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APPLICATION NUMBER: *13/084,543*
FILING DATE: *April 11, 2011*
PATENT NUMBER: *8,353,913*
ISSUE DATE: *January 15, 2013*

By Authority of the
Under Secretary of Commerce for Intellectual Property
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PTO/SB/81 (01-09)
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POWER OF ATTORNEY OR REVOCATION OF POWER OF ATTORNEY WITH A NEW POWER OF ATTORNEY AND CHANGE OF CORRESPONDENCE ADDRESS

Application Number	11/842,855
Filing Date	08/21/2007
First Named Inventor	MOSKOWITZ, ET AL.
Title	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL ...
Art Unit	3733
Examiner Name	Philogene, Pedro
Attorney Docket Number	3003/0105PUS1

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

☐ A Power of Attorney is submitted herewith.

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

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OR

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

I am the:

☒ Applicant/Inventor.

OR

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

SIGNATURE of Applicant or Assignee of Record

Signature	Ahmnon D. Moskowitz	Date	10/30/10
Name	Ahmnon D. MOSKOWITZ	Telephone	301-774-5160
Title and Company			

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

☒ *Total of 4 forms are submitted.

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Title	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL ...
Art Unit	3733
Examiner Name	Philogene, Pedro
Attorney Docket Number	3003/0105PUS1

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Address	PO BOX 650903				
City	POTOMAC FALLS	State	VA	Zip	20165
Country	US				
Telephone	571-333-0930	Email	mailroom@dreschiplaw.com		

I am the:

☒ Applicant/Inventor.

OR

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

SIGNATURE of Applicant or Assignee of Record

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

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☒ *Total of 4 forms are submitted.

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UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	MOSKOWITZ, et al.
Application Number:	Not yet assigned
Filing Date:	Concurrently herewith
Group Art Unit:	Not yet assigned
Examiner:	Not yet assigned
Confirmation No.:	Not yet assigned
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

PRELIMINARY AMENDMENT

Dear Sir:

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

Amendments to the Specification begin on page 2 of this paper;
Amendments to the Claims, as reflected in the listing of claims, begin on page 4 of this paper; and
Remarks begin on page 8 of this paper.

AMENDMENTS TO THE SPECIFICATION:

On Page 1, please replace paragraph [0001] with the following new paragraph:

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

On Page 3, please amend paragraph [0008] as follows:

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.

On Page 13, please amend paragraph [0038] as follows:

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 1 D) views.

On Pages 6-7, please amend paragraph [0014] as follows:

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.

IN THE CLAIMS:

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

1-9. (Canceled)

10. (Currently amended) A self-drilling bone fusion screw apparatus, comprising: ~~which comprises:~~

a box portion including a first integral screw guide having a first predetermined angle and a second integral screw guide having a second predetermined angle;

a first screw member having a tapered end and a threaded body, wherein the first screw member is disposed in the first integral screw guide at the first predetermined angle and ~~disposed~~ at least partially within the box portion and laterally aligned with the box portion;

a second screw member having a tapered end and a threaded body, wherein the second screw member is disposed in the second integral screw guide at the second predetermined angle and ~~disposed~~ at least partially within the box portion and laterally aligned with the box portion, ~~box; and~~

wherein the box portion includes a side having a plurality of ridges ~~disposed on along the sides of the box~~.

11. (Currently amended) The self-drilling bone fusion screw apparatus according to claim 10, wherein the box portion includes a plurality of holes for bone grafts ~~which further includes bone graft holes~~.

12. (Currently amended) The self-drilling bone fusion screw apparatus according to claim 11, where the box portion includes a screw insert for securing ~~which is attachable to~~ a second self-drilling fusion screw apparatus via a plate.

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

a first box;

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

a second box;

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

an attachment member for engaging the first and second boxes.

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

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

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

a handle;

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

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

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

18. (Original) A cervical facet staple, comprising:

a curved staple base;

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

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

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

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

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

a handle;

a stem attached to the handle;

a plurality of wings for contacting the cervical facet staple; and

an insertion member for coupling the cervical facet staple to the impaction tool.

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

23. (Original) A lumbar facet staple, comprising:

a pair of rotating arms;

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

a ratchet attached to one of the rotating arms;

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

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

25. (Original) The tool assembly according to claim 16, further comprising

a driver assembly, the driver assembly comprising:

a handle;

a drive bit portion; and

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

REMARKS

Claims 1-25 were previously pending in the application. This Amendment cancels claims 1-9 and amends claims 10-12 to correct informalities. Claims 13-25 remain unchanged.

Claims 10, 13, 16, 18, 21, and 23 are independent.

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

Early and favorable prosecution on the merits is respectfully requested.

CONCLUSION

In view of the above, entry of the present Amendment and allowance of Claims 10-25 are respectfully requested. If the Examiner has any questions regarding this amendment, the Examiner is requested to contact the undersigned.

