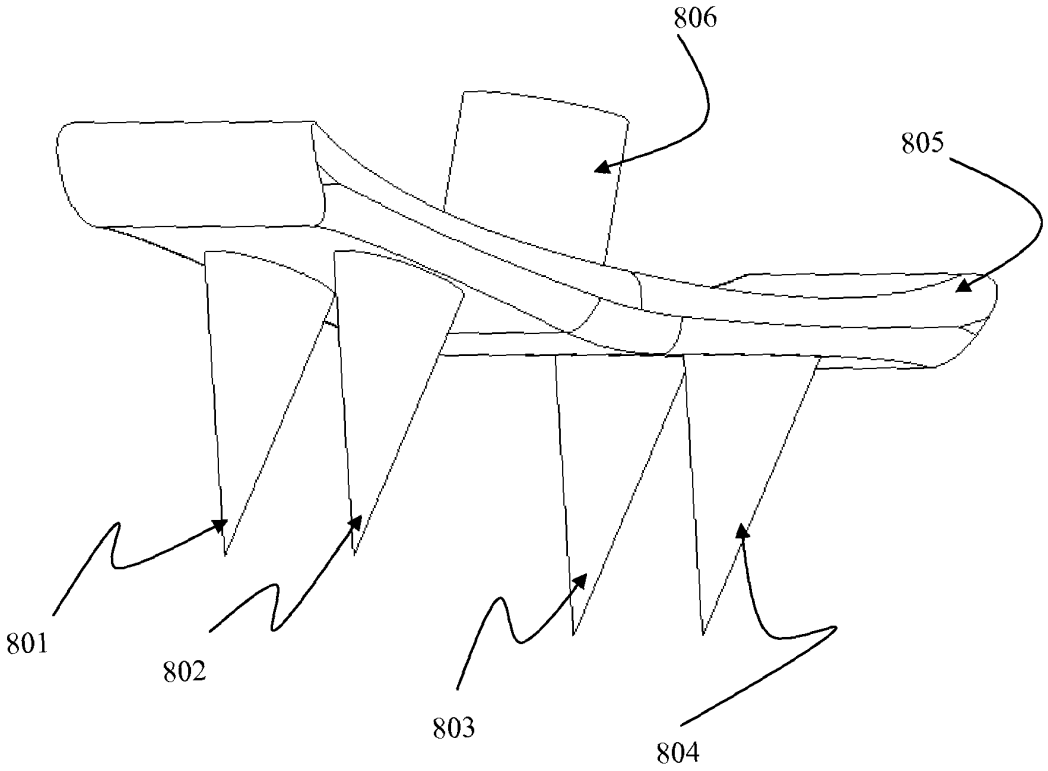


Fig. 8A

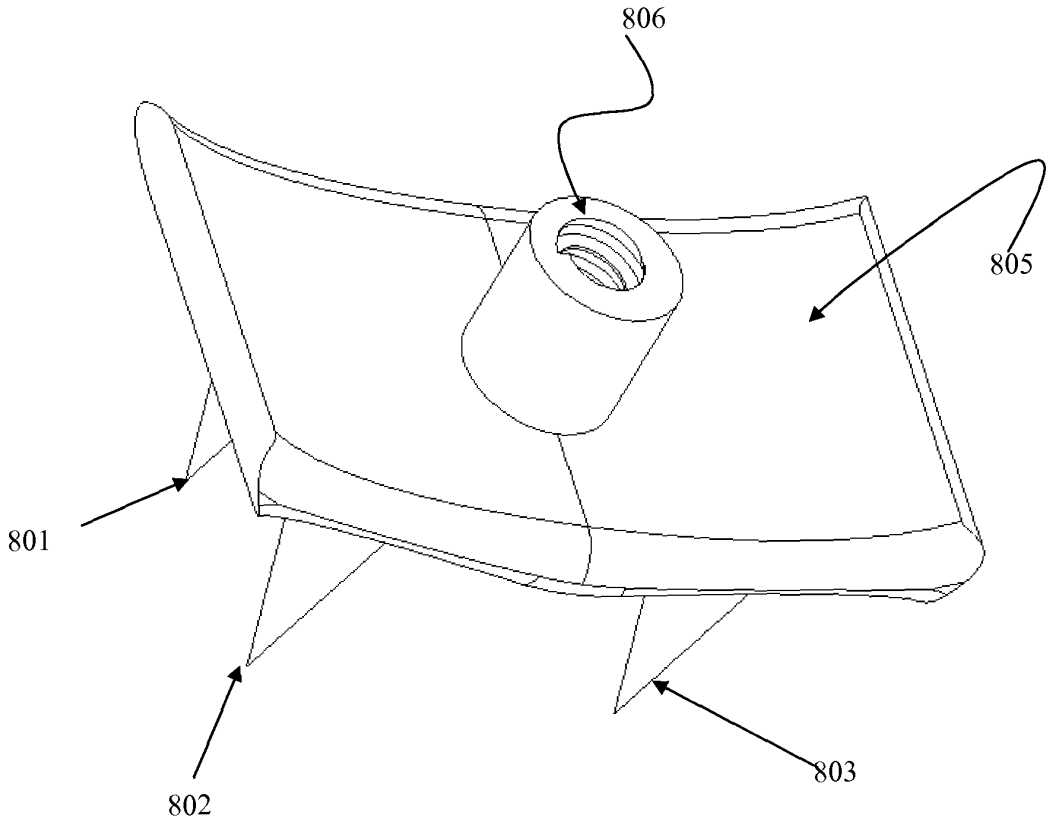


Fig. 8B

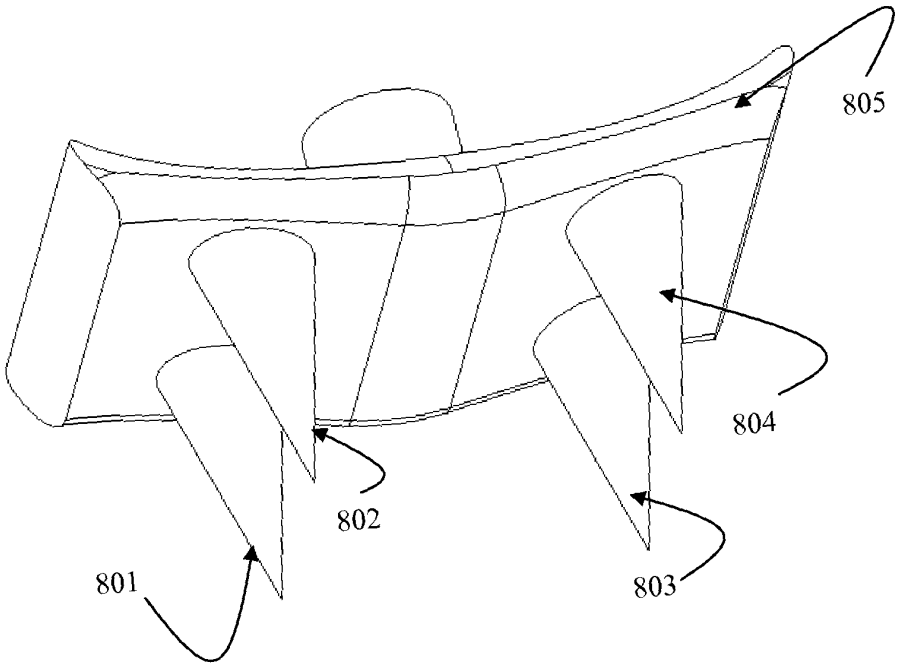


Fig. 8C

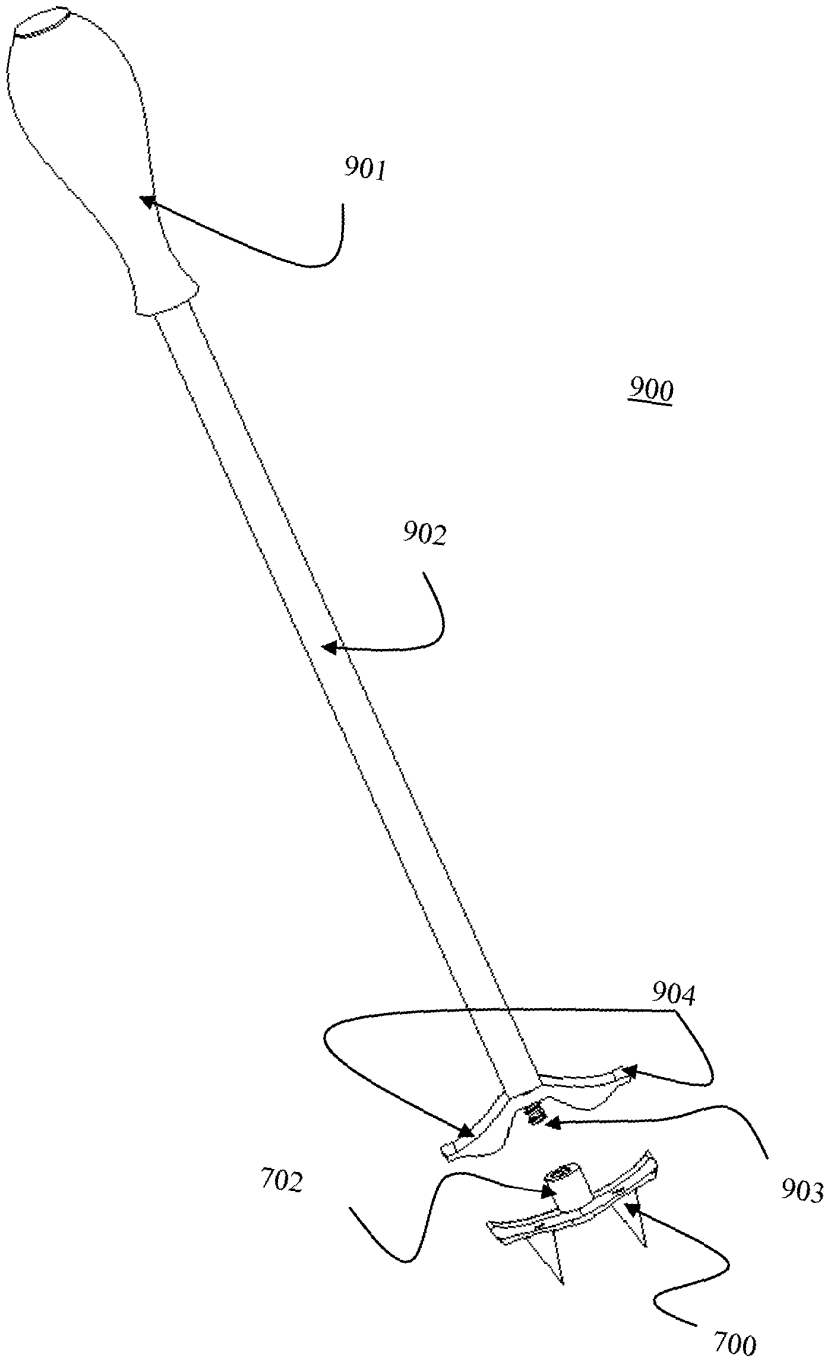


Fig. 9A

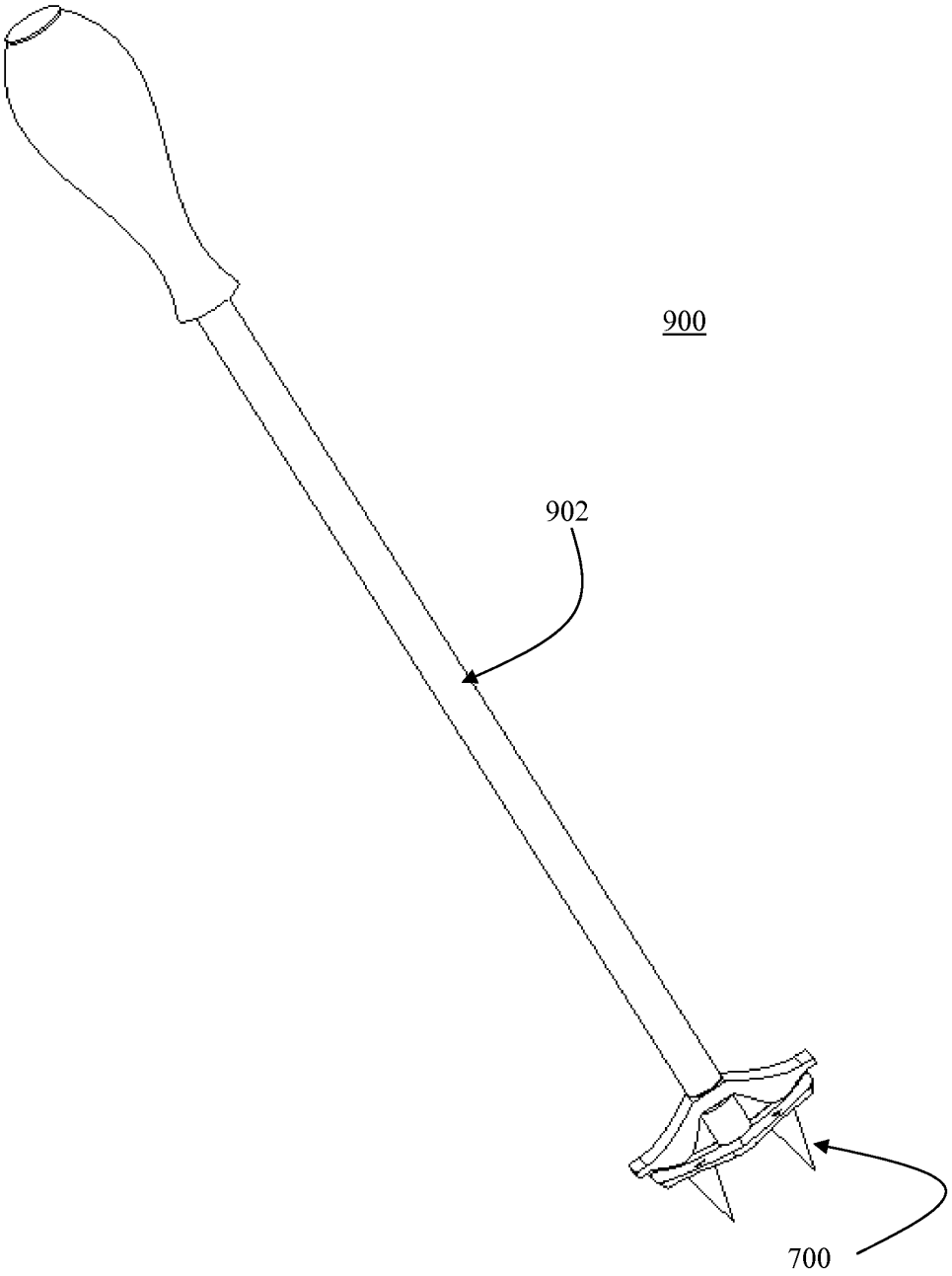


Fig. 9B

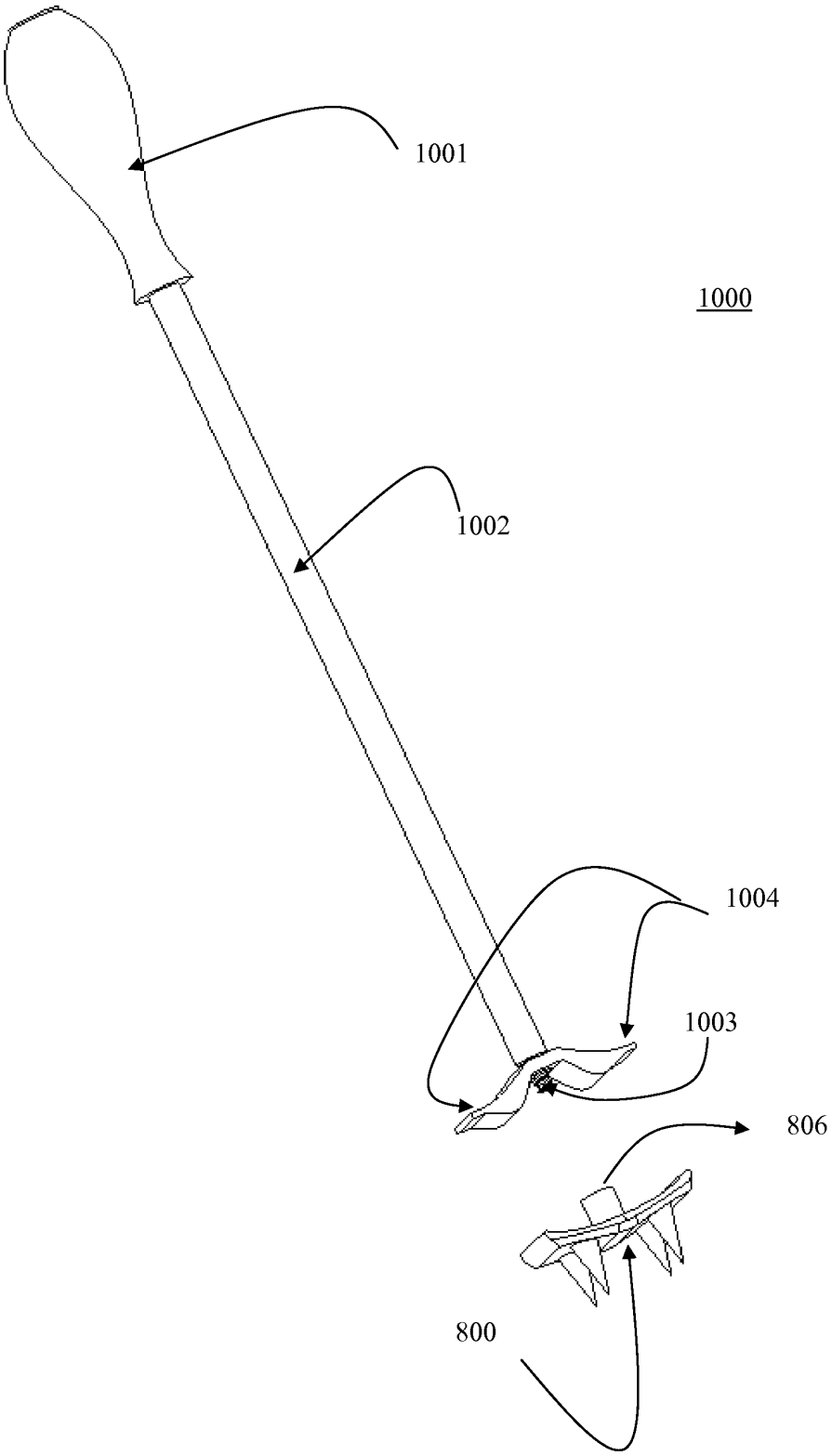


Fig. 10A

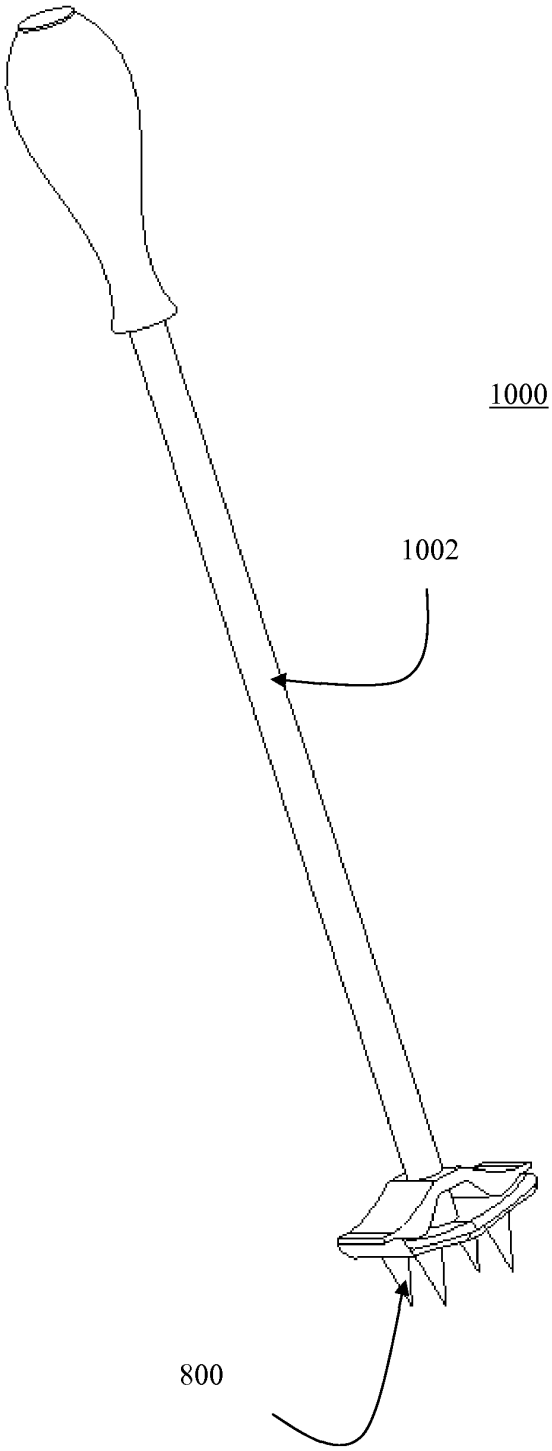


Fig. 10B

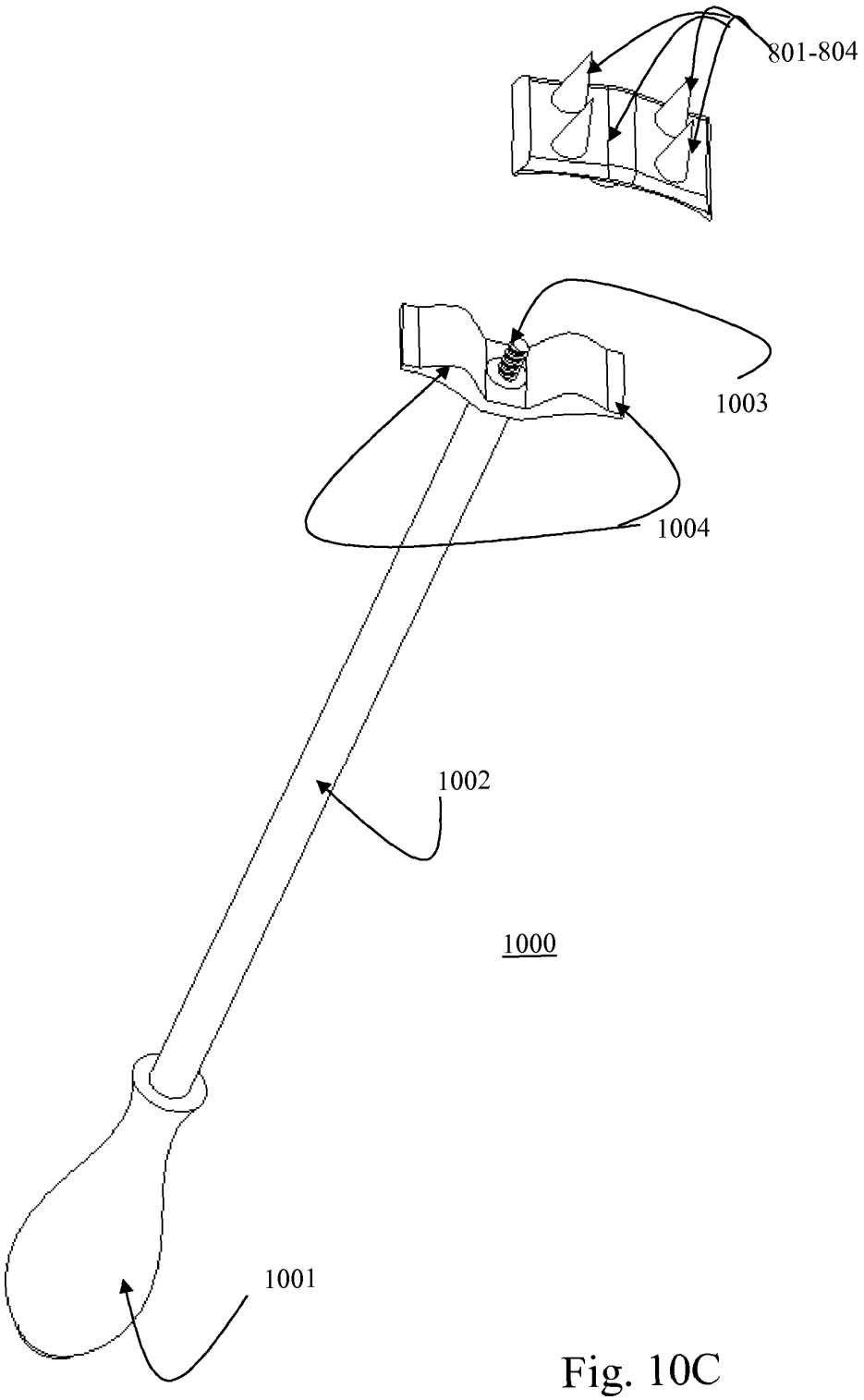


Fig. 10C

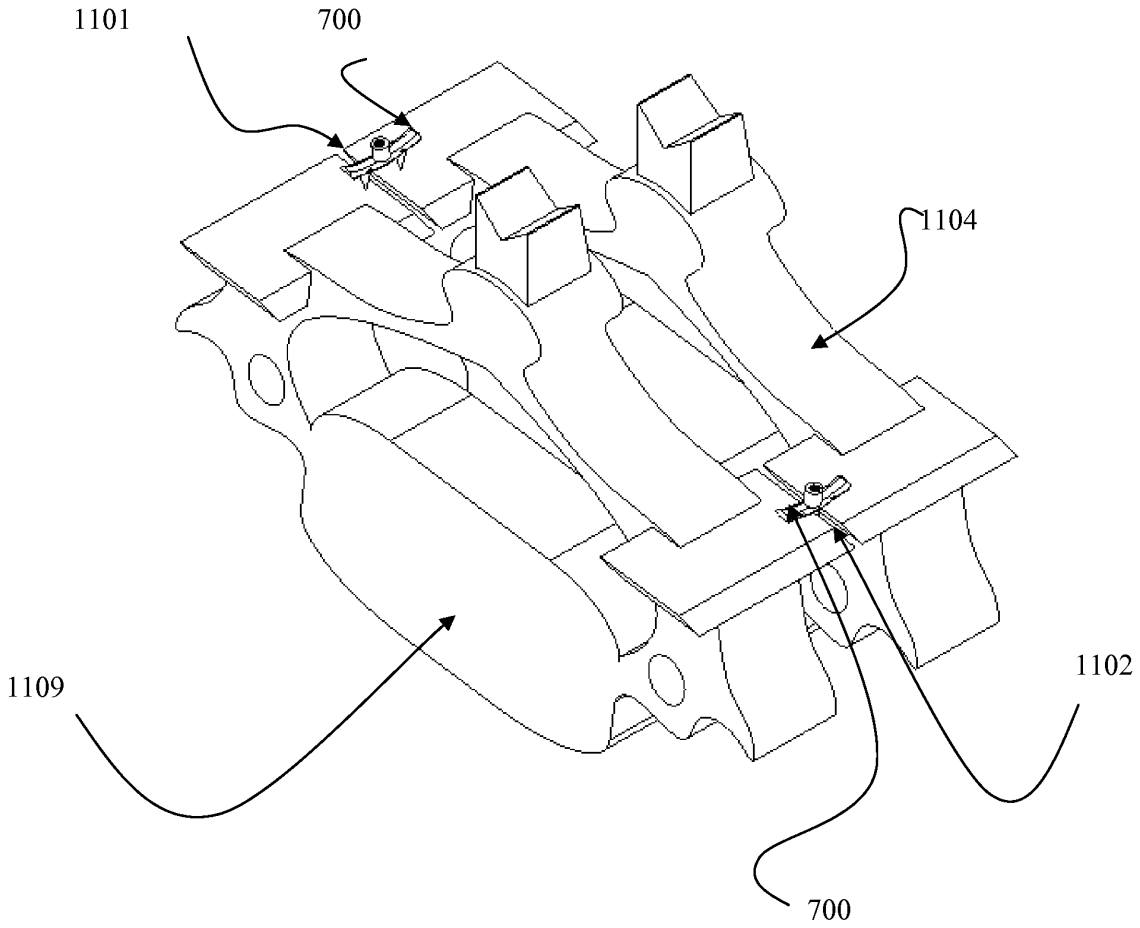


Fig. 11A

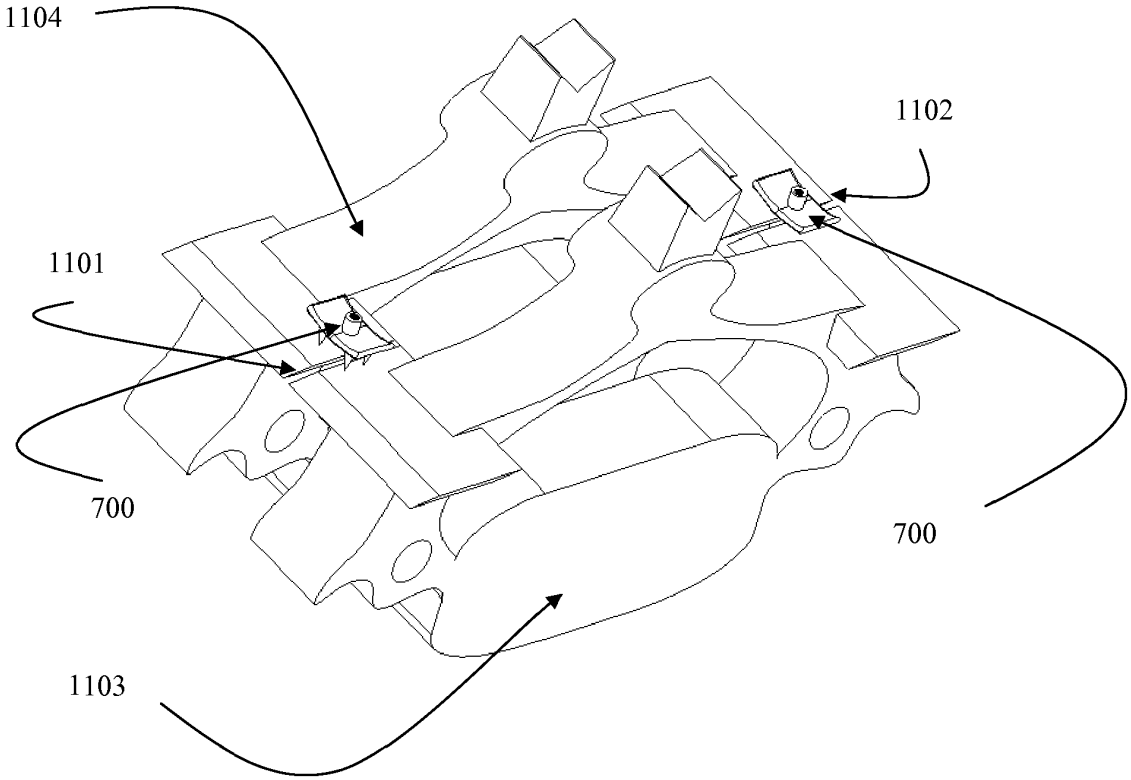


Fig. 11B

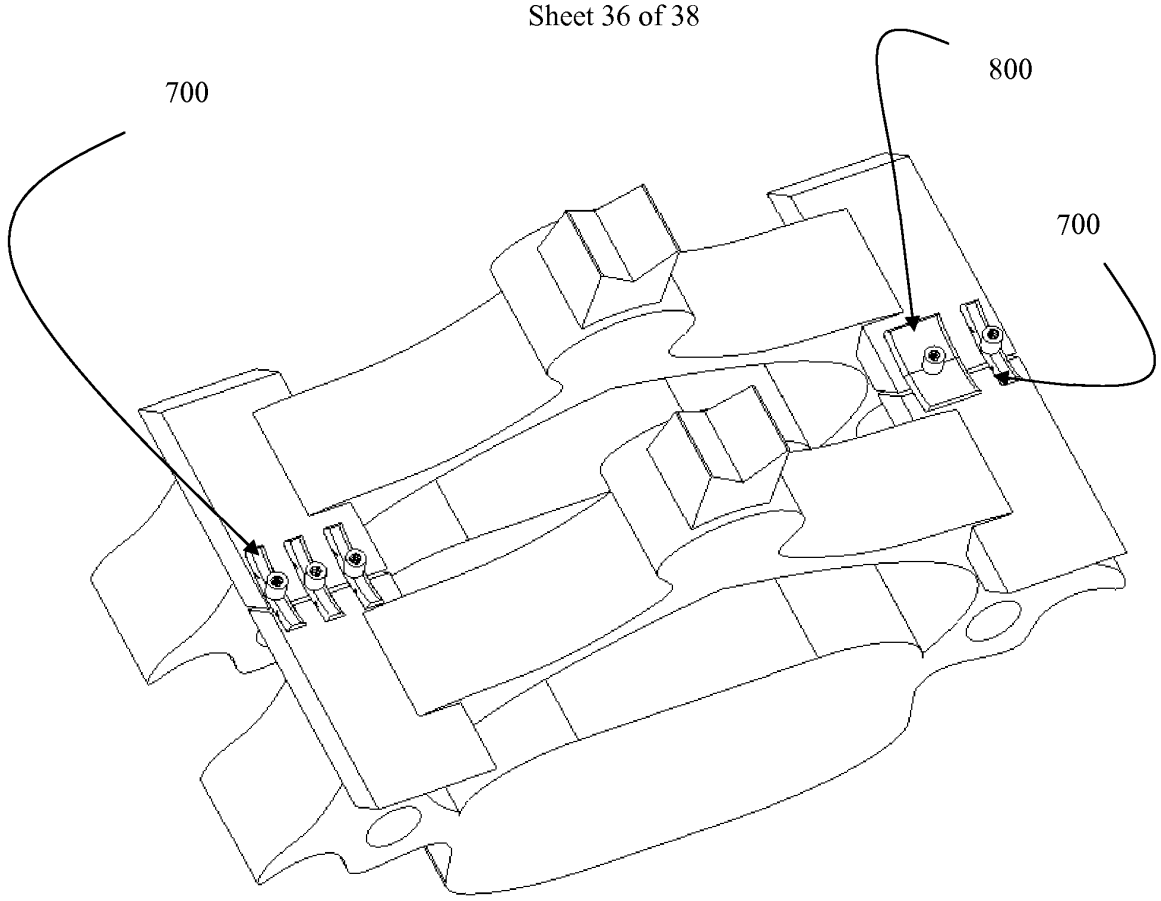


Fig. 11C

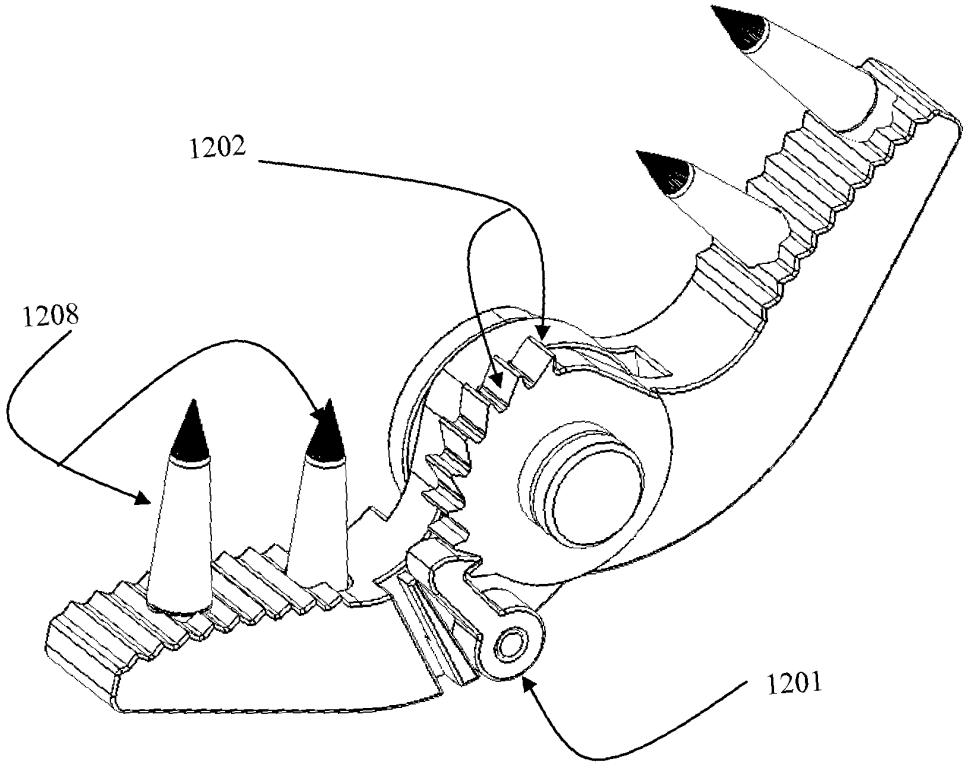


Fig. 12A

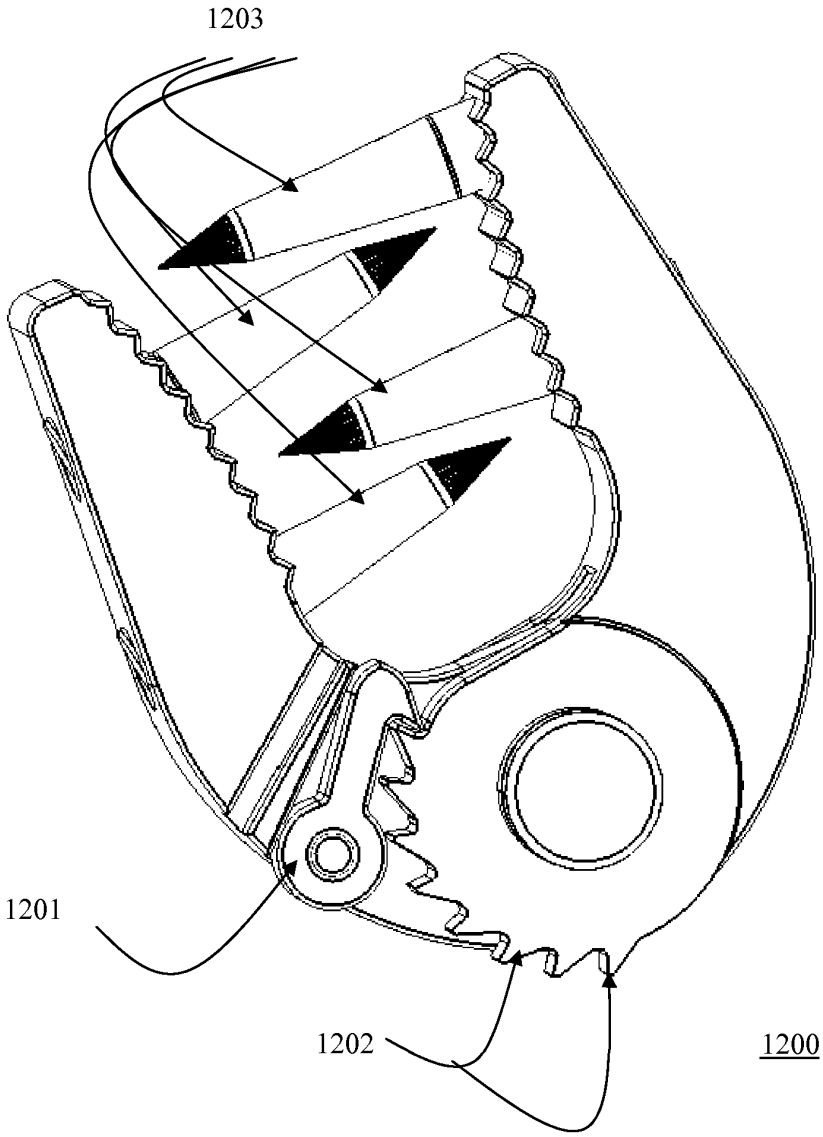


Fig. 12B

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 interverterbral 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 caudaly 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 lumber 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 transpediclar 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 (Figure2B), 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 t 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 tooll/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 (Figure5H), 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 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 901of 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 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-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.

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. .

Electronic Patent Application Fee Transmittal	
Application Number:	
Filing Date:	
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:	46440-0009013
Filed as Small Entity	
Filing Fees for **Track I Prioritized Examination - Nonprovisional Application under 35 USC 111(a)**	

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
UTILITY FILING FEE (ELECTRONIC FILING)	4011	1	75	75
UTILITY SEARCH FEE	2111	1	330	330
UTILITY EXAMINATION FEE	2311	1	380	380
REQUEST FOR PRIORITIZED EXAMINATION	2817	1	2000	2000
Pages:				
Claims:				
Miscellaneous-Filing:				
PROCESSING FEE, EXCEPT PROV. APPLS.	2830	1	70	70

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**2855**

Electronic Acknowledgement Receipt	
EFS ID:	32589846
Application Number:	15976340
International Application Number:	
Confirmation Number:	1449
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/Jennifer MacKenzie
Filer Authorized By:	Stuart A. Nelson
Attorney Docket Number:	46440-0009013
Receipt Date:	10-MAY-2018
Filing Date:	
Time Stamp:	15:37:53
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$2855
RAM confirmation Number	051118INTEFSW00002039061050
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	TrackOne Request	Track1.pdf	144187 4773e44862e7b01786cefd0d5ba726f876654b97	no	1
Warnings:					
Information:					
2	Application Data Sheet	ADS.pdf	1256920 fc1caa7ea76c801a485be1b2ac8ba7737ea13017	no	10
Warnings:					
Information:					
3	Transmittal of New Application	PapTrans.pdf	112827 39fdf0802377183322a2060c94405d5cf0f71958	no	3
Warnings:					
Information:					
4	Power of Attorney	POA.pdf	755739 4c218af9c61465ce93cef741b875d3c6a7f2a3cb	no	2
Warnings:					
Information:					
5	Drawings-only black and white line drawings	Drawings.pdf	1106080 aa1065dff04fe690d9819ed000431f3b4c79227e	no	38
Warnings:					
Information:					
6		Spec.pdf	25330504 7acdb57969602d2cd0910d65d22f386403614a84	yes	30

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**

	Specification		1		27
	Claims		28		29
	Abstract		30		30
Warnings:					
Information:					
7	Fee Worksheet (SB06)	fee-info.pdf	38814 d5713a11d21bd6495d9e6e845f295cb4a3cbd3bc	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	28745071		

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.

CERTIFICATION AND REQUEST FOR PRIORITIZED EXAMINATION UNDER 37 CFR 1.102(e) (Page 1 of 1)

First Named Inventor:	Ahmnon D. Moskowitz	Non provisional Application Number (if known):	
Title of Invention:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION		

APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS PRIORITIZED EXAMINATION FOR THE ABOVE-IDENTIFIED APPLICATION.

1. The processing fee set forth in 37 CFR 1.17(i)(1), the prioritized examination fee set forth in 37 CFR 1.17(c), and if not already paid, the publication fee set forth in 37 CFR 1.18(d) have been filed with the request. The basic filing fee, search fee, and examination fee are filed with the request or have been already been paid. I understand that any required excess claims fees or application size fee must be paid for the application.

2. I understand that the application may not contain, or be amended to contain, more than four independent claims, more than thirty total claims, or any multiple dependent claims.

3. The applicable box is checked below:

I. ☒ Original Application (Track One) - Prioritized Examination under § 1.102(e)(1)

i. (a) The application is an original non provisional utility application filed under 35 U.S.C. 111(a). This certification and request is being filed with the utility application via EFS-Web.

---OR---

(b) The application is an original non provisional plant application filed under 35 U.S.C. 111(a). This certification and request is being filed with the plant application in paper.

ii. An executed inventor's oath or declaration under 37 CFR 1.63 or 37 CFR 1.64 for each inventor, **or** the application data sheet meeting the conditions specified in 37 CFR 1.53(f)(3)(i) is filed with the application.

II. ☐ Request for Continued Examination - Prioritized Examination under § 1.102(e)(2)

i. A request for continued examination has been filed with, or prior to, this form.
ii. If the application is a utility application, this certification and request is being filed via EFS-Web.
iii. The application is an original non provisional utility application filed under 35 U.S.C. 111(a), or is a national stage entry under 35 U.S.C. 371.
iv. This certification and request is being filed prior to the mailing of a first Office action responsive to the request for continued examination.
v. No prior request for continued examination has been granted prioritized examination status under 37 CFR 1.102(e)(2).

Signature /Stuart A. Nelson/	Date 5/10/2018
Name (Print/Typed) Stuart A. Nelson	Practitioner Registration Number 63,947

Note: *This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. Submit multiple forms if more than one signature is required.**

☐ *Total of _____ forms are submitted.