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

Respectfully Submitted,

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

April 11, 2011

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MOSKOWITZ-00001907

PTO/SB/14 (11-08)
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	3003/0105PUS2
	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.)

Applicant Information:

Applicant 1 Remove

Applicant Authority ◉ Inventor ○ Legal Representative under 35 U.S.C. 117 ○ Party of Interest under 35 U.S.C. 118

Prefix	Given Name	Middle Name	Family Name	Suffix
	Ahmnon	D.	MOSKOWITZ	

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

City	Rockville	State/Province	MD	Country of Residence i	US

Citizenship under 37 CFR 1.41(b) i: US

Mailing Address of Applicant:

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

Applicant 2 Remove

Applicant Authority ◉ Inventor ○ Legal Representative under 35 U.S.C. 117 ○ Party of Interest under 35 U.S.C. 118

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

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

City	Rockville	State/Province	MD	Country of Residence i	US

Citizenship under 37 CFR 1.41(b) i: US

Mailing Address of Applicant:

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

Applicant 3 Remove

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Prefix	Given Name	Middle Name	Family Name	Suffix
	Nathan	C.	MOSKOWITZ	

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

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Citizenship under 37 CFR 1.41(b) i	US				
Mailing Address of Applicant:					
Address 1	212 North Adams St.				
Address 2					
City	Rockville	**State/Province**	MD		
Postal Code	20850	**Country**i	US		

Applicant 4 Remove

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	Pablo	A Valdivia Y	ALVARADO	

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City	Cambridge	**State/Province**	MA	**Country of Residence** i	US
Citizenship under 37 CFR 1.41(b) i	BO				
Mailing Address of Applicant:					
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Address 2	Apt. #2				
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All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

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Title of the Invention	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION		
Attorney Docket Number	3003/0105PUS2	**Small Entity Status Claimed**	☒
Application Type	Nonprovisional		
Subject Matter	Utility		
Suggested Class (if any)		**Sub Class (if any)**	
Suggested Technology Center (if any)			
Total Number of Drawing Sheets (if any)	38	**Suggested Figure for Publication (if any)**	2A

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Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
	Division of	11842855	2007-08-21

Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
11842855	Continuation in part of	11536815	2006-09-29	7846188	2010-12-07

Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
11536815	Continuation in part of	11208644	2005-08-23	7704279	2010-04-27

Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
11208644	non provisional of	60670231	2005-04-12

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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 benefit of foreign priority and to identify any prior foreign application for which priority is not claimed. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55(a).

Remove

Application Number	Country [i]	Parent Filing Date (YYYY-MM-DD)	Priority Claimed
			(•) Yes ( ) No

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Assignee Information:

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Assignee 1 Remove

If the Assignee is an Organization check here. ☐

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

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Country [i]		Postal Code	
Phone Number		Fax Number	
Email Address			

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Signature:

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

Signature	/John J. Dresch/			Date (YYYY-MM-DD)	2011-04-11
First Name	John	Last Name	Dresch	Registration Number	46672

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2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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 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 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.

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

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

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

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

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

a box;

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

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

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

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

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

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

a first box;

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

a second box;

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

an attachment member for engaging the first and second boxes.

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

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

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

a handle;

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

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

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

18. A cervical facet staple, comprising:

a curved staple base;

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

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

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

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

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

a handle;

a stem attached to the handle;

a plurality of wings for contacting the cervical facet staple; and

an insertion member for coupling the cervical facet staple to the impaction tool.

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

23. A lumbar facet staple, comprising:

a pair of rotating arms;

at least two prongs attached to the inner surfaces of the rotating arms;

a plurality of spurs attached to one of the rotating arms; and

a ratchet attached to one of the rotating arms;

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

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

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

a handle;

a drive bit portion; and

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

ABSTRACT OF THE DISCLOSURE

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

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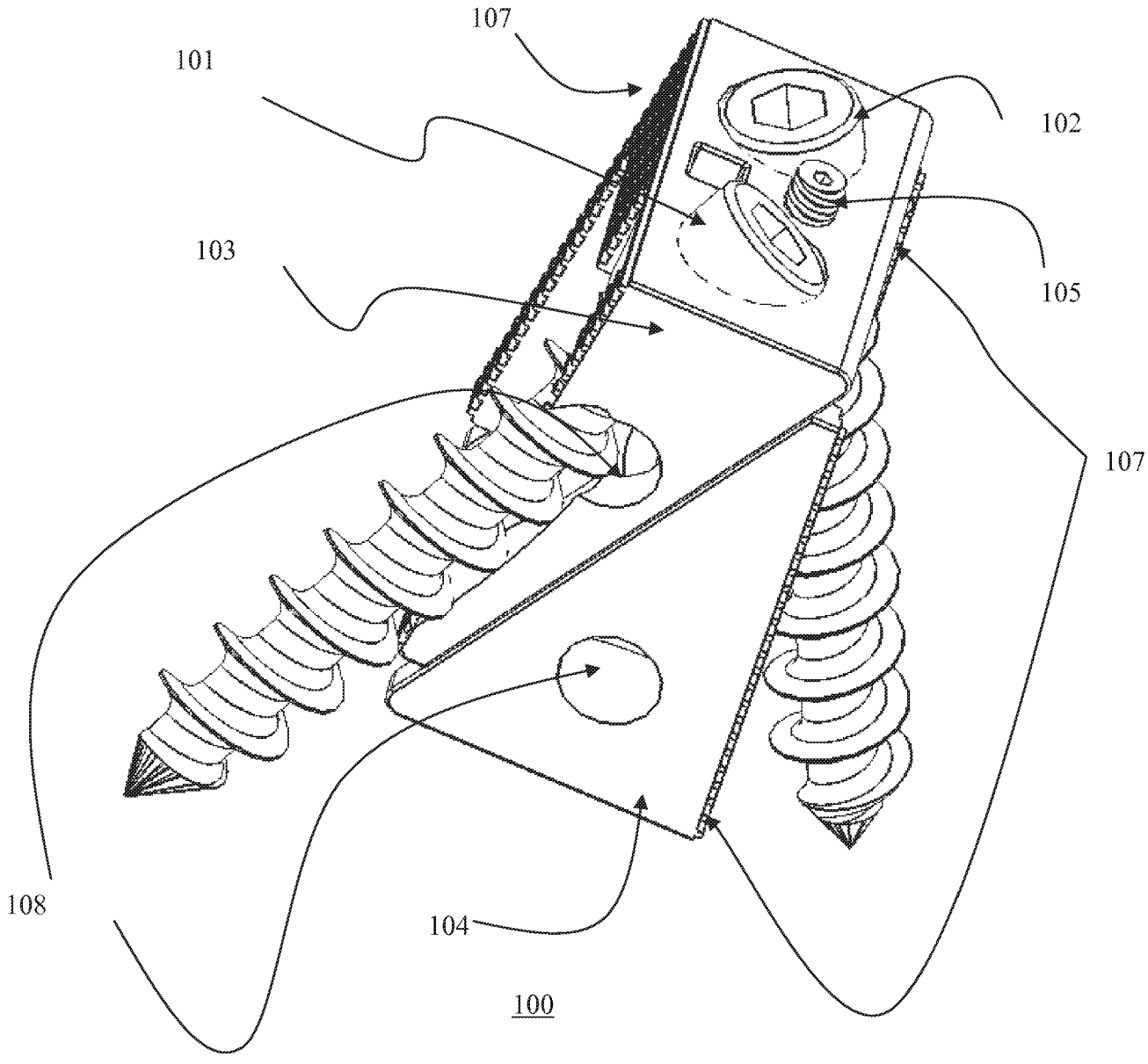