61682746.doc

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	46440-0009013
	Application Number	
Title of Invention	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION	

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.
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.

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.)

Inventor Information:

Inventor 1 Remove

Legal Name

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	State/Province	Country of Residence
Rockville	MD	US

Mailing Address of Inventor:

Address 1	212 North Adams St.
Address 2	
City	Rockville
State/Province	MD
Postal Code	20850
Country	US

Inventor 2 Remove

Legal Name

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	State/Province	Country of Residence
Cambridge	MA	US

Mailing Address of Inventor:

Address 1	13 Lancaster St. #2
Address 2	
City	Cambridge
State/Province	MA
Postal Code	02139
Country	US

Inventor 3 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Mosheh	T.	Moskowitz	

Residence Information (Select One) ◉ US Residency Non US Residency Active US Military Service

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	46440-0009013
	Application Number	
Title of Invention	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION	

City	Rockville	State/Province	MD	Country of Residence	US

Mailing Address of Inventor:

Address 1	212 North Adams Street		
Address 2			
City	Rockville	State/Province	MD
Postal Code	20850	Country	US

Inventor 4 Remove

Legal Name

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	US

Mailing Address of Inventor:

Address 1	212 North Adams Street		
Address 2			
City	Rockville	State/Province	MD
Postal Code	20850	Country	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	26191		
Email Address	apsi@fr.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	46440-0009013	Small Entity Status Claimed	☒
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	38	Suggested Figure for Publication (if any)	

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	46440-0009013
	Application Number	
Title of Invention	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION	

Filing By Reference:

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country

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).
Either enter 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	26191		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim 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.
When referring to the current application, please leave the "Application Number" field blank.

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
	Continuation of	15894471	2018-02-12

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	46440-0009013
	Application Number	
Title of Invention	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION	

Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
15894471	Continuation of	13210157	2011-08-15	9889022	2018-02-13
Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
13210157	Continuation of	13084543	2011-04-11	8353913	2013-01-15
Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
13210157	Continuation of	13108982	2011-05-16	9005293	2015-04-14
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	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)
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	Abandoned				Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)		
11536815	Continuation in part of	11208644	2005-08-23		
Prior Application Status	Expired				Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)		
11208644	Claims benefit of provisional	60670231	2005-04-12		
Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button.					Add

Foreign Priority Information:

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	46440-0009013
	Application Number	
Title of Invention	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION	

This section allows for the applicant to claim priority to a foreign application. 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. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)[i] the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

Remove

Application Number	Country[i]	Filing Date (YYYY-MM-DD)	Access Code[i] (if applicable)

Additional Foreign Priority Data may be generated within this form by selecting the **Add** button. Add

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.
NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	46440-0009013
	Application Number	
Title of Invention	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION	

Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant **must opt-out** of the authorization by checking the corresponding box A or B or both in subsection 2 below.

NOTE: This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

A. Priority Document Exchange (PDX) - Unless box A in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h)(1).

B. Search Results from U.S. Application to EPO - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)

☐ A. Applicant **DOES NOT** authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.

☐ B. Applicant **DOES NOT** authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

NOTE: Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	46440-0009013
	Application Number	
Title of Invention	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION	

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Applicant 1 — Remove

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

Clear

● Assignee	Legal Representative under 35 U.S.C. 117	Joint Inventor
Person to whom the inventor is obligated to assign.	Person who shows sufficient proprietary interest	

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor:

If the Applicant is an Organization check here. ☒

Organization Name	Moskowitz Family LLC		
Mailing Address Information For Applicant:			
Address 1	212 North Adams Street		
Address 2			
City	Rockville	**State/Province**	MD
Country	US	Postal Code	20850
Phone Number		Fax Number	
Email Address			

Additional Applicant Data may be generated within this form by selecting the Add button. Add

Assignee Information including Non-Applicant Assignee Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	46440-0009013
	Application Number	
Title of Invention	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION	

Assignee 1

Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

Remove

If the Assignee or Non-Applicant Assignee is an Organization check here. ☐

Prefix	**Given Name**	Middle Name	**Family Name**	Suffix

Mailing Address Information For Assignee including Non-Applicant Assignee:

Address 1			
Address 2			
City		**State/Province**	
Country i		Postal Code	
Phone Number		Fax Number	
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Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button. Add

Signature:

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NOTE: This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b). **However, if this Application Data Sheet is submitted with the INITIAL filing of the application and either box A or B is not checked in subsection 2 of the "Authorization or Opt-Out of Authorization to Permit Access" section, then this form must also be signed in accordance with 37 CFR 1.14(c).**

This Application Data Sheet **must** be signed by a patent practitioner if one or more of the applicants is a **juristic entity** (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, **all** joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of **all** joint inventor-applicants.

See 37 CFR 1.4(d) for the manner of making signatures and certifications.

Signature	/Stuart A. Nelson/			Date (YYYY-MM-DD)	2018-05-10
First Name	Stuart A.	Last Name	Nelson	Registration Number	63,947

Additional Signature may be generated within this form by selecting the Add button. Add

PTO/AIA/14 (02-18)
Approved for use through 11/30/2020. OMB 0651-0032
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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	46440-0009013
	Application Number	
Title of Invention	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION	

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 CooperationTreaty.

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.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor	:	Ahmnon D. Moskowitz	Art Unit	:	Unknown
Application No.	:	15/976,340	Examiner	:	Unknown
Filed	:	May 10, 2018	Conf. No.	:	1449
Title	:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION			

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

PRELIMINARY AMENDMENT

Prior to examination, please amend the application as indicated on the following pages.

Amendments to the Specification:

Please replace the Title with the following amended Title:

INTERVERTEBRAL EXPANDABLE IMPLANT

Please replace the paragraph beginning after the title with the following amended paragraphs:

This application is a Continuation of Application Serial Number 15/894,471, filed February 12, 2018, which is a Continuation of Application Serial Number 13/210,157, filed August 15, 2011, now U.S. Patent No. 9,889,022, which is a Continuation of Application Serial Numbers 13/084,543, filed April 4, 2011, now U.S. Patent No. 8,353,913, and 13/108,982, filed May 16, 2011, now U.S. Patent No. 9,005,293.

Application Serial Number 13/084,543 is a Continuation of Application Serial Number 11/842,855, filed August 21, 2007, now U.S. Patent No. 7,942,903. Application Serial Number 13/108,982 is a Continuation of Application Serial Number 11/842,855, filed August 21, 2007, now U.S. Patent No. 7,942,903, which is a Continuation in part of 11/536,815, filed September 29, 2006, now U.S. Patent No. 7,846,188, which is a Continuation in part of 11/208,644 filed August 23, 2005, which claims priority to 60/670,231, filed April 12, 2005. The entire contents of all of the above identified patent applications are hereby incorporated by reference.

Please replace the Abstract with the following amended Abstract:

An intervertebral expandable implant with first and second vertebral body engagement surfaces includes first and second implant structures defining first and second angled wedge portions. The first angled wedge portion has first and second inwardly-facing rails and first and second inwardly-facing slots. The second angled wedge portion has first and second outwardly-facing rails and first and second outwardly facing slots. The first implant structure is slidably-engaged with the second implant structure with the first inwardly-facing rail positioned in the

first outwardly-facing slot, the second inwardly-facing rail positioned in the second outwardly facing slot, the first outwardly-facing rail positioned in the first inwardly-facing slot, and the second outwardly-facing rail positioned in the second inwardly-facing slot.

Amendments to the Claims:

This listing of claims replaces all prior versions and listings of claims in the application:

Listing of Claims:

1-10 (Cancelled)

11. (New) An intervertebral expandable implant having an inferior surface for engaging an inferior vertebral body and a superior surface for engaging a superior vertebral body, wherein the superior surface is positioned opposite of the inferior surface, the intervertebral expandable implant comprising:

a first implant structure defining the inferior surface and a first angled wedge portion that is angled with respect to the inferior surface, wherein the first angled wedge portion comprises a first inwardly-facing rail and a second inwardly-facing rail, wherein a first inwardly-facing slot is defined at a location adjacent the first inwardly-facing rail between the first inwardly-facing rail and the inferior surface, wherein a second inwardly-facing slot is defined at a location adjacent the second inwardly-facing rail between the second inwardly-facing rail and the inferior surface, wherein the first implant structure defines first and second opposing side surfaces positioned on opposite sides of the inferior surface, wherein the first implant structure defines at least first, second, and third openings with the first opening extending through the inferior surface of the first implant and the second and third openings extending through the first and second side surfaces; and

a second implant structure defining a second angled wedge portion that comprises a first outwardly-facing rail and a second outwardly-facing rail that faces outwardly in a direction opposite that of the first outwardly-facing rail, wherein a first outwardly-facing slot is defined at a location adjacent the first outwardly-facing rail, wherein a second outwardly-facing slot is defined at a location adjacent the second

outwardly-facing rail, wherein the first implant structure is slidably-engaged with the second implant structure such that the first angled wedge portion engages the second angled wedge portion with the first inwardly-facing rail of the first implant structure positioned in the first outwardly-facing slot of the second implant structure, the second inwardly-facing rail of the first implant structure positioned in the second outwardly facing slot of the second implant structure, the first outwardly-facing rail of the second implant structure positioned in the first inwardly-facing slot of the first implant structure, and the second outwardly-facing rail of the second implant structure positioned in the second inwardly-facing slot of the first implant structure.

12. (New) The intervertebral expandable implant of claim 11, wherein the second implant structure defines first and second screw guides angled to guide screws bi-directionally into the superior and inferior vertebral bodies.

13. (New) The intervertebral expandable implant of claim 11, and further comprising an adjusting screw having a threaded shaft, wherein the adjusting screw extends through at least part of the first implant structure and the second implant structure.

14. (New) The intervertebral expandable implant of claim 13, wherein the second implant structure defines a threaded hole, wherein the adjusting screw comprises a threaded shaft, wherein the threaded shaft is positioned in the threaded hole, and wherein rotation of the adjusting screw with respect to the second implant structure moves the second implant structure with respect to the first implant structure to slide the first angled wedge portion with respect to the second angled wedge portion and expand the intervertebral expandable implant.

15. (New) The intervertebral expandable implant of claim 13, wherein the adjusting screw extends through a portion of the first implant structure that is larger than a diameter of the threaded shaft of the adjusting screw so as to allow the first implant structure to move with

respect to the adjusting screw along a direction normal to the inferior surface of the first implant structure when the intervertebral expandable implant is expanded.

16. (New) The intervertebral expandable implant of claim 11, and further comprising means for sliding the first implant structure with respect to the second implant structure to adjusting height of the expandable intervertebral implant.

17. (New) The intervertebral expandable implant of claim 16, and further comprising means to facilitate incorporation into and fusion with the superior and inferior vertebral bodies.

18. (New) The intervertebral expandable implant of claim 17, and further comprising means to connect the intervertebral expandable implant to the inferior and superior vertebral bodies.

19. (New) The intervertebral expandable implant of claim 11, wherein the second and third openings have a substantially circular cross-section and are co-axially aligned with one-another at a location nearer a first end of the first implant structure than a second end of the first implant structure.

20. (New) The intervertebral expandable implant of claim 11, wherein the second implant structure defines first, second, and third holes, wherein the second hole is positioned between the first and third holes, and wherein an adjusting screw extends through the second hole.

21. (New) The intervertebral expandable implant of claim 11, wherein the second implant structure defines the superior surface.

22. (New) An intervertebral expandable implant having a first vertebral body engagement surface and a second vertebral body engagement surface positioned opposite of the first vertebral body engagement surface for engaging inferior and superior vertebral bodies, the intervertebral expandable implant comprising:

a first implant structure defining the first vertebral body engagement surface and a first angled wedge portion that is angled with respect to the first vertebral body engagement surface, wherein the first angled wedge portion comprises a first inwardly-facing rail and a second inwardly-facing rail, wherein a first inwardly-facing slot is defined at a location adjacent the first inwardly-facing rail between the first inwardly-facing rail and the first vertebral body engagement surface, wherein a second inwardly-facing slot is defined at a location adjacent the second inwardly-facing rail between the second inwardly-facing rail and the first vertebral body engagement surface, wherein the first implant structure defines first and second opposing side surfaces positioned on opposite sides of the first vertebral body engagement surface;

a second implant structure defining a second angled wedge portion that comprises a first outwardly-facing rail and a second outwardly-facing rail that faces outwardly in a direction opposite that of the first outwardly-facing rail, wherein a first outwardly-facing slot is defined at a location adjacent the first outwardly-facing rail, wherein a second outwardly-facing slot is defined at a location adjacent the second outwardly-facing rail, wherein the first implant structure is slidably-engaged with the second implant structure such that the first angled wedge portion engages the second angled wedge portion with the first inwardly-facing rail of the first implant structure positioned in the first outwardly-facing slot of the second implant structure, the second inwardly-facing rail of the first implant structure positioned in the second outwardly facing slot of the second implant structure, the first outwardly-facing rail of the second implant structure positioned in the first inwardly-facing slot of the first implant structure, and the second outwardly-facing rail of the second implant structure positioned in the second inwardly-facing slot of the first implant structure; and

an adjusting screw having a threaded shaft, wherein the second implant structure defines a screw hole, wherein the threaded shaft of the adjusting screw is positioned in the screw hole of the second implant structure, wherein the first implant structure defines a space that is larger than a diameter of the threaded shaft of the adjusting

screw so as to allow the first implant structure to move with respect to the adjusting screw along a direction normal to the first vertebral body engagement surface when the intervertebral expandable implant is expanded, and wherein rotation of the adjusting screw with respect to the second implant structure moves the second implant structure with respect to the first implant structure to slide the first angled wedge portion with respect to the second angled wedge portion and expand the intervertebral expandable implant.

.

23. (New) The intervertebral expandable implant of claim 22, wherein the second implant structure defines first and second screw guides angled to guide screws bi-directionally into the superior and inferior vertebral bodies.

24. (New) The intervertebral expandable implant of claim 22, and further comprising means to facilitate incorporation into and fusion with the superior and inferior vertebral bodies.

25. (New) The intervertebral expandable implant of claim 24, and further comprising means to connect the intervertebral expandable implant to the inferior and superior vertebral bodies.

26. (New) The intervertebral expandable implant of claim 22, wherein the second implant structure defines an indentation adjacent the screw hole.

27. (New) The intervertebral expandable implant of claim 22, wherein the second implant structure defines the second vertebral body engagement surface.

28. (New) An intervertebral expandable implant having a first vertebral body engagement surface and a second vertebral body engagement surface positioned opposite of the first vertebral body engagement surface for engaging inferior and superior vertebral bodies, the intervertebral expandable implant comprising:

a first implant structure defining the first vertebral body engagement surface and a first angled wedge portion that is angled with respect to the first vertebral body

engagement surface, wherein the first angled wedge portion comprises a first inwardly-facing rail and a second inwardly-facing rail, wherein a first inwardly-facing slot is defined at a location adjacent the first inwardly-facing rail between the first inwardly-facing rail and the first vertebral body engagement surface, wherein a second inwardly-facing slot is defined at a location adjacent the second inwardly-facing rail between the second inwardly-facing rail and the first vertebral body engagement surface, wherein the first implant structure defines first and second opposing side surfaces positioned on opposite sides of the first vertebral body engagement surface; and

a second implant structure defining a second angled wedge portion that comprises a first outwardly-facing rail and a second outwardly-facing rail that faces outwardly in a direction opposite that of the first outwardly-facing rail, wherein a first outwardly-facing slot is defined at a location adjacent the first outwardly-facing rail, wherein a second outwardly-facing slot is defined at a location adjacent the second outwardly-facing rail, wherein the first implant structure is slidably-engaged with the second implant structure such that the first angled wedge portion engages the second angled wedge portion with the first inwardly-facing rail of the first implant structure positioned in the first outwardly-facing slot of the second implant structure, the second inwardly-facing rail of the first implant structure positioned in the second outwardly facing slot of the second implant structure, the first outwardly-facing rail of the second implant structure positioned in the first inwardly-facing slot of the first implant structure, and the second outwardly-facing rail of the second implant structure positioned in the second inwardly-facing slot of the first implant structure,

wherein the intervertebral expandable implant defines first and second screw guides positioned and configured to guide screws into the superior and inferior vertebral bodies, and wherein at least one of the first and second implant structures defines at least one of the first and second screw guides.

29. (New) The intervertebral expandable implant of claim 28, wherein the at least one of the first and second implant structures defines both of the first and second screw guides.

30. (New) The intervertebral expandable implant of claim 28, and further comprising:

an adjusting screw having a threaded shaft, wherein the second implant structure defines a screw hole, wherein the threaded shaft of the adjusting screw is positioned in the screw hole of the second implant structure, wherein the first implant structure defines a space that is larger than a diameter of the threaded shaft of the adjusting screw so as to allow the first implant structure to move with respect to the adjusting screw along a direction normal to the first vertebral body engagement surface when the intervertebral expandable implant is expanded, and wherein rotation of the adjusting screw with respect to the second implant structure moves the second implant structure with respect to the first implant structure to slide the first angled wedge portion with respect to the second angled wedge portion and expand the intervertebral expandable implant.

31. (New) The intervertebral expandable implant of claim 28, wherein the threaded shaft of the adjusting screw is threaded around an exterior circumference of the threaded shaft.

32. (New) The intervertebral expandable implant of claim 28, wherein the threaded shaft of the adjusting screw is threaded along substantially a full length of the threaded shaft.

33. (New) The intervertebral expandable implant of claim 28, and further comprising means for sliding the first implant structure with respect to the second implant structure to adjusting height of the expandable intervertebral implant.

34. (New) The intervertebral expandable implant of claim 33, and further comprising means to facilitate incorporation into and fusion with the superior and inferior vertebral bodies.

35. (New) The intervertebral expandable implant of claim 34, and further comprising means to connect the intervertebral expandable implant to the inferior and superior vertebral bodies.

36. (New) The intervertebral expandable implant of claim 28, wherein the second implant structure defines a first hole having a first centerline axis, wherein the first screw guide has a second centerline axis that is angled with respect to the first centerline axis so as to guide a first screw into one of the superior and inferior vertebral bodies, and wherein the second screw guide has a third centerline axis that is angled with respect to both of the first and second centerline axes so as to guide a second screw into the other of the superior and inferior vertebral bodies.

REMARKS

With this amendment, claims 1-10 are cancelled without prejudice. Claims 11-36 are added. Support for these amendments can be found throughout the amended specification and figures, for example, including but not limited to Figures 1A-1E and the corresponding specification text.

Applicant asks that this application be examined in view of the amendments. Please apply any necessary charges or credits to Deposit Account 06-1050, referencing the above attorney docket number.

Respectfully submitted,

Date: 5/14/2018

/Stuart A. Nelson/
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Facsimile: (877) 769-7945

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Electronic Patent Application Fee Transmittal

Application Number:	15976340
Filing Date:	
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:	46440-0009013

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	6	50	300
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**300**

Electronic Acknowledgement Receipt	
EFS ID:	32618269
Application Number:	15976340
International Application Number:	
Confirmation Number:	1449
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:	46440-0009013
Receipt Date:	14-MAY-2018
Filing Date:	
Time Stamp:	16:56:20
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$300
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Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		Prelim.pdf	96413 d65d2e27384b724ca72bc46d49a3cbb831264ae5	yes	12
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Preliminary Amendment		1	1	
	Specification		2	3	
	Claims		4	11	
	Applicant Arguments/Remarks Made in an Amendment		12	12	
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30619 5d8a287699e49dc87ed0ec7787113dc60f9e1036	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	127032		

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If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

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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	:	Unknown
Serial No.	:	15/976,340	Examiner	:	Unknown
Filed	:	May 10, 2018	Conf. No.	:	1449
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. Foreign patent documents and non-patent literature are enclosed; cited U.S. patents and patent application publications will be provided on request. A copy of a communication from a foreign patent office in a counterpart application is also enclosed.

This statement is being filed within three months of the filing date of the application. 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: 5/31/2018

/Stuart A. Nelson/
Stuart A. Nelson
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Substitute Disclosure Form	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No. 46440-0009013	Application No. 15/976,340
Information Disclosure Statement by Applicant (Use several sheets if necessary)		Applicant Moskowitz Family LLC	
(37 CFR §1.98(b))		Filing Date May 10, 2018	Group Art Unit

U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	1.	5123926	6/23/1992	Pisharodi			
	2.	5514180	5/7/1996	Heggeness et al.			
	3.	6368350	4/9/2002	Erickson et al.			
	4.	6419704	7/16/2002	Ferree			
	5.	6458159	10/1/2002	Thalgott			
	6.	6527804	3/4/2003	Gauche! et al.			
	7.	6533818	3/18/2003	Weber et al.			
	8.	6579318	6/17/2003	Varga et al.			
	9.	6582468	6/24/2003	Gauchet			
	10.	6719794	4/13/2004	Gerber			
	11.	6733532	5/11/2004	Gauche! et al.			
	12.	6764491	7/20/2004	Frey et al.			
	13.	6770094	8/3/2004	Fehling et al.			
	14.	6572653	6/3/2003	Simonson			
	15.	5782832	7/21/1998	Larsen et al.			
	16.	6641614	11/4/2003	Wagner et al.			
	17.	6126689	10/3/2000	Brett			
	18.	6375682	4/23/2002	Fleischmann et al.			
	19.	6723126	4/20/2004	Berry			
	20.	5667472	9/7/1997	Finn et al.			
	21.	6955671	10/18/2005	Uchikubo			
	22.	7037258	5/2/2006	Chatenever et al.			
	23.	6904308	6/7/2005	Frisch et al.			
	24.	7097615	8/29/2006	Banik et al.			
	25.	7030904	4/18/2006	Adair et al.			
	26.	4997432	3/5/1991	Keller			

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. 46440-0009013	Application No. 15/976,340
Information Disclosure Statement by Applicant (Use several sheets if necessary)		Applicant Moskowitz Family LLC	
(37 CFR §1.98(b))		Filing Date May 10, 2018	Group Art Unit

U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	27.	5960522	10/5/1999	Boe			
	28.	5660188	8/26/1997	Groiso			
	29.	4960420	10/2/1990	Goble et al.			
	30.	4636217	1/13/1987	Ogilvie et al.			
	31.	4554914	11/26/1985	Kapp et al.			
	32.	6953477	10/11/2005	Berry			
	33.	4599086	7/8/1986	Doty			
	34.	5062850	11/5/1991	MacMillan et al.			
	35.	5290312	3/1/1994	Kojimoto et al.			
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Substitute Disclosure Form

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Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))	46440-0009013	15/976,340
	Applicant: Moskowitz Family LLC	
	Filing Date: May 10, 2018	Group Art Unit

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(12) NACH DEM VERTRAG ÜBER DIE INTERNATIONALE ZUSAMMENARBEIT AUF DEM GEBIET DES PATENTWESENS (PCT) VERÖFFENTLICHTE INTERNATIONALE ANMELDUNG

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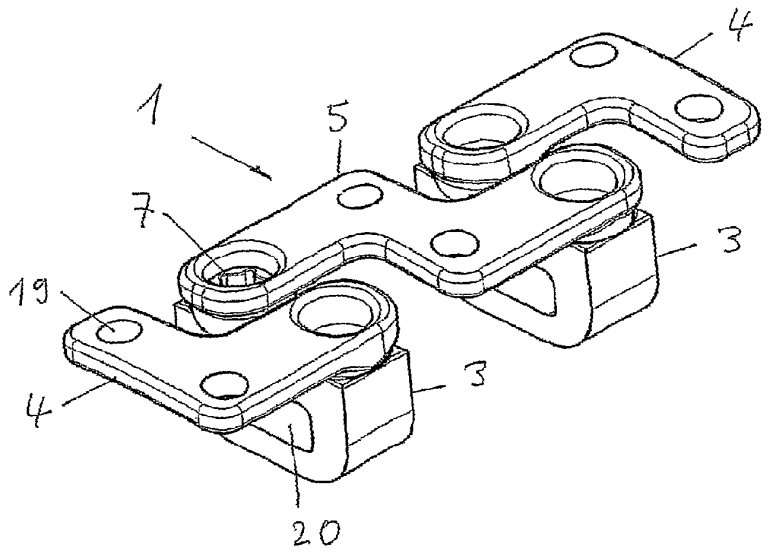
(74) Anwalt: **GRONER, Manfred**; Isler & Pedrazzini AG, Gotthardtstrasse 53, Postfach 6940, CH-8023 Zürich (CH).

(81) Bestimmungsstaaten *(soweit nicht anders angegeben, für jede verfügbare nationale Schutzrechtsart)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

[Fortsetzung auf der nächsten Seite]

(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]

WO 2004/093749 A1

(84) Bestimmungsstaaten *(soweit nicht anders angegeben, für jede verfügbare regionale Schutzrechtsart)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), eurasisches (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), europäisches (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Veröffentlicht:
— *mit internationalem Recherchenbericht*

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 Intervertebralimplantat (3) und wenigstens eine Platte (4,5) auf, die mit dem Intervertebralimplantat (3) und einem benachbarten Wirbel (21-23) zu verbinden ist. Das Intervertebralimplantat (3) ist mit wenigstens zwei im Abstand zueinander angeordneten Platten (4,5) verbunden. Beide Platten (4,5) bilden jeweils an einem Ende mit dem Intervertebralimplantat (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 flügelförmige 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 Gewindeschaft 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 winkelstabil 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 Kugelkopfschraube 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 Kugelkopfschrauben 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 folgenschweren 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 Kugelkopfschraube 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 Kugelkopfschraube 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 arrodiert 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	Gewindeschaft		
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 Kugelgelen kes 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.

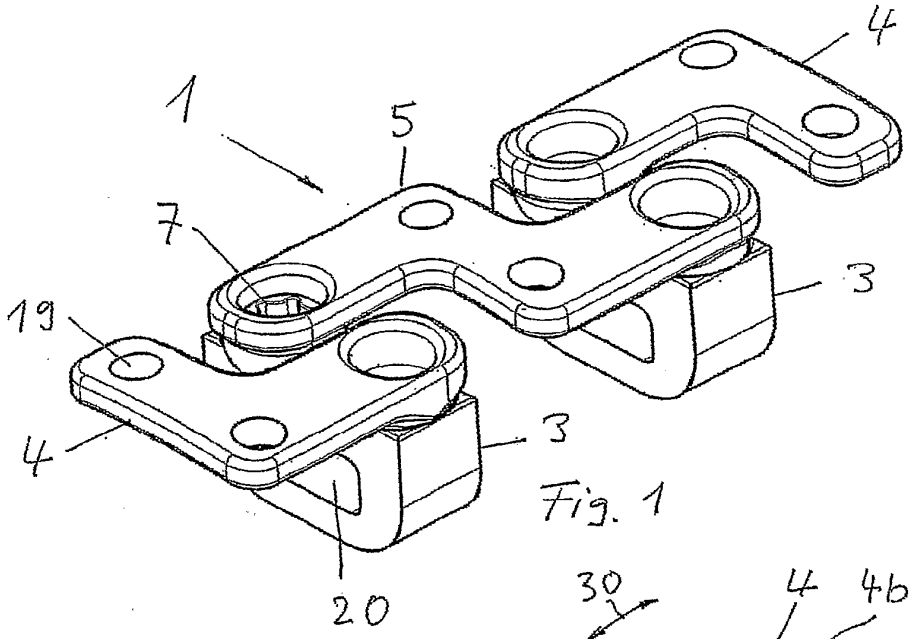


Fig. 1

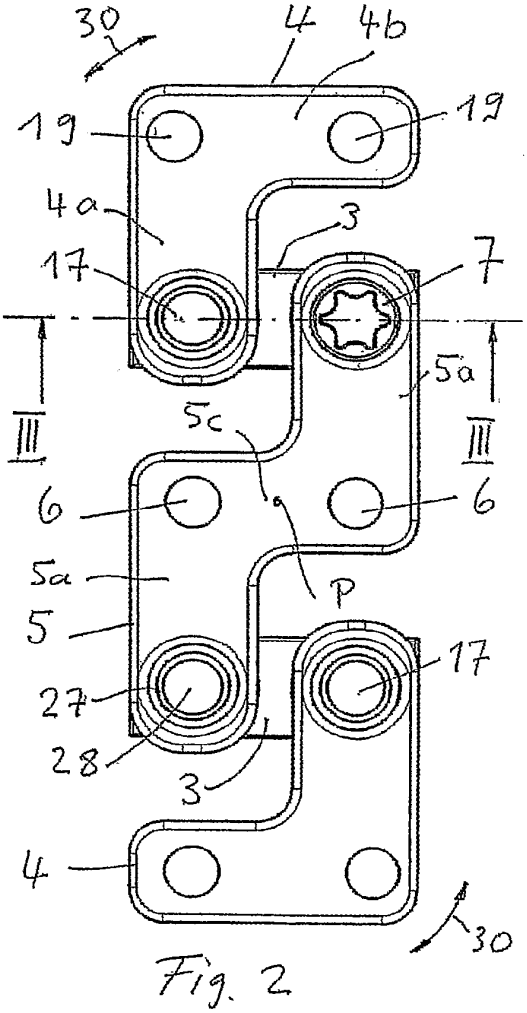


Fig. 2

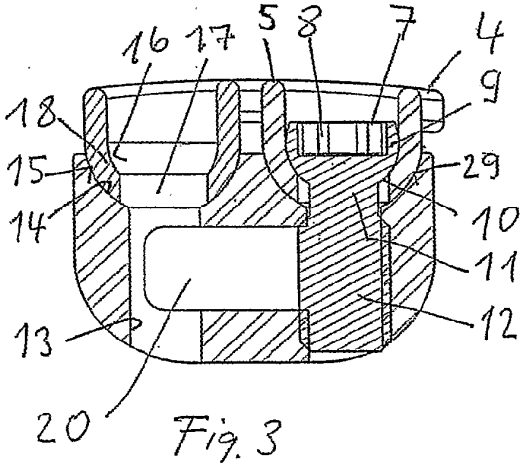


Fig. 3

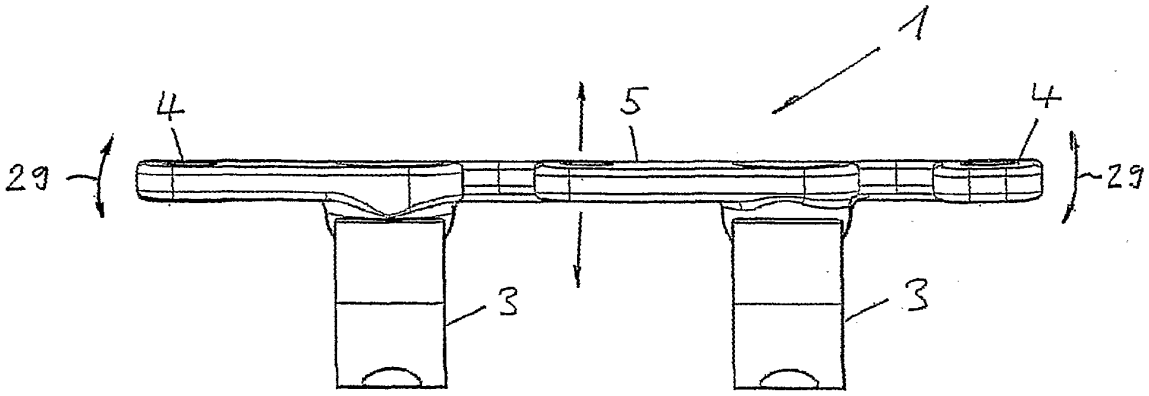


Fig. 4

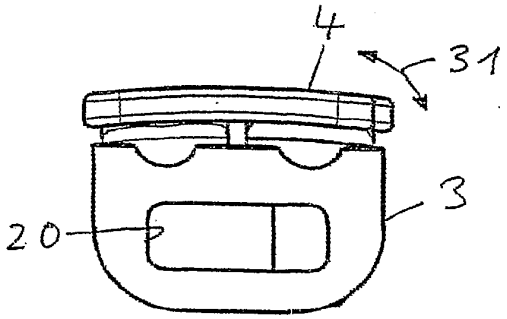


Fig. 5

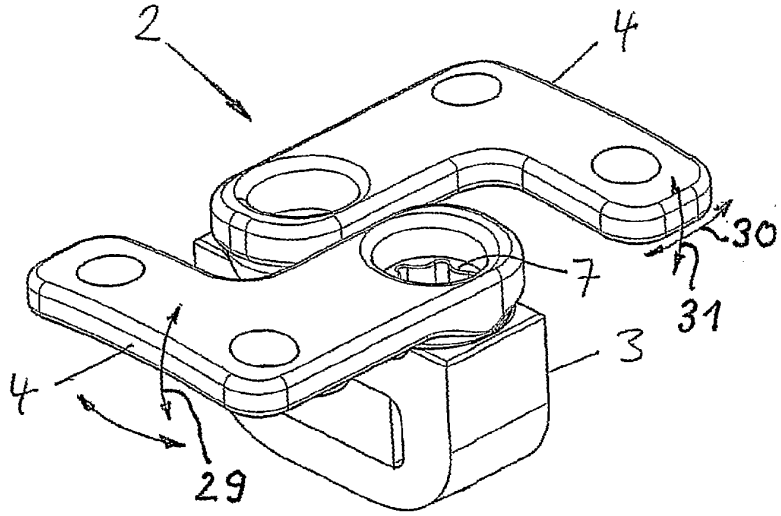


Fig. 6

ERSATZBLATT (REGEL 26)

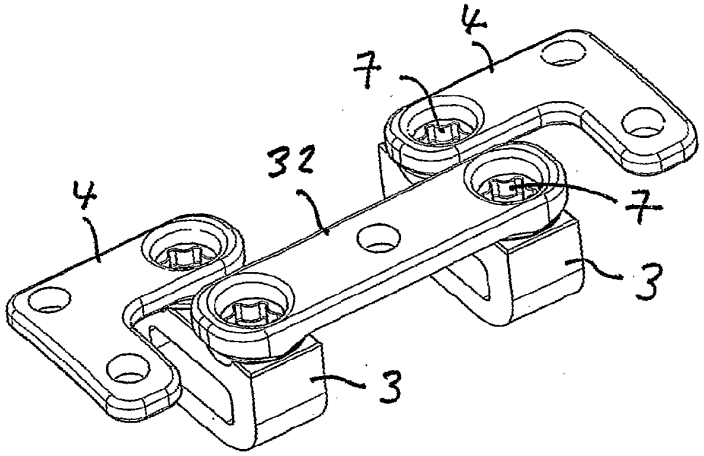


Fig. 7

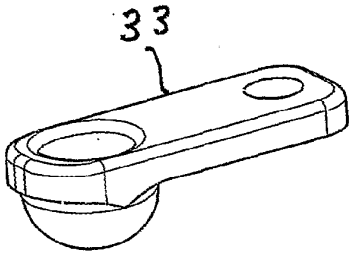


Fig. 8

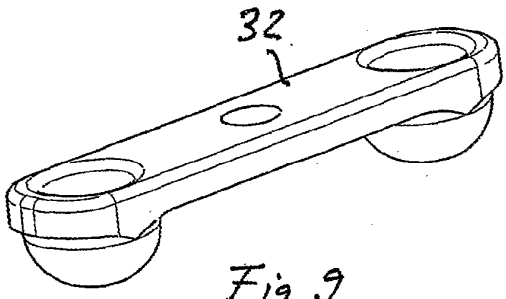


Fig. 9

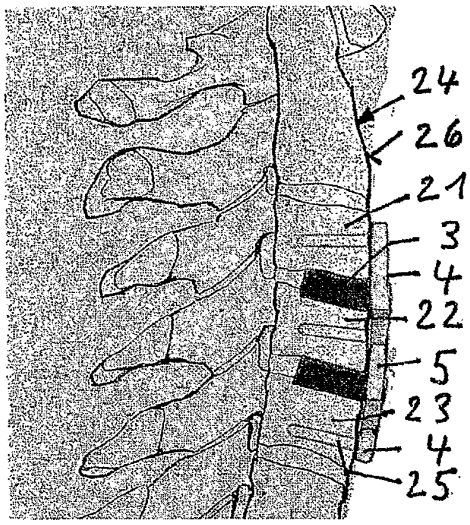


Fig. 10

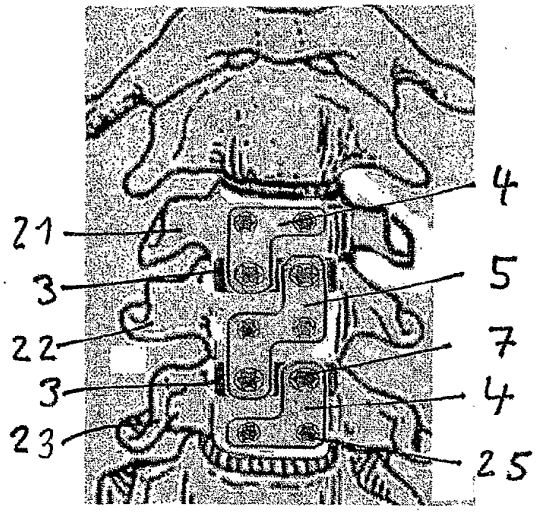


Fig. 11

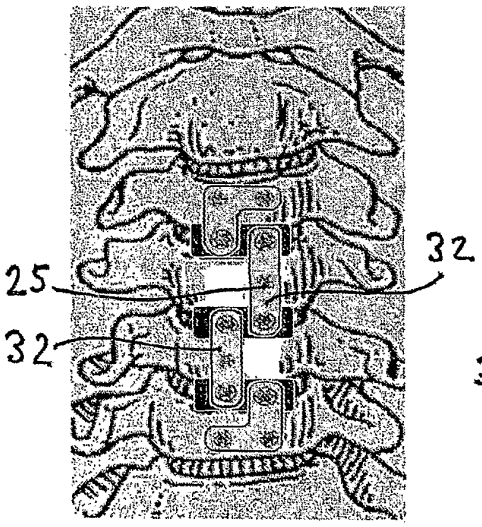


Fig. 12

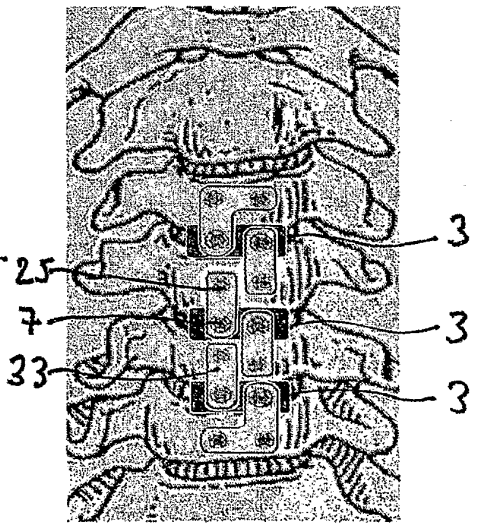


Fig. 13

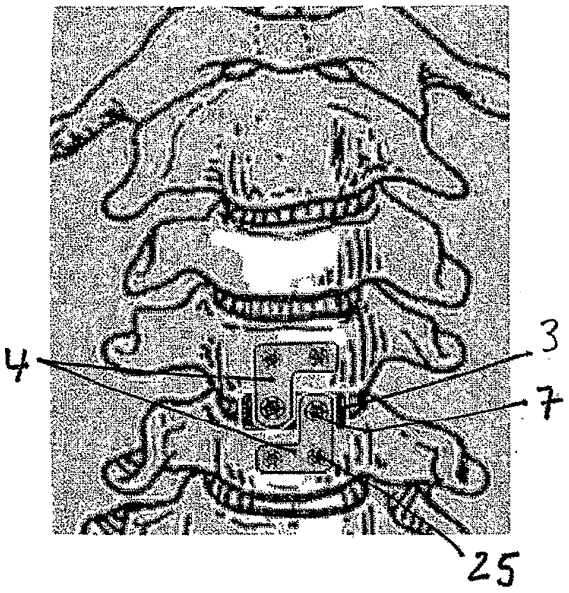


Fig. 14

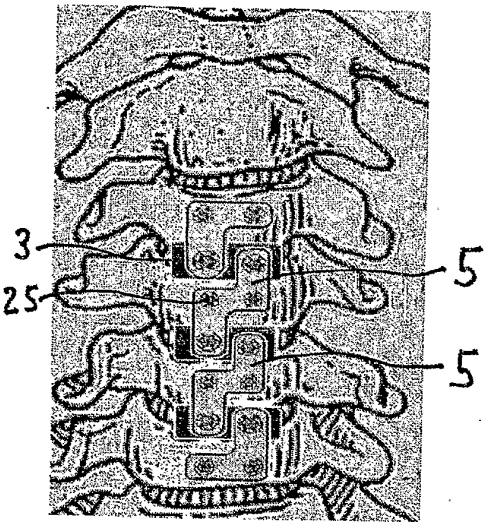


Fig. 15

INTERNATIONAL SEARCH REPORT

ɔnal 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		8
A		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

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
30 July 2004	09/08/2004

Name and mailing address of the ISA	Authorized officer
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	Stach, R

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 00/22998 A (JACKSON ROGER P) 27 April 2000 (2000-04-27) figures 12,13	8
A		1-4,7,9, 13
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	1,5,13, 14
A	US 6 306 136 B1 (BACCELLI CHRISTIAN) 23 October 2001 (2001-10-23) figures 3,7,8	1,2,7,8, 13
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formation on patent family members

ınal Application No
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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

Recherchierter 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)
EPO-Internal

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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[X] Weitere Veröffentlichungen sind der Fortsetzung von Feld C zu entnehmen

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30. Juli 2004	09/08/2004

Name und Postanschrift der Internationalen Recherchenbehörde	Bevollmächtigter Bediensteter
Europäisches Patentamt, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Stach, R

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INTERNATIONALER RECHERCHENBERICHT

Internales Aktenzeichen
PCT/CH2004/000244

C.(Fortsetzung) ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie°	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
Y	WO 00/22998 A (JACKSON ROGER P) 27. April 2000 (2000-04-27) Abbildungen 12,13	8
A		1-4,7,9, 13
A	US 6 156 037 A (LEHUEC JEAN-CHARLES ET AL) 5. Dezember 2000 (2000-12-05) Anspruch 1; Abbildungen 2-6,13-16 Spalte 3, Zeile 51 - Spalte 4, Zeile 14	1,5,13, 14
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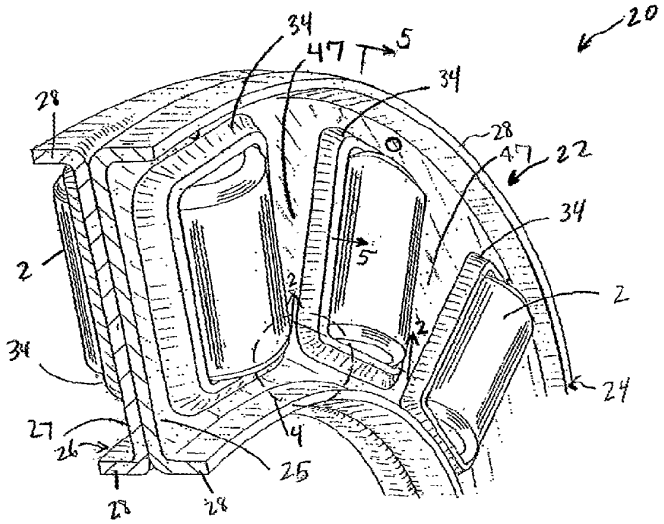
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(54) Title: THRUST BEARING ASSEMBLY



(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 circumf erentially 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) circumf erentially 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. 1