Fig. 1A

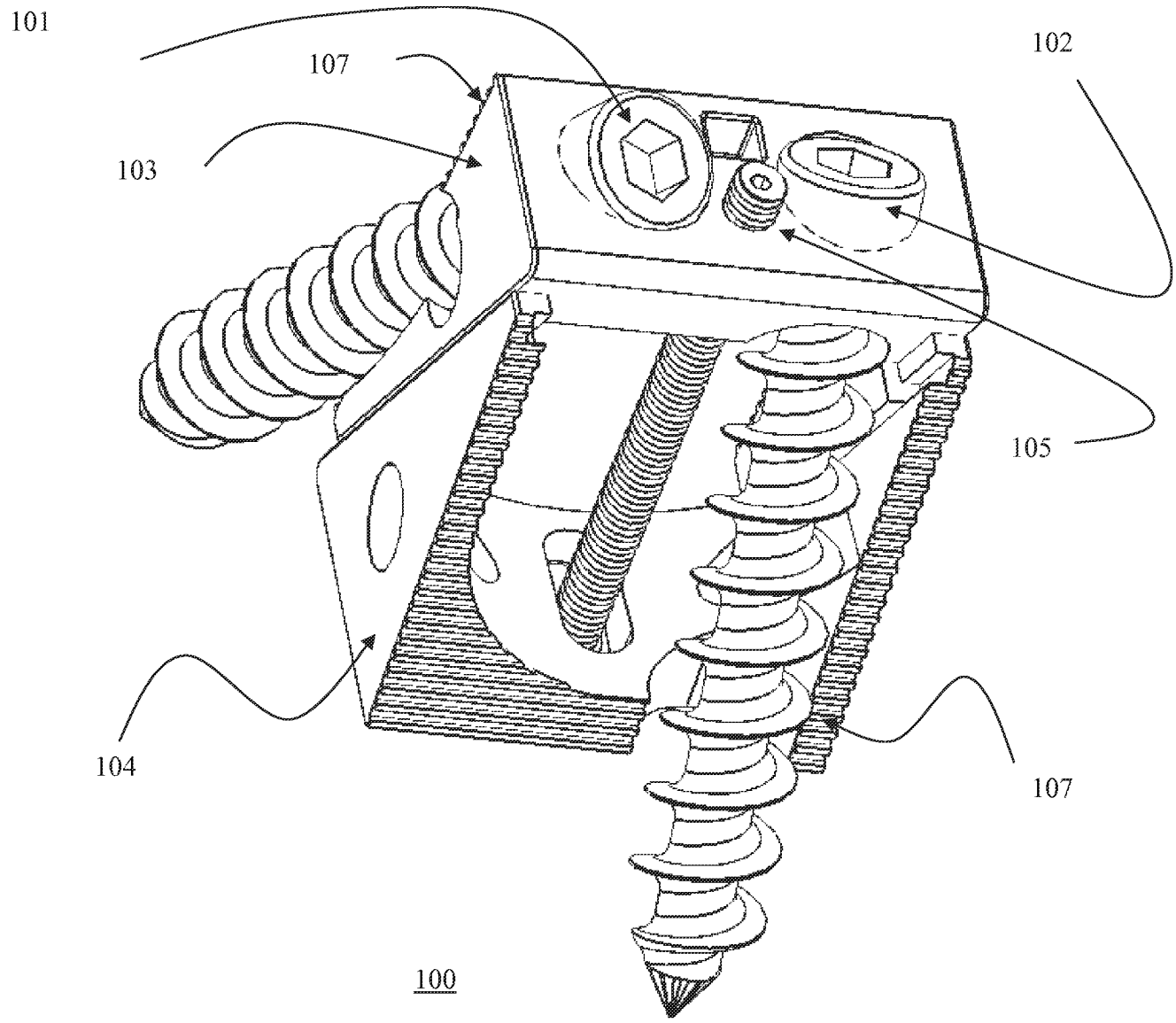


Fig. 1B

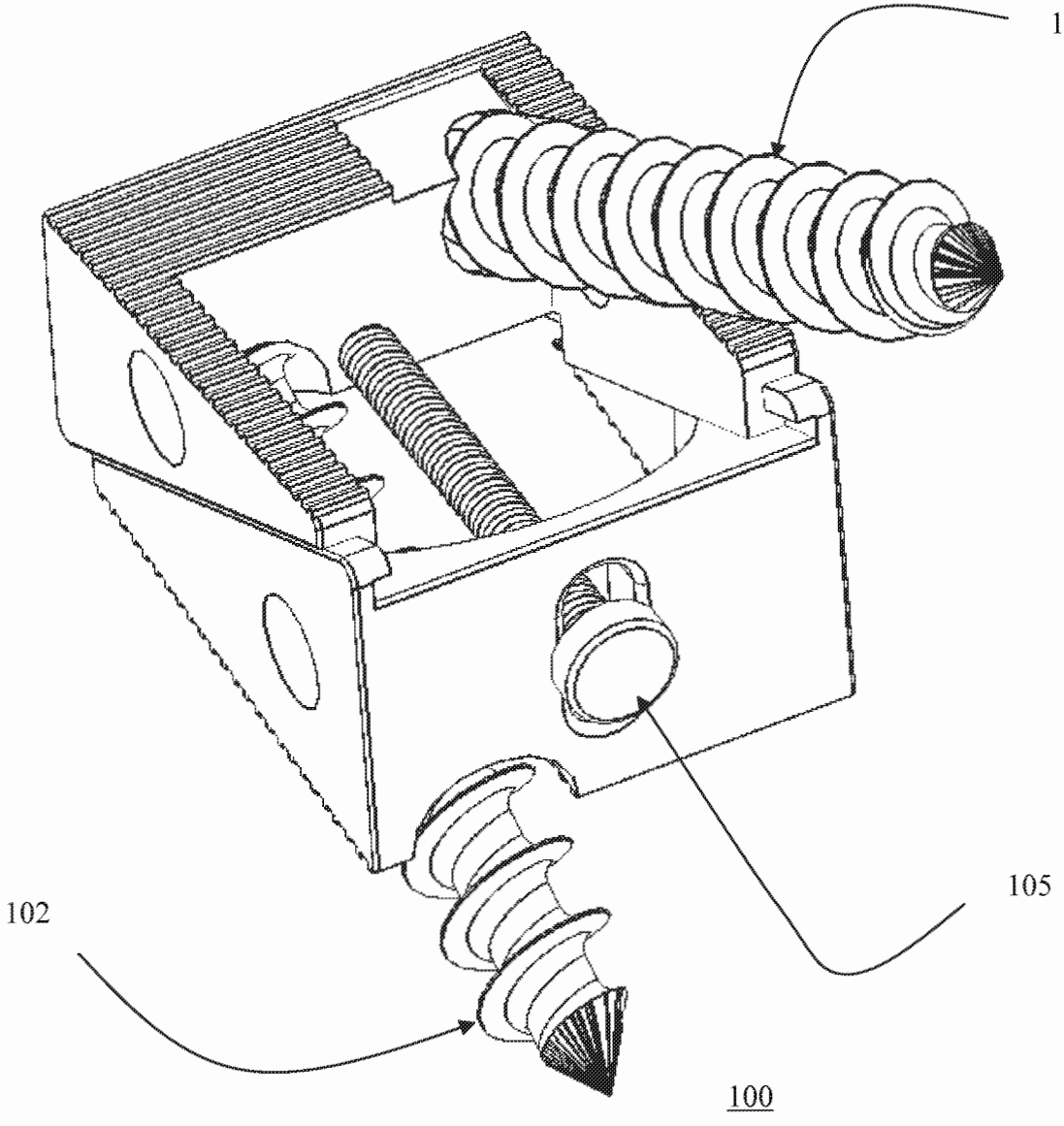


Fig. 1C

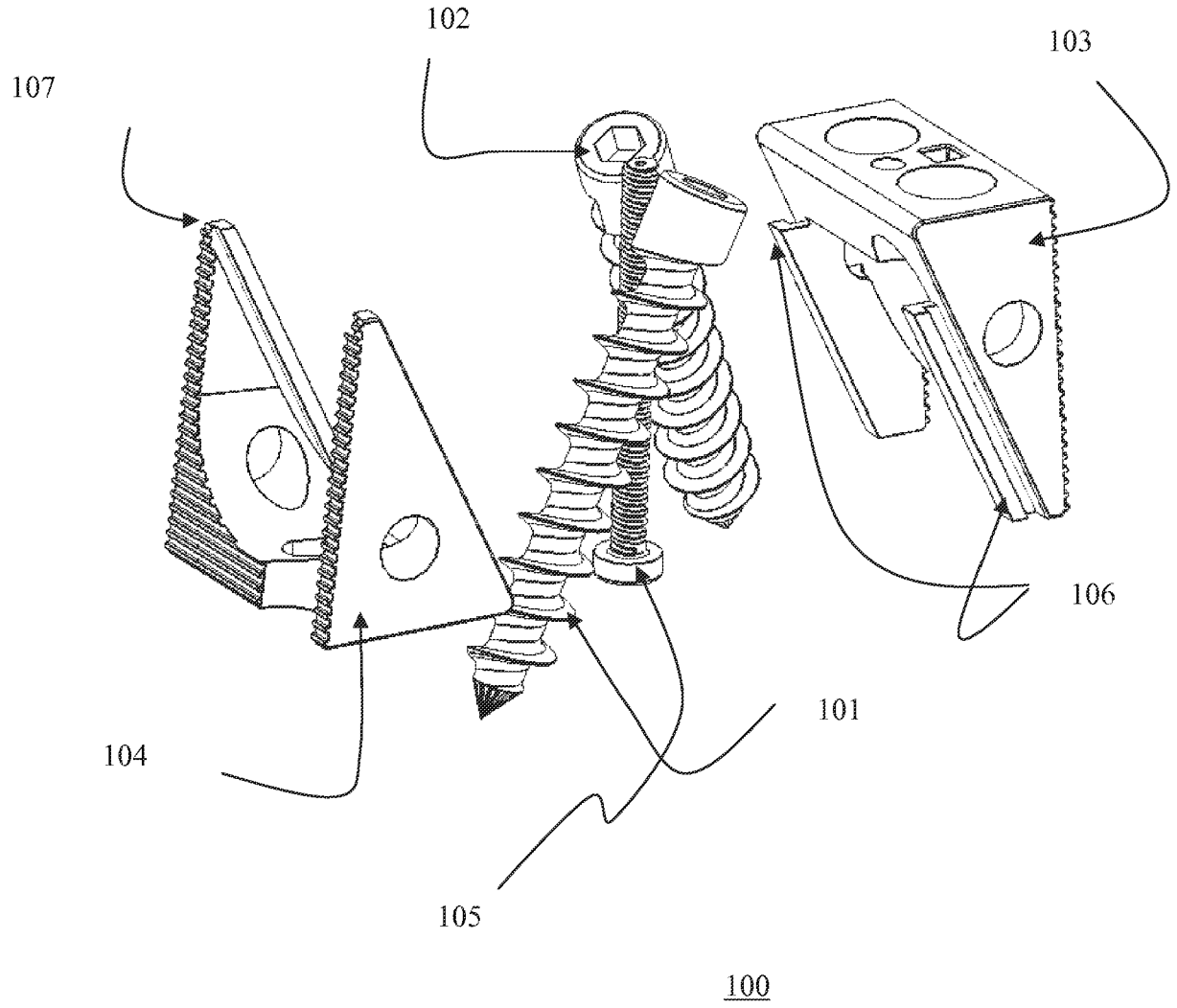