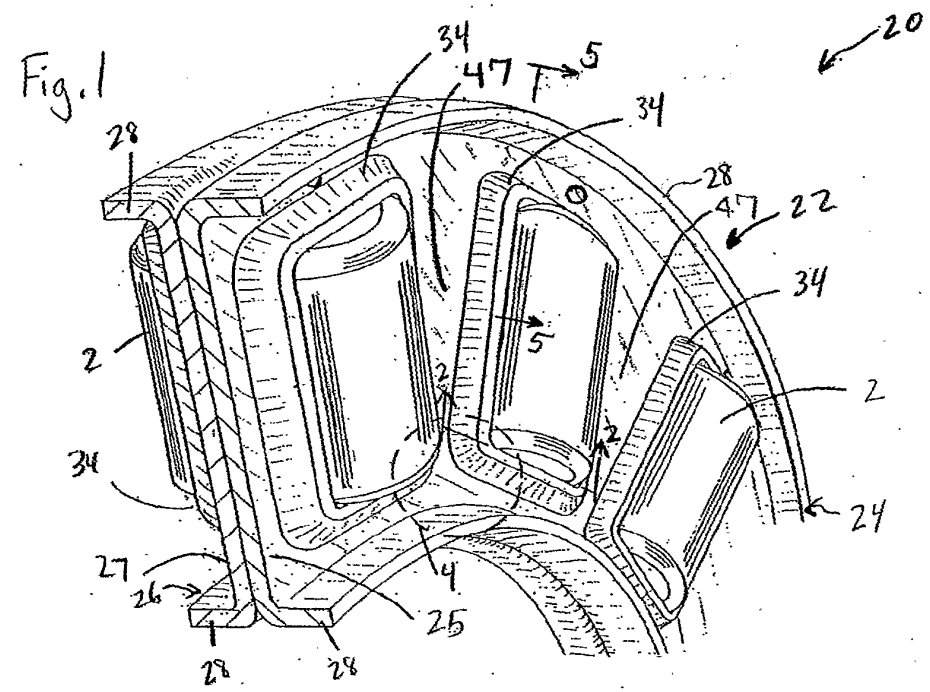


Fig. 2

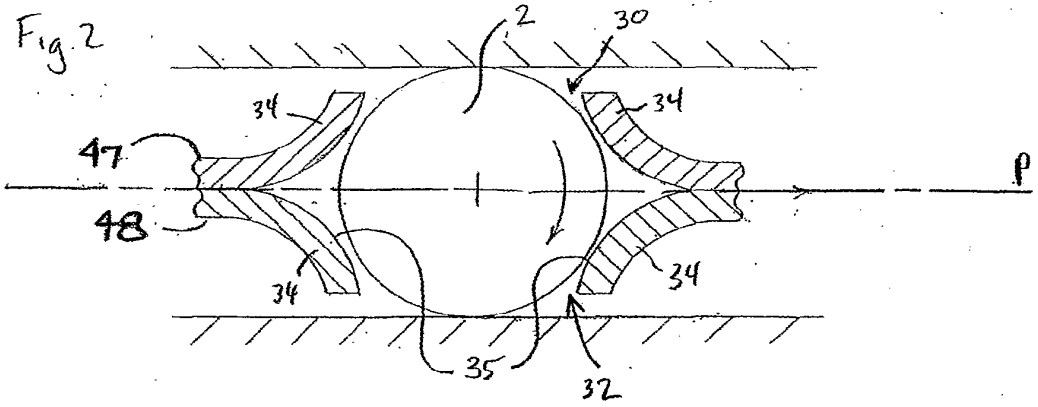


Fig. 3

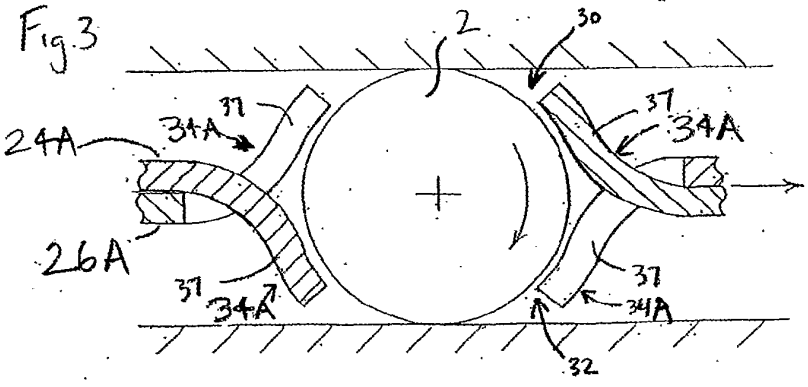
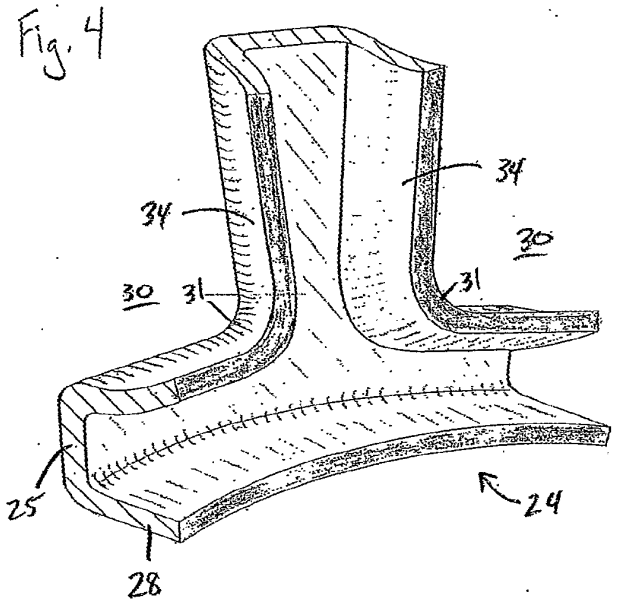


Fig. 4



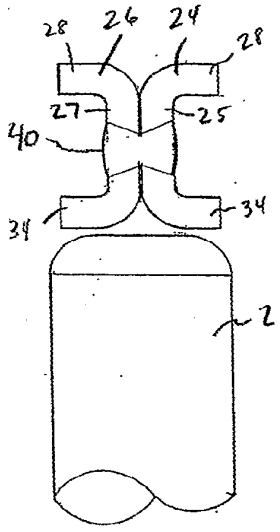


Fig. 5

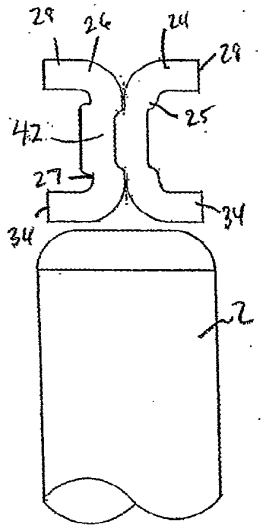


Fig. 6

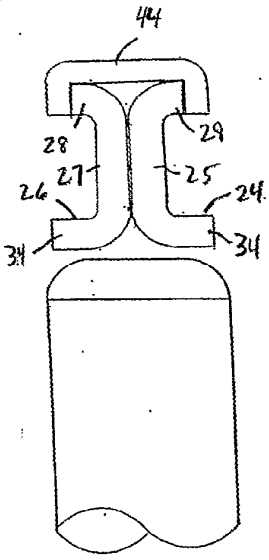


Fig. 7

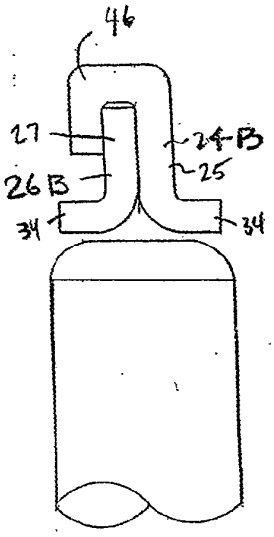


Fig. 8

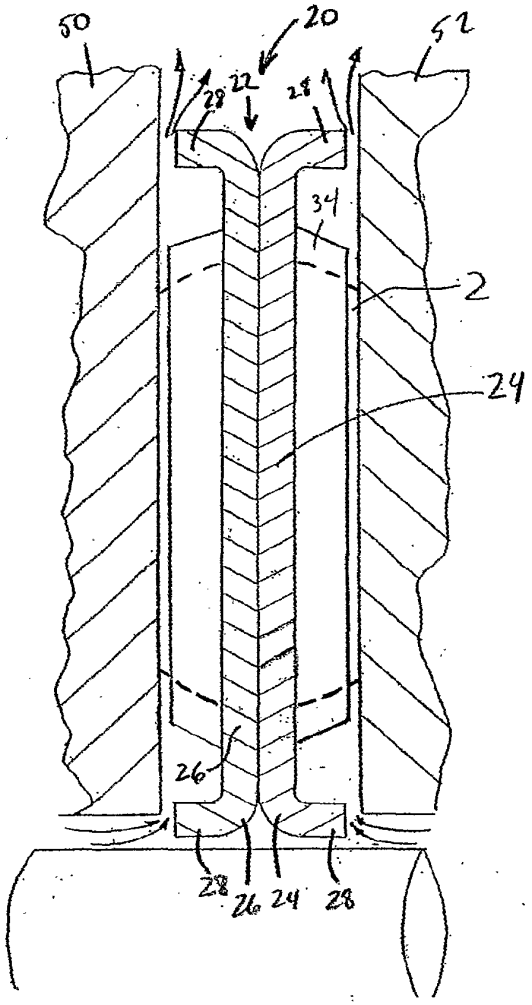


Fig. 9

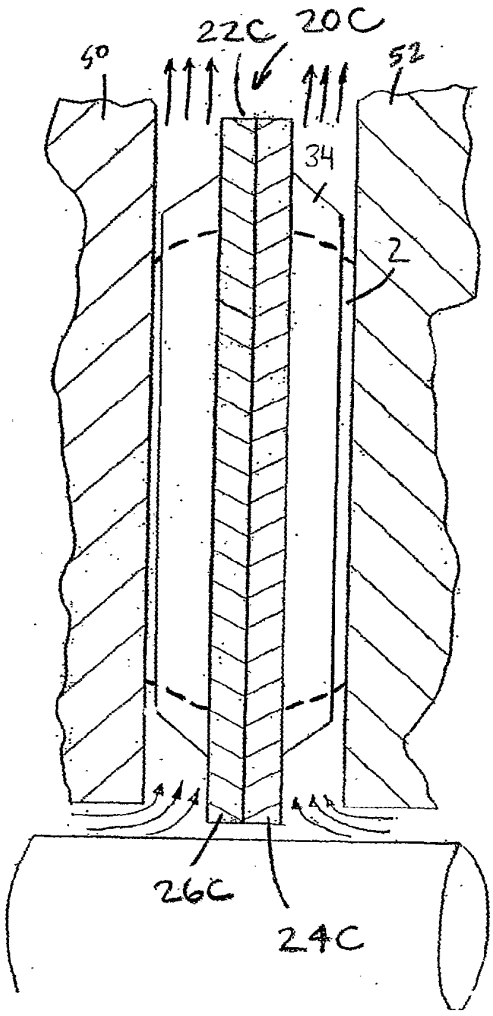


Fig. 10

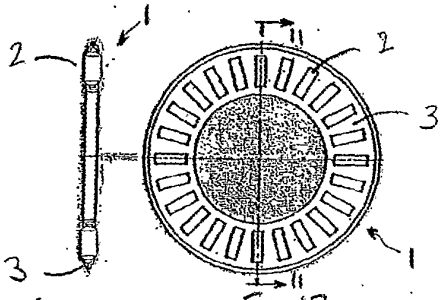


Fig. 11 (Prior Art)

Fig. 12 (Prior Art)

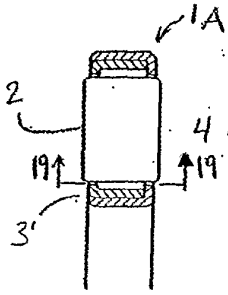


Fig. 13 (Prior Art)

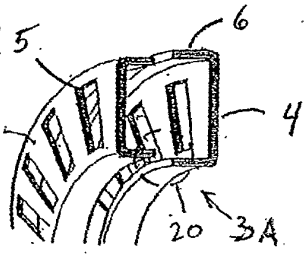


Fig. 14 (Prior Art)

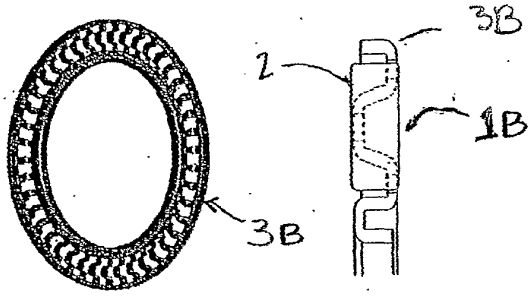


Fig. 15 (Prior Art)

Fig. 16 (Prior Art)

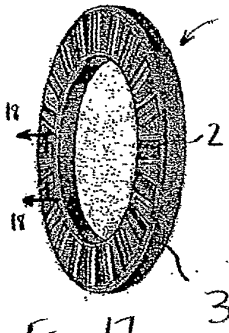


Fig. 17 (Prior Art)

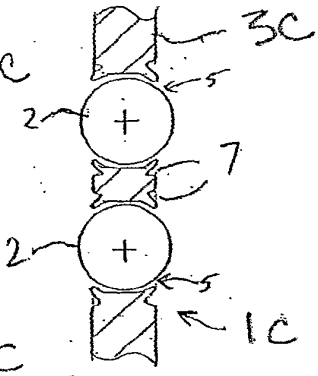


Fig. 18 (Prior Art)

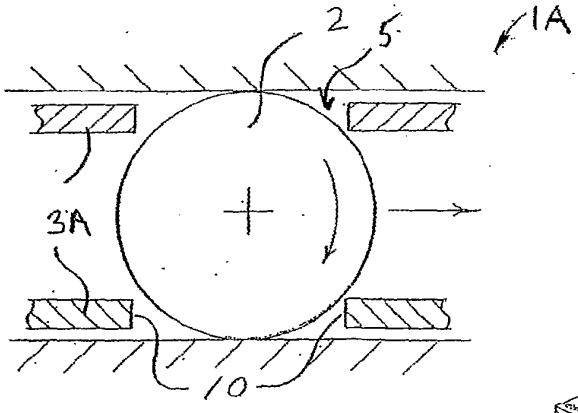


Fig. 19 (Prior Art)

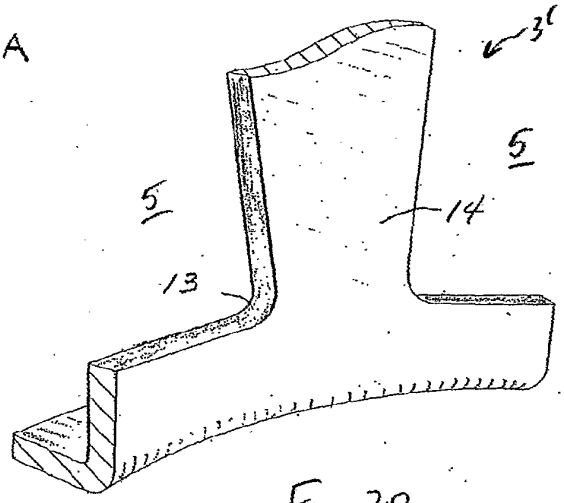


Fig. 20 (Prior Art)

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	US 1 734 222 A (MARLES HENRY) 5 November 1929 (1929-11-05)	1,2,4, 7-10
A	page 1, line 31 - line 83; figures 1-4	6

-/--

[X] Further documents are listed in the continuation of Box C. [X] 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
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"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	Date of mailing of the international search report
15 June 2006	30/06/2006

Name and mailing address of the ISA/	Authorized officer
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	Axelsson, T

Form PCT/ISA/210 (second sheet) (April 2005)

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

Form PCT/ISA/210 (continuation of second sheet) (April 2005)

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	

Espacenet

Bibliographic data: FR2727003 (A1) — 1996-05-24

Lumbar-sacral vertebrae anterior stabiliser

Inventor(s): TISSERAND PHILIPPE ± (TISSERAND PHILIPPE)

Applicant(s): EUROS SA [FR] ± (EUROS SA)

Classification: - international: ***A61F2/44;*** *A61B17/86; A61F2/00; A61F2/28; A61F2/30;* (IPC1-7): A61B17/70; A61F2/44
- cooperative: **A61F2/442; A61F2/4455;** A61B17/86; A61F2/30965; A61F2002/2835; A61F2002/30112; A61F2002/30153; A61F2002/30271; A61F2002/30777; A61F2002/30782; A61F2002/30785; A61F2002/30787; A61F2002/30789; A61F2002/30794; A61F2002/30904; A61F2002/4475; A61F2230/0004; A61F2230/0019; A61F2230/0082; A61F2310/00023

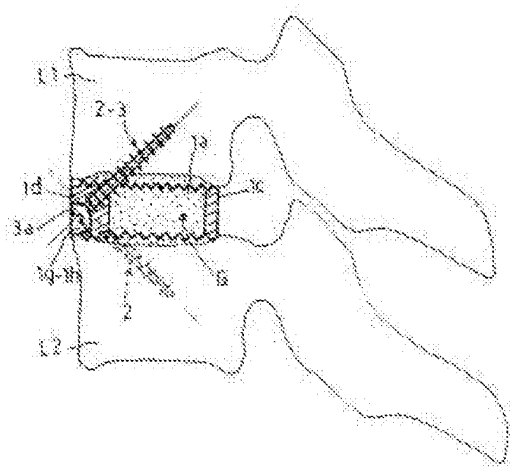
Application number: FR19940014067 19941118

Priority number(s): FR19940014067 19941118

Also published as: FR2727003 (B1)

Abstract of FR2727003 (A1)

The stabiliser consists of an insert designed to fit between two vertebrae (L1,L2) to maintain the spacing between them and receive spongy grafts, permitting their intersomatic fusion. The insert has holes (1g,1h) for fixings (2,3) which engage with the adjacent vertebrae and are angled at 90 deg to one another. The inset is three-dimensional and hollow, generally rectangular and shaped to conform to the anatomy of the adjacent vertebrae. It has a concave posterior surface (1c) and a rounded anterior surface (1d), with the anterior surface having a greater height than the posterior one to conform to the lumbar-sacral lordosis. Its upper and lower surfaces are grooved to ensure primary stability. The insert can be made from titanium or a polymer reinforced with carbon fibres.



(19) RÉPUBLIQUE FRANÇAISE

INSTITUT NATIONAL
DE LA PROPRIÉTÉ INDUSTRIELLE

PARIS

(11) N° de publication : **2 727 003**
(à n'utiliser que pour les commandes de reproduction)

(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.

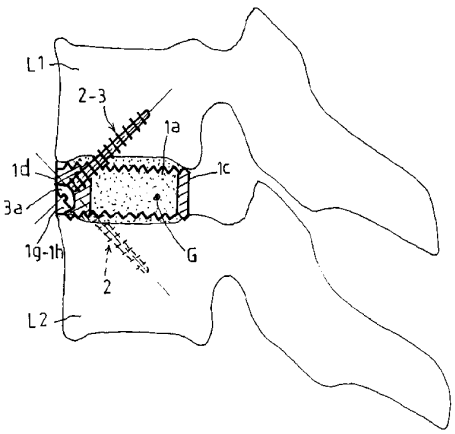
(72) **Inventeur(s) :** TISSERAND PHILIPPE.

(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.

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.

Pour assurer une telle stabilisation, il est connu d'utiliser des implants sous forme de plateaux, destinés à être inserrés 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 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.

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 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 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.

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 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, 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.

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 pour faciliter la stabilité primaire.

L'invention est exposée, ci-après plus en détail à l'aide des dessins annexés, dans lesquels :

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.

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 avantageusement prélevés sur la crête iliaque ou dans l'extrémité supérieure du tibia.

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 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), 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 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 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 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).

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 carbonne.

A noter que l'élément (1) est réalisé selon essentiellement 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,
- 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 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 essentillement soit à la charnière lombosacrée soit aux vertèbres sus-

jacentes, notamment au niveau des espaces L3-L4 et L4-L5.

Les avantages ressortent bien de la description, en particulier 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.

REVENDICATIONS

-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.

-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 rapport à l'autre, selon un angle d'environ 90°.

-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.

-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.

-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.

-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.

-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.

-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.

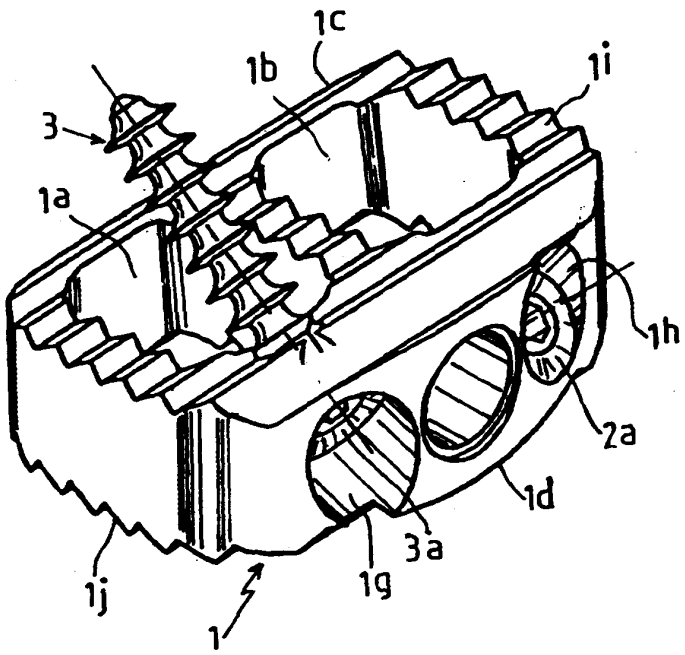


FIG.1

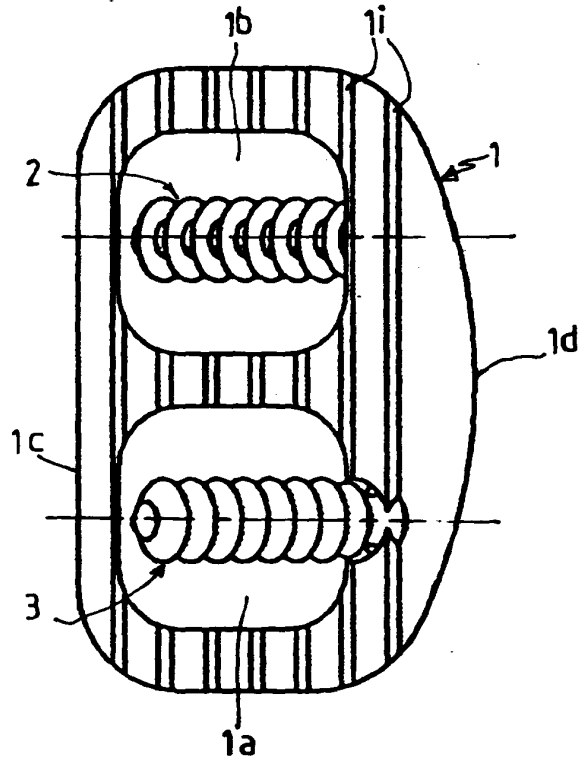
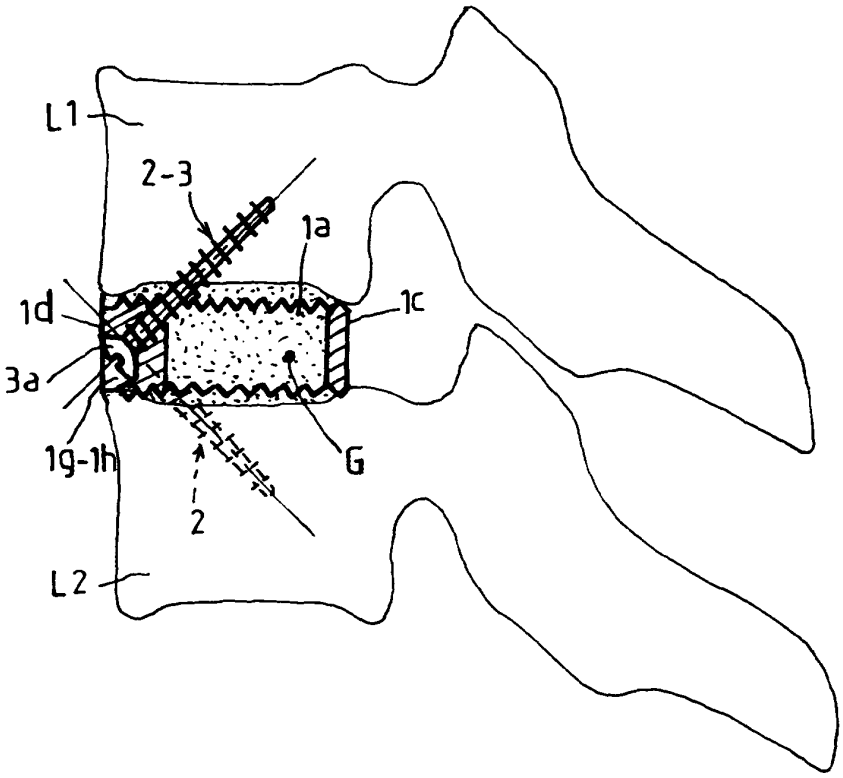


FIG.2

FIG. 3



REPUBLIQUE FRANÇAISE

2727003

N° d'enregistrement national

INSTITUT NATIONAL de la PROPRIETE INDUSTRIELLE

RAPPORT DE RECHERCHE PRELIMINAIRE

établi sur la base des dernières revendications déposées avant le commencement de la recherche

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: 19 Juillet 1995

Examinateur: Neumann, E

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& : membre de la même famille, document correspondant

1

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McGrath, Geissler, Olds & Richardson, PLLC
P.O. Box 1364
Fairfax, Virginia 22038

CFT 12/6/07
due: 2/3/08

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)

	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 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	Authorized officer:
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

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))

To:

MCGRATH, Richard
McGrath, Geissler, Olds & Richardson, PLLC
P.O. Box 1364
Fairfax, Virginia 22038
ETATS-UNIS D'AMERIQUE

Date of mailing *(day/month/year)* 22 November 2007 (22.11.2007)	
Applicant's or agent's file reference 3003/101PWO2	**IMPORTANT NOTICE**

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2007/005005	28 February 2007 (28.02.2007)	04 April 2006 (04.04.2006)

Applicant: MOSKOWITZ, Nathan et al

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 93*bis*.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 93*bis*.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

CFJ 12/4/07
CIA

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No. +41 22 338 82 70

Authorized officer: MG-IP Law, PLLC
Beate Giffo-Schmitt CFJ

e-mail: pt03.pct@wipo.int

Form PCT/IB/308(First Notice) (January 2004)

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: Richard McGrath
McGrath, Geissler, Olds & Richardson, PLLC
P.O. Box 1364
Fairfax, Virginia 22038

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)

	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 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: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 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 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 *(day/month/year)* 28 February 2007 (28.02.2007)	(Earliest) Priority Date *(day/month/year)* 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 43.6*bis*(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: 623/17.15

Documentation 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, expansible, 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 -- Y	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	11-15 and 18 --- 1-10, 16, 17 and 19-23

☐ 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	Date of mailing of the international search report
03 October 2007 (03.10.2007)	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 43*bis*.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.	International filing date *(day month year)*	Priority date *(day month year)*
PCT/US 07/05005	28 February 2007 (28.02.2007)	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 43*bis*.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 66.1*bis*(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	Date of completion of this opinion	Authorized officer:
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	03 October 2007 (03.10.2007)	Lee W. Young 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/US 07/05005

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/US 07/05005

Box No. V **Reasoned statement under Rule 43*bis*.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:

Claims 11-13 and 18 lack novelty under PCT Article 33(2) as being anticipated by US 4,997,432 A (Keller).

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).

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).

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).

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).

Claims 14 and 15 lack an inventive step under PCT Article 33(3) as being obvious over Keller.

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.

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).

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').

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.

---Continued in Supplemental Box---

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---

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 66.1*bis*(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 43*bis*.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.

RECEIVED
MAY 23 2008
MG-IP LAW, PLLC

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: Matthew T. Shanley
McGrath Geissler Olds & Richardson, PPLC
PO Box 1364
Fairfax, Virginia 22082

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CF35 [illegible] 08
MG

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)

Date of mailing *(day/month/year)*	
Applicant's or agent's file reference 30030104PW02	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
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 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. Copenheaver Telephone No. 571-272-7774

Form PCT/ISA/220 (January 2004) *(See notes on accompanying sheet)*

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: Matthew T. Shanley
McGrath Geissler Olds & Richardson, PPLC
PO Box 1364
Fairfax, Virginia 22082

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)

	Date of mailing *(day/month/year)* 21 MAY 2008
Applicant's or agent's file reference 30030104PW02	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
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 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. 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 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 *(day/month/year)* 01 October 2007	(Earliest) Priority Date *(day/month/year)* 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 teethed 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 --- Y	US 4,636,217 A (OGILVIE et al) 13 January 1987 (13.01.1987) entire document	1-8, 11 --- 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	Date of mailing of the international search report
05 May 2008	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

To: Matthew T. Shanley
McGrath Geissler Olds & Richardson, PPLC
PO Box 1364
Fairfax, Virginia 22082

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)* 21 MAY 2008

Applicant's or agent's file reference
30030104PW02

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2007/021015	01 October 2007	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

1. This opinion contains indications relating to the following items:

- [X] 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
- [X] Box No. IV Lack of unity of invention
- [X] Box No. V Reasoned statement under Rule 43*bis*.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 66.1*bis*(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	Date of completion of this opinion	Authorized officer:
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	05 May 2008	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/US2007/021015

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 appicable 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

Form PCT/ISA/237 (Box No. IV) (April 2007)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2007/021015

Box No. V **Reasoned statement under Rule 43*bis*.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:

Claims 1-7 lack novelty under PCT Article 33(2) as being anticipated by Ogilvie et al.

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).

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).

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).

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).

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).

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).

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)

Claims 8 and 11 lack an inventive step under PCT Article 33(3) as being obvious over Ogilvie et al.

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.

(Continued in Supplemental Box)

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 Mageri 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. Mageri 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 Mageri 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 Mageri et al. in further view of Orbay et al.
Regarding claim 10, Ogilvie et al. and Mageri et al. disclose that as applied to claim 9. Neither Ogilvie et al. or Mageri 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 66.1*bis*(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 43*bis*.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

To: MATTHEW T. SHANLEY
McGrath Geissler Olds & Richardson, PLLC
PO Box 1364
Fairfax, Virginia 22082

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)

	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. Copenheaver Telephone No. 571-272-7774

RECEIVED

Form PCT/ISA/220 (January 2004) *(See notes on accompanying sheet)*

JUL 10 2008

ENTERED
Docketed 108
DUE: 8/9/08

MG-IP Law, PLLC

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: MATTHEW T. SHANLEY
McGrath Geissler Olds & Richardson, PLLC
PO Box 1364
Fairfax, Virginia 22082

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)

	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. 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	**FOR FURTHER ACTION**	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/US2007/021013	International filing date *(day/month/year)* 01 October 2007	(Earliest) Priority Date *(day/month/year)* 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.

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	Date of mailing of the international search report
25 June 2008	09 JUL 2008

Name and mailing address of the ISA/US	Authorized officer:
Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	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

To: MATTHEW T. SHANLEY
McGrath Geissler Olds & Richardson, PLLC
PO Box 1364
Fairfax, Virginia 22082

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

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.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2007/021013	01 October 2007	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:

- [X] 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
- [X] Box No. IV Lack of unity of invention
- [X] Box No. V Reasoned statement under Rule 43*bis*.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 66.1*bis*(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	Date of completion of this opinion	Authorized officer:
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	25/June/2008	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 appicable 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

Form PCT/ISA/237 (Box No. IV) (April 2007)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2007/021013

Box No. V **Reasoned statement under Rule 43*bis*.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 enages (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.

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.

Electronic Acknowledgement Receipt

EFS ID:	32770946
Application Number:	15976340
International Application Number:	
Confirmation Number:	1449
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:	46440-0009013
Receipt Date:	31-MAY-2018
Filing Date:	
Time Stamp:	15:05:26
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	Information Disclosure Statement (IDS) Form (SB08)	Transmittal.pdf	67892 b8bc8fd40ba8cab8c8e18d2d4eea13377162c323	no	1

Warnings:

Information:					
This is not an USPTO supplied IDS fillable form					
2	Information Disclosure Statement (IDS) Form (SB08)	PTO-1449.pdf	162633 6f618ad34ac3b7a730fc7b4d19237f4b278fe7e7	no	9
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
3	Foreign Reference	WO2004093749.pdf	8060108 a1cab22f6415aada187d3b5a0607113e57144029	no	35
Warnings:					
Information:					
4	Foreign Reference	WO2006091503.pdf	4256674 afdfdde07b037d12ec859ba138441fd3078ea9f6	no	20
Warnings:					
Information:					
5	Foreign Reference	FR2727003.pdf	1532286 0aa11efa6354403787574 2106ecef4a047ae5caa	no	14
Warnings:					
Information:					
6	Non Patent Literature	Traynelis.pdf	1935154 fcb99c1a6f52a84ade29b7921aaf7334ae2eaf1e	no	8
Warnings:					
Information:					
7	Non Patent Literature	Wai.pdf	1892725 49c5a4f89243b628b858548f143e4e1ba29e882a	no	10
Warnings:					
Information:					
8	Non Patent Literature	Guyer.pdf	2292941 30fe3d2eaf55ec30e258cd488b5ff925c76c86cb	no	10
Warnings:					

Information:					
9	Non Patent Literature	Grob.pdf	1793707 dbe18385ce9ec6e48612e4e95f9e16dfa1a2d5d3	no	8
Warnings:					
Information:					
10	Non Patent Literature	ISR_12-3-2007.pdf	1631466 6224b2c21d9f6a3a8dc571a723d08b88af5b0d1f	no	11
Warnings:					
Information:					
11	Non Patent Literature	ISR_5-21-2008.pdf	5407617 c405f1655824fb598a18b00978e8c24fbf727dd7	no	12
Warnings:					
Information:					
12	Non Patent Literature	ISR_7-9-2008.pdf	4981490 c66e241190165e40674c381bbffd626f8b20f7be	no	11
Warnings:					
Information:					
			Total Files Size (in bytes):	34014693	

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.

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 15/976,340

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	75		N/A	
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	330		N/A	
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	380		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	26 minus 20 =	* 6	x 50 =	300	OR		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	3 minus 3 =	*	x 230 =	0.00			
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			0.00			
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				0.00			
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	1085		TOTAL	

APPLICATION AS AMENDED - PART II

AMENDMENT A

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
Application Size Fee (37 CFR 1.16(s))									
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

AMENDMENT B

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
Application Size Fee (37 CFR 1.16(s))									
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE		OR	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.

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
15/976,340	05/10/2018	Ahmnon D. Moskowitz	46440-0009013

CONFIRMATION NO. 1449

26191
FISH & RICHARDSON P.C. (TC)
PO BOX 1022
MINNEAPOLIS, MN 55440-1022

FORMALITIES LETTER

OC00000009996793

Date Mailed: 06/05/2018

NOTICE TO FILE CORRECTED APPLICATION PAPERS

Filing Date Granted

An application number and filing date have been accorded to this application. The application is informal since it does not comply with the regulations for the reason(s) indicated below. Applicant is given TWO MONTHS from the date of this Notice within which to correct the informalities indicated below. 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 required item(s) identified below must be timely submitted to avoid abandonment:

- Replacement drawings in compliance with 37 CFR 1.84 and 37 CFR 1.121(d) are required. The drawings submitted are not acceptable because:
  - The drawings submitted to the Office are not electronically reproducible because portions of figures 6A-B are missing and/or blurry.

Applicant is cautioned that correction of the above items may cause the specification and drawings page count to exceed 100 pages. If the specification and drawings exceed 100 pages, applicant will need to submit the required application size fee.

- Surcharge as set forth in 37 CFR 1.16(f) must be submitted.
  The surcharge is due for any one of:
  - late submission of the basic filing fee, search fee, or examination fee,
  - late submission of inventor's oath or declaration,
  - filing an application that does not contain at least one claim on filing, or
  - submission of an application filed by reference to a previously filed application.

SUMMARY OF FEES DUE:

The fee(s) required within **TWO MONTHS** from the date of this Notice to avoid abandonment is/are itemized below. Small entity discount is in effect. If applicant is qualified for micro entity status, an acceptable Certification of Micro Entity Status must be submitted to establish micro entity status. (See 37 CFR 1.29 and forms PTO/SB/15A and 15B.)

- $ **80** surcharge.
- $(**0**) previous unapplied payment amount.
- $ **80** TOTAL FEE BALANCE DUE.

Items Required To Avoid Processing Delays:

Applicant is notified that the above-identified application contains the deficiencies noted below. No period for reply is set forth in this notice for correction of these deficiencies. However, if a deficiency relates to the inventor's oath or declaration, the applicant must file an oath or declaration in compliance with 37 CFR 1.63, or a substitute statement in compliance with 37 CFR 1.64, executed by or with respect to each actual inventor no later than the expiration of the time period set in the "Notice of Allowability" to avoid abandonment. See 37 CFR 1.53(f).

- A properly executed inventor's oath or declaration has not been received for the following inventor(s):
  Ahmnon D. Moskowitz
  Pablo A. Valdivia Y. Alvarado
  Mosheh T. Moskowitz
  Nathan C. Moskowitz

Replies must be received in the USPTO within the set time period or must include a proper Certificate of Mailing or Transmission under 37 CFR 1.8 with a mailing or transmission date within the set time period. For more information and a suggested format, see Form PTO/SB/92 and MPEP 512.

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, including a copy of this Notice and selecting the document description "Applicant response to Pre-Exam Formalities Notice". 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.

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**.

/bzewdie/

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	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
15/976,340	05/10/2018	3775	1085	46440-0009013	26	3

CONFIRMATION NO. 1449

26191
FISH & RICHARDSON P.C. (TC)
PO BOX 1022
MINNEAPOLIS, MN 55440-1022

FILING RECEIPT

OC000000099998792

Date Mailed: 06/05/2018

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)

Moskowitz Family LLC, Rockville, MD;

Power of Attorney: The patent practitioners associated with Customer Number 26191

Domestic Priority data as claimed by applicant

This application is a CON of 15/894,471 02/12/2018
which is a CON of 13/210,157 08/15/2011 PAT 9889022
which is a CON of 13/084,543 04/11/2011 PAT 8353913
and is a CON of 13/108,982 05/16/2011 PAT 9005293
and said 13/084,543 04/11/2011
is a CON 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 for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.) - None.
Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

If Required, Foreign Filing License Granted: 06/04/2018

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 15/976,340**

Projected Publication Date: To Be Determined - pending completion of Corrected Papers

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

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

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

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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 (1-866-999-4258).

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Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

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NOT GRANTED

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor	:	Ahmnon D. Moskowitz	Art Unit	:	3775
Application No.	:	15/976,340	Examiner	:	Unknown
Filed	:	May 10, 2018	Conf. No.	:	1449
Title	:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION			

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

REPLY TO NOTICE TO FILE CORRECTED APPLICATION PAPERS DATED JUNE 5, 2018

The applicant as a small entity submits:

☒ Substitute drawings (2 sheet) in compliance with 37 CFR §1.84.

☐ A substitute specification in compliance with 37 CFR §1.52. No new matter has been added.

☐ A substitute Abstract not exceeding 150 words in length in compliance with 37 CFR §1.72(b). No new matter has been added.

The applicant understands that this perfects the application and no additional papers or filing fees are required.

Please apply any necessary charges or credits to Deposit Account 06-1050, referencing the above attorney docket number.

Respectfully submitted,

Date: 8/3/2018

/Stuart A. Nelson/
Stuart A. Nelson
Reg. No. 63,947

Customer Number 26191
Fish & Richardson P.C.
Telephone: (612) 337-2538
Facsimile: (877) 769-7945

61730947.doc

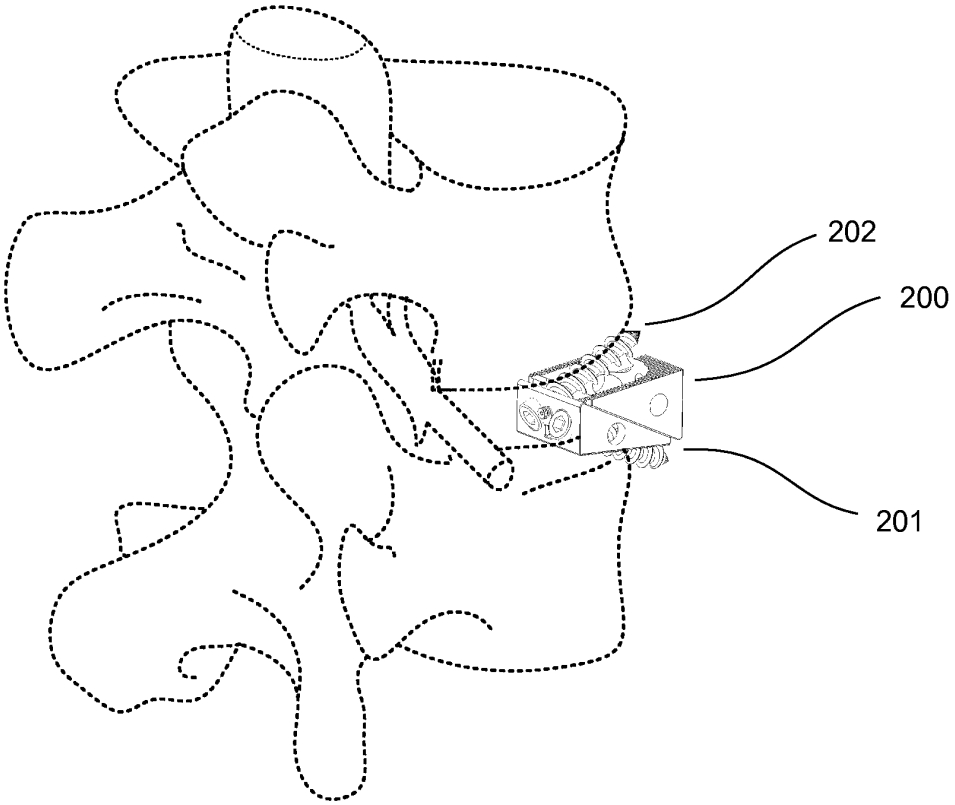


Fig. 6A

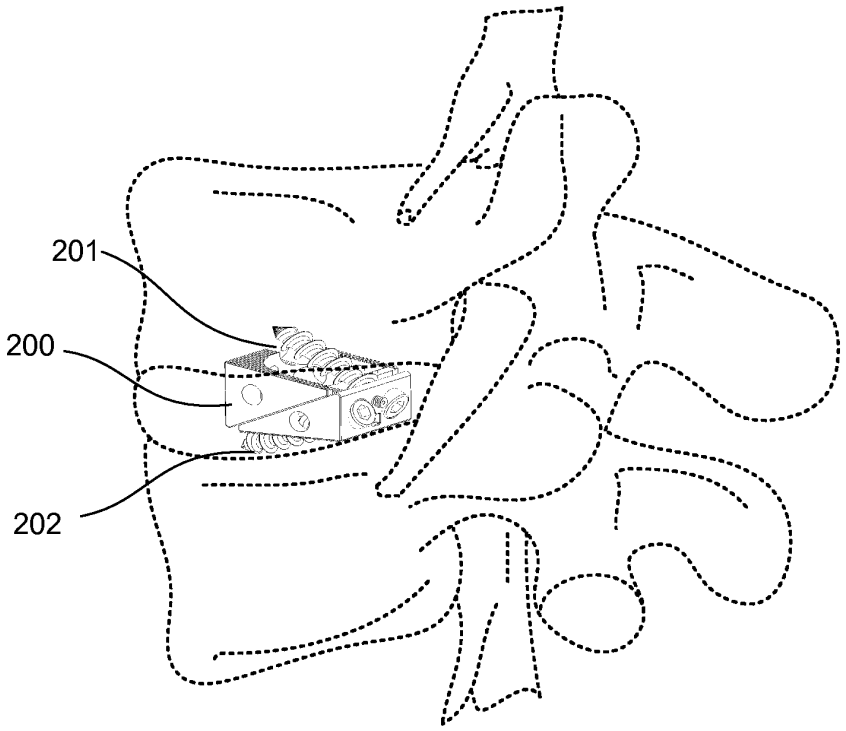


Fig. 6B

Electronic Patent Application Fee Transmittal

Application Number:	15976340
Filing Date:	10-May-2018
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:	46440-0009013

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:				
LATE FILING FEE FOR OATH OR DECLARATION	2051	1	80	80
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**80**

Electronic Acknowledgement Receipt	
EFS ID:	33370364
Application Number:	15976340
International Application Number:	
Confirmation Number:	1449
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:	46440-0009013
Receipt Date:	03-AUG-2018
Filing Date:	10-MAY-2018
Time Stamp:	14:48:02
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$80
RAM confirmation Number	080618INTEFSW00001068061050
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	Applicant Response to Pre-Exam Formalities Notice	Response.pdf	61396 2a00f80549354f22154dcc954560b9b3476f2b4c	no	1
Warnings:					
Information:					
2	Drawings-only black and white line drawings	ReplacementFigures.pdf	1195115 2f4b60084004l6f0baa98f5d5ef91d02452b33b1	no	2
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	31032 91bd224d65cc2d88846ceb69ef968dd16dda227e	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	1287543		

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
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PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 15/976,340

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	75		N/A	
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	330		N/A	
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	380		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	26 minus 20 =	* 6	x 50 =	300	OR		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	3 minus 3 =	*	x 230 =	0.00			
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			0.00			
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				0.00			
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	1085		TOTAL	

APPLICATION AS AMENDED - PART II

AMENDMENT A

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
Application Size Fee (37 CFR 1.16(s))									
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

AMENDMENT B

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
Application Size Fee (37 CFR 1.16(s))									
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.