Fig. 1D

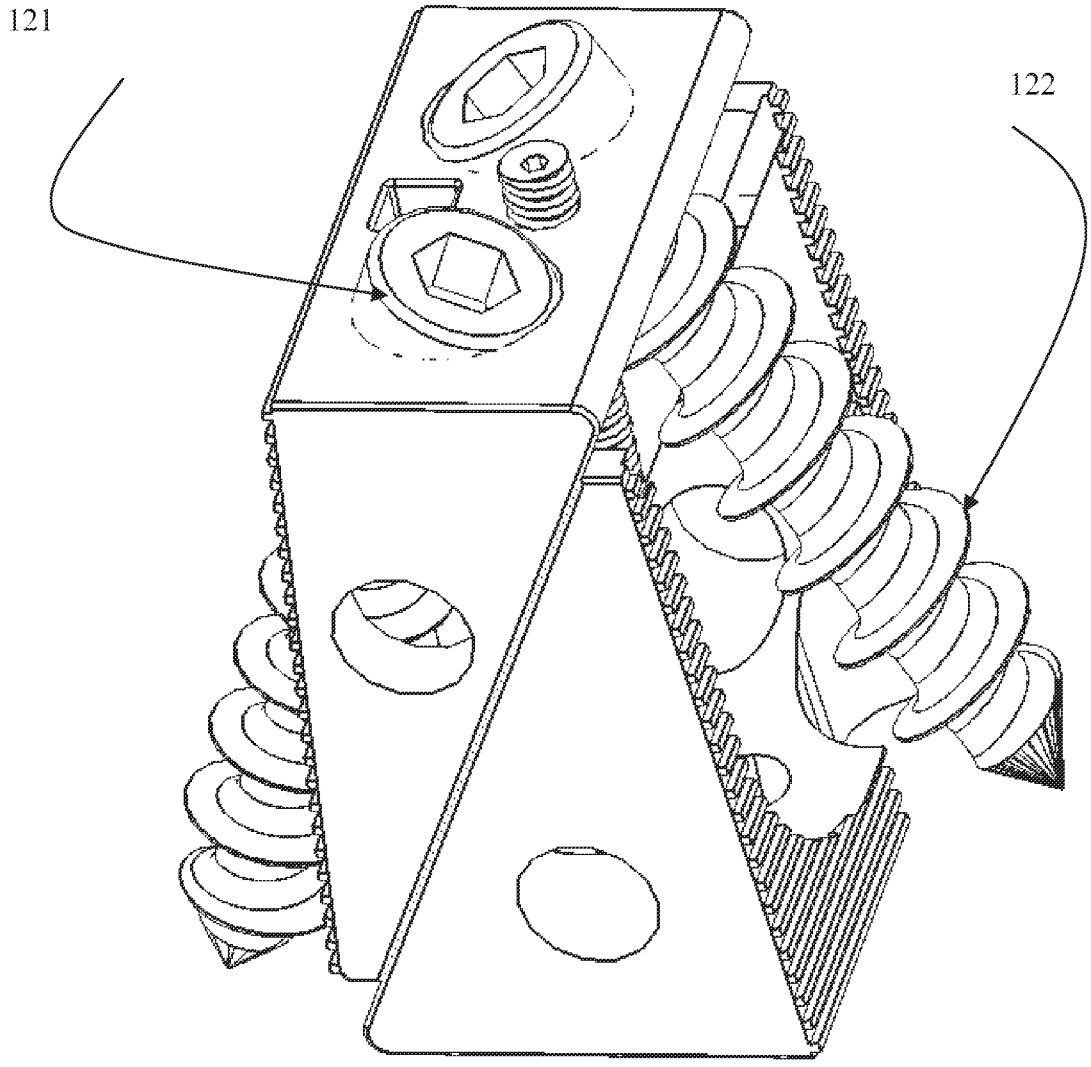


Fig. 1E