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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
15/976,340	05/10/2018	3775	1165	46440-0009013	26	3

CONFIRMATION NO. 1449

UPDATED FILING RECEIPT

26191
FISH & RICHARDSON P.C. (TC)
PO BOX 1022
MINNEAPOLIS, MN 55440-1022

OC000000101508247

Date Mailed: 08/09/2018

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Moskowitz Family LLC, Rockville, MD;

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Projected Publication Date: 11/15/2018

Non-Publication Request: No

Early Publication Request: No

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Title 37, Code of Federal Regulations, 5.11 & 5.15

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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	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
15/976,340	05/10/2018	Ahmnon D. Moskowitz	46440-0009013

CONFIRMATION NO. 1449

26191
FISH & RICHARDSON P.C. (TC)
PO BOX 1022
MINNEAPOLIS, MN 55440-1022

INFORMAL NOTICE

OC000000101508248

Date Mailed: 08/09/2018

INFORMATIONAL NOTICE TO APPLICANT

Applicant is notified that the above-identified application contains the deficiencies noted below. No period for reply is set forth in this notice for correction of these deficiencies. However, if a deficiency relates to the inventor's oath or declaration, the applicant must file an oath or declaration in compliance with 37 CFR 1.63, or a substitute statement in compliance with 37 CFR 1.64, executed by or with respect to each actual inventor no later than the expiration of the time period set in the "Notice of Allowability" to avoid abandonment. See 37 CFR 1.53(f).

The item(s) indicated below are also required and should be submitted with any reply to this notice to avoid further processing delays.

- A properly executed inventor's oath or declaration has not been received for the following inventor(s):
  Ahmnon D. Moskowitz
  Pablo A. Valdivia Y. Alvarado
  Mosheh T. Moskowitz
  Nathan C. Moskowitz

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**.

/ebekele/

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UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/976,340	05/10/2018	Ahmnon D. Moskowitz	46440-0009013	1449

26191 7590 09/05/2018

FISH & RICHARDSON P.C. (TC)
PO BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER	
ROBERT, EDUARDO C	

ART UNIT	PAPER NUMBER
3733	

NOTIFICATION DATE	DELIVERY MODE
09/05/2018	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

Decision Granting Request for Prioritized Examination (Track I)	**Application No.** 15/976,340	**Applicant(s)** Moskowitz et al.	
	Examiner JoAnne Burke	**Art Unit** OPET	**AIA (First Inventor to File) Status** No

1. THE REQUEST FILED 10 May 2018 IS **GRANTED** .

The above-identified application has met the requirements for prioritized examination

A. ☑ for an original nonprovisional application (Track I).
B. ☐ for an application undergoing continued examination (RCE).

2. **The above-identified application will undergo prioritized examination**. The application will be accorded special status throughout its entire course of prosecution until one of the following occurs:

A. filing a **petition for extension of time** to extend the time period for filing a reply;

B. filing an **amendment to amend the application to contain more than four independent claims, more than thirty total claims** , or a multiple dependent claim;

C. filing a **request for continued examination** ;

D. filing a notice of appeal;

E. filing a request for suspension of action;

F. mailing of a notice of allowance;

G. mailing of a final Office action;

H. completion of examination as defined in 37 CFR 41.102; or

I. abandonment of the application.

Telephone inquiries with regard to this decision should be directed to JoAnne Burke at (571)272-4584. In his/her absence, calls may be directed to Petition Help Desk at (571) 272-3282.

/JOANNE L BURKE/ Paralegal Specialist, OPET	

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/976,340	05/10/2018	Ahmnon D. Moskowitz	46440-0009013	1449

26191 7590 10/18/2018
FISH & RICHARDSON P.C. (TC)
PO BOX 1022
MINNEAPOLIS, MN 55440-1022
UNITED STATES OF AMERICA

EXAMINER	
COMSTOCK, DAVID C	

ART UNIT	PAPER NUMBER
3773	

NOTIFICATION DATE	DELIVERY MODE
10/18/2018	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. 15/976,340	Applicant(s) MOSKOWITZ ET AL.	
	Examiner DAVID C. COMSTOCK	Art Unit 3773	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 *14 May 2018*.

☐ 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) *12-36* 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) *12-36* 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 *03 August 2018* 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)

2) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date *31 MAY 2018*.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

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

Claim Interpretation

The following is a quotation of 35 U.S.C. 112(f):

> (f) Element in Claim for a Combination. – An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The following is a quotation of pre-AIA 35 U.S.C. 112, sixth paragraph:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The claims in this application are given their broadest reasonable interpretation using the plain meaning of the claim language in light of the specification as it would be understood by one of ordinary skill in the art. The broadest reasonable interpretation of a claim element (also commonly referred to as a claim limitation) is limited by the description in the specification when 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is invoked.

As explained in MPEP § 2181, subsection I, claim limitations that meet the following three-prong test will be interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph:

(A) the claim limitation uses the term “means” or “step” or a term used as a substitute for “means” that is a generic placeholder (also called a nonce term or a non-structural term having no specific structural meaning) for performing the claimed function;

(B) the term “means” or “step” or the generic placeholder is modified by functional language, typically, but not always linked by the transition word “for” (e.g., “means for”) or another linking word or phrase, such as “configured to” or “so that”; and

(C) the term “means” or “step” or the generic placeholder is not modified by sufficient structure, material, or acts for performing the claimed function.

Use of the word “means” (or “step”) in a claim with functional language creates a rebuttable presumption that the claim limitation is to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites sufficient structure, material, or acts to entirely perform the recited function.

Absence of the word “means” (or “step”) in a claim creates a rebuttable presumption that the claim limitation is not to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is not interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites function without reciting sufficient structure, material or acts to entirely perform the recited function.

Claim limitations in this application that use the word “means” (or “step”) are being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action. Conversely, claim limitations in this application that do not use the word “means” (or “step”) are not being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action.

Therefore, the “means for sliding” (in claims 16 and 33) are interpreted as an adjusting screw (e.g. 105) and equivalents consistent with the specification and drawings. The "means to facilitate incorporation" (in claims 17, 24 and 34) are interpreted as surface ridges (e.g. 107) and equivalents consistent with the specification and drawings. The “means to connect” are considered to be screws (e.g. 101) and/or the ridges (e.g. 107) and equivalents consistent with the specification and drawings.

Claim Rejections - 35 USC § 102

In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for

the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

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 –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 11, 13-18, 20-22 and 24-27 are rejected under pre-AIA 35 U.S.C. 102(a) as being anticipated by Bahnham et al. (2007/0270968).

Baynham et al. disclose the claimed invention including an implant (e.g. Fig. 1) comprising angled wedge-shaped first and second implant structures (e.g. 11, 47/13). The structures including cooperating inwardly/outwardly facing rails (e.g. 43) and slots (e.g. 26). A threaded adjusting screw (67) passes through the implant structures, and a first structure comprises an opening (e.g. in 29) larger than the adjusting screw to allow relative movement between first and second structures (see, e.g. Figs. 1 and 3). The implant comprises ridges (e.g. 15) on respective superior and inferior surfaces of the implant structures to engage adjacent vertebral bodies. The implant comprises openings (e.g. the triangular openings in Fig. 1) on the sides thereof, and an indentation adjacent to the adjustment screw (Fig. 1).

Claim Rejections - 35 USC § 103

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

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

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

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

Claim 19 is rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Bahnham et al. (2007/0270968).

Baynham et al. disclose the claimed invention except for explicitly reciting the openings having a circular shape. Forming openings with a basic shape such as circular would be an obvious design choice, e.g. to facilitate manufacturing. It would have been obvious to a person having ordinary skill in the art at the time of the invention to have formed any of the various openings on the implant of Bayham et al. with a circular shape, e.g. to facilitate manufacturing. It would have been further obvious to locate the openings on any desired surface of the implant such as the sides, e.g. to facilitate loading of fusion promoting material into the implant.

Claims 12, 23 and 28-36 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Bahnham et al. (2007/0270968) in view of Euros (FR 2727003; cited by Applicant).

Baynham et al. disclose the claimed invention except for the angled bi-directional screw guides and screws. Euros teaches that fusion implants (e.g. 1) can be provided with angled bi-directional screw guides (e.g. 1g, 1h) and screws (e.g. 2, 3) to engage adjacent vertebrae and ensure stability (see, e.g. Fig. 1 and Abstract). It would have been obvious to a person having ordinary skill in the art at the time of the invention to have provided the implant of Baynham et al. with angled bi-directional screw guides and screws, in view of Euros, in order to engage adjacent vertebrae and ensure stability.

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 11-36 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 7,942,903. Although the claims at issue are not identical, they are not patentably distinct from each other because the differences amount to minor changes in the phraseology and arrangement of the claim limitations. The claims of both the issued patent and the present application are directed to the substantially same invention of an expanding implant comprising angled implant structures that slide relative to each other on cooperating rail structures and by means of a threaded adjustment screw. Furthermore, both recite openings and means for incorporating into adjacent vertebrae. Where differences exist, the issued patent is more specific, e.g. reciting "ridges" instead of

merely "means to facilitate incorporation". Thus, the invention of the patent claims are in effect a "species" of the "generic" invention of the application claims. It has been held that the generic invention is "anticipated" by the "species". See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since the application claims are anticipated by the patent claims, they are not patentably distinct from the patent claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Comstock whose telephone number is (571) 272-4710. The examiner can normally be reached Monday-Friday, 9 a.m. - 6 p.m.

If attempts to reach the examiner by telephone are unsuccessful, ***please contact*** **the examiner's supervisor, SPE, *at* (571) 272-4760**. 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.

/DAVID C COMSTOCK/
Examiner, Art Unit 3773
/PEDRO PHILOGENE/
Primary Examiner, Art Unit 3773

Notice of References Cited	Application/Control No. 15/976,340	Applicant(s)/Patent Under Reexamination MOSKOWITZ ET AL.	
	Examiner DAVID C. COMSTOCK	Art Unit 3773	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-7,942,903 B2	05-2011	Moskowitz; Ahmnon D.	A61B17/0642	606/251
*	B	US-2007/0270968 A1	11-2007	Baynham; Bret O.	A61F2/447	623/17.11
*	C	US-2010/0211176 A1	08-2010	GREENHALGH; E. Skott	A61F2/447	623/17.15
	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
L11	1226	(623/17.15).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/10/14 15:29
L16	7881	(623/17.11,17.15,17.16).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/10/14 15:53
L17	29583	A61F2/4611,4465,447.cpc. A61B17/0642,809,8635,8894,92,86.cpc. A61B2017/00407,0641,0648,922.cpc. A61F2002/2835,30133,30387,30448,30507,3055,30579,30604,30772,30878,30879,30904,4475,448,4627,4681,4687.cpc. A61F2220/0025,005.cpc. A61F2230/0015.cpc. A61F2250/0007.cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2018/10/14 16:03
L18	1021	(16 17) and ((ramp$3 or cam$4 or wedge or triang$4) same (slid$4 or translat$3) same (adjust$4 or expand$4))	US-PGPUB; USPAT; USOCR	OR	ON	2018/10/14 16:05

EAST Search History (Interference)

<This search history is empty>

10/14/2018 4:11:56 PM
C:\Users\dcomstock\Documents\EAST\Workspaces\default.wsp

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BIB DATA SHEET

CONFIRMATION NO. 1449

SERIAL NUMBER	FILING or 371(c) DATE RULE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
15/976,340	05/10/2018	623	3773	46440-0009013

APPLICANTS

Moskowitz Family LLC, Rockville, MD;

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 15/894,471 02/12/2018
which is a CON of 13/210,157 08/15/2011 PAT 9889022
which is a CON of 13/084,543 04/11/2011 PAT 8353913
and is a CON of 13/108,982 05/16/2011 PAT 9005293
and said 13/084,543 04/11/2011
is a CON 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 **
06/04/2018

Foreign Priority claimed ☐ Yes ☑ No 35 USC 119(a-d) conditions met ☐ Yes ☑ No Verified and Acknowledged /DAVID C COMSTOCK/ Examiner's Signature	☐ Met after Allowance Initials	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
		MD	38	26	3

ADDRESS

FISH & RICHARDSON P.C. (TC)
PO BOX 1022
MINNEAPOLIS, MN 55440-1022
UNITED STATES OF AMERICA

TITLE

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

FILING FEE RECEIVED	FEES: Authority has been given in Paper No._____ to charge/credit DEPOSIT ACCOUNT	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue)

BIB (Rev. 05/07).

Substitute Disclosure Form	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No. 46440-0009013	Application No. 15/976,340
Information Disclosure Statement by Applicant (Use several sheets if necessary)		Applicant Moskowitz Family LLC	
(37 CFR §1.98(b))		Filing Date May 10, 2018	Group Art Unit

U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	1.	5123926	6/23/1992	Pisharodi			
	2.	5514180	5/7/1996	Heggeness et al.			
	3.	6368350	4/9/2002	Erickson et al.			
	4.	6419704	7/16/2002	Ferree			
	5.	6458159	10/1/2002	Thalgott			
	6.	6527804	3/4/2003	Gauche! et al.			
	7.	6533818	3/18/2003	Weber et al.			
	8.	6579318	6/17/2003	Varga et al.			
	9.	6582468	6/24/2003	Gauchet			
	10.	6719794	4/13/2004	Gerber			
	11.	6733532	5/11/2004	Gauche! et al.			
	12.	6764491	7/20/2004	Frey et al.			
	13.	6770094	8/3/2004	Fehling et al.			
	14.	6572653	6/3/2003	Simonson			
	15.	5782832	7/21/1998	Larsen et al.			
	16.	6641614	11/4/2003	Wagner et al.			
	17.	6126689	10/3/2000	Brett			
	18.	6375682	4/23/2002	Fleischmann et al.			
	19.	6723126	4/20/2004	Berry			
	20.	5667472	9/7/1997	Finn et al.			
	21.	6955671	10/18/2005	Uchikubo			
	22.	7037258	5/2/2006	Chatenever et al.			
	23.	6904308	6/7/2005	Frisch et al.			
	24.	7097615	8/29/2006	Banik et al.			
	25.	7030904	4/18/2006	Adair et al.			
	26.	4997432	3/5/1991	Keller			

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

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /D.C.C/

Substitute Disclosure Form	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No. 46440-0009013	Application No. 15/976,340
Information Disclosure Statement by Applicant (Use several sheets if necessary)		Applicant Moskowitz Family LLC	
(37 CFR §1.98(b))		Filing Date May 10, 2018	Group Art Unit

U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	27.	5960522	10/5/1999	Boe			
	28.	5660188	8/26/1997	Groiso			
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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

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /D.C.C/

Substitute Disclosure Form	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No. 46440-0009013	Application No. 15/976,340
Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))		Applicant Moskowitz Family LLC	
		Filing Date May 10, 2018	Group Art Unit

U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
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U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
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U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
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U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
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Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))	46440-0009013	15/976,340
	Applicant: Moskowitz Family LLC	
	Filing Date: May 10, 2018	Group Art Unit

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	Date Considered

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		Filing Date May 10, 2018	Group Art Unit

U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
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Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation Yes	Translation No
	197.	2004093749	11/4/2004	WO			English Abstract	
	198.	2006091503	8/31/2006	WO				
	199.	2727003	5/24/1996	FR			English Abstract	

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
	200.	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

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(37 CFR §1.98(b))		Filing Date: May 10, 2018	Group Art Unit

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
	201.	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.
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Examiner Signature	Date Considered
/DAVID C COMSTOCK/	10/14/2018

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Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15976340	MOSKOWITZ ET AL.
	Examiner	Art Unit
	DAVID C COMSTOCK	3773

CPC- SEARCHED		
Symbol	Date	Examiner
A61F2/4611, 4465, 447	10/14/2018	/DC/
A61B17/0642, 809, 8635, 8894, 92, 86	10/14/2018	/DC/
A61B2017/00407, 0641, 0648, 922	10/14/2018	/DC/
A61F2002/2835, 30133, 30387, 30448, 30507, 3055, 30579, 30604, 30772, 30878, 30879, 30904, 4475, 448, 4627, 4681, 4687	10/14/2018	/DC/
A61F2220/0025, 005	10/14/2018	/DC/
A61F2230/0015	10/14/2018	/DC/
A61F2250/0007	10/14/2018	/DC/

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
623	17.11, 17.15, 17.16	10/14/2018	/DC/

* 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 text search--see EAST search history	10/14/2018	/DC/
Inventor name search--see EAST search history	10/14/2018	/DC/

INTERFERENCE SEARCH

/DAVID C COMSTOCK/ Examiner.Art Unit 3773	

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

/DAVID C COMSTOCK/ Examiner.Art Unit 3773	

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15976340	MOSKOWITZ ET AL.
	Examiner	**Art Unit**
	DAVID C COMSTOCK	3773

✓	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	10/14/2018								
	1	-								
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	10	-								
	11	✓								
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	34	✓								
	35	✓								
	36	✓								

Document code: WFEE

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Sales Receipt for Accounting Date: 11/13/2018

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor	:	Ahmnon D. Moskowitz	Art Unit	:	3773
Application No.	:	15/976,340	Examiner	:	David Comstock
Filed	:	May 10, 2018	Conf. No.	:	1449
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 OCTOBER 18, 2018

Please consider the following reply.

Electronic Patent Application Fee Transmittal

Application Number:	15976340
Filing Date:	10-May-2018
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:	46440-0009013

Filed as Large 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	1201	1	460	460
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**460**

Electronic Acknowledgement Receipt	
EFS ID:	34091806
Application Number:	15976340
International Application Number:	
Confirmation Number:	1449
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:	46440-0009013
Receipt Date:	23-OCT-2018
Filing Date:	10-MAY-2018
Time Stamp:	16:37:05
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$460
RAM confirmation Number	102418INTEFSW00003421061050
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		Response.pdf	160516 b556d59de0c67621d3044f39f820469e6bc55a9b	yes	19
	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Applicant Arguments/Remarks Made in an Amendment		16	19	
	Claims		2	15	
	Amendment/Req. Reconsideration-After Non-Final Reject		1	1	
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	31186 f407f96cfdc7ed220a4b2f30ebf4a905ffaa04c8	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	191702		

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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.

REMARKS

With this amendment, claims 16-18, 29, and 33-35 are cancelled without prejudice. Claims 37-47 are added. Support for these amendments can be found throughout the specification and figures, for example, including but not limited to Figures 1A-1E, and 5A-6B as well as the corresponding specification text.

Claim Rejections - 35 USC § 102 and 103

Claims 11, 13-18, 20-22 and 24-27 were rejected under pre-AIA 35 U.S.C. 102(a) as being anticipated by Bahnham et al. (2007/0270968). Claim 19 was rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Bahnham et al. (2007/0270968). Claims 12, 23 and 28-36 were rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Bahnham et al. (2007/0270968) in view of Euros (FR 2727003). Applicant respectfully traverses the rejection, because the claims recite a number of features not taught by the cited references.

For example, claim 11 requires: "An intervertebral expandable implant having an **inferior surface** for engaging an inferior vertebral body" and "a first implant structure defining the inferior surface and a first angled wedge portion that is angled with respect to the inferior surface, wherein the first angled wedge portion comprises a first **inwardly-facing** rail and a second **inwardly-facing** rail" (emphasis added). Baynham does not disclose a first implant structure with both an inferior surface for engaging an inferior vertebral body and first and second inwardly-facing rails, particularly as claimed. Accordingly, claim 11 and all claims depending therefrom are patentable over the cited art for at least this reason.

Claim 11 also requires that the first implant structure (the structure that has an inferior surface for engaging an inferior vertebral body) define certain first and second inwardly-facing slots, which is also not taught by the cited art. Accordingly, claim 11 and all claims depending therefrom are patentable over the cited art for at least this additional reason.

Claim 11 also requires that the first implant defines "second and third openings extending **through the first and second side surfaces**" (emphasis added), which is also not taught by the cited art. The Office Action argues that "[t]he implant comprises openings (e.g. the triangular openings in Fig. 1) on the sides thereof", however claim 11 requires more than openings

extending *anywhere* through an implant. Rather, claim 11 requires that the second and third openings extend through the first and second side surfaces of the first implant structure. Bahnham discloses no such thing. Accordingly, claim 11 and all claims depending therefrom are patentable over the cited art for at least this additional reason.

Claim 22 requires "a first implant structure defining the **first vertebral body engagement** surface and a first angled wedge portion that is angled with respect to the first vertebral body engagement surface, wherein the first angled wedge portion comprises a first **inwardly-facing** rail and a second **inwardly-facing** rail" (emphasis added). Baynham does not disclose a first implant structure with both a first vertebral body engagement surface and first and second inwardly-facing rails, particularly as claimed. Accordingly, claim 22 and all claims depending therefrom are patentable over the cited art for at least this reason.

Claim 22 also requires that the first implant structure (the structure that has a first vertebral body engagement surface) define certain first and second inwardly-facing slots, which is also not taught by the cited art. Accordingly, claim 22 and all claims depending therefrom are patentable over the cited art for at least this additional reason.

Claim 28 requires "a first implant structure defining the **first vertebral body engagement surface** and a first angled wedge portion that is angled with respect to the first vertebral body engagement surface, wherein the first angled wedge portion comprises a first **inwardly-facing** rail and a second **inwardly-facing** rail" (emphasis added). Baynham does not disclose a first implant structure with both a first vertebral body engagement surface and first and second inwardly-facing rails, particularly as claimed. Accordingly, claim 28 and all claims depending therefrom are patentable over the cited art for at least this reason.

Claim 28 also requires that the first implant structure (the structure that has a first vertebral body engagement surface) define certain first and second inwardly-facing slots, which is also not taught by the cited art. Accordingly, claim 28 and all claims depending therefrom are patentable over the cited art for at least this additional reason.

New independent claim 37 also requires "a first implant structure defining the **first vertebral body engagement surface** and a first angled wedge portion that is angled with respect to the first vertebral body engagement surface, wherein the first angled wedge portion comprises a first **inwardly-facing** rail and a second **inwardly-facing** rail (emphasis added)" as well as

certain first and second inwardly-facing slots. Accordingly, new claim 37 and all claims depending therefrom are patentable over the cited references for at least these reasons. Additionally, new claim 37 also includes additional features that, as combined with the other features of claim 37, further distinguish over the cited references.

Moreover, the dependent claims contain additional features that further distinguish over the cited references, such as particular tools and particular method steps.

Double Patenting

Claims 11-36 were rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 7,942,903.

Without conceding the merits of this rejection but to further prosecution, a terminal disclaimer is filed herewith to obviate this rejection.

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 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.

The fees for excess claims 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: 10/22/2018

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List of claims (replacing prior versions).

1-10 (Cancelled)

11. (Previously Presented) An intervertebral expandable implant having an inferior surface for engaging an inferior vertebral body and a superior surface for engaging a superior vertebral body, wherein the superior surface is positioned opposite of the inferior surface, the intervertebral expandable implant comprising:

a first implant structure defining the inferior surface and a first angled wedge portion that is angled with respect to the inferior surface, wherein the first angled wedge portion comprises a first inwardly-facing rail and a second inwardly-facing rail, wherein a first inwardly-facing slot is defined at a location adjacent the first inwardly-facing rail between the first inwardly-facing rail and the inferior surface, wherein a second inwardly-facing slot is defined at a location adjacent the second inwardly-facing rail between the second inwardly-facing rail and the inferior surface, wherein the first implant structure defines first and second opposing side surfaces positioned on opposite sides of the inferior surface, wherein the first implant structure defines at least first, second, and third openings with the first opening extending through the inferior surface of the first implant and the second and third openings extending through the first and second side surfaces; and

a second implant structure defining a second angled wedge portion that comprises a first outwardly-facing rail and a second outwardly-facing rail that faces outwardly in a direction opposite that of the first outwardly-facing rail, wherein a first outwardly-facing slot is defined at a location adjacent the first outwardly-facing rail, wherein a second outwardly-facing slot is defined at a location adjacent the second outwardly-facing rail, wherein the first implant structure is slidably-engaged with the second implant structure such that the first angled wedge portion engages the

second angled wedge portion with the first inwardly-facing rail of the first implant structure positioned in the first outwardly-facing slot of the second implant structure, the second inwardly-facing rail of the first implant structure positioned in the second outwardly facing slot of the second implant structure, the first outwardly-facing rail of the second implant structure positioned in the first inwardly-facing slot of the first implant structure, and the second outwardly-facing rail of the second implant structure positioned in the second inwardly-facing slot of the first implant structure.

12. (Previously Presented) The intervertebral expandable implant of claim 11, wherein the second implant structure defines first and second screw guides angled to guide screws bi-directionally into the superior and inferior vertebral bodies.

13. (Previously Presented) The intervertebral expandable implant of claim 11, and further comprising an adjusting screw having a threaded shaft, wherein the adjusting screw extends through at least part of the first implant structure and the second implant structure.

14. (Previously Presented) The intervertebral expandable implant of claim 13, wherein the second implant structure defines a threaded hole, wherein the adjusting screw comprises a threaded shaft, wherein the threaded shaft is positioned in the threaded hole, and wherein rotation of the adjusting screw with respect to the second implant structure moves the second implant structure with respect to the first implant structure to slide the first angled wedge portion with respect to the second angled wedge portion and expand the intervertebral expandable implant.

15. (Previously Presented) The intervertebral expandable implant of claim 13, wherein the adjusting screw extends through a portion of the first implant structure that is larger than a diameter of the threaded shaft of the adjusting screw so as to allow the first implant structure to move with respect to the adjusting screw along a direction normal to the inferior surface of the first implant structure when the intervertebral expandable implant is expanded.

16. (Cancelled)

17. (Cancelled)

18. (Cancelled)

19. (Previously Presented) The intervertebral expandable implant of claim 11, wherein the second and third openings have a substantially circular cross-section and are co-axially aligned with one-another at a location nearer a first end of the first implant structure than a second end of the first implant structure.

20. (Previously Presented) The intervertebral expandable implant of claim 11, wherein the second implant structure defines first, second, and third holes, wherein the second hole is positioned between the first and third holes, and wherein an adjusting screw extends through the second hole.

21. (Previously Presented) The intervertebral expandable implant of claim 11, wherein the second implant structure defines the superior surface.

22. (Previously Presented) An intervertebral expandable implant having a first vertebral body engagement surface and a second vertebral body engagement surface positioned opposite of the first vertebral body engagement surface for engaging inferior and superior vertebral bodies, the intervertebral expandable implant comprising:

a first implant structure defining the first vertebral body engagement surface and a first angled wedge portion that is angled with respect to the first vertebral body engagement surface, wherein the first angled wedge portion comprises a first inwardly-facing rail and a second inwardly-facing rail, wherein a first inwardly-facing slot is defined at a location adjacent the first inwardly-facing rail between the first inwardly-facing rail and the first vertebral body engagement surface, wherein a second inwardly-facing slot is defined at a location adjacent the second

inwardly-facing rail between the second inwardly-facing rail and the first vertebral body engagement surface, wherein the first implant structure defines first and second opposing side surfaces positioned on opposite sides of the first vertebral body engagement surface;

a second implant structure defining a second angled wedge portion that comprises a first outwardly-facing rail and a second outwardly-facing rail that faces outwardly in a direction opposite that of the first outwardly-facing rail, wherein a first outwardly-facing slot is defined at a location adjacent the first outwardly-facing rail, wherein a second outwardly-facing slot is defined at a location adjacent the second outwardly-facing rail, wherein the first implant structure is slidably-engaged with the second implant structure such that the first angled wedge portion engages the second angled wedge portion with the first inwardly-facing rail of the first implant structure positioned in the first outwardly-facing slot of the second implant structure, the second inwardly-facing rail of the first implant structure positioned in the second outwardly facing slot of the second implant structure, the first outwardly-facing rail of the second implant structure positioned in the first inwardly-facing slot of the first implant structure, and the second outwardly-facing rail of the second implant structure positioned in the second inwardly-facing slot of the first implant structure; and

an adjusting screw having a threaded shaft, wherein the second implant structure defines a screw hole, wherein the threaded shaft of the adjusting screw is positioned in the screw hole of the second implant structure, wherein the first implant structure defines a space that is larger than a diameter of the threaded shaft of the adjusting screw so as to allow the first implant structure to move with respect to the adjusting screw along a direction normal to the first vertebral body engagement surface when the intervertebral expandable implant is expanded, and wherein rotation of the adjusting screw with respect to the second implant structure moves the second implant structure with respect to the first implant structure to slide the first angled wedge portion with respect to the second angled wedge portion and expand the intervertebral expandable implant.

23. (Previously Presented) The intervertebral expandable implant of claim 22, wherein the second implant structure defines first and second screw guides angled to guide screws bi-directionally into the superior and inferior vertebral bodies.

24. (Previously Presented) The intervertebral expandable implant of claim 22, and further comprising means to facilitate incorporation into and fusion with the superior and inferior vertebral bodies.

25. (Previously Presented) The intervertebral expandable implant of claim 24, and further comprising means to connect the intervertebral expandable implant to the inferior and superior vertebral bodies.

26. (Previously Presented) The intervertebral expandable implant of claim 22, wherein the second implant structure defines an indentation adjacent the screw hole.

27. (Previously Presented) The intervertebral expandable implant of claim 22, wherein the second implant structure defines the second vertebral body engagement surface.

28. (Previously Presented) An intervertebral expandable implant having a first vertebral body engagement surface and a second vertebral body engagement surface positioned opposite of the first vertebral body engagement surface for engaging inferior and superior vertebral bodies, the intervertebral expandable implant comprising:

a first implant structure defining the first vertebral body engagement surface and a first angled wedge portion that is angled with respect to the first vertebral body engagement surface, wherein the first angled wedge portion comprises a first inwardly-facing rail and a second inwardly-facing rail, wherein a first inwardly-facing slot is defined at a location adjacent the first inwardly-facing rail between the first inwardly-facing rail and the first vertebral body engagement surface, wherein a second inwardly-facing slot is defined at a location adjacent the second inwardly-facing rail between the second inwardly-facing rail and the first

vertebral body engagement surface, wherein the first implant structure defines first and second opposing side surfaces positioned on opposite sides of the first vertebral body engagement surface; and

a second implant structure defining a second angled wedge portion that comprises a first outwardly-facing rail and a second outwardly-facing rail that faces outwardly in a direction opposite that of the first outwardly-facing rail, wherein a first outwardly-facing slot is defined at a location adjacent the first outwardly-facing rail, wherein a second outwardly-facing slot is defined at a location adjacent the second outwardly-facing rail, wherein the first implant structure is slidably-engaged with the second implant structure such that the first angled wedge portion engages the second angled wedge portion with the first inwardly-facing rail of the first implant structure positioned in the first outwardly-facing slot of the second implant structure, the second inwardly-facing rail of the first implant structure positioned in the second outwardly facing slot of the second implant structure, the first outwardly-facing rail of the second implant structure positioned in the first inwardly-facing slot of the first implant structure, and the second outwardly-facing rail of the second implant structure positioned in the second inwardly-facing slot of the first implant structure,

wherein the intervertebral expandable implant defines first and second screw guides positioned and configured to guide screws into the superior and inferior vertebral bodies, and wherein at least one of the first and second implant structures defines at least one of the first and second screw guides.

29. (Cancelled)

30. (Previously Presented) The intervertebral expandable implant of claim 28, and further comprising:

an adjusting screw having a threaded shaft, wherein the second implant structure defines a screw hole, wherein the threaded shaft of the adjusting screw is positioned in the screw hole of the second implant structure, wherein the first implant structure

defines a space that is larger than a diameter of the threaded shaft of the adjusting screw so as to allow the first implant structure to move with respect to the adjusting screw along a direction normal to the first vertebral body engagement surface when the intervertebral expandable implant is expanded, and wherein rotation of the adjusting screw with respect to the second implant structure moves the second implant structure with respect to the first implant structure to slide the first angled wedge portion with respect to the second angled wedge portion and expand the intervertebral expandable implant.

31. (Previously Presented) The intervertebral expandable implant of claim 28, wherein the threaded shaft of the adjusting screw is threaded around an exterior circumference of the threaded shaft.

32. (Previously Presented) The intervertebral expandable implant of claim 28, wherein the threaded shaft of the adjusting screw is threaded along substantially a full length of the threaded shaft.

33. (Cancelled)

34. (Cancelled)

35. (Cancelled)

36. (Previously Presented) The intervertebral expandable implant of claim 28, wherein the second implant structure defines a first hole having a first centerline axis, wherein the first screw guide has a second centerline axis that is angled with respect to the first centerline axis so as to guide a first screw into one of the superior and inferior vertebral bodies, and wherein the second screw guide has a third centerline axis that is angled with respect to both of the first and second centerline axes so as to guide a second screw into the other of the superior and inferior vertebral bodies.

37. (New) An intervertebral expandable implant having a first vertebral body engagement surface for engaging a first vertebral body and a second vertebral body engagement surface for engaging a second vertebral body, wherein the second vertebral body engagement surface is positioned opposite of the first vertebral body engagement surface, the intervertebral expandable implant comprising:

a first implant structure defining the first vertebral body engagement surface and a first angled wedge portion that is angled with respect to the first vertebral body engagement surface, wherein the first angled wedge portion comprises a first inwardly-facing rail and a second inwardly-facing rail, wherein a first inwardly-facing slot is defined at a location adjacent the first inwardly-facing rail between the first inwardly-facing rail and the first vertebral body engagement surface, wherein a second inwardly-facing slot is defined at a location adjacent the second inwardly-facing rail between the second inwardly-facing rail and the first vertebral body engagement surface, wherein the first implant structure defines first and second opposing side surfaces positioned on opposite sides of the first vertebral body engagement surface, wherein the first implant structure defines an end gap between the first and second opposing side surfaces at a first end of the first vertebral body engagement surface, wherein the first vertebral body engagement surface comprises a plurality of ridges extending from the first vertebral body engagement surface, wherein at least some of the ridges are positioned on the first vertebral body engagement surface on opposite sides of the end gap;

a second implant structure defining a second angled wedge portion that comprises a first outwardly-facing rail and a second outwardly-facing rail that faces outwardly in a direction opposite that of the first outwardly-facing rail, wherein a first outwardly-facing slot is defined at a location adjacent the first outwardly-facing rail, wherein a second outwardly-facing slot is defined at a location adjacent the second outwardly-facing rail, wherein the first implant structure is slidably-engaged with the second implant structure such that the first angled wedge portion engages the

second angled wedge portion with the first inwardly-facing rail of the first implant structure positioned in the first outwardly-facing slot of the second implant structure, the second inwardly-facing rail of the first implant structure positioned in the second outwardly facing slot of the second implant structure, the first outwardly-facing rail of the second implant structure positioned in the first inwardly-facing slot of the first implant structure, and the second outwardly-facing rail of the second implant structure positioned in the second inwardly-facing slot of the first implant structure, wherein the second implant structure defines third and fourth opposing side surfaces positioned on opposite sides of the second vertebral body engagement surface, wherein the second implant defines first and second tool engagement indentations on the second and third opposing side surfaces, respectively, wherein the first and second tool engagement indentations are positioned proximate a proximate end of the second implant structure, and wherein the second implant structure defines an adjusting screw hole sized for receiving an adjusting screw at a proximal portion of the second implant structure between the third and fourth side surfaces; and

an adjusting screw positioned in the adjusting screw hole.

38. (New) The intervertebral expandable implant of claim 37, wherein rotation of the adjusting screw with respect to the second implant structure moves the second implant structure with respect to the first implant structure to slide the first angled wedge portion with respect to the second angled wedge portion and expand the intervertebral expandable implant.

39. (New) The intervertebral expandable implant of claim 37, wherein the adjusting screw extends through a portion of the first implant structure that is larger than a diameter of the threaded shaft of the adjusting screw so as to allow the first implant structure to move with respect to the adjusting screw along a direction normal to the first vertebral body engagement surface of the first implant structure when the intervertebral expandable implant is expanded.

40. (New) A system comprising:

the intervertebral expandable implant of claim 37;

a first tool having a first proximal end and a first distal end with first and second engagement prongs positioned at the first distal end and defining an adjusting tool passage extending through the first tool from the first proximal end to the first distal end, wherein the first and second engagement prongs are sized and positioned to extend into the first and second tool engagement indentations of the second implant structure so as to allow the first tool to engage the intervertebral expandable implant; and

a second adjusting tool having a second proximal end and a second distal end with a handle positioned at the second proximal end, a screw engagement portion positioned at the second distal end, and a shaft extending from the handle to the screw engagement portion, wherein the screw engagement portion is sized and configured for engaging and turning the adjusting screw when the screw engagement portion is engaged with the adjusting screw, wherein the shaft of the second adjusting tool is sized with a smaller diameter than that of the adjusting tool passage such that the second adjusting tool can extend through the adjusting tool passage of the first tool to engage and turn the adjusting screw of the intervertebral expandable implant to expand the intervertebral expandable implant when the first and second engagement prongs of the first tool are engaged with the first and second tool engagement indentations of the intervertebral expandable implant.

41. (New) A method of using the system of claim 40, the method comprising:

connecting the first tool to the intervertebral expandable implant with the first and second engagement prongs engaged with the first and second tool engagement indentations;

implanting the intervertebral expandable implant into a disc space in a lumbar spine via the first tool using a transforaminal lumbar interbody fusion (TLIF) approach;

extending the second adjusting tool through the first tool to engage the adjusting screw of the intervertebral expandable implant; and

expanding the intervertebral expandable implant by turning the second adjusting tool to turn the adjusting screw of the intervertebral expandable implant.

42. (New) A method of using the system of claim 40, the method comprising:

connecting the first tool to the intervertebral expandable implant with the first and second engagement prongs engaged with the first and second tool engagement indentations;

implanting the intervertebral expandable implant into a disc space in a lumbar spine via the first tool using a posterior lumbar interbody fusion (PLIF) approach;

extending the second adjusting tool through the first tool to engage the adjusting screw of the intervertebral expandable implant; and

expanding the intervertebral expandable implant by turning the second adjusting tool to turn the adjusting screw of the intervertebral expandable implant.

43. (New) A method of using the system of claim 40 to insert the intervertebral expandable implant into a disc space of a spine from an anterior or lateral path, the method comprising:

connecting the first tool to the intervertebral expandable implant with the first and second engagement prongs engaged with the first and second tool engagement indentations;

implanting the intervertebral expandable implant into the disc space via the first tool;

extending the second adjusting tool through the first tool to engage the adjusting screw of the intervertebral expandable implant; and

expanding the intervertebral expandable implant by turning the second adjusting tool to turn the adjusting screw of the intervertebral expandable implant.

44. (New) A system comprising:

the intervertebral expandable implant of claim 11, and further comprising an adjusting screw, wherein the second implant structure defines first and second tool

engagement indentations on opposing side surfaces of the second implant structure;

a first tool having a first proximal end and a first distal end with first and second engagement prongs positioned at the first distal end and defining an adjusting tool passage extending through the first tool from the first proximal end to the first distal end, wherein the first and second engagement prongs are sized and positioned to extend into the first and second tool engagement indentations of the second implant structure so as to allow the first tool to engage the intervertebral expandable implant; and

a second adjusting tool having a second proximal end and a second distal end with a handle positioned at the second proximal end, a screw engagement portion positioned at the second distal end, and a shaft extending from the handle to the screw engagement portion, wherein the screw engagement portion is sized and configured for engaging and turning the adjusting screw when the screw engagement portion is engaged with the adjusting screw, wherein the shaft of the second adjusting tool is sized with a smaller diameter than that of the adjusting tool passage such that the second adjusting tool can extend through the adjusting tool passage of the first tool to engage and turn the adjusting screw of the intervertebral expandable implant to expand the intervertebral expandable implant when the first and second engagement prongs of the first tool are engaged with the first and second tool engagement indentations of the intervertebral expandable implant.

45. (New) A method of using the system of claim 44, the method comprising:

connecting the first tool to the intervertebral expandable implant with the first and second engagement prongs engaged with the first and second tool engagement indentations;

implanting the intervertebral expandable implant into a disc space in a lumbar spine via the first tool using a transforaminal lumbar interbody fusion (TLIF) approach;

extending the second adjusting tool through the first tool to engage the adjusting screw of the intervertebral expandable implant; and

expanding the intervertebral expandable implant by turning the second adjusting tool to turn the adjusting screw of the intervertebral expandable implant.

46. (New) A system comprising:

the intervertebral expandable implant of claim 28, and further comprising an adjusting screw, wherein the second implant structure defines first and second tool engagement indentations on opposing side surfaces of the second implant structure;

a first tool having a first proximal end and a first distal end with first and second engagement prongs positioned at the first distal end and defining an adjusting tool passage extending through the first tool from the first proximal end to the first distal end, wherein the first and second engagement prongs are sized and positioned to extend into the first and second tool engagement indentations of the second implant structure so as to allow the first tool to engage the intervertebral expandable implant; and

a second adjusting tool having a second proximal end and a second distal end with a handle positioned at the second proximal end, a screw engagement portion positioned at the second distal end, and a shaft extending from the handle to the screw engagement portion, wherein the screw engagement portion is sized and configured for engaging and turning the adjusting screw when the screw engagement portion is engaged with the adjusting screw, wherein the shaft of the second adjusting tool is sized with a smaller diameter than that of the adjusting tool passage such that the second adjusting tool can extend through the adjusting tool passage of the first tool to engage and turn the adjusting screw of the intervertebral expandable implant to expand the intervertebral expandable implant when the first and second engagement prongs of the first tool are engaged with the first and second tool engagement indentations of the intervertebral expandable implant.

47. (New) A method of using the system of claim 46 to insert the intervertebral expandable implant into a disc space of a spine from an anterior or lateral path, the method comprising:

connecting the first tool to the intervertebral expandable implant with the first and second engagement prongs engaged with the first and second tool engagement indentations;

implanting the intervertebral expandable implant into the disc space via the first tool;

extending the second adjusting tool through the first tool to engage the adjusting screw of the intervertebral expandable implant; and

expanding the intervertebral expandable implant by turning the second adjusting tool to turn the adjusting screw of the intervertebral expandable implant.

Doc Code: DIST.E.FILE Document Description: Electronic Terminal Disclaimer - Filed	PTO/SB/26 U.S. Patent and Trademark Office Department of Commerce

Electronic Petition Request	**TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT**
Application Number	15976340
Filing Date	10-May-2018
First Named Inventor	Ahmnon Moskowitz
Attorney Docket Number	46440-0009013
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
Moskowitz Family LLC	100%

The owner(s) with 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 prior patent number(s)

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as the term of said prior patent is presently shortened by any terminal disclaimer. 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 the prior patent 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 the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term of the prior patent, "as the term of said prior patent is presently shortened by any terminal disclaimer," in the event that said prior patent later:
- 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 presently shortened by any terminal disclaimer.

◉ 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 63947 ○ 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:	15976340
Filing Date:	10-May-2018
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:	46440-0009013
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.: 15976340

Filing Date: 10-May-2018

Applicant/Patent under Reexamination: Moskowitz

Electronic Terminal Disclaimer filed on October 23, 2018

☒ 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:	34091321
Application Number:	15976340
International Application Number:	
Confirmation Number:	1449
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:	46440-0009013
Receipt Date:	23-OCT-2018
Filing Date:	10-MAY-2018
Time Stamp:	16:39:34
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	102418INTEFSW00003458061050
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	Terminal Disclaimer-Filed (Electronic)	eTerminal-Disclaimer.pdf	33672 eb386a3e3996ac2622e1a62f7ed8e0c078d29c87	no	2
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30834 38c3cf85c873bde8efff1b57c27ffe41b8839514	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	64506		

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.

PTO/SB/06 (09-11)
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 15/976,340	Filing Date 05/10/2018	☐ To be Mailed

ENTITY: ☐ LARGE ☑ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $50 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $230 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	10/23/2018	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 30	Minus	** 26	= 4		x $50 =	200
	Independent (37 CFR 1.16(h))	* 4	Minus	*** 3	= 1		x $230 =	230
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	430

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	SLIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	KIMBERLY D WILLIAMS
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".	
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.	

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/976,340	05/10/2018	Ahmnon D. Moskowitz	46440-0009013	1449

26191 7590 11/09/2018

FISH & RICHARDSON P.C. (TC)
PO BOX 1022
MINNEAPOLIS, MN 55440-1022
UNITED STATES OF AMERICA

EXAMINER	
COMSTOCK, DAVID C	

ART UNIT	PAPER NUMBER
3773	

NOTIFICATION DATE	DELIVERY MODE
11/09/2018	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

Applicant-Initiated Interview Summary	Application No.	Applicant(s)	
	15/976,340	MOSKOWITZ ET AL.	
	Examiner	Art Unit	
	DAVID C. COMSTOCK	3773	

All participants (applicant, applicant's representative, PTO personnel):

(1) *David Comstock*. (3)_____.

(2) *Stuart Nelson*. (4)_____.

Date of Interview: *02 November 2018*.

Type: ☒ Telephonic ☐ Video Conference
☐ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☒ No.
If Yes, brief description: _____.

Issues Discussed ☐101 ☐112 ☒102 ☒103 ☐Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: *11,22,28 and 37*.

Identification of prior art discussed: *Baynham et al. (2007/0270968); Euros (FR 2727003)*.

Substance of Interview
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

Several features discussed were viewed by Examiner as disclosed or obvious, including the direction the grooves face and the shape of the holes on the side of the device. Applicant will consider amending the claims to distinguish over the prior art. One difference that was noted is the substantially U-shaped portion of the implant of the present application; whereas Baynham et al. teaches multiple cross supports and a closed end. Further consideration of the formal amendment, as well as an updated search, will be necessary to make a further determination.

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

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

☐ Attachment

/DAVID C COMSTOCK/ Examiner, Art Unit 3773	/Pedro Philogene/ Primary Examiner, Art Unit 3773

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:
1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
15/976,340	05/10/2018	Ahmnon D. Moskowitz	46440-0009013

CONFIRMATION NO. 1449

26191
FISH & RICHARDSON P.C. (TC)
PO BOX 1022
MINNEAPOLIS, MN 55440-1022

PUBLICATION NOTICE

OC000000103830815

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

Publication No.US-2018-0325697-A1
Publication Date:11/15/2018

NOTICE OF PUBLICATION OF APPLICATION

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

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

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

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

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

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

PTO/AIA/01 (06-12)
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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

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

As the below named inventor, I hereby declare that:

This declaration is directed to:

[ ] The attached application, or

[X] United States application or PCT international application number 15/894,471

filed on February 12, 2018.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

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.

LEGAL NAME OF INVENTOR

Inventor: Ahmnon D. Moskowitz Date (Optional) :

Signature:

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. 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 minute 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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LEGAL NAME OF INVENTOR

Inventor: Pablo A. Valdivia Y. Alvarado Date (Optional): 30/5/2018

Signature:

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

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LEGAL NAME OF INVENTOR

Inventor: Mosheh T. Moskowitz Date (Optional): 5/11/18

Signature:

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. 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 minute 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/AIA/01 (06-12)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

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

As the below named inventor, I hereby declare that:

This declaration is directed to:

[ ] The attached application, or

[X] United States application or PCT international application number 15/894,471

filed on February 12, 2018.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

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.

LEGAL NAME OF INVENTOR

Inventor: Nathan C. Moskowitz Date (Optional): 5/11/18

Signature:

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. 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 minute 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:	34800082
Application Number:	15976340
International Application Number:	
Confirmation Number:	1449
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:	46440-0009013
Receipt Date:	09-JAN-2019
Filing Date:	10-MAY-2018
Time Stamp:	10:00:48
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	Oath or Declaration filed	Declarations.pdf	4510683 5da5082309496bb7aa08a3ec1ff8fc03902ce4ab	no	4

Warnings:

Information:	
Total Files Size (in bytes):	4510683

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.

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
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 displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 15/976,340	Filing Date 05/10/2018	☐ To be Mailed

ENTITY: ☐ LARGE ☑ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $50 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $230 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	01/25/2019	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 26	Minus	** 30	= 0		x $50 =	0
	Independent (37 CFR 1.16(h))	* 3	Minus	*** 4	= 0		x $230 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	LIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/THUY T TA/
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".	
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.	

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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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 NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/976,340	05/10/2018	Ahmnon D. Moskowitz	46440-0009013	1449

26191 7590 01/25/2019

FISH & RICHARDSON P.C. (TC)
PO BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER	
COMSTOCK, DAVID C	

ART UNIT	PAPER NUMBER
3773	

NOTIFICATION DATE	DELIVERY MODE
01/25/2019	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. 15/976,340	Applicant(s) Moskowitz et al.	
	Examiner DAVID C COMSTOCK	Art Unit 3773	AIA 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 23 October 2018.

☐ 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) 11-15,19-28,30-32 and 36-47 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) 11-15,19-28,30-32 and 36-39 is/are rejected.

8) ☑ Claim(s) 40-47 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 03 August 2018 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)

2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

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

Claim Rejections - 35 USC § 102

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

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 –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 11, 13-15, 20-22 and 24-27 are rejected under pre-AIA 35 U.S.C. 102(a) as being anticipated by Bahnham et al. (2007/0270968).

Baynham et al. disclose the claimed invention including an implant (e.g. Fig. 1) comprising angled wedge-shaped first and second implant structures (e.g. 11, 47/13). The structures including cooperating inwardly/outwardly facing rails (e.g. 43) and slots (e.g. 26). A threaded adjusting screw (67) passes through the implant structures, and a first structure comprises an opening (e.g. in 29) larger than the adjusting screw to allow relative movement between first and second structures (see, e.g. Figs. 1 and 3). The implant comprises ridges (e.g.

15) on respective superior and inferior surfaces of the implant structures to engage adjacent vertebral bodies. The implant comprises openings (e.g. the triangular openings in Fig. 1) on the sides thereof, and an indentation adjacent to the adjustment screw (Fig. 1).

Claim Rejections - 35 USC § 103

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

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

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

Claims 19 and 37-39 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Bahnham et al. (2007/0270968).

Baynham et al. disclose the claimed invention except for explicitly reciting the openings having a circular shape or the location of the indentations. Forming openings with a basic shape such as circular would be an obvious design choice, e.g. to facilitate manufacturing. Likewise, positioning the indentations on the side surfaces, e.g. to facilitate gripping by surgical tools such as forceps would involve nothing more than an obvious design choice. It would have been obvious to a person having ordinary skill in the art at the time of the invention to have formed

any of the various openings on the implant of Bayham et al. with a circular shape, e.g. to facilitate manufacturing, and to position the openings and indentations on the side surfaces, e.g. to facilitate gripping by surgical tools such as forceps.

Claims 12, 23, 28, 30-32 and 36 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Bahnham et al. (2007/0270968) in view of Euros (FR 2727003; cited by Applicant).

Baynham et al. disclose the claimed invention except for the angled bi-directional screw guides and screws. Euros teaches that fusion implants (e.g. 1) can be provided with angled bi-directional screw guides (e.g. 1g, 1h) and screws (e.g. 2, 3) to engage adjacent vertebrae and ensure stability (see, e.g. Fig. 1 and Abstract). It would have been obvious to a person having ordinary skill in the art at the time of the invention to have provided the implant of Baynham et al. with angled bi-directional screw guides and screws, in view of Euros, in order to engage adjacent vertebrae and ensure stability.

Terminal Disclaimer

The terminal disclaimer filed on 23 October 2018 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Pat. No. 7,942,903 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Allowable Subject Matter

Claims 40-47 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 Arguments

Applicant's arguments filed 23 October 2018 have been fully considered but they are not persuasive.

The cited art comprises inwardly-facing rails and slots as well as the claimed openings. It is noted that the implant structure and the side surfaces each comprise various portions.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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 David Comstock whose telephone number is (571) 272-4710. The examiner can normally be reached Monday-Friday, 9 a.m. - 6 p.m.

If attempts to reach the examiner by telephone are unsuccessful, ***please contact* the examiner's supervisor, SPE, *at* (571) 272-4760**. 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.

/DAVID C COMSTOCK/
Examiner, Art Unit 3773
/PEDRO PHILOGENE/
Primary Examiner, Art Unit 3773

Notice of References Cited	Application/Control No. 15/976,340	Applicant(s)/Patent Under Reexamination	
	Examiner DAVID C COMSTOCK	Art Unit 3773	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-20060058876-A1	03-2006	McKinley; Laurence M.	A61F2/4455	623/17.11
	B					
	C					
	D					
	E					
	F					
	G					
	H					
	I					
	J					
	K					
	L					
	M					

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.

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/976,340	Moskowitz et al.
	Examiner	Art Unit
	DAVID C COMSTOCK	3773

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

CLAIMS

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	10/14/2018	01/19/2019							
	1	-	-							
	2	-	-							
	3	-	-							
	4	-	-							
	5	-	-							
	6	-	-							
	7	-	-							
	8	-	-							
	9	-	-							
	10	-	-							
	11	✓	✓							
	12	✓	✓							
	13	✓	✓							
	14	✓	✓							
	15	✓	✓							
	16	✓	-							
	17	✓	-							
	18	✓	-							
	19	✓	✓							
	20	✓	✓							
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	26	✓	✓							
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	30	✓	✓							
	31	✓	✓							
	32	✓	✓							
	33	✓	-							
	34	✓	-							
	35	✓	-							
	36	✓	✓							
	37		✓							
	38		✓							
	39		✓							
	40		O							
	41		O							
	42		O							

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/976,340	Moskowitz et al.
	Examiner	Art Unit
	DAVID C COMSTOCK	3773

CLAIM		DATE								
Final	Original	10/14/2018	01/19/2019							
	43		O							
	44		O							
	45		O							
	46		O							
	47		O							

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/976,340	Moskowitz et al.
	Examiner	Art Unit
	DAVID C COMSTOCK	3773

CPC - Searched*		
Symbol	**Date**	**Examiner**
A61F2/4611, 4465, 447	10/14/2018	/DC/
A61B17/0642, 809, 8635, 8894, 92, 86	10/14/2018	/DC/
A61B2017/00407, 0641, 0648, 922	10/14/2018	/DC/
A61F2002/2835, 30133, 30387, 30448, 30507, 3055, 30579, 30604, 30772, 30878, 30879, 30904, 4475, 448, 4627, 4681, 4687	10/14/2018	/DC/
A61F2220/0025, 005	10/14/2018	/DC/
A61F2230/0015	10/14/2018	/DC/
A61F2250/0007	10/14/2018	/DC/
Search updated	01/19/2019	/DC/

CPC Combination Sets - Searched*		
Symbol	**Date**	**Examiner**

US Classification - Searched*			
Class	**Subclass**	**Date**	**Examiner**
623	17.11, 17.15, 17.16	10/14/2018	/DC/
Search updated		01/19/2019	/DC/

* 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 text search--see EAST search history	10/14/2018	/DC/
Inventor name search--see EAST search history	10/14/2018	/DC/
EAST text search updated--see EAST search history	01/19/2019	/DC/

	/DAVID C COMSTOCK/ Examiner.Art Unit 3773

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/976,340	Moskowitz et al.
	Examiner	Art Unit
	DAVID C COMSTOCK	3773

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

	/DAVID C COMSTOCK/ Examiner.Art Unit 3773

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L6	7881	(623/17.11,17.15,17.16).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/01/17 21:06
L7	30243	A61F2/4611,4465,447.cpc. A61B17/0642,809,8635,8894,92,86.cpc. A61B2017/00407,0641,0648,922.cpc. A61F2002/2835,30133,30387,30448,30507,3055,30579,30604,30772,30878,30879,30904,4475,448,4627,4681,4687.cpc. A61F2220/0025,005.cpc. A61F2230/0015.cpc. A61F2250/0007.cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2019/01/17 21:08
L8	2845	(606/90,86A).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/01/17 21:09
L9	946	8 and (tool or instrument) and (expansion or expand$4) and (catch$3 or hook$3 or finger$1 or prong$1 or grip$4)	US-PGPUB; USPAT; USOCR	OR	ON	2019/01/17 21:10
L22	1080	(6 7) and ((ramp$3 or cam$4 or wedge or triang$4) same (slid$4 or translat$3) same (adjust$4 or expand$4))	US-PGPUB; USPAT; USOCR	OR	ON	2019/01/17 23:06
L23	53	22 and @pd>"20181014"	US-PGPUB; USPAT; USOCR	OR	ON	2019/01/17 23:07
L24	611	(6 7) and @pd>"20181014"	US-PGPUB; USPAT; USOCR	OR	ON	2019/01/17 23:09
L25	558	24 not 23	US-PGPUB; USPAT; USOCR	OR	ON	2019/01/17 23:09

1/17/2019 11:30:41 PM
C:\Users\dcomstock\Documents\EAST\Workspaces\default.wsp

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor	:	Ahmnon D. Moskowitz	Art Unit	:	3773
Application No.	:	15/976,340	Examiner	:	David Comstock
Filed	:	May 10, 2018	Conf. No.	:	1449
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 JANUARY 25, 2019

Please consider the following reply.

List of claims (replacing prior versions).

1-11 (Cancelled)

12. (Currently Amended) ~~The intervertebral expandable implant of claim 11~~ The system of claim 44, wherein the second implant structure defines first and second screw guides angled to guide screws bi-directionally into the superior and inferior vertebral bodies.

13. (Currently Amended) ~~The intervertebral expandable implant of claim 11, and further comprising an adjusting screw having a threaded shaft~~ The system of claim 44, wherein the adjusting screw extends through at least part of the first implant structure and the second implant structure.

14. (Currently Amended) ~~The intervertebral expandable implant of claim 13~~ The system of claim 13, wherein the second implant structure defines a threaded hole, wherein the adjusting screw comprises a threaded shaft, wherein the threaded shaft is positioned in the threaded hole, and wherein rotation of the adjusting screw with respect to the second implant structure moves the second implant structure with respect to the first implant structure to slide the first angled wedge portion with respect to the second angled wedge portion and expand the intervertebral expandable implant.

15. (Currently Amended) ~~The intervertebral expandable implant of claim 13~~ The system of claim 13, wherein the adjusting screw extends through a portion of the first implant structure that is larger than a diameter of the threaded shaft of the adjusting screw so as to allow the first implant structure to move with respect to the adjusting screw along a direction normal to the inferior surface of the first implant structure when the intervertebral expandable implant is expanded.

16. (Cancelled)

17. (Cancelled)

18. (Cancelled)

19. (Currently Amended) ~~The intervertebral expandable implant of claim 11~~ The system of claim 44, wherein the second and third openings have a substantially circular cross-section and are co-axially aligned with one-another at a location nearer a first end of the first implant structure than a second end of the first implant structure.

20. (Currently Amended) ~~The intervertebral expandable implant of claim 11~~ The system of claim 44, wherein the second implant structure defines first, second, and third holes, wherein the second hole is positioned between the first and third holes, and wherein an adjusting screw extends through the second hole.

21. (Currently Amended) ~~The intervertebral expandable implant of claim 11~~ The system of claim 44, wherein the second implant structure defines the superior surface.

22. (Cancelled)

23. (Currently Amended) ~~The intervertebral expandable implant of claim 22~~ The system of claim 40, wherein the second implant structure defines first and second screw guides angled to guide screws bi-directionally into the superior and inferior vertebral bodies.

24. (Currently Amended) ~~The intervertebral expandable implant of claim 22~~ The system of claim 40, and further comprising means to facilitate incorporation into and fusion with the superior and inferior vertebral bodies.

25. (Currently Amended) ~~The intervertebral expandable implant of claim 24~~ The system of claim 24, and further comprising means to connect the intervertebral expandable implant to the inferior and superior vertebral bodies.

26. (Currently Amended) ~~The intervertebral expandable implant of claim 22~~ The system of claim 40, wherein the second implant structure defines an indentation adjacent the screw hole.

27. (Currently Amended) ~~The intervertebral expandable implant of claim 22~~ The system of claim 40, wherein the second implant structure defines the second vertebral body engagement surface.

28. (Cancelled)

29. (Cancelled)

30. (Currently Amended) ~~The intervertebral expandable implant of claim 28, and further comprising: an adjusting screw having~~ The system of claim 46, wherein the adjusting screw has a threaded shaft, wherein the second implant structure defines a screw hole, wherein the threaded shaft of the adjusting screw is positioned in the screw hole of the second implant structure, wherein the first implant structure defines a space that is larger than a diameter of the threaded shaft of the adjusting screw so as to allow the first implant structure to move with respect to the adjusting screw along a direction normal to the first vertebral body engagement surface when the intervertebral expandable implant is expanded, and wherein rotation of the adjusting screw with respect to the second implant structure moves the second implant structure with respect to the first implant structure to slide the first angled wedge portion with respect to the second angled wedge portion and expand the intervertebral expandable implant.

31. (Currently Amended) ~~The intervertebral expandable implant of claim 28, wherein the~~ The system of claim 46, wherein a threaded shaft of the adjusting screw is threaded around an exterior circumference of the threaded shaft.

32. (Currently Amended) ~~The intervertebral expandable implant of claim 28, wherein the~~ The system of claim 46, wherein a threaded shaft of the adjusting screw is threaded along substantially a full length of the threaded shaft.

33. (Cancelled)

34. (Cancelled)

35. (Cancelled)

36. (Currently Amended) ~~The intervertebral expandable implant of claim 28,~~ The system of claim 46, wherein the second implant structure defines a first hole having a first centerline axis, wherein the first screw guide has a second centerline axis that is angled with respect to the first centerline axis so as to guide a first screw into one of the superior and inferior vertebral bodies, and wherein the second screw guide has a third centerline axis that is angled with respect to both of the first and second centerline axes so as to guide a second screw into the other of the superior and inferior vertebral bodies.

37. (Cancelled)

38. (Currently Amended) ~~The intervertebral expandable implant of claim 37~~ The system of claim 40, wherein rotation of the adjusting screw with respect to the second implant structure moves the second implant structure with respect to the first implant structure to slide the first angled wedge portion with respect to the second angled wedge portion and expand the intervertebral expandable implant.

39. (Currently Amended) ~~The intervertebral expandable implant of claim 37~~ The system of claim 40, wherein the adjusting screw extends through a portion of the first implant structure that is larger than a diameter of the threaded shaft of the adjusting screw so as to allow the first implant

structure to move with respect to the adjusting screw along a direction normal to the first vertebral body engagement surface of the first implant structure when the intervertebral expandable implant is expanded.

40. (Currently Amended) A system comprising:

~~the intervertebral expandable implant of claim 37;~~

an intervertebral expandable implant having a first vertebral body engagement surface for engaging a first vertebral body and a second vertebral body engagement surface for engaging a second vertebral body, wherein the second vertebral body engagement surface is positioned opposite of the first vertebral body engagement surface, the intervertebral expandable implant comprising:

a first implant structure defining the first vertebral body engagement surface and a first angled wedge portion that is angled with respect to the first vertebral body engagement surface, wherein the first angled wedge portion comprises a first inwardly-facing rail and a second inwardly-facing rail, wherein a first inwardly-facing slot is defined at a location adjacent the first inwardly-facing rail between the first inwardly-facing rail and the first vertebral body engagement surface, wherein a second inwardly-facing slot is defined at a location adjacent the second inwardly-facing rail between the second inwardly-facing rail and the first vertebral body engagement surface, wherein the first implant structure defines first and second opposing side surfaces positioned on opposite sides of the first vertebral body engagement surface, wherein the first implant structure defines an end gap between the first and second opposing side surfaces at a first end of the first vertebral body engagement surface, wherein the first vertebral body engagement surface comprises a plurality of ridges extending from the first vertebral body engagement surface, wherein at least some of the ridges are positioned on the first vertebral body engagement surface on opposite sides of the end gap;

a second implant structure defining a second angled wedge portion that comprises a first outwardly-facing rail and a second outwardly-facing rail that faces outwardly in a direction opposite that of the first outwardly-facing rail, wherein a first outwardly-facing slot is defined at a location adjacent the first outwardly-facing rail, wherein a second outwardly-facing slot is defined at a location adjacent the second outwardly-facing rail, wherein the first implant structure is slidably-engaged with the second implant structure such that the first angled wedge portion engages the second angled wedge portion with the first inwardly-facing rail of the first implant structure positioned in the first outwardly-facing slot of the second implant structure, the second inwardly-facing rail of the first implant structure positioned in the second outwardly facing slot of the second implant structure, the first outwardly-facing rail of the second implant structure positioned in the first inwardly-facing slot of the first implant structure, and the second outwardly-facing rail of the second implant structure positioned in the second inwardly-facing slot of the first implant structure, wherein the second implant structure defines third and fourth opposing side surfaces positioned on opposite sides of the second vertebral body engagement surface, wherein the second implant defines first and second tool engagement indentations on the second and third opposing side surfaces, respectively, wherein the first and second tool engagement indentations are positioned proximate a proximate end of the second implant structure, and wherein the second implant structure defines an adjusting screw hole sized for receiving an adjusting screw at a proximal portion of the second implant structure between the third and fourth side surfaces; and

an adjusting screw positioned in the adjusting screw hole;

a first tool having a first proximal end and a first distal end with first and second engagement prongs positioned at the first distal end and defining an adjusting tool passage extending through the first tool from the first proximal end to the first

distal end, wherein the first and second engagement prongs are sized and positioned to extend into the first and second tool engagement indentations of the second implant structure so as to allow the first tool to engage the intervertebral expandable implant; and

a second adjusting tool having a second proximal end and a second distal end with a handle positioned at the second proximal end, a screw engagement portion positioned at the second distal end, and a shaft extending from the handle to the screw engagement portion, wherein the screw engagement portion is sized and configured for engaging and turning the adjusting screw when the screw engagement portion is engaged with the adjusting screw, wherein the shaft of the second adjusting tool is sized with a smaller diameter than that of the adjusting tool passage such that the second adjusting tool can extend through the adjusting tool passage of the first tool to engage and turn the adjusting screw of the intervertebral expandable implant to expand the intervertebral expandable implant when the first and second engagement prongs of the first tool are engaged with the first and second tool engagement indentations of the intervertebral expandable implant.

41. (Previously Presented) A method of using the system of claim 40, the method comprising:

connecting the first tool to the intervertebral expandable implant with the first and second engagement prongs engaged with the first and second tool engagement indentations;

implanting the intervertebral expandable implant into a disc space in a lumbar spine via the first tool using a transforaminal lumbar interbody fusion (TLIF) approach;

extending the second adjusting tool through the first tool to engage the adjusting screw of the intervertebral expandable implant; and

expanding the intervertebral expandable implant by turning the second adjusting tool to turn the adjusting screw of the intervertebral expandable implant.

42. (Previously Presented) A method of using the system of claim 40, the method comprising:

connecting the first tool to the intervertebral expandable implant with the first and second engagement prongs engaged with the first and second tool engagement indentations;

implanting the intervertebral expandable implant into a disc space in a lumbar spine via the first tool using a posterior lumbar interbody fusion (PLIF) approach;

extending the second adjusting tool through the first tool to engage the adjusting screw of the intervertebral expandable implant; and

expanding the intervertebral expandable implant by turning the second adjusting tool to turn the adjusting screw of the intervertebral expandable implant.

43. (Previously Presented) A method of using the system of claim 40 to insert the intervertebral expandable implant into a disc space of a spine from an anterior or lateral path, the method comprising:

connecting the first tool to the intervertebral expandable implant with the first and second engagement prongs engaged with the first and second tool engagement indentations;

implanting the intervertebral expandable implant into the disc space via the first tool;

extending the second adjusting tool through the first tool to engage the adjusting screw of the intervertebral expandable implant; and

expanding the intervertebral expandable implant by turning the second adjusting tool to turn the adjusting screw of the intervertebral expandable implant.

44. (Currently Amended) A system comprising:

an intervertebral expandable implant having an inferior surface for engaging an inferior vertebral body and a superior surface for engaging a superior vertebral body, wherein the superior surface is positioned opposite of the inferior surface, the intervertebral expandable implant comprising:

a first implant structure defining the inferior surface and a first angled wedge portion that is angled with respect to the inferior surface, wherein the first angled wedge portion comprises a first inwardly-facing rail and a second

inwardly-facing rail, wherein a first inwardly-facing slot is defined at a location adjacent the first inwardly-facing rail between the first inwardly-facing rail and the inferior surface, wherein a second inwardly-facing slot is defined at a location adjacent the second inwardly-facing rail between the second inwardly-facing rail and the inferior surface, wherein the first implant structure defines first and second opposing side surfaces positioned on opposite sides of the inferior surface, wherein the first implant structure defines at least first, second, and third openings with the first opening extending through the inferior surface of the first implant and the second and third openings extending through the first and second side surfaces; and

a second implant structure defining a second angled wedge portion that comprises a first outwardly-facing rail and a second outwardly-facing rail that faces outwardly in a direction opposite that of the first outwardly-facing rail, wherein a first outwardly-facing slot is defined at a location adjacent the first outwardly-facing rail, wherein a second outwardly-facing slot is defined at a location adjacent the second outwardly-facing rail, wherein the first implant structure is slidably-engaged with the second implant structure such that the first angled wedge portion engages the second angled wedge portion with the first inwardly-facing rail of the first implant structure positioned in the first outwardly-facing slot of the second implant structure, the second inwardly-facing rail of the first implant structure positioned in the second outwardly facing slot of the second implant structure, the first outwardly-facing rail of the second implant structure positioned in the first inwardly-facing slot of the first implant structure, and the second outwardly-facing rail of the second implant structure positioned in the second inwardly-facing slot of the first implant structure; and

~~the intervertebral expandable implant of claim 11, and further comprising~~

an adjusting screw, wherein the second implant structure defines first and second tool engagement indentations on opposing side surfaces of the second implant structure;

a first tool having a first proximal end and a first distal end with first and second engagement prongs positioned at the first distal end and defining an adjusting tool passage extending through the first tool from the first proximal end to the first distal end, wherein the first and second engagement prongs are sized and positioned to extend into the first and second tool engagement indentations of the second implant structure so as to allow the first tool to engage the intervertebral expandable implant; and

a second adjusting tool having a second proximal end and a second distal end with a handle positioned at the second proximal end, a screw engagement portion positioned at the second distal end, and a shaft extending from the handle to the screw engagement portion, wherein the screw engagement portion is sized and configured for engaging and turning the adjusting screw when the screw engagement portion is engaged with the adjusting screw, wherein the shaft of the second adjusting tool is sized with a smaller diameter than that of the adjusting tool passage such that the second adjusting tool can extend through the adjusting tool passage of the first tool to engage and turn the adjusting screw of the intervertebral expandable implant to expand the intervertebral expandable implant when the first and second engagement prongs of the first tool are engaged with the first and second tool engagement indentations of the intervertebral expandable implant.

45. (Previously Presented) A method of using the system of claim 44, the method comprising:

connecting the first tool to the intervertebral expandable implant with the first and second engagement prongs engaged with the first and second tool engagement indentations;

implanting the intervertebral expandable implant into a disc space in a lumbar spine via the first tool using a transforaminal lumbar interbody fusion (TLIF) approach;

extending the second adjusting tool through the first tool to engage the adjusting screw of the intervertebral expandable implant; and

expanding the intervertebral expandable implant by turning the second adjusting tool to turn the adjusting screw of the intervertebral expandable implant.

46. (Currently Amended) A system comprising:

~~the intervertebral expandable implant of claim 28, and further comprising~~

an intervertebral expandable implant having a first vertebral body engagement surface and a second vertebral body engagement surface positioned opposite of the first vertebral body engagement surface for engaging inferior and superior vertebral bodies, the intervertebral expandable implant comprising:

a first implant structure defining the first vertebral body engagement surface and a first angled wedge portion that is angled with respect to the first vertebral body engagement surface, wherein the first angled wedge portion comprises a first inwardly-facing rail and a second inwardly-facing rail, wherein a first inwardly-facing slot is defined at a location adjacent the first inwardly-facing rail between the first inwardly-facing rail and the first vertebral body engagement surface, wherein a second inwardly-facing slot is defined at a location adjacent the second inwardly-facing rail between the second inwardly-facing rail and the first vertebral body engagement surface, wherein the first implant structure defines first and second opposing side surfaces positioned on opposite sides of the first vertebral body engagement surface; and

a second implant structure defining a second angled wedge portion that comprises a first outwardly-facing rail and a second outwardly-facing rail that faces outwardly in a direction opposite that of the first outwardly-facing rail, wherein a first outwardly-facing slot is defined at a location adjacent the first outwardly-facing rail, wherein a second outwardly-facing slot is defined at a location adjacent the second outwardly-facing rail, wherein the first implant structure is slidably-engaged with the second implant

structure such that the first angled wedge portion engages the second angled wedge portion with the first inwardly-facing rail of the first implant structure positioned in the first outwardly-facing slot of the second implant structure, the second inwardly-facing rail of the first implant structure positioned in the second outwardly facing slot of the second implant structure, the first outwardly-facing rail of the second implant structure positioned in the first inwardly-facing slot of the first implant structure, and the second outwardly-facing rail of the second implant structure positioned in the second inwardly-facing slot of the first implant structure,

wherein the intervertebral expandable implant defines first and second screw guides positioned and configured to guide screws into the superior and inferior vertebral bodies, wherein at least one of the first and second implant structures defines at least one of the first and second screw guides, wherein the intervertebral expandable implant further comprises an adjusting screw, and wherein the second implant structure defines first and second tool engagement indentations on opposing side surfaces of the second implant structure;

a first tool having a first proximal end and a first distal end with first and second engagement prongs positioned at the first distal end and defining an adjusting tool passage extending through the first tool from the first proximal end to the first distal end, wherein the first and second engagement prongs are sized and positioned to extend into the first and second tool engagement indentations of the second implant structure so as to allow the first tool to engage the intervertebral expandable implant; and

a second adjusting tool having a second proximal end and a second distal end with a handle positioned at the second proximal end, a screw engagement portion positioned at the second distal end, and a shaft extending from the handle to the screw engagement portion, wherein the screw engagement portion is sized and configured for engaging and turning the adjusting screw when the screw engagement portion is engaged with the adjusting screw, wherein the shaft of the

second adjusting tool is sized with a smaller diameter than that of the adjusting tool passage such that the second adjusting tool can extend through the adjusting tool passage of the first tool to engage and turn the adjusting screw of the intervertebral expandable implant to expand the intervertebral expandable implant when the first and second engagement prongs of the first tool are engaged with the first and second tool engagement indentations of the intervertebral expandable implant.

47. (Previously Presented) A method of using the system of claim 46 to insert the intervertebral expandable implant into a disc space of a spine from an anterior or lateral path, the method comprising:

connecting the first tool to the intervertebral expandable implant with the first and second engagement prongs engaged with the first and second tool engagement indentations;

implanting the intervertebral expandable implant into the disc space via the first tool;

extending the second adjusting tool through the first tool to engage the adjusting screw of the intervertebral expandable implant; and

expanding the intervertebral expandable implant by turning the second adjusting tool to turn the adjusting screw of the intervertebral expandable implant.

REMARKS

With this amendment, claims 12-15, 19-21, 23-27, 30-32, 36, 38-40, 44, and 46 have been amended and claims 11, 22, 28, and 37 have been cancelled without prejudice in order to write the allowable claims in independent form.

Claim Rejections - 35 USC § 102 and 103

Claims 11, 13-15, 20-22 and 24-27 were rejected under pre-AIA 35 U.S.C. 102(a) as being anticipated by Bahnham et al. (2007/0270968). Claims 19 and 37-37 were rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Bahnham et al. (2007/0270968). Claims 12, 23, 28, 30-32, and 36 were rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Bahnham et al. (2007/0270968) in view of Euros (FR 2727003).

Claims 40-47 were identified as allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Without conceding the merits of the rejection but to further prosecution, the claims have been amended to cover the subject matter identified as allowable. Claims 40, 44, and 46 have been written into independent form. Other claims have been amended to correct dependency and address issues of antecedent. Accordingly, all pending claims are either the same claims that were identified as allowable or depend from one of the allowable base 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 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: 1/25/2019

/Stuart A. Nelson/
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Electronic Acknowledgement Receipt	
EFS ID:	34966140
Application Number:	15976340
International Application Number:	
Confirmation Number:	1449
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:	46440-0009013
Receipt Date:	25-JAN-2019
Filing Date:	10-MAY-2018
Time Stamp:	16:17:05
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	132119 ebeca9cab63cb66957aed6a54eeef9ac8ac69559	yes	16

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Response After Final Action	1	1
	Claims	2	14
	Applicant Arguments/Remarks Made in an Amendment	15	16
Warnings:			
Information:			
	Total Files Size (in bytes):	132119	

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.

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If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.
<u>National Stage of an International Application under 35 U.S.C. 371</u>
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.
<u>New International Application Filed with the USPTO as a Receiving Office</u>
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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NOTICE OF ALLOWANCE AND FEE(S) DUE

26191 7590 03/06/2019
FISH & RICHARDSON P.C. (TC)
PO BOX 1022
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EXAMINER	
COMSTOCK, DAVID C	
ART UNIT	PAPER NUMBER
3773	

DATE MAILED: 03/06/2019

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/976,340	05/10/2018	Ahmnon D. Moskowitz	46440-0009013	1449

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	$0.00	$0.00	$500	06/06/2019

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.

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I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (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 03/06/2019
FISH & RICHARDSON P.C. (TC)
PO 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 transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/976,340	05/10/2018	Ahmnon D. Moskowitz	46440-0009013	1449

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	$0.00	$0.00	$500	06/06/2019

EXAMINER	ART UNIT	CLASS-SUBCLASS
COMSTOCK, DAVID C	3773	623-017160

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 03-09 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,
(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.

1 _____
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 must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). 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. Fees submitted: ❑ Issue Fee ❑ Publication Fee (if required) ❑ Advance Order - # of Copies _____

4b. Method of Payment: *(Please first reapply any previously paid fee shown above)*

❑ Electronic Payment via EFS-Web ❑ Enclosed check ❑ Non-electronic payment by credit card (Attach form PTO-2038)

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

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
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/976,340	05/10/2018	Ahmnon D. Moskowitz	46440-0009013	1449

26191 7590 03/06/2019

FISH & RICHARDSON P.C. (TC)
PO BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER	
COMSTOCK, DAVID C	
ART UNIT	PAPER NUMBER
3773	

DATE MAILED: 03/06/2019

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 30 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. 15/976,340	Applicant(s) Moskowitz et al.	
	Examiner DAVID C COMSTOCK	Art Unit 3773	AIA (FITF) 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 amendment filed 25 January 2019.
   ☐ 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 See Continuation Sheet . 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 areply 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)
2. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____.
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date. _____.
5. ☐ Examiner's Amendment/Comment
6. ☐ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/DAVID C COMSTOCK/ Examiner, Art Unit 3773	/Pedro Philogene/ Primary Examiner, Art Unit 3773

Continuation of 3. The allowed claim(s) is/are: 12-15,19-21,23-27,30-32,36 and 38-47

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/976,340	Moskowitz et al.
	Examiner	Art Unit
	DAVID C COMSTOCK	3773

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

CLAIMS

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	10/14/2018	01/19/2019	02/14/2019						
	1	-	-	-						
	2	-	-	-						
	3	-	-	-						
	4	-	-	-						
	5	-	-	-						
	6	-	-	-						
	7	-	-	-						
	8	-	-	-						
	9	-	-	-						
	10	-	-	-						
	11	✓	✓	-						
13	12	✓	✓	=						
14	13	✓	✓	=						
15	14	✓	✓	=						
16	15	✓	✓	=						
	16	✓	-	-						
	17	✓	-	-						
	18	✓	-	-						
17	19	✓	✓	=						
18	20	✓	✓	=						
19	21	✓	✓	=						
	22	✓	✓	-						
2	23	✓	✓	=						
3	24	✓	✓	=						
4	25	✓	✓	=						
5	26	✓	✓	=						
6	27	✓	✓	=						
	28	✓	✓	-						
	29	✓	-	-						
22	30	✓	✓	=						
23	31	✓	✓	=						
24	32	✓	✓	=						
	33	✓	-	-						
	34	✓	-	-						
	35	✓	-	-						
25	36	✓	✓	=						
	37		✓	-						
7	38		✓	=						
8	39		✓	=						
1	40		O	=						
9	41		O	=						
10	42		O	=						

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/976,340	Moskowitz et al.
	Examiner	Art Unit
	DAVID C COMSTOCK	3773

CLAIM		DATE								
Final	Original	10/14/2018	01/19/2019	02/14/2019						
11	43		O	=						
12	44		O	=						
20	45		O	=						
21	46		O	=						
26	47		O	=						

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/976,340	Moskowitz et al.
	Examiner	Art Unit
	DAVID C COMSTOCK	3773

CPC									
Symbol							Type	Version	
A61F	/	2	/	4611			F	2013-01-01	
A61B	/	17	/	0642			I	2013-01-01	
A61B	/	17	/	7064			I	2013-01-01	
A61B	/	17	/	809			I	2013-01-01	
A61B	/	17	/	8894			I	2013-01-01	
A61F	/	2	/	4465			I	2013-01-01	
A61F	/	2	/	447			I	2013-01-01	
A61B	/	17	/	8635			I	2013-01-01	
A61B	/	17	/	92			I	2013-01-01	
A61B	/	17	/	86			A	2013-01-01	
A61B	/	2017	/	0641			A	2013-01-01	
A61B	/	2017	/	0648			A	2013-01-01	
A61B	/	2017	/	922			A	2013-01-01	
A61F	/	2002	/	2835			A	2013-01-01	
A61F	/	2002	/	30133			A	2013-01-01	
A61F	/	2002	/	30387			A	2013-01-01	
A61F	/	2002	/	30448			A	2013-01-01	
A61F	/	2002	/	30507			A	2013-01-01	
A61F	/	2002	/	3055			A	2013-01-01	
A61F	/	2002	/	30579			A	2013-01-01	
A61F	/	2002	/	30604			A	2013-01-01	
A61F	/	2002	/	30772			A	2013-01-01	
A61F	/	2002	/	30878			A	2013-01-01	
A61F	/	2002	/	4475			A	2013-01-01	
A61F	/	2002	/	448			A	2013-01-01	
A61F	/	2002	/	4627			A	2013-01-01	
A61F	/	2002	/	4681			A	2013-01-01	
A61F	/	2220	/	0025			A	2013-01-01	
A61F	/	2220	/	005			A	2013-01-01	
A61F	/	2230	/	0015			A	2013-01-01	
A61F	/	2250	/	0007			A	2013-01-01	

/DAVID C COMSTOCK/ Examiner, Art Unit 3773	15 February 2019	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	26	
/PEDRO PHILOGENE/ Primary Examiner, Art Unit 3773	18 February 2019	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	5C

U.S. Patent and Trademark Office — Part of Paper No.: 20190214

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/976,340	Moskowitz et al.
	Examiner	Art Unit
	DAVID C COMSTOCK	3773

CPC								
Symbol							Type	Version
A61F	/	2002	/	4687			A	2013-01-01
A61B	/	2017	/	00407			A	2013-01-01
A61F	/	2002	/	30879			A	2013-01-01
A61F	/	2002	/	30904			A	2013-01-01
A61B	/	17	/	0644			A	2013-01-01

CPC Combination Sets								
Symbol					Type	Set	Ranking	Version
	/		/					

/DAVID C COMSTOCK/ Examiner, Art Unit 3773	15 February 2019	Total Claims Allowed:	
(Assistant Examiner)	(Date)	26	
/PEDRO PHILOGENE/ Primary Examiner, Art Unit 3773	18 February 2019	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	5C

U.S. Patent and Trademark Office — Part of Paper No.: 20190214

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/976,340	Moskowitz et al.
	Examiner	Art Unit
	DAVID C COMSTOCK	3773

INTERNATIONAL CLASSIFICATION				
CLAIMED				
A61B	/	17	/	70

NON-CLAIMED				
	/		/	

US ORIGINAL CLASSIFICATION	
CLASS	SUBCLASS
623	17.16

CROSS REFERENCES(S)						
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)					

/DAVID C COMSTOCK/ Examiner, Art Unit 3773	15 February 2019	Total Claims Allowed:	
(Assistant Examiner)	(Date)	26	
/PEDRO PHILOGENE/ Primary Examiner, Art Unit 3773	18 February 2019	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	5C

U.S. Patent and Trademark Office — Part of Paper No.: 20190214

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/976,340	Moskowitz et al.
	Examiner	Art Unit
	DAVID C COMSTOCK	3773

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIMS

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
	1		10	17	19		28		37	21	46				
	2		11	18	20		29	7	38	26	47				
	3	13	12	19	21	22	30	8	39						
	4	14	13		22	23	31	1	40						
	5	15	14	2	23	24	32	9	41						
	6	16	15	3	24		33	10	42						
	7		16	4	25		34	11	43						
	8		17	5	26		35	12	44						
	9		18	6	27	25	36	20	45						

/DAVID C COMSTOCK/ Examiner, Art Unit 3773	15 February 2019	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	26	
/PEDRO PHILOGENE/ Primary Examiner, Art Unit 3773	18 February 2019	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	5C

U.S. Patent and Trademark Office Part of Paper No.: 20190214

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/976,340	Moskowitz et al.
	Examiner	Art Unit
	DAVID C COMSTOCK	3773

CPC - Searched*		
Symbol	**Date**	**Examiner**
A61F2/4611, 4465, 447	10/14/2018	/DC/
A61B17/0642, 809, 8635, 8894, 92, 86	10/14/2018	/DC/
A61B2017/00407, 0641, 0648, 922	10/14/2018	/DC/
A61F2002/2835, 30133, 30387, 30448, 30507, 3055, 30579, 30604, 30772, 30878, 30879, 30904, 4475, 448, 4627, 4681, 4687	10/14/2018	/DC/
A61F2220/0025, 005	10/14/2018	/DC/
A61F2230/0015	10/14/2018	/DC/
A61F2250/0007	10/14/2018	/DC/
Search updated	01/19/2019	/DC/
Search updated	02/14/2019	/DC/

CPC Combination Sets - Searched*		
Symbol	**Date**	**Examiner**

US Classification - Searched*			
Class	**Subclass**	**Date**	**Examiner**
623	17.11, 17.15, 17.16	10/14/2018	/DC/
Search updated		01/19/2019	/DC/
Search updated		02/14/2019	/DC/

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

	/DAVID C COMSTOCK/ Examiner.Art Unit 3773

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	15/976,340	Moskowitz et al.
	Examiner	Art Unit
	DAVID C COMSTOCK	3773

Search Notes		
Search Notes	**Date**	**Examiner**
EAST text search--see EAST search history	10/14/2018	/DC/
Inventor name search--see EAST search history	10/14/2018	/DC/
EAST text search updated--see EAST search history	01/19/2019	/DC/
EAST text search updated--see EAST search history	02/14/2019	/DC/

Interference Search			
US Class/CPC Symbol	**US Subclass/CPC Group**	**Date**	**Examiner**
See EAST interference search history		02/14/2019	/DC/

	/DAVID C COMSTOCK/ Examiner.Art Unit 3773

OK TO ENTER: /DC/
02/14/2019

Attorney Docket No.: 46440-0009013

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor	:	Ahmnon D. Moskowitz	Art Unit	:	3773
Application No.	:	15/976,340	Examiner	:	David Comstock
Filed	:	May 10, 2018	Conf. No.	:	1449
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 JANUARY 25, 2019

Please consider the following reply.

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L12	7882	(623/17.11,17.15,17.16).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/02/14 23:39
L13	30469	A61F2/4611,4465,447.cpc. A61B17/0642,809,8635,8894,92,86.cpc. A61B2017/00407,0641,0648,922.cpc. A61F2002/2835,30133,30387,30448,30507,3055,30579,30604,30772,30878,30879,30904,4475,448,4627,4681,4687.cpc. A61F2220/0025,005.cpc. A61F2230/0015.cpc. A61F2250/0007.cpc.	US-PGPUB; USPAT; USOCR	OR	ON	2019/02/14 23:42
L14	947	606/90,86A.ccls. and (tool or instrument) and (expansion or expand$4) and (catch$3 or hook$3 or finger$1 or prong$1 or grip$4)	US-PGPUB; USPAT; USOCR	OR	ON	2019/02/14 23:43
L15	1093	(12 13) and ((ramp$3 or cam$4 or wedge or triang$4) same (slid$4 or translat$3) same (adjust$4 or expand$4))	US-PGPUB; USPAT; USOCR	OR	ON	2019/02/14 23:44
L16	14	(14 15) and @pd>"20190117"	US-PGPUB; USPAT; USOCR	OR	ON	2019/02/14 23:45
L17	189	(12 13) and @pd>"20190117"	US-PGPUB; USPAT; USOCR	OR	ON	2019/02/14 23:46
L18	175	17 not 16	US-PGPUB; USPAT; USOCR	OR	ON	2019/02/14 23:46

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L19	0	(intervertebral and expandable and implant and first and vertebral and engagement and surface and structure and angled and wedge and portion and inwardly-facing and slot and location and rail and second and opposing and side and end and gap and plurality and ridges and outwardly and tool and engagement and indentations and adjusting and screw and hole and tool and prongs and passage and handle and turning).clm.	US-PGPUB; USPAT	OR	ON	2019/02/14 23:54

2/14/2019 11:55:23 PM
C:\Users\dcomstock\Documents\EAST\Workspaces\default.wsp

Electronic Patent Application Fee Transmittal

Application Number:	15976340
Filing Date:	10-May-2018
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:	46440-0009013

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	500	500

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**500**

Electronic Acknowledgement Receipt	
EFS ID:	35351191
Application Number:	15976340
International Application Number:	
Confirmation Number:	1449
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/Paul Stovenour
Filer Authorized By:	Stuart A. Nelson
Attorney Docket Number:	46440-0009013
Receipt Date:	07-MAR-2019
Filing Date:	10-MAY-2018
Time Stamp:	12:19:07
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$500
RAM confirmation Number	030719INTEFSW00012612061050
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	Issue Fee Payment (PTO-85B)	IssueFee.pdf	164790 7edfe79e2e785727ac9a440e622c4cd8a28c7ea0	no	2
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30851 1ce50376f2c9d4ebfa0b718df3f5a0e02e5c89dc	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	195641		

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.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor	:	Ahmnon D. Moskowitz	Art Unit	:	3773
			Examiner	:	David Comstock
Application No.	:	15/976,340	Confirmation No.	:	1449
Filed	:	May 10, 2018	Notice of Allowance Date: March 6, 2019		

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 March 6, 2019, 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: 3/7/2019

/Stuart A. Nelson/
Stuart A. Nelson
Reg. No. 63,947

Customer Number 26191
Fish & Richardson P.C.
Telephone: (612) 337-2538
Facsimile: (877) 769-7945

100024000.doc

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22314-1450

By fax, send to: (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 03/06/2019

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 transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/976,340	05/10/2018	Ahmnon D. Moskowitz	46440-0009013	1449

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	06/06/2019

EXAMINER	ART UNIT	CLASS-SUBCLASS
COMSTOCK, DAVID	3773	623-017160

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 03-09 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,

(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.