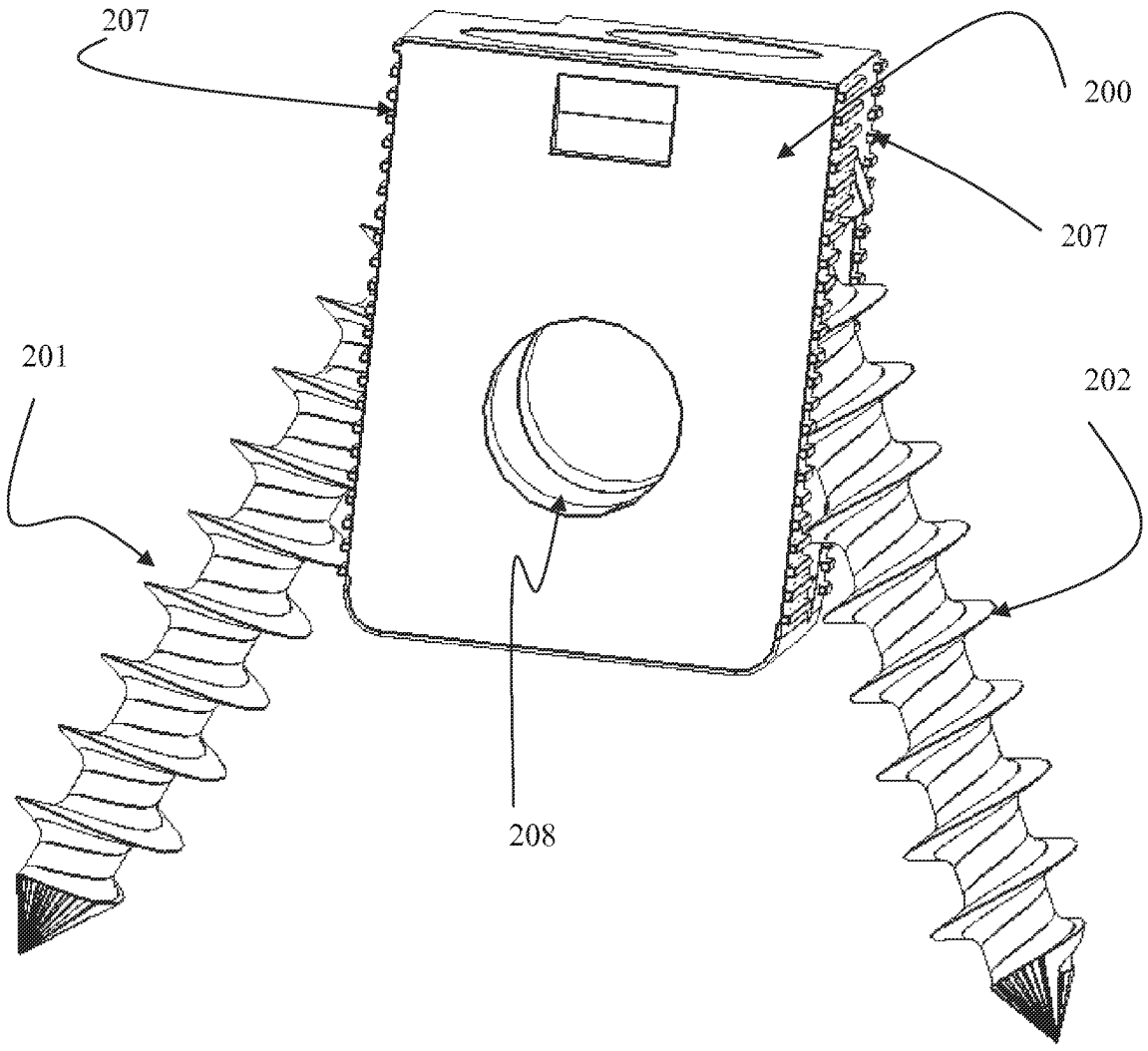


Fig. 2A

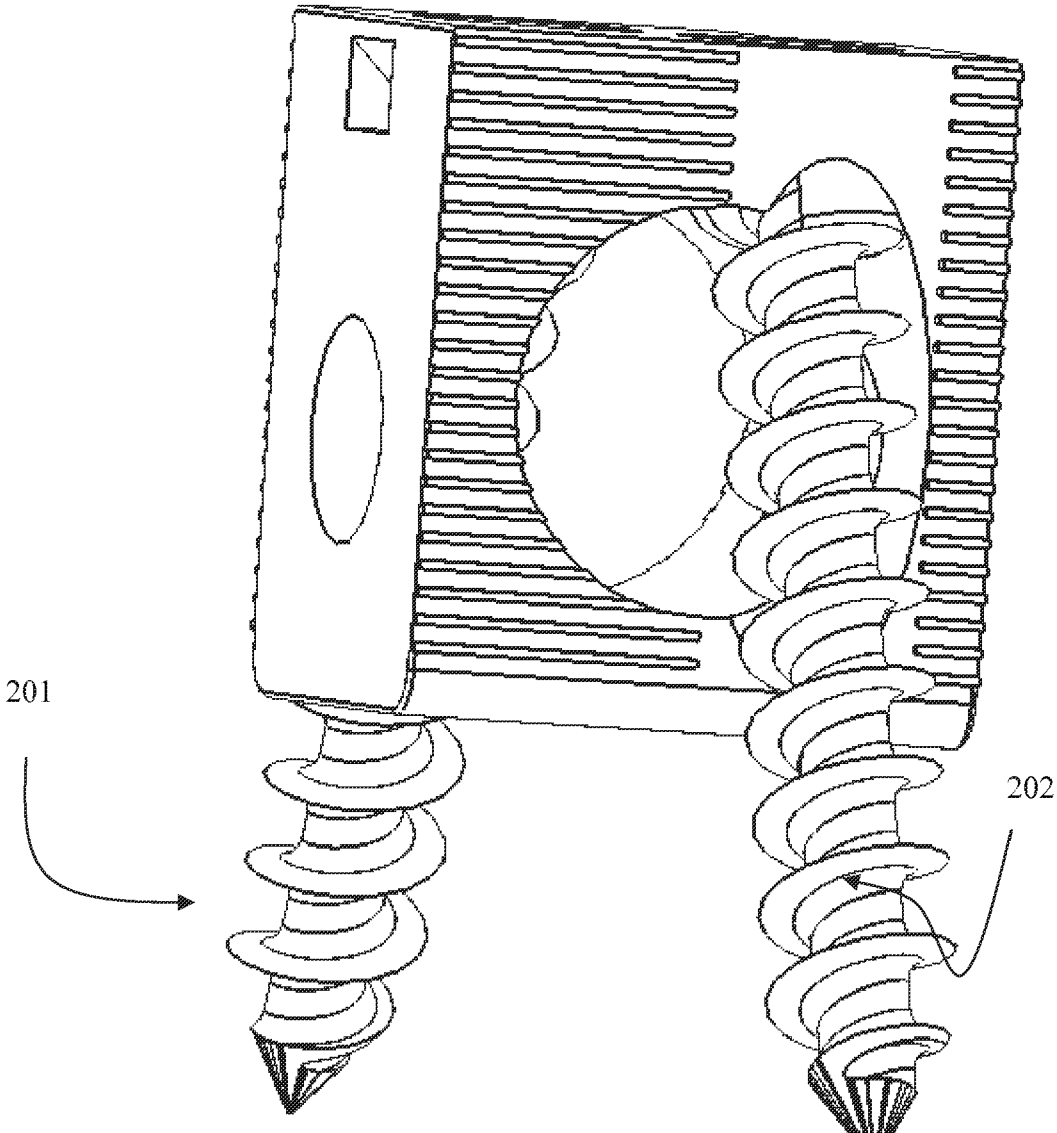