1 Fish & Richardson P.C.
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 must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE: Moskowitz Family LLC

(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 [X] Corporation or other private group entity [ ] Government

4a. Fees Submitted: [X] Issue Fee [ ] Publication Fee (if required) [ ] Advance Order - # of Copies

4b. Method of Payment (*Please first reapply any previously paid fee shown above*):

[ ] Electronic Payment via EFS-Web [ ] Enclosed check [ ] Non-electronic payment by credit card (Attach form PTO-2038)

[X] The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account No. 06-1050

5. **Change of Entity Status** (from status indicated above)

[ ] Applicant certifying micro entity status. See 37 CFR 1.29 — **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.

[ ] Applicant asserting small entity status. See 37 CFR 1.27. — **NOTE**: If the application was previously under micro entity status, checking this box will be taken as a notification of loss of entitlement to micro entity status.

[ ] Applicant changing to regular undiscounted fee status. — **NOTE**: Checking this box will be taken as 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 /Stuart A. Nelson/ Date 3/7/2019

Typed or printed name Stuart A. Nelson Registration No. 63,947

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	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
15/976,340	05/10/2018	3773	1825	46440-0009013	26	3

CONFIRMATION NO. 1449

CORRECTED FILING RECEIPT

26191
FISH & RICHARDSON P.C. (TC)
PO BOX 1022
MINNEAPOLIS, MN 55440-1022

OC000000108385586

Date Mailed: 03/14/2019

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)

Moskowitz Family LLC, Rockville, MD;

Power of Attorney: The patent practitioners associated with Customer Number 26191

Domestic Priority data as claimed by applicant

This application is a CON of 15/894,471 02/12/2018
which is a CON of 13/210,157 08/15/2011 PAT 9889022
which is a CON of 13/084,543 04/11/2011 PAT 8353913
and is a CON of 13/108,982 05/16/2011 PAT 9005293
and said 13/084,543 04/11/2011
is a CON 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 for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.) - None.
Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

If Required, Foreign Filing License Granted: 06/04/2018
The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 15/976,340**
Projected Publication Date: Not Applicable
Non-Publication Request: No
Early Publication Request: No
**** SMALL ENTITY ****
Title

INTERVERTEBRAL EXPANDABLE IMPLANT

Preliminary Class

623

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

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 (1-866-999-4258).

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 AssetsControl, 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).

SelectUSA

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The U.S. offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to promote and facilitate business investment. SelectUSA provides information assistance to the international investor

community; serves as an ombudsman for existing and potential investors; advocates on behalf of U.S. cities, states, and regions competing for global investment; and counsels U.S. economic development organizations on investment attraction best practices. To learn more about why the United States is the best country in the world to develop technology, manufacture products, deliver services, and grow your business, visit http://www.SelectUSA.gov or call +1-202-482-6800.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/976,340	05/10/2018	Ahmnon D. Moskowitz	46440-0009013	1449

26191 7590 03/22/2019
FISH & RICHARDSON P.C. (TC)
PO BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER	
COMSTOCK, DAVID C	

ART UNIT	PAPER NUMBER
3773	

NOTIFICATION DATE	DELIVERY MODE
03/22/2019	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

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

Application No. : 15976340
Applicant : Moskowitz
Filing Date : 05/10/2018
Date Mailed : 03/22/2019

NOTICE TO FILE CORRECTED APPLICATION PAPERS

Notice of Allowance Mailed

This application has been accorded an Allowance Date and is being prepared for issuance. The application, however, is incomplete for the reasons below.

Applicant is given two (2) months from the mail date of this Notice within which to respond. This time period for reply is extendable under 37 CFR 1.136(a) for only TWO additional MONTHS.

The informalities requiring correction are indicated in the attachment(s). If the informality pertains to the abstract, specification (including claims) or drawings, the informality must be corrected with an amendment in compliance with 37 CFR 1.121 (or, if the application is a reissue application, 37 CFR 1.173). Such an amendment may be filed after payment of the issue fee if limited to correction of informalities noted herein. See Waiver of 37 CFR 1.312 for Documents Required by the Office of Patent Publication, 1280 Off. Gaz. Patent Office 918 (March 23, 2004). In addition, if the informality is not corrected until after payment of the issue fee, for purposes of 35 U.S.C. 154(b)(1)(iv), "all outstanding requirements" will be considered to have been satisfied when the informality has been corrected. A failure to respond within the above-identified time period will result in the application being ABANDONED.

See attachment(s).

A copy of this notice MUST be returned with the reply. Please address response to "Mail Stop Issue Fee, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450".

/Joseph Boris/
Publication Branch
Office of Data Management
(571) 272-4200

Application No. 15976340

IDENTIFICATION OF APPLICATION DEFICIENCIES IN APPLICATION FILED ON OR AFTER SEPTEMBER 16, 2012

☐ Applicant must provide legible text for the following item(s).

- ☐ Specification filed , page(s) .
- ☐ Claims filed , claim(s) .
- ☐ Other: .

☒ Applicant must provide missing information on the following page(s) of the specification by amending the specification to add the missing text. No new matter may be added.
Page/line no(s). Page 3 - paragraph 0008 emds incompletely.

☐ The specification refers to one or more applications by attorney docket number and does not show the U.S. application number(s). Applicant must supply the U.S. application number in place of each attorney docket number.
Page/line no(s).

☐ Applicant must provide an Abstract of the Disclosure.

☐ The Application Data Sheet (ADS dated) does not supply the inventor's city and/or does not supply the inventor's U.S. state and/or does not supply the inventor's country. Applicant must submit a signed, in accordance with 37 CFR 1.76(e) and 1.33(b), application data sheet that corrects this deficiency. To be in compliance with 37 CFR 1.76, the corrected application data sheet must identify the information being changed by using underlining for additions and strikethroughs or brackets for deletions.

☐ Other:

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor	:	Ahmnon D. Moskowitz	Art Unit	:	3773
Application No.	:	15/976,340	Examiner	:	David Comstock
Filed	:	May 10, 2018	Conf. No.	:	1449
Title	:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION			

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

REPLY TO NOTICE TO FILE CORRECTED APPLICATION PAPERS DATED MARCH 22, 2019

The applicant as a small entity submits:

☒ A substitute specification in compliance with 37 CFR §1.52. Paragraph 0008 has been amended to include the missing information. No new matter has been added.

The applicant understands that this perfects the application and no additional papers or filing fees are required.

Please apply any necessary charges or credits to Deposit Account 06-1050, referencing the above attorney docket number.

Respectfully submitted,

Date: 3/22/2019

/Stuart A. Nelson/
Stuart A. Nelson
Reg. No. 63,947

Customer Number 26191
Fish & Richardson P.C.
Telephone: (612) 337-2538
Facsimile: (877) 769-7945

100025337.doc

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 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

[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 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 interverterbral 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 caudaly 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 lumber 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 transpediclar 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 1 B), 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 (Figure2B), 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 t 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 E-G illustrate the sequential steps (I-III) of the positioning tooll/screw guide/box expander assembly. Step I (Figure5E), 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] Figures7A-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 1 1A 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 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 (Figure5H), 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 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 901of 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 1 1A 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 11 C 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 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-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.

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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 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

[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 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 interverterbral 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 caudaly 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 lumber 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 transpediclar 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 1 B), 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 (Figure2B), 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 t 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 E-G illustrate the sequential steps (I-III) of the positioning tooll/screw guide/box expander assembly. Step I (Figure5E), 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] Figures7A-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 1 1A 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 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 (Figure5H), 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 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 901of 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 1 1A 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 11 C 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 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-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.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor	:	Ahmnon D. Moskowitz	Art Unit	:	3773
			Examiner	:	David Comstock
Application No.	:	15/976,340	Confirmation No.	:	1449
Filed	:	May 10, 2018	Notice of Allowance Date: 3/6/2019		

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

AMENDMENT AFTER ALLOWANCE
PURSUANT TO 37 C.F.R. §1.312

Please amend the application as indicated on the following pages. This amendment is being filed concurrently with the payment of the issue fee.

Amendments to the Specification:

Please replace paragraph [0014] with the following amended paragraph:

[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.

REMARKS

In response to a request from Examiner Comstock received telephonically on 4/2/2019, the specification has been amended to replace text previously missing from paragraph [0014].

Please apply any necessary charges or credits to Deposit Account 06-1050, referencing the above attorney docket number.

Respectfully submitted,

Date: 4/3/2019 /Stuart A. Nelson/

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100026071.doc

Electronic Acknowledgement Receipt	
EFS ID:	35618373
Application Number:	15976340
International Application Number:	
Confirmation Number:	1449
Title of Invention:	INTERVERTEBRAL EXPANDABLE IMPLANT
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:	46440-0009013
Receipt Date:	03-APR-2019
Filing Date:	10-MAY-2018
Time Stamp:	15:49:01
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		312Amendment.pdf	77386 a5a109a23c9c5099c023d43def92312f71f5d6a8	yes	3

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment after Notice of Allowance (Rule 312)	1	1
	Specification	2	2
	Applicant Arguments/Remarks Made in an Amendment	3	3
Warnings:			
Information:			
	Total Files Size (in bytes):	77386	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

<u>New Applications Under 35 U.S.C. 111</u>
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.
<u>National Stage of an International Application under 35 U.S.C. 371</u>
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.
<u>New International Application Filed with the USPTO as a Receiving Office</u>
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/976,340	05/10/2018	Ahmnon D. Moskowitz	46440-0009013	1449

26191 7590 04/26/2019

FISH & RICHARDSON P.C. (TC)
PO BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER	
COMSTOCK, DAVID C	

ART UNIT	PAPER NUMBER
3773	

NOTIFICATION DATE	DELIVERY MODE
04/26/2019	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

UNITED STATES DEPARTMENT OF COMMERCE
U.S. Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450

APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR/ PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
15/976,340	05/10/2018	Moskowitz et al.	46440-0009013

FISH & RICHARDSON P.C. (TC)
PO BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER	
DAVID C COMSTOCK	
ART UNIT	PAPER
3773	20190404

DATE MAILED: _____

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

Commissioner for Patents

The substitute specification filed on 22 March 2019 (in response to the Notice to File Corrected Application Papers, from the Publication Branch), and the Amendment under Rule 312 filed on 03 April 2019 have been entered.

/DAVID C COMSTOCK/ Examiner, Art Unit 3773	/PEDRO PHILOGENE/ Primary Examiner, Art Unit 3773

PTO-90C (Rev.04-03)

Response to Rule 312 Communication	Application No.	Applicant(s)	
	15/976,340	Moskowitz et al.	
	Examiner	Art Unit	AIA Status
	DAVID C COMSTOCK	3773	No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

1. ☑ The amendment filed on 03 April 2019 under 37 CFR 1.312 has been considered, and has been:

a) ☑ entered.

b) ☐ entered as directed to matters of form not affecting the scope of the invention.

c) ☐ disapproved because the amendment was filed after the payment of the issue fee.

Any amendment filed after the date the issue fee is paid must be accompanied by a petition under 37 CFR 1.313(c)(1) and the required fee to withdraw the application from issue.

d) ☐ disapproved. See explanation below.

e) ☐ entered in part. See explanation below.

/DAVID C COMSTOCK/ Examiner, Art Unit 3773	/Pedro Philogene/ Primary Examiner, Art Unit 3773

312 - ENTER
/DC/
04 APRIL 2019

Attorney's Docket No.: 46440-0009013

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor	:	Ahmnon D. Moskowitz	Art Unit	: 3773
			Examiner	: David Comstock
Application No.	:	15/976,340	Confirmation No.	: 1449
Filed	:	May 10, 2018	Notice of Allowance Date: 3/6/2019	

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

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P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT AFTER ALLOWANCE
PURSUANT TO 37 C.F.R. §1.312

Please amend the application as indicated on the following pages. This amendment is being filed concurrently with the payment of the issue fee.

OK TO ENTER: /DC/
04/12/2019

Attorney's Docket No.: 46440-0009013

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor	:	Ahmnon D. Moskowitz	Art Unit	:	3773
Application No.	:	15/976,340	Examiner	:	David Comstock
Filed	:	May 10, 2018	Conf. No.	:	1449
Title	:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION			

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

REPLY TO NOTICE TO FILE CORRECTED APPLICATION PAPERS DATED MARCH 22, 2019

The applicant as a small entity submits:

☒ A substitute specification in compliance with 37 CFR §1.52. Paragraph 0008 has been amended to include the missing information. No new matter has been added.

The applicant understands that this perfects the application and no additional papers or filing fees are required.

Please apply any necessary charges or credits to Deposit Account 06-1050, referencing the above attorney docket number.

Respectfully submitted,

Date: 3/22/2019

/Stuart A. Nelson/
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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/976,340	06/04/2019	10307268	46440-0009013	1449

26191 7590 05/15/2019

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 0 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;
Moskowitz Family LLC, Rockville, MD;
Pablo A. Valdivia Y. Alvarado, Cambridge, MA;
Mosheh T. Moskowitz, Rockville, MD;
Nathan C. Moskowitz, Rockville, MD;

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IR103 (Rev. 10/09)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor	:	Ahmnon D. Moskowitz	Art Unit	:	3773
Patent No.	:	10,307,268	Examiner	:	David Comstock
Issue Date	:	June 4, 2019	Conf. No.	:	1449
Serial No.	:	15/976,340			
Filed	:	May 10, 2018			

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
P.O. Box 1450
Alexandria, VA 22313-1450

REQUEST FOR CERTIFICATE OF CORRECTION

Please issue a certificate of correction in accordance with the attached form. The corrections are plainly of a clerical nature and the mistakes requiring the correction would have been readily recognized from the other text surrounding those mistakes. The corrections do not involve changes that constitute new matter or require reexamination.

One or more of the errors to be corrected were made by applicant. The fee of $150 is being paid with this request.

Apply any other necessary charges or credits to Deposit Account 06-1050, referencing the above attorney docket number.

Respectfully submitted,

Date: 6/10/2019

/Stuart A. Nelson/
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PTO/SB/44 (09-07)
Approved for use through 08/31/2013. OMB 0651-0033
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(Also Form PTO-1050)

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 10,307,268

APPLICATION NO.: 15/976,340

ISSUE DATE : June 4, 2019

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 62 (Claims): In Claim 1, after “second implant” add - - structure - -.

Column 13, Line 64 (Claims): In Claim 1, delete “second and third” and insert - - third and fourth - -, therefor.

Column 14, Line 48 (Claims): In Claim 5, after “the” add - - adjusting - -.

Column 16, Line 5 (Claims): In Claim 12, delete “and”.

Column 17, Line 15 (Claims): In Claim 16, delete “the” and insert - - a - -, therefor.

MAILING ADDRESS OF SENDER (Please do not use customer number below):
Fish & Richardson P.C.
P.O. Box 1022
Minneapolis, MN 55440-1022

This collection of information is required by 37 CFR 1.322, 1.323, and 1.324. 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 1.0 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: Attention Certificate of Corrections Branch, 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 selection option2.

Electronic Patent Application Fee Transmittal

Application Number:	15976340
Filing Date:	10-May-2018
Title of Invention:	INTERVERTEBRAL EXPANDABLE IMPLANT
First Named Inventor/Applicant Name:	Ahmnon D. Moskowitz
Filer:	Stuart A. Nelson/Abby Remer
Attorney Docket Number:	46440-0009013

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:				
CERTIFICATE OF CORRECTION	2811	1	150	150

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**150**

Electronic Acknowledgement Receipt	
EFS ID:	36251856
Application Number:	15976340
International Application Number:	
Confirmation Number:	1449
Title of Invention:	INTERVERTEBRAL EXPANDABLE IMPLANT
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:	46440-0009013
Receipt Date:	10-JUN-2019
Filing Date:	10-MAY-2018
Time Stamp:	15:08:56
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$150
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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	132843 691e6cbbb9756de2414f9ebab8aa719556f61127	no	2
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30402 12c31b4ebac96ddd63ae4256b75b42ebfc5111a4	no	2
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If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.
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If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.
New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/976,340	05/10/2018	Ahmnon D. Moskowitz	46440-0009013	1449

26191 7590 08/22/2019

FISH & RICHARDSON P.C. (TC)
PO BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER	
COMSTOCK, DAVID C	

ART UNIT	PAPER NUMBER
3773	

NOTIFICATION DATE	DELIVERY MODE
08/22/2019	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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Commissioner for Patents
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Patent No.: 10307268
Issue Date: 06/04/2019
Appl. No.: 15/976,340
Filed: 05/10/2018

PART (A) RESPONSE FOR CERTIFICATES OF CORRECTION

This is a decision on the Certificate of Correction request filed 10 June 2019.

The request for issuance of Certificate of Correction for the above-identified correction(s) under the provisions of 37 CFR 1.322 and/or 1.323 is hereby:

(Check one)
☑ Approved ☐ Approved in Part ☐ Denied

Comments: ____

PART (B) PETITION UNDER 37 CFR 1.324 OR 37 CFR 1.48

☐ This is a decision on the petition filed ____ to correct inventorship under 37 CFR 1.324.

☐ This is a decision on the request under 37 CFR 1.48, petition filed ____. In view of the fact that the patent has already issued, the request under 37 CFR 1.48 has been treated as a petition to correct inventorship under 37 CFR 1.324.

The petition is hereby: ☐ Granted ☐ Dismissed

Comment: ____

The patented filed is being forwarded to Certificate of Corrections Branch for issuance of a certificate naming only the actual inventor or inventors.

/EDUARDO C ROBERT/
Supervisory Patent Examiner, Art Unit 3773
Technology Center 3700
Phone: (571)272-4719

Certificates of Correction Branch email: CustomerServiceCoC@uspto.gov CoC Central Phone Number: (703) 756-1814

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 10,307,268 B2
APPLICATION NO. : 15/976340
DATED : June 4, 2019
INVENTOR(S) : Ahmnon D. Moskowitz et al.

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 62: In Claim 1, after "second implant" add -- structure --.

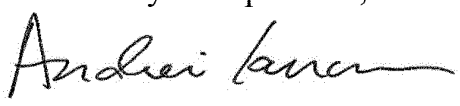
Column 13, Line 64: In Claim 1, delete "second and third" and insert -- third and fourth --, therefor.

Column 14, Line 48: In Claim 5, after "the" add -- adjusting --.

Column 16, Line 5: In Claim 12, delete "and".

Column 17, Line 15: In Claim 16, delete "the" and insert -- a --, therefor.

Signed and Sealed this
Tenth Day of September, 2019



Andrei Iancu
Director of the United States Patent and Trademark Office

AO 120 (Rev. 08/10)

TO:	REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK
Mail Stop 8 Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450	

In Compliance with 35 U.S.C. § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been filed in the U.S: District Court Western District of Texas - Waco Division on the following

☐ Trademarks or ☑ Patents. (☐ the patent action involves 35 U.S.C. § 292.):

DOCKET NO.	DATE FILED	U.S. DISTRICT COURT
6:19-cv-672	11/20/2019	Western District of Texas - Waco Division

PLAINTIFF	DEFENDANT
MOSKOWITZ FAMILY LLC	GLOBUS MEDICAL, INC.

	PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1	SEE ATTACHED		
2	8,353,913		
3	9,889,022		
4	10,028,740		
5	10,076,367		

In the above—entitled case, the following patent(s)/ trademark(s) have been included:

DATE INCLUDED	INCLUDED BY ☐ Amendment ☐ Answer ☐ Cross Bill ☐ Other Pleading	
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1 10,307,268		
2 10,251,643		
3 10,376,386		
4 10,478,319		
5		

In the above—entitled case, the following decision has been rendered or judgement issued:

DECISION/JUDGEMENT

CLERK	(BY) DEPUTY CLERK	DATE
Jeannette J. Clack		11/21/2019

Copy 1—Upon initiation of action, mail this copy to Director **Copy 3—Upon termination of action, mail this copy to Director**
Copy 2—Upon filing document adding patent(s), mail this copy to Director **Copy 4—Case file copy**

Trials@uspto.gov
571-272-7822

Paper 7
Entered: January 26, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GLOBUS MEDICAL, INC.,
Petitioner,

v.

MOSKOWITZ FAMILY LLC,
Patent Owner.

IPR2020-01303
Patent 10,307,268 B2

Before NEIL T. POWELL, JAMES A. TARTAL, and JAMES J. MAYBERRY, *Administrative Patent Judges*.

POWELL, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

A. Background and Summary

Globus Medical, Inc. ("Petitioner") filed a Petition (Paper 1, "Pet.") requesting an *inter partes* review of claims 1, 3, 5, 7–11, and 21–26 ("the Challenged Claims") of U.S. Patent No. 10,307,268 B2 (Ex. 1001, "the '268 patent"). Mosowitz Family LLC ("Patent Owner") filed a Preliminary Response (Paper 6, "Prelim. Resp.") to the Petition.

An *inter partes* review may not be instituted unless "the information presented in the petition . . . and any response . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). We determine that Petitioner does not demonstrate a reasonable likelihood of prevailing in showing that at least one of the challenged claims of the '268 patent is unpatentable. Accordingly, the Petition is denied, and no trial is instituted.

B. Real Parties in Interest

Petitioner identifies itself, Globus Medical, Inc., as the real party in interest. Pet. 2. Patent Owner identifies itself as the real party in interest. Paper 4, 2.

C. Related Matters

The parties indicate that the '268 patent is the subject of the following district court case: *Moskowitz Family LLC v. Globus Medical, Inc.*, Civil Action No. 2:20-cv-03271 (E.D. Pa.). Pet. 2; Paper 4, 2. The parties indicate that this district court case was transferred from the following prior district court case: *Moskowitz Family LLC v. Globus Medical, Inc.*, Civil Action No. 6:19-cv-672 (W.D. Tex.). Pet. 2; Paper 4, 2. Patent Owner

notes that the '268 patent has also been challenged by Petitioner in IPR2020-01304. Paper 4, 2.

D. The '268 Patent

The '268 patent discloses inserting screw box constructs that have bi-directional fixating transvertebral (BDFT) screws into a denuded intervertebral disc space. Ex. 1001, 7:41–44. The '268 patent discusses one embodiment of a screw box in connection with Figures 1A–1E. Figure 1B is reproduced below.

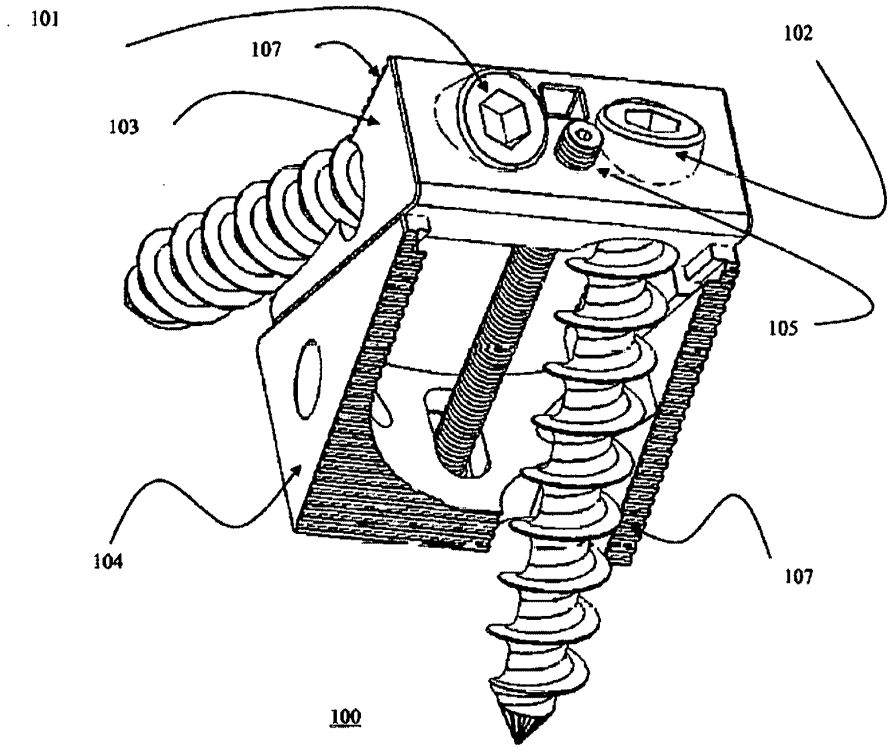


Fig. 1B

Figure 1B shows screw box 100, which includes BDFT screws 101, 102, triangular sliding bases 103, 104, and height/depth adjusting screw 105. *Id.* at 7:45–56.

Screw box 100 has provisions for adjusting its depth and height. *Id.* at 7:56–64. Triangular base 103 has sliding rails 106. *Id.* at 7:58–59. Triangular base 104 has corresponding rail inserts 107, on which rails 106 slide when adjusting screw 105 is turned. *Id.* at 7:56–60. When rails 106 slide on rail inserts 107, the height and depth of screw box 100 changes. *Id.* at 7:56–62. This allows customizing screw box 100 to the disc space. *Id.* at 7:60–64.

Each triangular base has ridges 107. *Id.* at 8:1–4. Ridges 107 contact adjacent vertebrae. *Id.* at 8:2–4. This helps screw box 100 fuse with and incorporate into those vertebrae. *Id.* at 8:4–6.

Screw box 100 serves as both a bi-directional transvertebral screw fusion device and an intervertebral bone fusion spacer. *Id.* at 8:6–12. Toward this end, screw box 100 allows bone placement intended for fusion by including holes 108, which perforate triangular base 103 and triangular base 104. *Id.* at 8:6–8. Additionally, to enable bone filling, screw box 100 is hollow. *Id.* at 8:8–10.

The '268 patent also discloses external drill/screw guide-box expander 500. *Id.* at 8:58–62. External drill/screw guide-box expander 500 appears in Figures 5A–5C. *Id.* Figure 5A is reproduced below.

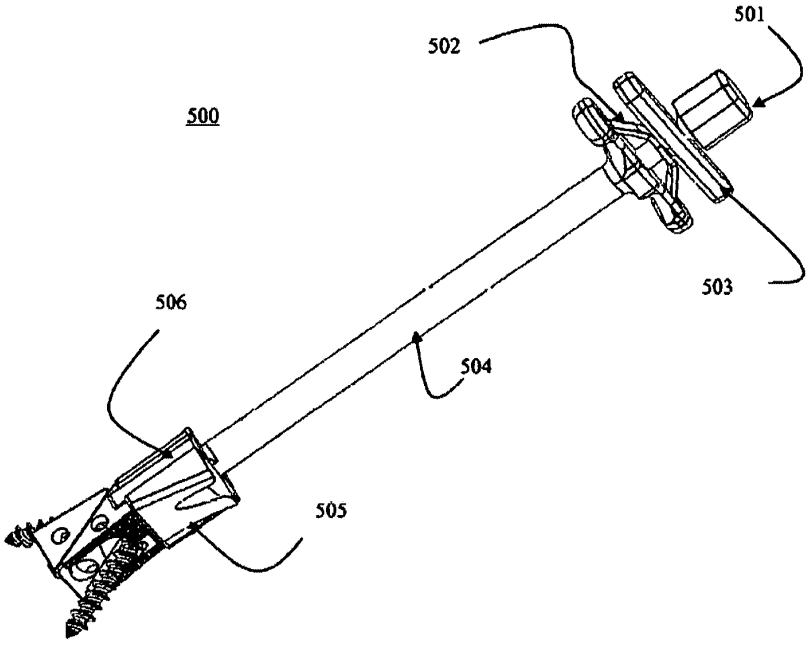


Fig. 5A

Figure 5A shows external drill/screw guide-box expander 500, which includes Allen key 501, spring 502, handle 503, griper 504, and screw guide 505. *Id.* at 8:58–65.

Griper 504 includes griper prongs 506. *Id.* at 9:1–2. Screw guide 505 has grooves into which griper prongs 506 insert. *Id.* at 9:2–3. Additionally, griper prongs 506 are inserted into a screw box. *Id.* This perfectly aligns them. *Id.* at 9:3–4.

The '268 patent explains the process of assembling external drill/screw guide-box expander 500. *Id.* at 9:9–15. Allen key 501 is inserted into handle 503. *Id.* at 9:11–12. Handle 503 is inserted through spring 502 and griper 504. *Id.* at 9:13–14. Griper 504 is inserted into screw guide 505. *Id.* at 9:14–15.

External drill/screw guide-box expander 500 can be used to adjust the width and depth of a screw box. *Id.* at 8:65–9:1. This is done by turning Allen key 501 to rotate the screw adjuster, "which in turn regulates top and bottom triangular screw box base sliding." *Id.*

E. Illustrative Claim

Of the challenged claims, claims 1 and 21 are independent. Claim 1 is reproduced below with certain reformatting.[1]

1. [1.1] A system comprising:

an intervertebral expandable implant having a first vertebral body engagement surface for engaging a first vertebral body and a second vertebral body engagement surface for engaging a second vertebral body, wherein the second vertebral body engagement surface is positioned opposite of the first vertebral body engagement surface, the intervertebral expandable implant comprising:

[1.2] a first implant structure defining the first vertebral body engagement surface and a first angled wedge portion that is angled with respect to the first vertebral body engagement surface, wherein the first angled wedge portion comprises a first inwardly-facing rail and a second inwardly-facing rail, wherein a first inwardly-facing slot is defined at a location adjacent the first inwardly-facing rail between the first inwardly-facing rail and the first

[1] We have added carriage returns and numbered the claim limitations with the same numbers used by the Petition to identify claim 1's limitations.

vertebral body engagement surface, wherein a second inwardly-facing slot is defined at a location adjacent the second inwardly-facing rail between the second inwardly-facing rail and the first vertebral body engagement surface,

[1.3] wherein the first implant structure defines first and second opposing side surfaces positioned on opposite sides of the first vertebral body engagement surface, wherein the first implant structure defines an end gap between the first and second opposing side surfaces at a first end of the first vertebral body engagement surface,

[1.4] wherein the first vertebral body engagement surface comprises a plurality of ridges extending from the first vertebral body engagement surface, wherein at least some of the ridges are positioned on the first vertebral body engagement surface on opposite sides of the end gap;

[1.5] a second implant structure defining a second angled wedge portion that comprises a first outwardly-facing rail and a second outwardly-facing rail that faces outwardly in a direction opposite that of the first outwardly-facing rail, wherein a first outwardly-facing slot is defined at a location adjacent the first outwardly-facing rail, wherein a second outwardly-facing slot is defined at a location adjacent the second outwardly-facing rail, wherein the first implant structure is slidably-engaged with the second implant structure such that the first angled wedge portion engages the second angled wedge portion with the first inwardly-facing rail of the first implant structure positioned in the first outwardly-facing slot of the second implant structure, the second inwardly-facing rail of the first implant structure positioned in the second outwardly facing slot of the second implant structure, the first outwardly-facing rail of the second implant structure positioned in the first

inwardly-facing slot of the first implant structure, and the second outwardly-facing rail of the second implant structure positioned in the second inwardly-facing slot of the first implant structure,

[1.6] wherein the second implant structure defines third and fourth opposing side surfaces positioned on opposite sides of the second vertebral body engagement surface,

[1.7] wherein the second implant defines first and second tool engagement indentations on the second and third opposing side surfaces, respectively, wherein the first and second tool engagement indentations are positioned proximate a proximate end of the second implant structure, and

[1.8] wherein the second implant structure defines an adjusting screw hole sized for receiving an adjusting screw at a proximal portion of the second implant structure between the third and fourth side surfaces; and

[1.9] an adjusting screw positioned in the adjusting screw hole;

[1.10] a first tool having a first proximal end and a first distal end with first and second engagement prongs positioned at the first distal end and defining an adjusting tool passage extending through the first tool from the first proximal end to the first distal end, wherein the first and second engagement prongs are sized and positioned to extend into the first and second tool engagement indentations of the second implant structure so as to allow the first tool to engage the intervertebral expandable implant; and

[1.11] a second adjusting tool having a second proximal end and a second distal end with a handle positioned at the second proximal end, a screw engagement portion positioned at the second distal end, and a shaft extending from the handle to the

> screw engagement portion, wherein the screw engagement portion is sized and configured for engaging and turning the adjusting screw when the screw engagement portion is engaged with the adjusting screw, wherein the shaft of the second adjusting tool is sized with a smaller diameter than that of the adjusting tool passage such that the second adjusting tool can extend through the adjusting tool passage of the first tool to engage and turn the adjusting screw of the intervertebral expandable implant to expand the intervertebral expandable implant when the first and second engagement prongs of the first tool are engaged with the first and second tool engagement indentations of the intervertebral expandable implant.

Ex. 1001, 13:2–14:36.

F. Evidence

Petitioner submits the following evidence:

Evidence	Exhibit No.
Declaration of Dr. Jorge A. Ochoa ("Ochoa Declaration")	1003
Baynham et al., US 2007/0270968 A1, published Nov. 22, 2007 ("Baynham")	1029
McLuen, US 2006/0253201 A1, published Nov. 9, 2006 ("McLuen")	1030
Allen, US 5,658,335, issued Aug. 19, 1997 ("Allen")	1031
Sutcliffe, US 2002/0143399 A1, published Oct. 3, 2002 ("Sutcliffe")	1032

G. Asserted Grounds

Petitioner asserts that the challenged claims are unpatentable on the following grounds:

Claims Challenged	35 U.S.C. §	Reference(s)/Basis
1, 3, 5, 7–11	103	Baynham, McLuen, Allen
21–26	103	Baynham, McLuen, Allen, Sutcliffe

II. ANALYSIS

A. Level of Ordinary Skill in the Art

The level of skill in the art is "a prism or lens" through which we view the prior art and the claimed invention. *Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001). Petitioner contends that a person having ordinary skill in the in the art "would have a Bachelor's or equivalent degree in Mechanical Engineering or a related discipline (e.g. biomechanics or biomedical engineering), and at least five years of experience." Pet. 15–16 (referencing Ex. 1003 ¶¶ 26–30, Ex. 1004). Petitioner adds that "[t]he experience would consist of: a) designing, developing, evaluating and/or using prosthetic devices, b) anatomy, physiology and biology of soft and calcified tissues including bone healing and fusion, and c) biomechanical and functional loading of orthopedic implants." *Id.* at 16. Petitioner contends, as an alternative, a person having ordinary skill in the art "could have an advanced degree in the technical disciplines noted above, or a Doctor of Medicine, and at least two years of experience in the subject areas provided above." *Id.*

Patent Owner does not contest Petitioner's contentions nor does Patent Owner offer its own level of ordinary skill.

We adopt Petitioner's level of ordinary skill for this Decision. We determine that the proposed level of ordinary skill is commensurate with the '268 patent and prior art of record.

B. Legal Principles

A claim is unpatentable for obviousness under 35 U.S.C. § 103(a) if the differences between the claimed subject matter 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." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) when in evidence, objective indicia of nonobviousness, i.e., secondary considerations.[2] *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

Additionally, the obviousness inquiry typically requires an analysis of "whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue." *KSR*, 550 U.S. at 418 (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (requiring "articulated reasoning with some rational underpinning to support the legal conclusion of obviousness")); *see In re Warsaw Orthopedic, Inc.*, 832 F.3d 1327, 1333 (Fed. Cir. 2016) (citing *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1360 (Fed. Cir. 2006)).

[2] At this time, the parties do not address objective indicia of nonobviousness, which accordingly do not form part of our analysis.

C. Claim Construction

In an *inter partes* review proceeding, a claim of a patent is construed using the same standard used in federal district court, including construing the claim in accordance with the ordinary and customary meaning of the claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent. 37 C.F.R. § 42.100(b) (2019). According to the applicable standard, claim terms "are generally given their ordinary and customary meaning" as understood by a person of ordinary skill in the art in question at the time of the invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc). "In determining the meaning of the disputed claim limitation, we look principally to the intrinsic evidence of record, examining the claim language itself, the written description, and the prosecution history, if in evidence." *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1014 (Fed. Cir. 2006) (citing *Phillips*, 415 F.3d at 1312–17). Extrinsic evidence is "less significant than the intrinsic record in determining 'the legally operative meaning of claim language.'" *Phillips*, 415 F.3d at 1317. Only those terms that are in controversy need be construed, and only to the extent necessary to resolve the controversy. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (citing *Vivid Techs., Inc. v. America Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

Arguing that most terms in the challenged claims "should be given their ordinary and customary meaning," Petitioner asserts that certain claim terms "should be construed in accordance with the intrinsic evidence and Petitioner offered the same constructions in the pending litigation." Pet. 14–15. Petitioner then offers proposed constructions for the claim language

"first implant structure," "second implant structure," "adjusting screw positioned in the adjusting screw hole," "an adjusting tool passage extending through the first tool from the first proximal end to the first distal end," and "an indentation adjacent to the screw hole." *Id.* at 15.

Patent Owner argues that Petitioner does not meet our requirements for construing claim language. Prelim. Resp. 9–18. Noting that Petitioner offers no construction for claim 3, Patent Owner argues that this omission violates 37 C.F.R. § 42.104(b)(3). *Id.* at 9–14. Patent Owner argues that "there is no dispute that" 35 U.S.C. § 112, ¶ 6 "controls" claim 3's recitation of "means to facilitate incorporation into and fusion with the superior and inferior vertebral bodies." *Id.* at 11. In support of this, Patent Owner notes that Petitioner identified this claim language as a means-plus-function term in the related district court proceeding. *Id.* Patent Owner also argues that Petitioner did not explain adequately its bases for the claim constructions that the Petition does propose. *Id.* at 15–18.

We find it necessary to discuss only one claim-construction issue. Specifically, we address the Petition's omission of any construction for claim 3's language "means to facilitate incorporation into and fusion with the superior and inferior vertebral bodies." We require that the Petition "set forth . . . [h]ow the challenged claim is to be construed," and "[w]here the claim to be construed contains a means-plus-function or step-plus-function limitation . . . , the construction of the claim must identify the specific portions of the specification that describe the structure, material, or acts corresponding to each claimed function." 37 C.F.R. § 42.104(b)(3). Additionally, where, as here, the claim language contains the word "means," we presume that the language is means-plus-function claim language.

Williamson v. Citrix Online, LLC, 792 F.3d 1339, 1349 (Fed. Cir. 2015) (citing *Personalized Media Commc'ns, LLC v. Int'l Trade Comm'n*, 161 F.3d 696, 703 (Fed. Cir. 1998)).

Petitioner has not argued that this presumption is rebutted, nor has Petitioner cited any evidence to rebut this presumption. *See generally,* Pet. Petitioner also has not identified the specific portions of the Specification that describe the structure, material, or acts corresponding to the function recited in claim 3. *See id.* Given our requirements and the presumption that claim 3 contains means-plus-function language, Petitioner's silence regarding the meaning of claim 3 supports denial of the Petition. To the extent the Petition does not violate Rule 42.104(b)(3) by omitting any discussion of claim 3's meaning, the omission creates burdensome issues for Patent Owner and the Board. In combination with certain deficiencies discussed in detail below, the Petition's silence regarding the meaning of claim 3 contributes to our decision to deny the Petition.

D. Alleged Obviousness of Claims 1, 3, 5, and 7–11 over Baynham, McLuen, and Allen

1. Overview of Baynham

Baynham's subject is implants for placement between vertebrae. Ex. 1029 ¶ 3. Baynham shows one such implant in Figures 1–3. *Id.* ¶¶ 16–18. Figures 1–3 are reproduced below.

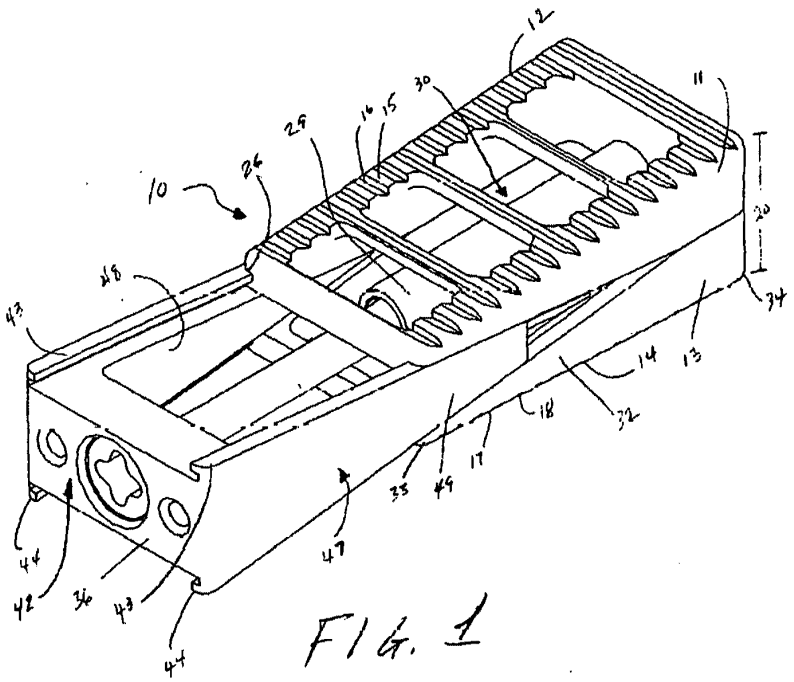

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FIG. 1

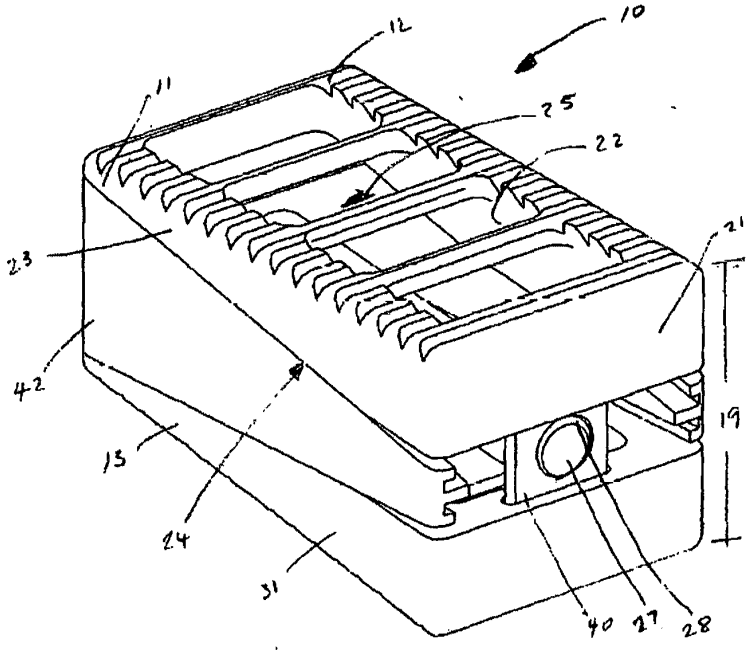

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FIG. 2

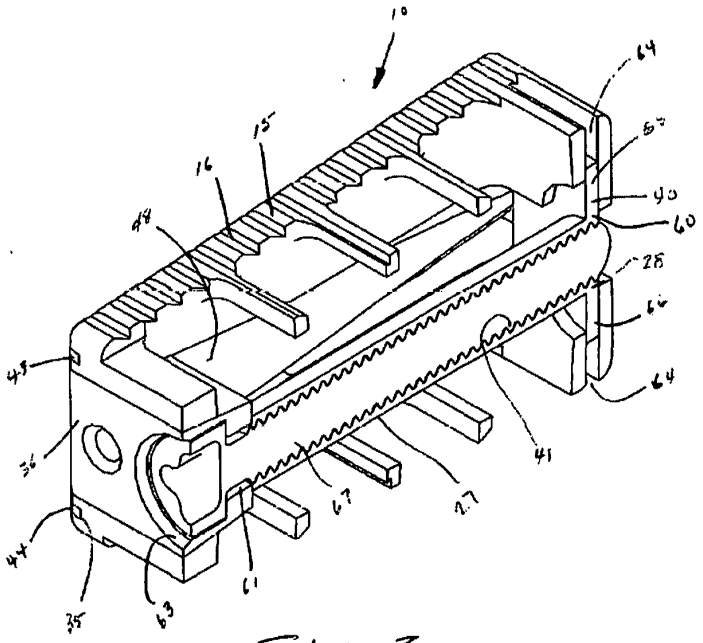


FIG. 3

Figures 1–3 provide different views of shows spinal fusion device 10, which includes upper section 11, lower section 13, link 40, distractor 42, and jack screw 67. *Id.* ¶¶ 16–18, 25–26, 29. Figures 1 "is a perspective view of the spinal fusion implant . . . in the thin mode." *Id.* ¶ 16. Figure 2 "is a perspective view of the spinal fusion device . . . in the deployed mode." *Id.* ¶ 17. Figure 3 "is a side view, partially in section." *Id.* ¶ 18.

Upper section 11 and distractor 42 engage one another in a manner that allows relative movement between them. *Id.* ¶ 25. Upper section 11 has sidewalls 22, 23, which terminate at inclined plane 24. *Id.* Extending along sidewalls 22, 23, upper section 11 has groove 26, which engages flange 43 on distractor 42. *Id.* This engagement guides relative movement between upper section 11 and distractor 42, holding alignment between distractor 42 and sidewalls 22, 23. *Id.*

Lower section 13 and distractor 42 also engage one another in a manner that allows relative movement between them. *Id.* ¶ 26. Lower section 13 has sidewalls 31, 32, which terminate in an inclined plane. *Id.* Along each of sidewalls 31, 32 extends groove 35. *Id.* "The movement of the flange 44 through the groove 35 contributes to the alignment of the distractor 42 and lower section as they move relative to each other." *Id.*

Distractor 42 includes end wall 36, body 47, and two rails 48, 49. *Id.* ¶ 28. End wall 36 includes bore 61 with countersunk bore 63. *Id.* Jack screw 67 extends through bore 61. *Id.* ¶ 29.

In use, "[t]he spinal fusion device is inserted in the disk space between adjacent vertebrae in the extended position with the top surface in contact with the end plate of one vertebra and the bottom surface in contact with the end plate of an adjacent vertebra." *Id.* ¶ 30. "The surgeon turns the jack screw 67 causing the upper and lower sections to move along the complementary inclined plane to shorten the fusion device and increase the distance between the end plates of the adjacent vertebrae." *Id.*

2. Overview of McLuen

McLuen discloses a bone fusion device as shown in Figure 16. Ex. 1030 ¶ 73. Figure 16 is reproduced below.

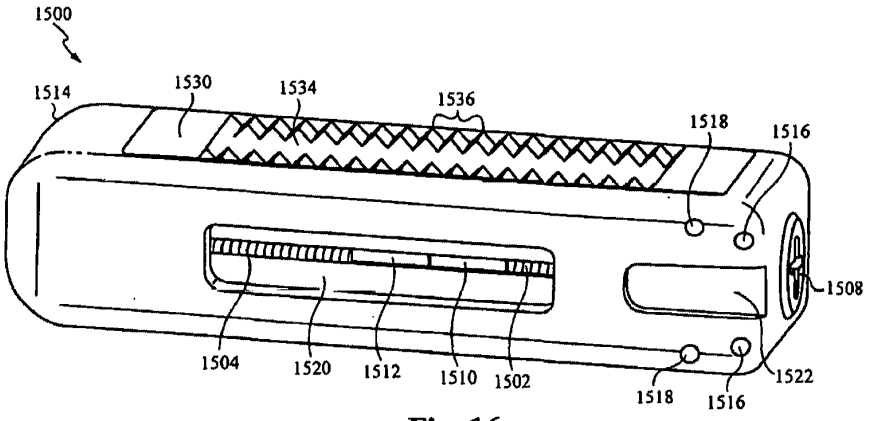


Fig. 16

Figure 16 shows bone fusion device 1500, which includes first screw 1502, second screw 1504, positioning means 1508, first extending block 1510, second extending block 1512, frame 1514, channels 1522, and tabs 1530. *Id.* ¶¶ 74, 76.

Bone fusion device 1500 functions as follows. Positioning means 1508 can be rotated to drive extending blocks 1510, 1512 closer to screws 1502, 1504. *Id.* ¶ 75. As this happens, tabs 1530 are pushed outward by blocks 1510, 1512. *Id.* This drives tabs 1530 against surrounding bones, thereby anchoring bone fusion device 1500 in place. *Id.* McLuen further explains that

> To secure the bone fusion device 1500 in place, a user generally utilizes an implement such as a screw driver to turn the positioning means 1508. Screw drivers unfortunately have the ability to slip out of place. When performing surgery near someone's spine, it is preferable to prevent or at least minimize the slipping ability. To do so, channels 1522 are implemented to receive a tool (not shown). The tool (not shown) has attachments that fit within the channels 1522 to secure the tool (not shown) in place.

Id. ¶ 76.

3. Overview of Allen

Allen discloses an embodiment of a spinal fixator in connection with Figures 1–13. Ex. 1031, 3:21–52. Figure 3 is reproduced below.

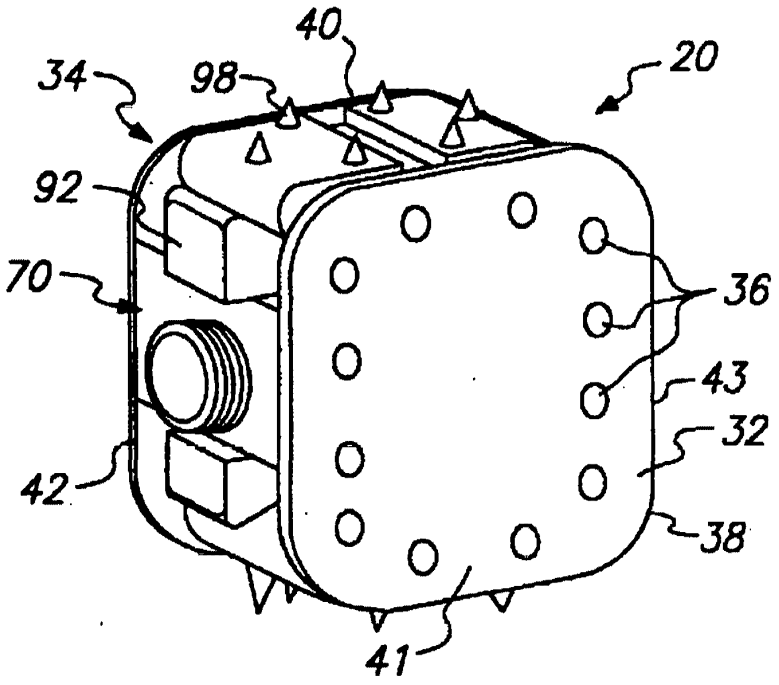


FIG. 3

Figure 3 is a perspective illustration of spinal fixator 20, which includes front cover 32, back cover 34, nut assemblies 70, and crown members 90 (not labeled in Figure 3). *Id.* at 3:29–30. "Each crown member defines a curved flange 92." *Id.* at 4:51–52. Conical teeth 98 project from crown members 90. *Id.* at 4:62–63.

Allen discusses inserting spinal fixator 20 between vertebrae as shown in Figure 12. *Id.* at 5:5–20. Figure 12 is reproduced below.

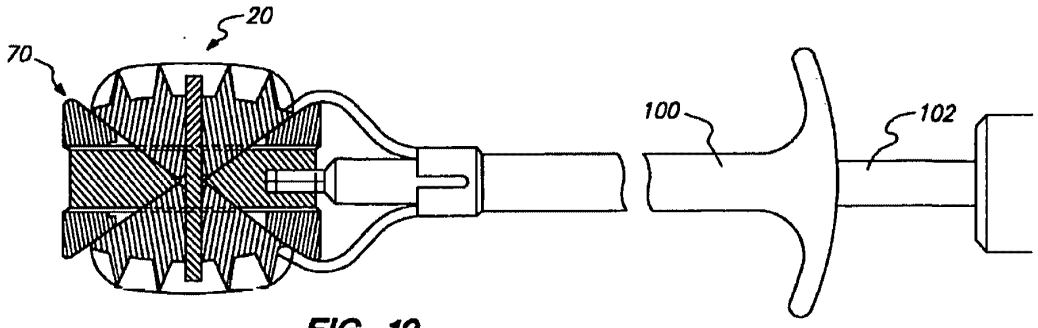


FIG. 12

Figure 12 shows spinal fixator 20 with hollow insertion tool 100 and tool 102. *Id.* at 3:48–50, 5:15–20.

Allen explains that "[a] conventional, hollow insertion tool 100 is used to gasp a nut assembly 70 to insert the retracted spinal fixator 20 between" vertebrae. *Id.* at 5:18–20. Subsequently, tool 102 is passed through hollow insertion tool 100 to engage within aperture 60 (not labeled in Figure 12) of core member 50 (not labeled in Figure 12). *Id.* at 5:21–23. Then, using tool 102, core member 50 is rotated, driving crowns 90 (not labeled in Figure 12) outward, pushing teeth 98 (not labeled in Figure 12) into adjacent vertebrae (not shown in Figure 12). *Id.* at 5:23–26. Tool 102 has "a terminus defining a hex configuration." *Id.* at 5:21–22.

4. Discussion

Petitioner asserts that it would have been obvious to modify and combine certain teachings of Baynham, McLuen, and Allen in ways that meet the limitations of claims 1, 3, 5, and 7–11. Pet. 23–51. Petitioner contends that it would have been obvious to modify Baynham's upper section 11 "to reverse the facing direction (inward verses outward) of the rails and corresponding slots." *Id.* at 25–27. Similarly, Petitioner asserts that it would have been obvious to modify Baynham's distractor 42 and lower section 13 "to reverse the facing direction (outward versus inward) of

the rails and corresponding slots." *Id.* at 30–33. Additionally, Petitioner argues that it would have been obvious to relocate indentations from Baynham's end wall 36 "to the third and fourth opposing side[s] of the second implant structure." *Id.* at 34–37. Petitioner adds that it would have been obvious "to combine the teachings of Baynham with McLuen to substitute the indentations disclosed in Baynham for the indentations in McLuen, moving the indentations from either side of the countersink (63) to a position proximatc a proximate (trailing) end of the second implant structure." *Id.* at 36. Petitioner also argues that it would have been obvious to use Allen's tools 100, 102 with Baynham's spinal fusion device 10. *Id.* at 38–42. Additionally, Petitioner asserts that it would have been obvious to use the combination of the references' teachings in certain ways required by method claims 9–11. *Id.* at 45–51.

Patent Owner argues that Petitioner has not demonstrated a reasonable likelihood of prevailing on its assertions of obviousness. Prelim. Resp. 1–2, 9–27. Patent Owner contends that "the Petition is plagued by multiple deficiencies, which provide multiple, independent bases to deny institution." *Id.* at 1.

For multiple, independent reasons, we agree with Patent Owner that the Petition fails to demonstrate a reasonable likelihood of prevailing on even one Challenged Claim. In the following sections, we address in detail at least some of the shortcomings of the Petition.

a. *Claim Limitation 1.2*

Claim limitation 1.2 recites, among other things, that

> the first angled wedge portion comprises a first *inwardly-facing* rail and a second *inwardly-facing* rail, wherein a first *inwardly-facing* slot is defined at a location adjacent the first *inwardly-*

> *facing* rail between the first *inwardly-facing* rail and the first vertebral body engagement surface, wherein a second *inwardly-facing* slot is defined at a location adjacent the second *inwardly-facing* rail between the second *inwardly-facing* rail and the first vertebral body engagement surface.

Ex. 1001, 13:14–24 (emphases added).

Petitioner asserts that Baynham's inclined plane 24 corresponds to the claimed "first angled wedge portion." Pet. 25. Petitioner also argues that

> [t]he first angled wedge portion engages with first and second rails and has a corresponding first slot (26) located adjacent to the first rail between the first rail and the first vertebral body engagement surface (12) and a corresponding second slot (26) located adjacent the second rail between the second rail and the first vertebral body engagement surface (12).

Id. at 25. Additionally, Petitioner argues that

> to the extent that Baynham does not explicitly disclose a first implant structure having first and second inwardly-facing rails and slots, it would have been obvious to a [person having ordinary skill in the art] to modify the first implant structure to reverse the facing direction (inward verses outward) of the rails and corresponding slots.

Id. at 27. In support of this assertion, Petitioner reasons that

> [a person having ordinary skill in the art] would have understood that the relative movement of the first and second implant structures along an inclined plane of the angled wedge portion (24) is not mandated by the facing direction of the first and second rails and slots of the first implant structure. EX1003 at ¶ 63.
>
> A [person having ordinary skill in the art] would have understood that modifying the Baynham reference to provide the first implant structure with inwardly-facing rails and slots is a simple and predictable substitution that would involve nothing more than an obvious design choice, yielding the identical function of providing guidance during movement of the first implant structure relative to the second implant structure.

Id. at 26–27.

Patent Owner argues that Petitioner has not demonstrated with particularity how limitation 1.2's requirement for "inwardly-facing" rails and slots are taught by or obvious in view of the cited references. Prelim. Resp. 20–25. Patent Owner argues that the rails and slots Petitioner cites face outwardly, not inwardly. *Id.* at 20–23. Patent Owner also argues that Petitioner does not support adequately its assertion that it would have been obvious to "reverse the facing direction" of Baynham's rails and slots. *Id.* at 23–25.

We agree with Patent Owner that Petitioner has not addressed persuasively limitation 1.2's requirements for inwardly-facing rails and slots. The Petition does not allege that Baynham's rails and slots cited by Petitioner are "inwardly-facing," as required by claim limitation 1.2. Nor does the Petition provide rational underpinning for its assertion that it would have been obvious to reverse the direction that the rails and slots face. Petitioner's obviousness assertion rests on Dr. Ochoa's testimony that

> [a person having ordinary skill in the art] would have understood that the relative movement of the first and second implant structures along an inclined plane of the angled wedge portion (24) is not mandated by the facing direction of the first and second rails and slots of the first implant structure. A [person having ordinary skill in the art] would have understood that modifying the Baynham reference to provide the first implant structure with inwardly-facing rails and slots is a simple and predictable substitution that would involve nothing more than an obvious design choice that would yield the identical function of providing guidance during movement of the first implant structure relative to the second implant structure. Therefore, to the extent that Baynham does not disclose a first implant structure having first and second inwardly-facing rails and slots, it would have been obvious to a [person having ordinary skill in

> the art] to modify the first implant structure to reverse the facing direction (inward verses outward) of the rails and corresponding slots.

Ex. 1003 ¶ 63. Dr. Ochoa provides no supporting evidence for his opinion regarding the ease and predictability of "revers[ing] the facing direction" of Baynham's rails and slots. Therefore, we find this testimony has little persuasive weight. *See* 37 C.F.R. § 42.65(a) ("Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight.").

Petitioner does not provide sufficiently persuasive evidence or explanation of a reason that a person having ordinary skill in the art would have reversed the direction that Baynham's rails and slots face. Petitioner does not support adequately its assertion that the proposed change would have been merely a design choice. Neither Petitioner nor Dr. Ochoa provide sufficiently persuasive evidence that the direction of Baynham's rails and slots solves no stated problem or is not critical to the function of Baynham's device, such that changing the directions of the rails and slots is merely a matter of design choice. Even assuming that changing the direction of rails and slots is easy and has only predictable results in an abstract sense, Petitioner does not show sufficiently that it is an uncritical design choice in the apparently crowded and nuanced field of spinal fusion technology, particularly in combination with the numerous other modifications proposed by Petitioner. *See Ex Parte Spangler*, Appeal No. 2018-00300 (PTAB Feb. 20, 2019) (informative); *see also Polaris Indus., Inc. v. Arctic Cat, Inc.*, 882 F.3d 1056, 1069 n.4 (Fed. Cir. 2018) ("The Board failed to consider that '[m]erely stating that a particular placement of an element is a design choice does not make it obvious.' Instead, the [Petitioner] must explain why a

person of ordinary skill in the art 'would have selected these components for combination in the manner claimed.'" (citations omitted); *cf. In re Kuhle*, 526 F.2d 553, 555 (CCPA 1975) ("Use of such means of electrical connection in lieu of those used in the references solve *no stated problem* and would be an obvious matter design choice within the skill in the art." (emphasis added)). Said another way, we find no persuasive argument or credible supporting evidence to explain that the directions of Baynham's rails and slots is not critical to some aspect of the function of its spinal fusion device 10 at some point in its service life.

For the foregoing reasons, Petitioner has not made a sufficiently persuasive showing with respect to limitation 1.2 to demonstrate a reasonable likelihood of prevailing on its assertion that independent claim 1 would have been obvious over Baynham, McLuen, and Allen. And Petitioner's discussion of dependent claims 3, 5, and 7–11 does not remedy the deficiency in its discussion of independent claim 1.

b. *Claim Limitation 1.5*

Claim limitation 1.5 recites, among other things,

> a second implant structure defining a second angled wedge portion that comprises a first *outwardly-facing* rail and a second *outwardly-facing* rail that *faces outwardly* in a direction opposite that of the first *outwardly-facing* rail, wherein a first *outwardly-facing* slot is defined at a location adjacent the first *outwardly-facing* rail, wherein a second *outwardly-facing* slot is defined at a location adjacent the second *outwardly-facing* rail.

Ex. 1001, 13:36–44 (emphases added).

Petitioner asserts that

> Baynham discloses a second implant structure (42 and 13) defining a second angled wedge portion that has first and second rails (43) that face in a direction opposite to each other and

> engage a first slot defined at a location adjacent the first rail (43) and a second slot defined at a location adjacent the second rail (43).

Pet. 31. Petitioner adds that "[t]he first implant structure (11) is slidably-engaged with the second implant structure (42 and 13) such that the first angled wedge portion (24) engages the second angled wedge portion of the second implant structure (42 and 13)." *Id.* Additionally, Petitioner argues that

> to the extent that Baynham does not explicitly disclose a second implant structure that has first and second outwardly-facing rails and slots, it would have been obvious to a [person having ordinary skill in the art] to modify the second implant structure to reverse the facing direction (outward versus inward) of the rails and corresponding slots.

Id. at 32–33. In support of this assertion, Petitioner reasons that

> [a person having ordinary skill in the art] would have understood that the relative movement of the first and second implant structures along an inclined plane of the angled wedge portion (24) is not mandated by the facing direction of the first and second rails and slots of the first implant structure or the second implant structure. As noted above, a [person having ordinary skill in the art] would have understood that modifying the Baynham reference to provide a first implant structure with inwardly-facing rails and inwardly-facing slots is a simple and predictable substitution that would involve nothing more than obvious design choice that would yield the identical function of providing guidance during movement of the contacting surfaces of the inclined planes of the first and second implant structures. This predicable substitution is equally as applicable to the second implant structure as it is to the first implant structure and when the modification is made to the first implant structure it also drives the modification to the second implant structure.

Id. at 32.

Patent Owner argues that Petitioner has not demonstrated with

particularity how limitation 1.5's requirement for "outwardly-facing" rails and slots are taught by or obvious in view of the cited references. Prelim. Resp. 25–27. Patent Owner argues that the rails and slots Petitioner cites face inwardly, not outwardly. *Id.* at 26. Patent Owner also argues that Petitioner does not support adequately its assertion that it would have been obvious to "reverse the facing direction" of Baynham's rails and slots. *Id.* at 26–27.

We agree with Patent Owner that Petitioner has not addressed persuasively limitation 1.5's requirements for outwardly-facing rails and slots. The Petition does not allege that Baynham's rails and slots cited by Petitioner are "outwardly-facing," as required by claim limitation 1.5. Nor does the Petition provide rational underpinning for its assertion that it would have been obvious to reverse the direction that the rails and slots face. Petitioner's obviousness assertion rests on Dr. Ochoa's testimony that

> [a person having ordinary skill in the art] would have understood that the relative movement of the first and second implant structures along an inclined plane of the angled wedge portion (24) is not mandated by the facing direction of the first and second rails and slots of the first implant structure or the second implant structure. As noted above, a [person having ordinary skill in the art] would have understood that modifying the Baynham reference to provide a first implant structure with inwardly-facing rails and inwardly-facing slots is a simple and predictable substitution that would involve nothing more than obvious design choice that would yield the identical function of providing guidance during movement of the contacting surfaces of the inclined planes of the first and second implant structures. This predicable substitution is equally as applicable to the second implant structure as it is to the first implant structure and when the modification is made to the first implant structure it also drives the modification to the second implant structure.

Ex. 1003 ¶ 68. Dr. Ochoa provides no supporting evidence for his opinion

regarding the ease and predictability of "revers[ing] the facing direction" of Baynham's rails and slots. Therefore, we find this testimony has little persuasive weight. *See* 37 C.F.R. § 42.65(a). As with claim limitation 1.2 discussed above in Section II.D.4.a, Petitioner does not provide sufficiently persuasive evidence or explanation of a reason that a person of ordinary skill in the art would have reversed the direction that Baynham's rails and slots face. Here again, Petitioner does not adequately support its conclusory assertion that reversing the rails and slots would have been merely a design choice, given the apparently crowded and nuanced field of spinal fusion technology, and particularly in view of the numerous other modifications proposed by Petitioner.

For the foregoing reasons, Petitioner has not made a sufficiently persuasive showing with respect to limitation 1.5 to demonstrate a reasonable likelihood of prevailing on its assertion that independent claim 1 would have been obvious over Baynham, McLuen, and Allen. And Petitioner's discussion of dependent claims 3, 5, and 7–11 does not remedy the deficiency in its discussion of independent claim 1.

c. *Claim Limitation 1.7*

Claim limitation 1.7 requires "wherein the second implant defines first and second tool engagement indentations on the second and third opposing side surfaces, respectively, wherein the first and second tool engagement indentations are positioned proximate a proximate end of the second implant structure." Ex. 1001, 13:62–67. Addressing this claim limitation, Petitioner asserts that "Baynham discloses the second implant [structure] (42 and 13) defines first and second indentations on the end wall (36) on either side of the countersink (63)." Pet. 34. Petitioner elaborates that "[w]hile the

function of the first and second tool engagement indentations is not expressly disclosed in Baynham, a [person having ordinary skill in the art] would have understood that these indentations could function as tool engagement indentations." *Id.* at 35. Petitioner adds that

> [t]o the extent that Baynham does not explicitly disclose first and second tool engagement indentations on the third and fourth opposing side surfaces of the second implant (42 and 13), it would have been obvious to a [person having ordinary skill in the art] as a matter of simple substitution to modify the implant disclosed to move the indentations from the end (36) to the third and fourth opposing side of the second implant structure, so that the first and second tool engagement indentations are positioned proximate a proximate end of the second implant structure. Stated another way, placement and positioning of indentations for insertion tool engagement at the trailing end of the second implant is a predictable substitution that does not affect the function of the implant. *Id.* at ¶¶ 72.

Id. at 35.

In support of its assertion that it would have been obvious to modify Baynham's spinal fusion device 10 to have indentations as recited in claim limitation 1.7, Petitioner also cites McLuen. *Id.* at 36–37. Petitioner argues that "McLuen discloses channels or indentations (1522) on opposing sides of the implant to receive a tool" to minimize or prevent a screwdriver from slipping out of place when using a screwdriver to turn screw 1508. *Id.* at 36. Petitioner concludes that

> [i]t would therefore have been obvious to a [person having ordinary skill in the art] to combine the teachings of Baynham with McLuen to substitute the indentations disclosed in Baynham for the indentations in McLuen, moving the indentations from either side of the countersink (63) to a position proximate a proximate (trailing) end of the second implant structure to provide the disclosed advantage of prevention or minimization of screw driver slippage. This substitution would

> represent a design choice which would yield a predictable result with a reasonable expectation of success.

Id. at 36–37; Ex. 1003 ¶ 72.

We find that Petitioner has not provided sufficient rational underpinning for its contention that it would have been obvious to modify Baynham's spinal fusion device 10 to have "first and second tool engagement indentations on the second and third opposing side surfaces," as required by claim limitation 1.7. For example, Petitioner does not provide persuasive evidence of its assertion that "placement and positioning of indentations for insertion tool engagement at the trailing end of the second implant structure is a predictable substitution that does not affect the function of the implant." Pet. 35. Dr. Ochoa's testimony matches Petitioner's assertion, but Dr. Ochoa cites no supporting evidence for this opinion. *See* Ex. 1003 ¶ 72. Therefore, we find Dr. Ochoa's testimony provides little persuasive support for the suggestion that the proposed modification amounts to no more than a predictable substitution. *See* 37 C.F.R. § 42.65(a). Petitioner's and Dr. Ochoa's other assertions regarding how easily the modification could have been made suffer from the same lack of persuasive supporting evidence. *See* Pet. 35–37; Ex. 1003 ¶ 72.

We also find Petitioner has not shown sufficient rational underpinning for its assertion that McLuen would have motivated a person of ordinary skill in the art to move Baynham's indentations. McLuen teaches that channels 1522 "receive a tool," suggesting that the ability of McLuen's bone fusion device 1500 to receive a tool mitigates the risk of screwdriver slippage. Ex. 1030 ¶ 76. But Petitioner does not provide persuasive evidence that Baynham's spinal fusion device 10 lacks provisions for mitigating screwdriver slippage by receiving a tool. To the contrary,

Petitioner suggests that Baynham's end wall 36 provides tool engagement indentations for receiving a tool, seemingly mitigating the risk of screwdriver slippage. Pet. 34–35. Additionally, Petitioner does not provide persuasive reasoning or evidence that a person of ordinary skill in the art would have viewed the particular locations of McLuen's channels 1522 as necessary or helpful to mitigating the risk of screwdriver slippage. McLuen does not even mention the location of its channels 1522. *See* Ex. 1030 ¶ 76. Accordingly, Petitioner does not provide sufficient rational underpinning for the assertion that McLuen would have motivated a person of ordinary skill in the art to move Baynham's indentations from their original locations to side surfaces.

d. *Claim Limitation 1.10*

Claim limitation 1.10 recites, among other things,

> a first tool having a first proximal end and a first distal end with first and second engagement prongs positioned at the first distal end and defining an adjusting tool passage extending through the first tool from the first proximal end to the first distal end.

Ex. 1001, 14:7–11. Addressing claim limitation 1.10, Petitioner asserts that "Allen discloses a hollow first tool (100) having a first proximal end and a first distal end with first and second engagement prongs positioned at the first distal end and an adjusting tool passage extending through the first tool from the first proximal end to the first distal end." Pet. 38. Petitioner argues that

> [i]t would have been obvious to a [person having ordinary skill in the art] to use prongs on the tool disclosed by Allen to engage the first and second tool engagement indentations of the implant structure disclosed by Baynham in combination with McLuen on placement of the indentations, to insert the implant into the disk space between adjacent vertebrae.

Id. at 39.

We find Petitioner has not provided sufficient rational underpinning for its assertion that it would have been obvious to modify Baynham's teachings to use Allen's tool 100. Petitioner supports its obviousness contention by asserting that a person having ordinary skill in the art would recognize Allen's tool 100 has been configured to engage Baynham's apparatus with modifications based on McLuen. *Id.* at 39. As noted above, Petitioner supports its obviousness contention with an assertion that

> [a person having ordinary skill in the art] would have understood that the first and second engagement prongs of [Allen's] insertion tool (100) are sized and positioned to extend into the first and second tool engagement indentations of a structure, such as the second implant structure (42 and 13) of Baynham in combination with McLuen, to allow the first tool to engage the intervertebral expandable implant.

Id. This assertion is not persuasive and lacks a logical foundation. In particular, there is no plausible support for Petitioner's assertion that the prongs of Allen's tool 100 "are sized and positioned to extend into" indentations of "the second implant structure (42 and 13) of Baynham in combination with McLuen." Petitioner presents no evidence that any structure of "Baynham in combination with McLuen" ever existed. Petitioner offers no rational reason that a person having ordinary skill in the art "would have understood that" Allen's tool 100 was created with prongs sized and positioned to engage indentations in a hypothetical structure that never existed.

Moreover, Dr. Ochoa's testimony does not support Petitioner's assertion that a person having ordinary skill in the art would have known Allen's tool 100 has prongs sized and positioned to engage indentations in

"the second implant structure (42 and 13) of Baynham in combination with McLuen." Instead, the cited portion of Dr. Ochoa's testimony asserts that

> [a person having ordinary skill in the art] would have understood that the first and second engagement prongs of the insertion tool (100) are sized and positioned to extend into the first and second tool engagement indentations of a structure, such as the second implant structure (42 and 13) *of Baynham*, to allow the first tool to engage the intervertebral expandable implant.

Ex. 1003 ¶ 75 (emphasis added). Thus, in contrast to Petitioner's suggestion that it would have been known that Allen's tool 100 has a construction for engaging indentations of "Baynham in combination with McLuen," Dr. Ochoa testifies that it would have been known that Allen's tool 100 has a construction for engaging indentations of Baynham. Dr. Ochoa does not provide supporting evidence for this testimony (*see id.*), diminishing its persuasive weight.

Moreover, even if we accepted this portion of Dr. Ochoa's testimony as factually accurate, it does not support Petitioner's suggestion that the claim as a whole would have been obvious. Petitioner's obviousness argument requires (1) modifying Baynham with tool engagement indentations in different locations than the indentations taught by Baynham (Pet. 34–37), and (2) using Allen's tool to interact with the modified tool engagement indentations (*id.* at 39). Thus, even if accurate, Dr. Ochoa's testimony that it would have been understood that Allen's tool would work with Baynham's original indentations does not support Petitioner's overall theory regarding the alleged obviousness of claim 1 over Baynham, McLuen, and Allen.

For the foregoing reasons, Petitioner has not provided sufficient rational underpinning for its assertion that it would have been obvious to use

Allen's tool 100 with Baynham's spinal fusion device 10. And Petitioner's assertions regarding dependent claims 3, 5, and 7–11 do not remedy this deficiency.

e. *Claim Limitation 1.11*

Claim limitation 1.11 recites, among other things,

> a second adjusting tool having a second proximal end and a second distal end with a handle positioned at the second proximal end, a screw engagement portion positioned at the second distal end, and a shaft extending from the handle to the screw engagement portion, wherein the screw engagement portion is sized and configured for engaging and turning the adjusting screw when the screw engagement portion is engaged with the adjusting screw.

Ex. 1001, 14:17–25. In addressing this claim limitation, Petitioner asserts that it would have been obvious to modify Baynham's teachings to use Allen's tool 102. Pet. 40–42. In support of this assertion, Petitioner first provides substantially the same reasoning we discussed above in Section II.D.4.d to assert that it would have been obvious to use Allen's tool 100 with Baynham's spinal fusion device 10. *Id.* at 41–42. Petitioner also asserts that "[a person having ordinary skill in the art] would have known and understood that orthopedic surgical instruments with cannulated handles bodies, through which instruments and devices could be delivered from the proximal (at the surgeon's hands) to the distal (implantation location) intrasurgical sites, were in common use the time." *Id.* at 42. Petitioner concludes that

> [i]t would have been obvious to a [person having ordinary skill in the art] to combine/use the first tool of Allen to position the first and second engagement prongs of Allen into the first and second tool engagement indentations of the second implant structure of Baynham in combination with McLuen on

> placement of the indentations, to insert the intervertebral expandable implant into the disk space between adjacent vertebrae. Then, using the second adjusting tool of Allen to pass through a cannula in the first tool to drive the adjusting screw to expand the implant of Baynham.

Id. at 42.

For multiple reasons, we find Petitioner has not provided sufficient rational underpinning for its assertion that it would have been obvious to modify Baynham's disclosure to use Allen's adjusting tool 102. For example, as discussed above in Section II.D.4.d, Petitioner does not provide sufficient rational underpinning for its first assertion that it would have been obvious to modify Baynham's teachings to use Allen's tool 100. Thus, Petitioner does not provide sufficient rational underpinning for its assertion that it would have been obvious to add both Allen's tool 100 and Allen's tool 102 to Baynham's teachings.

Additionally, Petitioner does not provide sufficient rational underpinning for its assertion that it would have been obvious to "us[e] the second adjusting tool [102] of Allen to pass through a cannula in the first tool to drive the adjusting screw to expand the implant of Baynham." Pet. 42. In support of this assertion, Petitioner cites matching testimony from Dr. Ochoa. *Id.* (citing Ex. 1003 ¶ 77). But neither Petitioner's assertion nor Dr. Ochoa's testimony makes sense. As both Petitioner and Dr. Ochoa note, Allen's tool 102 has a hex configuration for engaging an adjusting screw. Pet. 41; Ex. 1003 ¶ 77. Neither Petitioner nor Dr. Ochoa present evidence that such a hex configuration would have been compatible with Baynham's adjusting screw 67. *See id.* Indeed, Baynham itself appears to show its adjusting screw has a configuration other than a hex configuration. *See* Ex. 1001, Figs. 1, 3.

For the foregoing reasons, Petitioner has not demonstrated sufficient rational underpinning for its contention that claim limitation 1.11 would have been obvious in view of Baynham, McLuen, and Allen. And Petitioner's discussion of dependent claims 3, 5, and 7–11 does not remedy this deficiency.

E. Alleged Obviousness of Claims 21–26 over Baynham, McLuen, Allen, and Sutcliffe

a. *Overview of Sutcliffe*

Sutcliffe discloses an implant for insertion between vertebrae. Ex. 1032 ¶ 22. One embodiment of Sutcliffe's implant appears in Figure 6. *Id.* ¶ 21. Figure 6 is reproduced below.

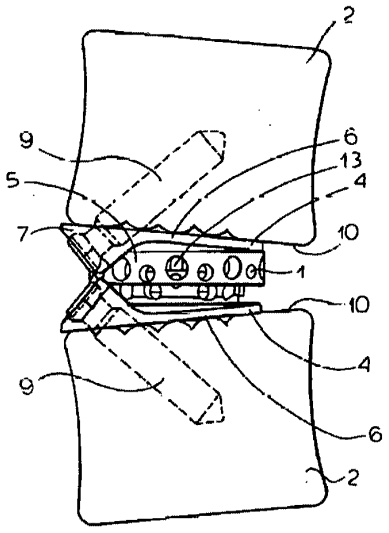


FIG.6

Figure 6 shows implant 1 disposed between vertebrae 2. *Id.* ¶¶ 21–22.

Implant 1 includes lower end part 3, upper end part 4, and center part 5. *Id.* ¶ 22. Each of lower end part 3, upper end part 4, and center part 5 has threads. *Id.* These threads connect lower end part 3, upper end

part 4, and center part 5 in a manner that allows spreading apart or pulling together upper end part 4 by rotating center part 5 in one direction or another. *Id.*

Lower part 3 has two eyes 6 with collars 7 forming holes or passages 8. *Id.* ¶ 24. To secure lower part 3 to a lower vertebra 2, cortical screws pass through eyes 6 and penetrate the lower vertebra 2. *Id.* Figure 6 shows upper end part 4 with a similar pair of eyes 6. *Id.*

b. *Discussion*

Petitioner's challenge of claims 21–26 builds from its challenge of independent claim 1 as allegedly obvious over Baynham, McLuen, and Allen. *See, e.g.,* Pet. 52–53. Petitioner's challenge of claims 21–26 does not remedy the deficiencies in the challenge of independent claim 1 as allegedly obvious. Accordingly, Petitioner does not demonstrate a reasonable likelihood of prevailing on its challenge of claims 21–26.

III. CONCLUSION

Petitioner does not demonstrate a reasonable likelihood of prevailing in showing that at least one of the challenged claims of the '268 patent is unpatentable.

IV. ORDER

It is hereby

ORDERED that the Petition is denied, and no trial is instituted.

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Paper 7
Entered: January 27, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GLOBUS MEDICAL, INC.,
Petitioner,

v.

MOSKOWITZ FAMILY LLC,
Patent Owner.

IPR2020-01304
Patent 10,307,268 B2

Before NEIL T. POWELL, JAMES A. TARTAL, and JAMES J. MAYBERRY, *Administrative Patent Judges*.

POWELL, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

A. Background and Summary

Globus Medical, Inc. ("Petitioner") filed a Petition (Paper 1, "Pet.") requesting an *inter partes* review of claims 1, 3, 5, 7–11, and 21–26 ("the Challenged Claims") of U.S. Patent No. 10,307,268 B2 (Ex. 1001, "the '268 patent"). Mosowitz Family LLC ("Patent Owner") filed a Preliminary Response (Paper 6, "Prelim. Resp.") to the Petition.

An *inter partes* review may not be instituted unless "the information presented in the petition . . . and any response . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). We determine that Petitioner does not demonstrate a reasonable likelihood of prevailing in showing that at least one of the challenged claims of the '268 patent is unpatentable. Accordingly, the Petition is denied, and no trial is instituted.

B. Real Parties in Interest

Petitioner identifies itself, Globus Medical, Inc., as the real party in interest. Pet. 1. Patent Owner identifies itself as the real party in interest. Paper 4, 2.

C. Related Matters

The parties indicate that the '268 patent is the subject of the following district court case: *Moskowitz Family LLC v. Globus Medical, Inc.*, Civil Action No. 2:20-cv-03271 (E.D. Pa.). Pet. 1–2; Paper 4, 2. The parties indicate that this district court case was transferred from the following prior district court case: *Moskowitz Family LLC v. Globus Medical, Inc.*, Civil Action No. 6:19-cv-672 (W.D. Tex.). Pet. 1–2; Paper 4, 2. Patent Owner

notes that the '268 patent has also been challenged by Petitioner in IPR2020-01303. Paper 4, 2.

D. The '268 Patent

The '268 patent discloses inserting screw box constructs that have bi-directional fixating transvertebral (BDFT) screws into a denuded intervertebral disc space. Ex. 1001, 7:41–44. The '268 patent discusses one embodiment of a screw box in connection with Figures 1A–1E. Figure 1B is reproduced below.

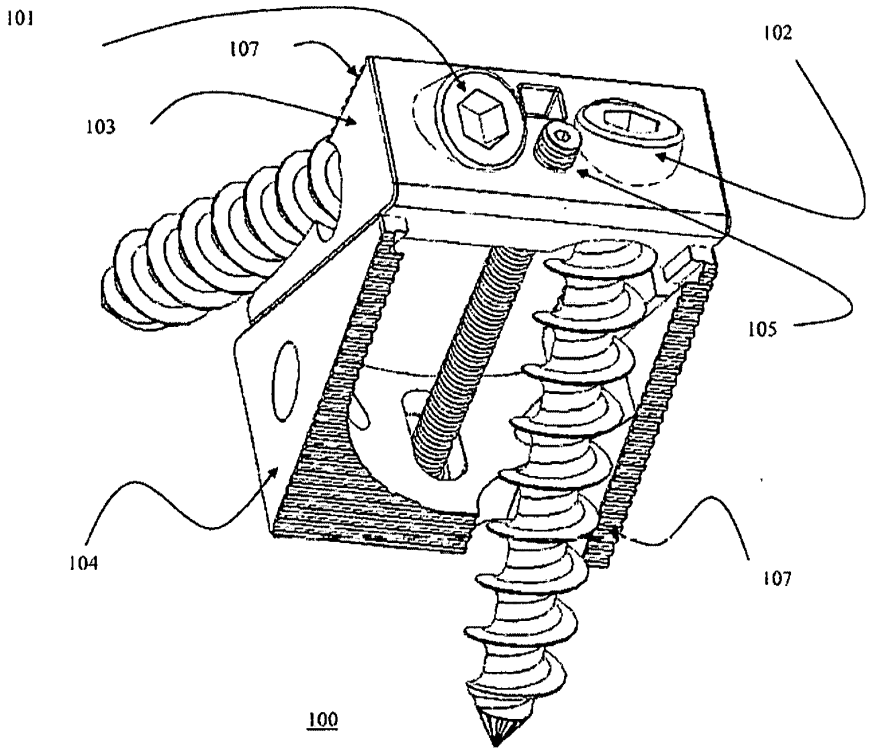


Fig. 1B

Figure 1B shows screw box 100, which includes BDFT screws 101, 102, triangular sliding bases 103, 104, and height/depth adjusting screw 105. *Id.* at 7:45–56.

Screw box 100 has provisions for adjusting its depth and height. *Id.* at 7:56–64. Triangular base 103 has sliding rails 106. *Id.* at 7:58–59. Triangular base 104 has corresponding rail inserts 107, on which rails 106 slide when adjusting screw 105 is turned. *Id.* at 7:56–60. When rails 106 slide on rail inserts 107, the height and depth of screw box 100 changes. *Id.* at 7:56–62. This allows customizing screw box 100 to the disc space. *Id.* at 7:60–64.

Each triangular base has ridges 107. *Id.* at 8:1–4. Ridges 107 contact adjacent vertebrae. *Id.* at 8:2–4. This helps screw box 100 fuse with and incorporate into those vertebrae. *Id.* at 8:4–6.

Screw box 100 serves as both a bi-directional transvertebral screw fusion device and an intervertebral bone fusion spacer. *Id.* at 8:6–12. Toward this end, screw box 100 allows bone placement intended for fusion by including holes 108, which perforate triangular base 103 and triangular base 104. *Id.* at 8:6–8. Additionally, to enable bone filling, screw box 100 is hollow. *Id.* at 8:8–10.

The '268 patent also discloses external drill/screw guide-box expander 500. *Id.* at 8:58–62. External drill/screw guide-box expander 500 appears in Figures 5A–5C. *Id.* Figure 5A is reproduced below.

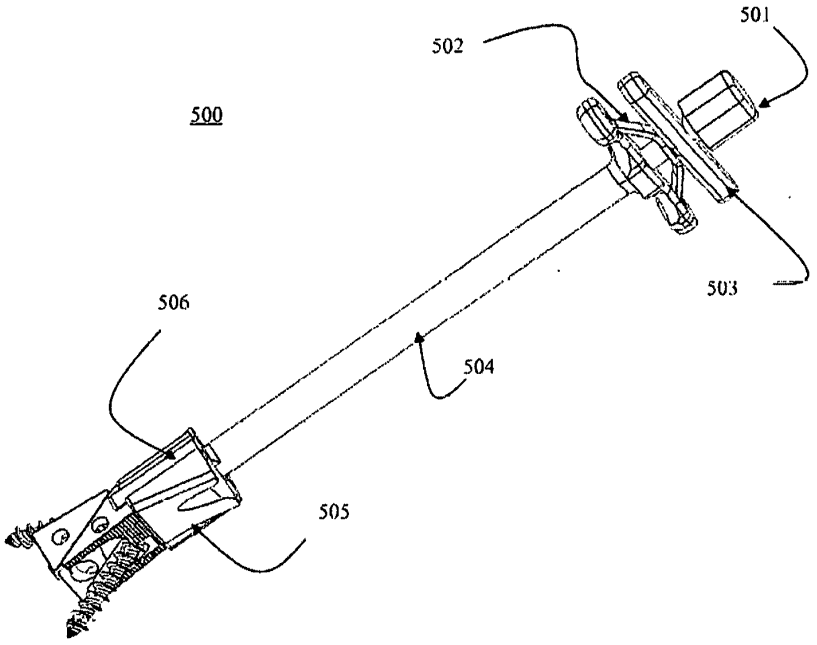


Fig. 5A

Figure 5A shows external drill/screw guide-box expander 500, which includes Allen key 501, spring 502, handle 503, griper 504, and screw guide 505. *Id.* at 8:58–65.

Griper 504 includes griper prongs 506. *Id.* at 9:1–2. Screw guide 505 has grooves into which griper prongs 506 insert. *Id.* at 9:2–3. Additionally, griper prongs 506 are inserted into a screw box. *Id.* This perfectly aligns them. *Id.* at 9:3–4.

The '268 patent explains the process of assembling external drill/screw guide-box expander 500. *Id.* at 9:9–15. Allen key 501 is inserted into handle 503. *Id.* at 9:11–12. Handle 503 is inserted through spring 502 and griper 504. *Id.* at 9:13–14. Griper 504 is inserted into screw guide 505. *Id.* at 9:14–15.

External drill/screw guide-box expander 500 can be used to adjust the width and depth of a screw box. *Id.* at 8:65–9:1. This is done by turning Allen key 501 to rotate the screw adjuster, "which in turn regulates top and bottom triangular screw box base sliding." *Id.*

E. Illustrative Claim

Of the challenged claims, claims 1 and 21 are independent. Claim 1 is reproduced below with certain reformatting.[1]

1. [1.1] A system comprising:

an intervertebral expandable implant having a first vertebral body engagement surface for engaging a first vertebral body and a second vertebral body engagement surface for engaging a second vertebral body, wherein the second vertebral body engagement surface is positioned opposite of the first vertebral body engagement surface, the intervertebral expandable implant comprising:

[1.2] a first implant structure defining the first vertebral body engagement surface and a first angled wedge portion that is angled with respect to the first vertebral body engagement surface, wherein the first angled wedge portion comprises a first inwardly-facing rail and a second inwardly-facing rail, wherein a first inwardly-facing slot is defined at a location adjacent the first inwardly-facing rail between the first inwardly-facing rail and the first

[1] We have added carriage returns and numbered the claim limitations with the same numbers used by the Petition to identify claim 1's limitations.

vertebral body engagement surface, wherein a second inwardly-facing slot is defined at a location adjacent the second inwardly-facing rail between the second inwardly-facing rail and the first vertebral body engagement surface,

[1.3] wherein the first implant structure defines first and second opposing side surfaces positioned on opposite sides of the first vertebral body engagement surface, wherein the first implant structure defines an end gap between the first and second opposing side surfaces at a first end of the first vertebral body engagement surface,

[1.4] wherein the first vertebral body engagement surface comprises a plurality of ridges extending from the first vertebral body engagement surface, wherein at least some of the ridges are positioned on the first vertebral body engagement surface on opposite sides of the end gap;

[1.5] a second implant structure defining a second angled wedge portion that comprises a first outwardly-facing rail and a second outwardly-facing rail that faces outwardly in a direction opposite that of the first outwardly-facing rail, wherein a first outwardly-facing slot is defined at a location adjacent the first outwardly-facing rail, wherein a second outwardly-facing slot is defined at a location adjacent the second outwardly-facing rail, wherein the first implant structure is slidably-engaged with the second implant structure such that the first angled wedge portion engages the second angled wedge portion with the first inwardly-facing rail of the first implant structure positioned in the first outwardly-facing slot of the second implant structure, the second inwardly-facing rail of the first implant structure positioned in the second outwardly facing slot of the second implant structure, the first outwardly-facing rail of the second implant structure positioned in the first

inwardly-facing slot of the first implant structure, and the second outwardly-facing rail of the second implant structure positioned in the second inwardly-facing slot of the first implant structure,

[1.6] wherein the second implant structure defines third and fourth opposing side surfaces positioned on opposite sides of the second vertebral body engagement surface,

[1.7] wherein the second implant defines first and second tool engagement indentations on the third and fourth opposing side surfaces, respectively, wherein the first and second tool engagement indentations are positioned proximate a proximate end of the second implant structure, and

[1.8] wherein the second implant structure defines an adjusting screw hole sized for receiving an adjusting screw at a proximal portion of the second implant structure between the third and fourth side surfaces; and

[1.9] an adjusting screw positioned in the adjusting screw hole;

[1.10] a first tool having a first proximal end and a first distal end with first and second engagement prongs positioned at the first distal end and defining an adjusting tool passage extending through the first tool from the first proximal end to the first distal end, wherein the first and second engagement prongs are sized and positioned to extend into the first and second tool engagement indentations of the second implant structure so as to allow the first tool to engage the intervertebral expandable implant; and

[1.11] a second adjusting tool having a second proximal end and a second distal end with a handle positioned at the second proximal end, a screw engagement portion positioned at the second distal end, and a shaft extending from the handle to the

> screw engagement portion, wherein the screw engagement portion is sized and configured for engaging and turning the adjusting screw when the screw engagement portion is engaged with the adjusting screw, wherein the shaft of the second adjusting tool is sized with a smaller diameter than that of the adjusting tool passage such that the second adjusting tool can extend through the adjusting tool passage of the first tool to engage and turn the adjusting screw of the intervertebral expandable implant to expand the intervertebral expandable implant when the first and second engagement prongs of the first tool are engaged with the first and second tool engagement indentations of the intervertebral expandable implant.

Ex. 1001, 13:2–14:36.

F. Evidence

Petitioner submits the following evidence:

Evidence	Exhibit No.
Declaration of Dr. Jorge A. Ochoa ("Ochoa Declaration")	1003
McLuen, US 2006/0253201 A1, published Nov. 9, 2006 ("McLuen")	1030
Allen, US 5,658,335, issued Aug. 19, 1997 ("Allen")	1031
Sutcliffe, US 2002/0143399 A1, published Oct. 3, 2002 ("Sutcliffe")	1032
Chung et al., KR 20-0290058, issued Sept. 10, 2002 ("Chung")	1033

G. Asserted Grounds

Petitioner asserts that the challenged claims are unpatentable on the following grounds:

Claims Challenged	35 U.S.C. §	Reference(s)/Basis
1, 3, 5, 7–10	103	Chung, McLuen, Allen
11, 21–26	103	Chung, McLuen, Allen, Sutcliffe

II. ANALYSIS

A. Level of Ordinary Skill in the Art

Regarding the level of skill in the art, Petitioner asserts that

> [a]s established in the Declaration of Dr. Ochoa, (EX1003, at ¶¶ 26-30; EX1004) a person having ordinary skill in the art (PHOSITA) of the '268 patent would have a Bachelor's or equivalent degree in Mechanical Engineering or a related discipline (e.g. biomechanics or biomedical engineering), and at least five years of experience. The experience would consist of a) designing, developing, evaluating and/or using prosthetic devices, b) anatomy, physiology and biology of soft and calcified tissues including bone healing and fusion, and c) biomechanical and functional loading of orthopedic implants. Alternatively, a PHOSITA could have an advanced degree in the technical disciplines noted above, or a Doctor of Medicine, and at least two years of experience in the subject areas provided above.

Pet. 14. Patent Owner does not dispute this characterization of the level of skill in the art. *See generally,* Prelim. Resp. For purposes of deciding whether to institute *inter partes* review, we adopt Petitioner's proposed level of skill in the art.

B. Legal Principles

A claim is unpatentable for obviousness under 35 U.S.C. § 103(a) if the differences between the claimed subject matter 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." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) when in evidence, objective indicia of nonobviousness, i.e., secondary considerations.[2] *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

Additionally, the obviousness inquiry typically requires an analysis of "whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue." *KSR*, 550 U.S. at 418 (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (requiring "articulated reasoning with some rational underpinning to support the legal conclusion of obviousness")); *see In re Warsaw Orthopedic, Inc.*, 832 F.3d 1327, 1333 (Fed. Cir. 2016) (citing *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1360 (Fed. Cir. 2006)).

C. Claim Construction

In an *inter partes* review proceeding, a claim of a patent is construed using the same standard used in federal district court, including construing the claim in accordance with the ordinary and customary meaning of the claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent. 37 C.F.R. § 42.100(b) (2019). According to the applicable standard, claim terms "are generally given their ordinary and customary meaning" as understood by a person of ordinary skill in the art in

[2] At this time, the parties do not address objective indicia of nonobviousness, which accordingly do not form part of our analysis.

question at the time of the invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc). "In determining the meaning of the disputed claim limitation, we look principally to the intrinsic evidence of record, examining the claim language itself, the written description, and the prosecution history, if in evidence." *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1014 (Fed. Cir. 2006) (citing *Phillips*, 415 F.3d at 1312–17). Extrinsic evidence is "less significant than the intrinsic record in determining 'the legally operative meaning of claim language.'" *Phillips*, 415 F.3d at 1317. Only those terms that are in controversy need be construed, and only to the extent necessary to resolve the controversy. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (citing *Vivid Techs., Inc. v. America Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

Arguing that most terms in the challenged claims "should be given their ordinary and customary meaning," Petitioner asserts that certain claim terms "should be construed in accordance with the intrinsic evidence and Petitioner offered the same constructions in the pending litigation." Pet. 12–13. Petitioner then offers proposed constructions for the claim language "first implant structure," "second implant structure," "adjusting screw positioned in the adjusting screw hole," "an adjusting tool passage extending through the first tool from the first proximal end to the first distal end," and "an indentation adjacent to the screw hole." *Id.* at 13.

Patent Owner argues that Petitioner does not meet our requirements for construing claim language. Prelim. Resp. 9–17. Noting that Petitioner offers no construction for claim 3, Patent Owner argues that this omission violates 37 C.F.R. § 42.104(b)(3). *Id.* at 9–14. Patent Owner argues that

"there is no dispute that" 35 U.S.C. § 112, ¶ 6 "controls" claim 3's recitation of "means to facilitate incorporation into and fusion with the superior and inferior vertebral bodies." *Id.* at 11. In support of this, Patent Owner notes that Petitioner identified this claim language as a means-plus-function term in the related district court proceeding. *Id.* Patent Owner also argues that Petitioner did not explain adequately its bases for the claim constructions that the Petition does propose. *Id.* at 15–17.

We find it necessary to discuss only one claim-construction issue. Specifically, we address the Petition's omission of any construction for claim 3's language "means to facilitate incorporation into and fusion with the superior and inferior vertebral bodies." We require that the Petition "set forth . . . [h]ow the challenged claim is to be construed," and "[w]here the claim to be construed contains a means-plus-function or step-plus-function limitation . . . , the construction of the claim must identify the specific portions of the specification that describe the structure, material, or acts corresponding to each claimed function." 37 C.F.R. § 42.104(b)(3). Additionally, where, as here, the claim language contains the word "means," we presume that the language is means-plus-function claim language. *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1349 (Fed. Cir. 2015) (citing *Personalized Media Commc'ns, LLC v. Int'l Trade Comm'n*, 161 F.3d 696, 703 (Fed. Cir. 1998)).

Petitioner has not argued that this presumption is rebutted, nor has Petitioner cited any evidence to rebut this presumption. *See generally,* Pet. Petitioner also has not identified the specific portions of the Specification that describe the structure, material, or acts corresponding to the function recited in claim 3. *See id.* Given our requirements and the presumption that

claim 3 contains means-plus-function language, Petitioner's silence regarding the meaning of claim 3 supports denial of the Petition. To the extent the Petition does not violate Rule 42.104(b)(3) by omitting any discussion of claim 3's meaning, this omission creates burdensome issues for Patent Owner and the Board. In combination with certain deficiencies discussed in detail below, the Petition's silence regarding the meaning of claim 3 contributes to our decision to deny the Petition.

D. Alleged Obviousness of Claims 1, 3, 5, and 7–10 over Chung, McLuen, and Allen

1. Overview of Chung

Chung discloses a lumbar holder. Ex. 1033, 5. Chung's lumbar holder appears in Figure 1. *Id.* at 2. Figure 1 of Chung is reproduced below.

Figure 1

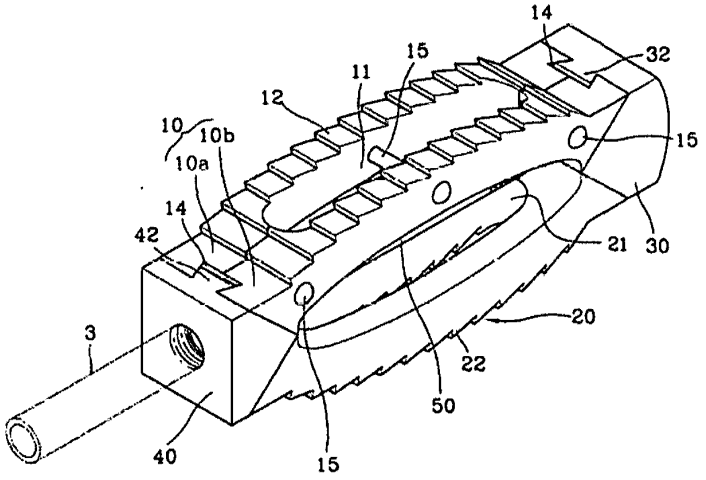


Figure 1 shows Chung's lumbar holder, which includes holder body (10), opposing holder body (20), lead wedge (30), and opposing wedge (40). *Id.* at 5.

Holder bodies (10), (20) have an arch shape. *Id.* Saw tooth (12) is on an outer surface of holder body (10). *Id.* Saw tooth (22) is on an outer surface of holder body (20). *Id.*

Figure 2 of Chung is reproduced below.

Figure 2

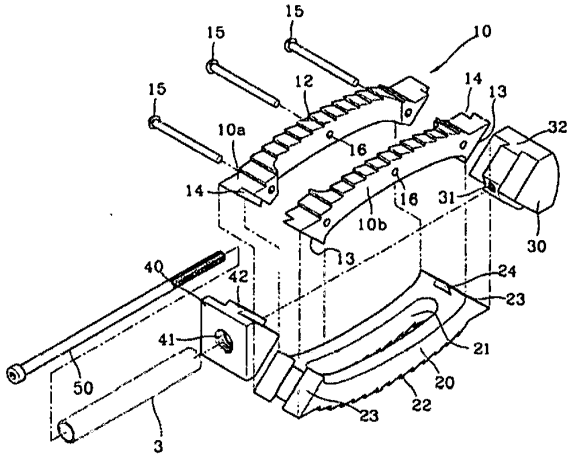


Figure 2 shows Chung's holder body in a disassembled state. *Id.* at 2.

Wedge (30) includes a dovetail (32), and wedge 40 includes a dovetail (42). *Id.* at 5. Corresponding dovetail grooves (14), (24) are formed on holder bodies (10), (20). *Id.* at 2, 5, Fig. 2. Holder bodies (10), (20) also have guiding surfaces (13), (23). *Id.* at 2, 5, Fig. 2.

Chung also discloses groove fastening screw (50). *Id.* at 2, 5, Fig. 2. Wedges (30), (40) have provisions for engaging groove fastening screw. *Id.* at 5. As Chung explains, "wedge (30) has a screw hole (31) of certain diameter formed at the center in order for the screw component of the aforementioned groove fastening screw (50) to be fastened." *Id.* at 6. Chung also teaches that "wedge (40) has a penetrating hole (41) with raised spot in order for the aforementioned groove fastening screw (50)'s head to be held." *Id.*

Chung also discloses wrapper (3). *Id.* at 2, 6, Fig. 2. Wedge (40) includes provisions for engaging wrapper (3). *Id.* at 6. As Chung explains,

> wedge (40)'s penetrating hole (41) has a double raised spot structure that expands to the external side, and on the inner circumference of the large diameter side of the aforementioned penetrating hole (41), a screw line is formed in the direction of the left screw so that a circular pipe wrapper (3) with which the operating person can wrap the aforementioned lumber holder can be combined.

Id.

Chung discusses how its lumbar holder is inserted between vertebrae in connection with Figure 3. *Id.* at 6. Figure 3 is reproduced below.

Figure 3

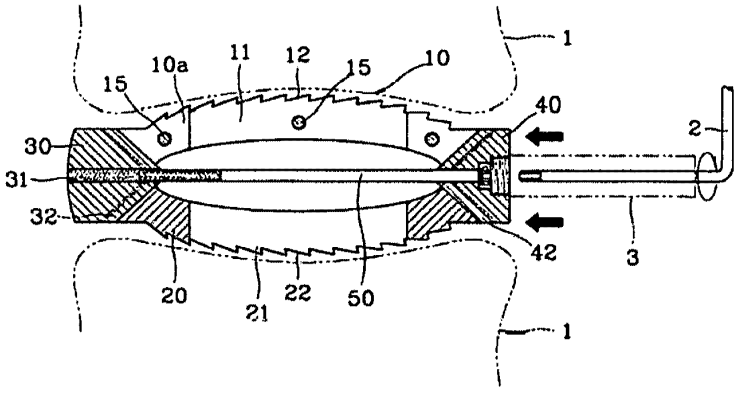


Figure 3 is a cross-sectional view of Chung's lumbar holder inserted between two vertebrae. *Id.* at 2.

Outlining details of the insertion process, Chung explains that

> with the lumber holder under the present invention with the aforementioned configuration, after holding the wrapper (30) and inserting between neighboring two back bones (1), a wrench (2) is inserted into the aforementioned wrapper (3) to fasten the aforementioned groove fastening screw (50) so that the outer surfaces of the main holder bodies (10) (20) are attached to the

surfaces of the aforementioned back bones (1) to fix them robustly.

Id. at 6.

Chung discusses the effect of adjusting groove fastening screw (50) in connection with Figure 4. *Id.* Figure 4 is reproduced below.

Figure 4

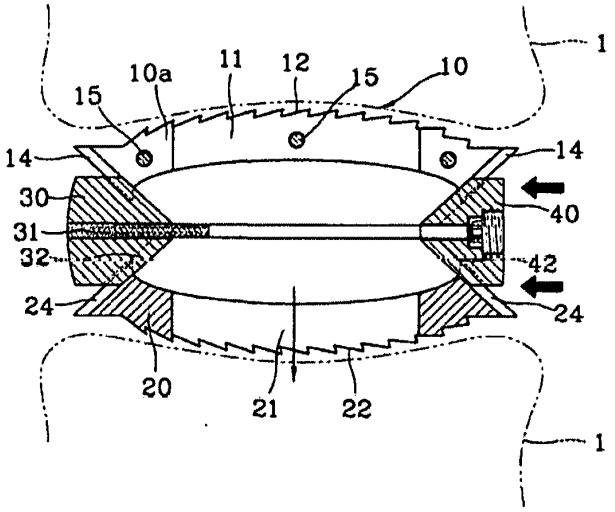


Figure 4 is a cross-sectional view of Chung's lumbar holder adjusting the space between vertebrae. *Id.* at 2.

Tightening groove fastening screw (50) draws wedges (30), (40) toward one another. *Id.* at 6. When this happens, the interaction between dovetails (32), (42) and guiding surfaces (13), (23) drives main bodies (10), (20) away from one another. *Id.*

2. Overview of McLuen

McLuen discloses a bone fusion device as shown in Figure 16. Ex. 1030 ¶ 73. Figure 16 is reproduced below.

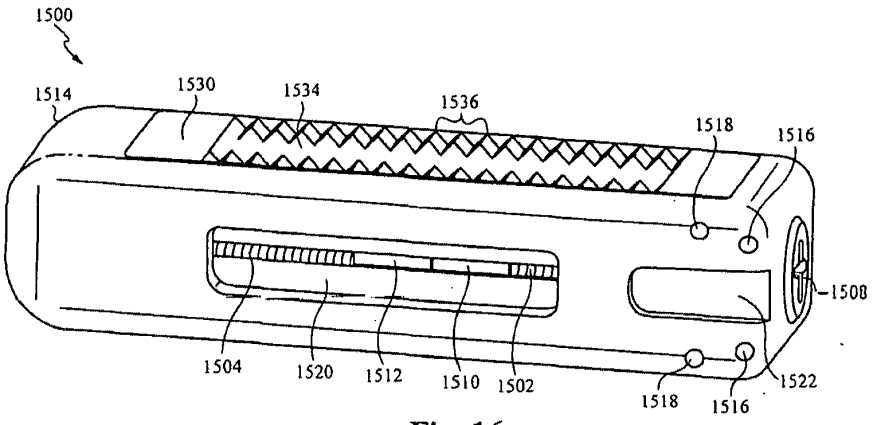


Fig. 16

Figure 16 shows bone fusion device 1500, which includes first screw 1502, second screw 1504, positioning means 1508, first extending block 1510, second extending block 1512, frame 1514, channels 1522, and tabs 1530. *Id.* ¶¶ 74, 76.

Bone fusion device 1500 functions as follows. Positioning means 1508 can be rotated to drive extending blocks 1510, 1512 closer to screws 1502, 1504. *Id.* ¶ 75. As this happens, tabs 1530 are pushed outward by blocks 1510, 1512. *Id.* This drives tabs 1530 against surrounding bones, thereby anchoring bone fusion device 1500 in place. *Id.* McLuen further explains that

> To secure the bone fusion device 1500 in place, a user generally utilizes an implement such as a screw driver to turn the positioning means 1508. Screw drivers unfortunately have the ability to slip out of place. When performing surgery near someone's spine, it is preferable to prevent or at least minimize the slipping ability. To do so, channels 1522 are implemented to receive a tool (not shown). The tool (not shown) has attachments that fit within the channels 1522 to secure the tool (not shown) in place.

Id. ¶ 76.

3. Overview of Allen

Allen discloses an embodiment of a spinal fixator in connection with Figures 1–13. Ex. 1031, 3:21–52. Figure 3 is reproduced below.

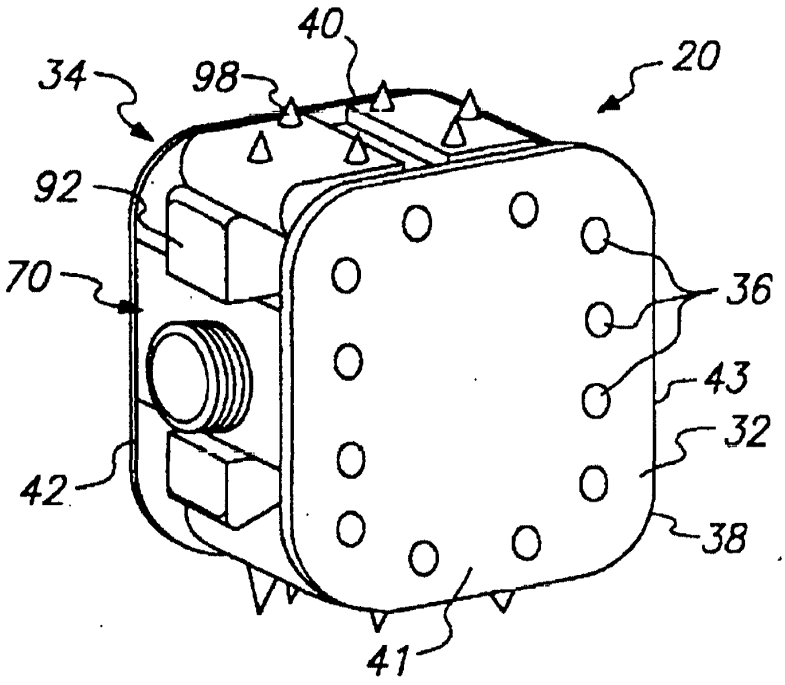


FIG. 3

Figure 3 is a perspective illustration of spinal fixator 20, which includes front cover 32, back cover 34, nut assemblies 70, and crown members 90 (not labeled in Figure 3). *Id.* at 3:29–30. "Each crown member defines a curved flange 92." *Id.* at 4:51–52. Conical teeth 98 project from crown members 90. *Id.* at 4:62–63.

Allen discusses inserting spinal fixator 20 between vertebrae as shown in Figure 12. *Id.* at 5:5–20. Figure 12 is reproduced below.

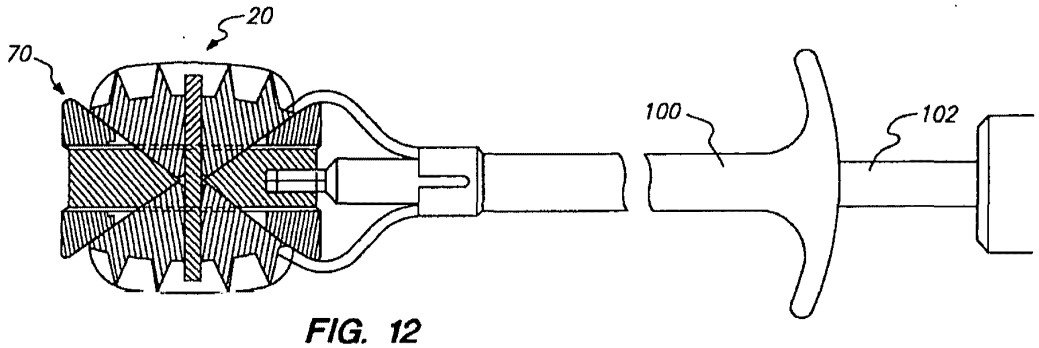


FIG. 12

Figure 12 shows spinal fixator 20 with hollow insertion tool 100 and tool 102. *Id.* at 3:48–50, 5:15–20.

Allen explains that "[a] conventional, hollow insertion tool 100 is used to gasp a nut assembly 70 to insert the retracted spinal fixator 20 between" vertebrae. *Id.* at 5:18–20. Subsequently, tool 102 is passed through hollow insertion tool 100 to engage within aperture 60 (not labeled in Figure 12) of core member 50 (not labeled in Figure 12). *Id.* at 5:21–23. Then, using tool 102, core member 50 is rotated, driving crowns 90 (not labeled in Figure 12) outward, pushing teeth 98 (not labeled in Figure 12) into adjacent vertebrae (not shown in Figure 12). *Id.* at 5:23–26. Tool 102 has "a terminus defining a hex configuration." *Id.* at 5:21–22.

4. Discussion

Petitioner asserts that it would have been obvious to modify and combine certain teachings of Chung, McLuen, and Allen in ways that meet the limitations of claims 1, 3, 5, and 7–10. Pet. 20–45. Asserting that Chung's apparatus has tool engagement indentations, the Petition asserts that it would have been obvious to move those tool engagement indentations to side surfaces of the apparatus. *Id.* at 30–33. Petitioner also argues that it would have been obvious to use Allen's tools 100, 102 with Chung's apparatus. *Id.* at 34–38. Additionally, Petitioner asserts that it would have

been obvious to the combination of the references' teachings in certain ways required by method claims 9 and 10. *Id.* at 41–45.

Patent Owner argues that Petitioner has not demonstrated a reasonable likelihood of prevailing on its assertions of obviousness. Prelim. Resp. 1–2, 9–27. Patent Owner argues that Petitioner has not supported sufficiently its assertions that it would have been obvious to make certain modifications to Chung's apparatus. *E.g., id.*, at 22–27.

We agree with Patent Owner that Petitioner has not carried its burden to demonstrate a reasonable likelihood of prevailing on even one Challenged Claim. In the following sections, we address in detail at least some of the Petition's shortcomings.

a. *Claim Limitation 1.7*

Claim limitation 1.7 requires "wherein the second implant defines first and second tool engagement indentations on the second and third opposing side surfaces, respectively, wherein the first and second tool engagement indentations are positioned proximate a proximate end of the second implant structure." Ex. 1001, 13:62–67. Addressing this claim limitation, Petitioner asserts that "Chung discloses the second implant [structure] (40 and 20) defines tool engagement indentations for engagement of tool (3)." Pet. 30. Petitioner elaborates that

> [a person having ordinary skill in the art] would have understood that Chung discloses that the opposing wedge (40) has a penetrating hole (41) with a counter bore ("double raised spot structure") that expands to the external side, and on the inner circumference of the large diameter side of the penetrating hole (41), a screw thread ("line") is formed so that a circular pipe tool ("wrapper") (3) can be used by the surgeon to hold and position the implant.

Id. at 31. Petitioner adds that

> [t]o the extent that Chung does not explicitly disclose first and second tool engagement indentations on the third and fourth opposing side surfaces of the second implant (40 and 20), it would have been obvious to [person having ordinary skill in the art] as a matter of simple substitution to modify the implant disclosed to move the indentation from the hole (41) to the third and fourth opposing sides of the second implant structure (40 and 20), so that the first and second tool engagement indentations are positioned proximate a proximate end of the second implant structure. Stated another way, placement and positioning of indentations for insertion tool engagement at the proximate end of the second implant structure is a predictable substitution that does not affect the function of the implant.

Id. at 31–32.

In support of its assertion that it would have been obvious to modify Chung's lumbar holder to have indentations as recited in claim limitation 1.7, Petitioner also cites McLuen. *Id.* at 32. Petitioner argues that McLuen "discloses channels or indentations (1522) on opposing sides of the implant to receive a tool" to minimize or prevent a screwdriver from slipping out of place when using a screwdriver to turn screw 1508. *Id.* Petitioner and Dr. Ochoa conclude that

> [i]t would therefore have been obvious to a [person having ordinary skill in the art] to combine the teachings of Chung with McLuen to modify the indentation disclosed in Chung as disclosed in McLuen, moving the indentation from the counter bored structure of penetrating hole (41) to a position proximate a proximate end of the second implant structure to provide the disclosed advantages of prevention or minimization of screw driver slippage.

Id. at 32–33; Ex. 1003 ¶ 121.

We do not find that Petitioner has provided sufficient rational underpinning for its contention that it would have been obvious to modify Chung's structure to have "first and second tool engagement indentations on

the second and third opposing side surfaces," as required by claim limitation 1.7. Petitioner's arguments regarding McLuen do not provide rational underpinning for Petitioner's obviousness assertion. Petitioner indicates that a person having ordinary skill in the art would add McLuen's indentations to Chung's system in order to prevent or minimize slippage of a screwdriver. Pet. 32. Petitioner fails, however, to present persuasive explanation or evidence that McLuen's concerns about screwdriver slippage would apply to Chung's system. In Chung's system, "a wrench (2) is inserted into the aforementioned wrapper (3) to fasten the aforementioned groove fastening screw (50) so that the outer surfaces of the main holder bodies (10) (20) are attached to the surfaces of the aforementioned back bones (1) to fix them robustly." Ex. 1033 6. Petitioner does not present persuasive evidence that Chung's system uses a screwdriver that could slip. Nor does Petitioner present persuasive evidence that a person having ordinary skill in the art would have had any concerns about tool slippage with wrench (2) inserted into wrapper (3). Therefore, Petitioner does not persuade us sufficiently that a person having ordinary skill in the art would have had reason based on McLuen to modify Chung's system.

Like its arguments regarding McLuen, Petitioner's other allegations in support of obviousness also fail to provide sufficient rational underpinning. For example, Petitioner does not provide persuasive evidence of its assertion that "placement and positioning of indentations for insertion tool engagement at the proximate end of the second implant structure is a predictable substitution that does not affect the function of the implant." Pet. 31–32. Dr. Ochoa's testimony matches Petitioner's assertion, but Dr. Ochoa cites no supporting evidence for this opinion. *See* Ex. 1003 ¶ 121.

Therefore, we find Dr. Ochoa's testimony provides little persuasive support for the suggestion that the proposed modification amounts to no more than a predictable substitution. *See* 37 C.F.R. § 42.65(a) ("Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight."). Petitioner's and Dr. Ochoa's other assertions regarding how easily the modification could have been made suffer from the same lack of persuasive supporting evidence. *See* Pet. 31–32; Ex. 1003 ¶ 121.

Moreover, even if we accepted as accurate the Petition's assertions regarding how easily a person having ordinary skill in the art could have modified Chung's system, these assertions do not provide rational underpinning for the assertion of obviousness, as Petitioner does not provide sufficiently persuasive reasoning or evidence of why a person having ordinary skill in the art would have modified Chung in the proposed manner. "[O]bviousness concerns whether a skilled artisan not only *could have made* but *would have been motivated to* make the combinations or modifications of prior art to arrive at the claimed invention." *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1073 (Fed. Cir. 2015) (emphases added).

For these reasons, the Petition does not provide sufficiently persuasive evidence that it would have been obvious to modify Chung's apparatus in a manner that it would meet claim limitation 1.7. Accordingly, the Petition does not demonstrate a reasonable likelihood of prevailing on its assertion that independent claim 1 would have been obvious over Chung, McLuen, and Allen. Additionally, the Petition's discussion of dependent claims 3, 5, and 7–10 fails to sure the deficiency in the discussion of independent claim 1.

Also, as discussed in detail immediately below in Section II.D.4.b, the Petition does not provide a sufficiently clear explanation of how the combination of the cited references' teachings would allegedly meet both claim limitation 1.7 and claim limitation 1.8.

b. *Claim Limitation 1.8*

Claim limitation 1.8 recites "wherein the second implant structure defines an adjusting screw hole sized for receiving an adjusting screw at a proximal portion of the second implant structure between the third and fourth side surfaces." Ex. 1001, 13:67–14:4. Addressing this claim language, the Petition vaguely cites some of the same portions of Chung's teachings that the Petition cites in addressing claim limitation 1.7's "tool indentations." In arguing that Chung teaches "tool engagement indentations," the Petition explains that "Chung discloses that the opposing wedge (40) has a penetrating hole (41) with a counter bore." Pet. 30–31. The Petition then argues that "it would have been obvious . . . to modify the implant disclosed to move the indentation from the hole (41) to the third and fourth opposing side surfaces of the second implant structure." *Id.* at 31. Subsequently, when addressing claim limitation 1.8, the Petition states that "Chung discloses the second implant structure (40 and 20) defines an adjusting hole (41) sized for receiving an adjusting screw (50) at a proximal portion of the second implant structure (40 and 20) between the third and fourth side surfaces." *Id.* at 33.

We find these vague explanations in the Petition do not explain with adequate clarity which features of Chung allegedly constitute claim limitation 1.7's "tool engagement indentations," and which allegedly constitute claim limitation 1.8's "adjusting screw hole." For example, the

Petition does not explain clearly enough how claim 1.7's "tool engagement indentations" are taught by "penetrating hole (41) with a counter bore." *See* Pet. 31. Additionally, the Petition does not explain with sufficient clarity how the same disclosed features of Chung's apparatus meet both claim limitation 1.7's "tool engagement indentations" and claim limitation 1.8's "adjusting screw hole." We find the explanation particularly confusing in view of the Petition's assertion that it would have been obvious to move the features of Chung constituting "tool engagement indentations" to third and fourth side surfaces. If a person having ordinary skill in the art would have moved the alleged "tool engagement indentations" of Chung to the third and fourth side surfaces, we find it unacceptably unclear how the Petition could rely on the same features as meeting claim 1.8's requirement for "an adjusting screw hole . . . between the third and fourth side surfaces."

The Petition's unacceptably confusing explanation of how both claim limitations 1.7 and 1.8 were taught by or obvious over Chung prevents Petitioner from demonstrating a reasonable likelihood of prevailing on its assertion that independent claim 1 would have been obvious over Chung, McLuen, and Allen. Additionally, the Petition's discussion of dependent claims 3, 5, and 7–10 does not remedy this deficiency.

c. *Claim Limitation 1.10*

Claim limitation 1.10 recites, among other things,

> a first tool having a first proximal end and a first distal end with first and second engagement prongs positioned at the first distal end and defining an adjusting tool passage extending through the first tool from the first proximal end to the first distal end.

Ex. 1001, 14:7–11. Addressing claim limitation 1.10, Petitioner asserts that

> [a person having ordinary skill in the art] would have understood that Chung discloses that a circular pipe tool ("wrapper") (3) can

> be used by the surgeon to hold and position the implant. EX1033 at 6 (¶ 2-3). Further, Chung discloses that the circular pipe tool (3) has an adjusting tool passage for receiving wrench (2). EX1033 at 6 (¶ 2-3); FIG. 3; EX1003 at ¶ 124.

Pet. 34. Petitioner adds that "Allen discloses a hollow first tool (100) having a first proximal end and a first distal end with first and second engagement prongs positioned at the first distal end and an adjusting tool passage extending through the first tool from the first proximal end to the first distal end." *Id.* Petitioner argues that

> [i]t would have been obvious to a [person having ordinary skill in the art] to use the prongs on the tool disclosed by Allen to engage the first and second tool indentations of the second implant structure disclosed by Chung in combination with McLuen to insert the implant into the disk space between adjacent vertebrae.

Id. at 35.

We do not find Petitioner has provided sufficient rational underpinning for its assertion that it would have been obvious to modify Chung's system to use Allen's tool 100. Petitioner supports its obviousness contention by asserting that a person having ordinary skill in the art would recognize Allen's tool 100 has been configured to engage Chung's apparatus with modifications based on McLuen. *Id.* at 35. Specifically, Petitioner argues that

> [a person having ordinary skill in the art] would have understood that the first and second engagement prongs of [Allen's] insertion tool (100) are sized and positioned to extend into the first and second tool engagement indentations of a structure (the second implant structure (40 and 20) of Chung in view of McLuen noted above) to allow the first tool to engage the intervertebral expandable implant.

Id. This exact assertion also appears in Dr. Ochoa's testimony, which cites

no supporting evidence for the assertion. Ex. 1003 ¶ 125. This unsupported assertion is unpersuasive and lacks a logical foundation. In particular, there is no plausible support for Petitioner's assertion that the prongs of Allen's tool 100 "are sized and positioned to extend into" indentations of "a structure . . . of Chung in view of McLuen." Petitioner presents no evidence that any structure of "Chung in view of McLuen" ever existed. Petitioner offers no rational reason that a person having ordinary skill in the art "would have understood that" Allen's tool 100 was created with prongs sized and positioned to engage indentations in a hypothetical structure that never existed. For at least this reason, Petitioner's obviousness contentions do not make sense.

Moreover, even if we accepted Petitioner's factual assertions as accurate, Petitioner does not provide sufficient rational underpinning for its assertion of obviousness. Even if accurate, Petitioner's assertions might demonstrate that a person having ordinary skill could have combined the references' teachings in the asserted manner, but they do not sufficiently support any reason that a person having ordinary skill in the art would have combined the references' teachings in the asserted manner. *See Belden*, 805 F.3d at 1073. Petitioner acknowledges that "[a person having ordinary skill in the art] would have understood that Chung discloses that circular pipe tool ('wrapper') (3) can be used by the surgeon to hold and position the implant" (Pet. 36), and Petitioner does not provide a persuasive reason that a person having ordinary skill in the art would have modified Chung's system to use Allen's tool 100 to hold and position the implant.

d. *Claim 9*

Claim 9 recites "[a] method of using the system of claim 1."

Ex. 1001, 14:66. The method of claim 9 includes, among other steps, "implanting the intervertebral expandable implant into a disc space in a lumbar spine via the first tool using a transforaminal lumbar interbody fusion (TLIF) approach." *Id.* at 15:5–8.

Petitioner's challenge of claim 9 builds on the challenge of independent claim 1 as allegedly obvious over Chung, McLuen, and Allen. *See* Pet. 41. Petitioner's challenge of claim 9 as obvious over Chung, McLuen, and Allen does not remedy the above-discussed deficiencies in the challenge of independent claim 1. For at least this reason, Petitioner has not demonstrated a reasonable likelihood of prevailing on its assertion that claim 9 would have been obvious over Chung, McLuen, and Allen.

Moreover, Petitioner's challenge of claim 9 suffers from its own, unique shortcomings. In particular, Petitioner's assertion that it would have been obvious to use Chung's system in accordance with the steps of claim 9 rests primarily on testimony of Dr. Ochoa, which we find has limited persuasive weight. Addressing claim 9's requirement for employing Chung's system "using a transforaminal lumbar interbody fusion (TLIF) approach," Dr. Ochoa testifies that

> [a person having ordinary skill in the art] would have understood that during the transforaminal approach, the surgical window is created through the removal of a facet joint to provide access to the disk space. A [person having ordinary skill in the art] would further have understood that this narrow surgical window requires an appropriately shaped cage. To the extent that Chung does not expressly disclose a use in a TLIF approach, a [person having ordinary skill in the art] would have further understood that the narrow, low profile geometry of the cage disclosed by Chung would be appropriate for use in a TLIF procedure. Further modifications for use in this application would be a matter of additional optimization of the geometry that would not

> affect the function of the invention and would therefore be an obvious design choice.

Ex. 1003 ¶ 138. In his testimony, Dr. Ochoa cites no supporting evidence for his opinions regarding the use and/or modification of Chung's system in a TLIF procedure. For example, he cites no supporting evidence of facts on which he bases his opinion that a person having ordinary skill in the art would have understood that Chung's implant "would be appropriate for use in a TLIF procedure." Nor does he cite any supporting evidence for his opinion that it "[f]urther modifications for use in [a TLIF] application would be a matter of additional optimization of the geometry that would not affect the function of the invention and would therefore be an obvious design choice." *Id.* Due to its lack of supporting evidence, we find Dr. Ochoa's testimony has little persuasive weight. *See* 37 C.F.R. § 42.65(a). This constitutes another reason that Petitioner has not demonstrated a reasonable likelihood of prevailing on its assertion that claim 9 would have been obvious over Chung, McLuen, and Allen.

e. *Claim 10*

Claim 10 recites "[a] method of using the system of claim 1." Ex. 1001, 15:15. The method of claim 10 includes, among other steps, "implanting the intervertebral expandable implant into a disc space in a lumbar spine via the first tool using a posterior lumbar interbody fusion (PLIF) approach." *Id.* at 15:21–23.

Petitioner's challenge of claim 10 builds on the challenge of independent claim 1 as allegedly obvious over Chung, McLuen, and Allen. *See* Pet. 44. Petitioner's challenge of claim 10 as obvious over Chung, McLuen, and Allen does not remedy the above-discussed deficiencies in the challenge of independent claim 1. For at least this reason, Petitioner has not

demonstrated a reasonable likelihood of prevailing on its assertion that claim 10 would have been obvious over Chung, McLuen, and Allen.

Moreover, Petitioner's challenge of claim 10 suffers from its own, unique shortcomings. In particular, Petitioner's assertion that it would have been obvious to use Chung's system in accordance with the steps of claim 10 rests primarily on testimony of Dr. Ochoa, which we find has limited persuasive weight. Addressing claim 10's requirement for employing Chung's system "using a transforaminal lumbar interbody fusion (TLIF) approach," Dr. Ochoa testifies that

> [t]o the extent that Chung does not expressly disclose a posterior lumbar interbody fusion (PLIF) approach, a [person having ordinary skill in the art] would have understood the Chung device is of a low-profile and narrow geometry typical for posterior devices. Further, a [person having ordinary skill in the art] would have understood that the lumbar spine is almost exclusively the location in which interbody cages are implanted using a posterior approach. Therefore, it would have been obvious that the implant disclosed by Chung would be appropriate for use in a PLIF procedure.

Ex. 1003 ¶ 141. In his testimony, Dr. Ochoa cites no supporting evidence for the alleged facts on which he bases his opinion that it would have been obvious that Chung's implant "would be appropriate for use in a PLIF procedure." Due to its lack of supporting evidence, we find Dr. Ochoa's testimony has little persuasive weight. *See* 37 C.F.R. § 42.65(a). This constitutes another reason that Petitioner has not demonstrated a reasonable likelihood of prevailing on its assertion that claim 10 would have been obvious over Chung, McLuen, and Allen.

E. Alleged Obviousness of Claims 11 and 21–26 over Chung, McLuen, Allen, and Sutcliffe

a. *Overview of Sutcliffe*

Sutcliffe discloses an implant for insertion between vertebrae. Ex. 1032 ¶ 22. One embodiment of Sutcliffe's implant appears in Figure 6. *Id.* ¶ 21. Figure 6 is reproduced below.

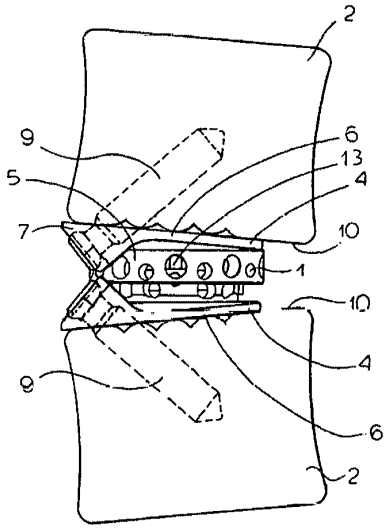


FIG.6

Figure 6 shows implant 1 disposed between vertebrae 2. *Id.* ¶¶ 21–22.

Implant 1 includes lower end part 3, upper end part 4, and center part 5. *Id.* ¶ 22. Each of lower end part 3, upper end part 4, and center part 5 has threads. *Id.* These threads connect lower end part 3, upper end part 4, and center part 5 in a manner that allows spreading apart or pulling together upper end part 4 by rotating center part 5 in one direction or another. *Id.*

Lower part 3 has two eyes 6 with collars 7 forming holes or passages 8. *Id.* ¶ 24. To secure lower part 3 to a lower vertebra 2, cortical

screws pass through eyes 6 and penetrate the lower vertebra 2. *Id.* Figure 6 shows upper end part 4 with a similar pair of eyes 6. *Id.*

b. *Discussion*

Petitioner's challenge of claims 11 and 21–26 builds from its challenge of independent claim 1 as allegedly obvious over Chung, McLuen, and Allen. *See, e.g.*, Pet. 45–53. Petitioner's challenge of claims 11 and 21–26 does not remedy the deficiencies in its challenge of independent claim 1. Accordingly, Petitioner has not demonstrated a reasonable likelihood of prevailing on its challenge of claims 11 and 21–26.

III. CONCLUSION

Petitioner does not demonstrate a reasonable likelihood of prevailing in showing that at least one of the challenged claims of the '268 patent is unpatentable.

IV. ORDER

It is hereby

ORDERED that the Petition is denied, and no trial is instituted.

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