Fig. 2B

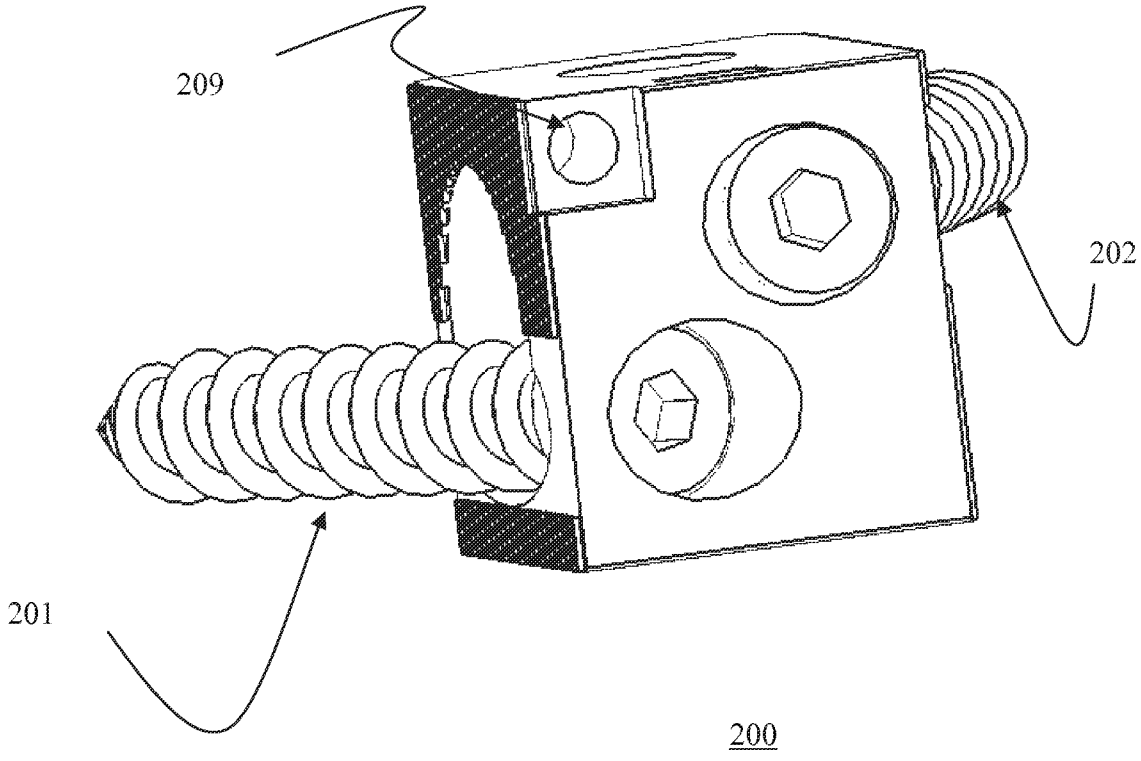


Fig. 2C

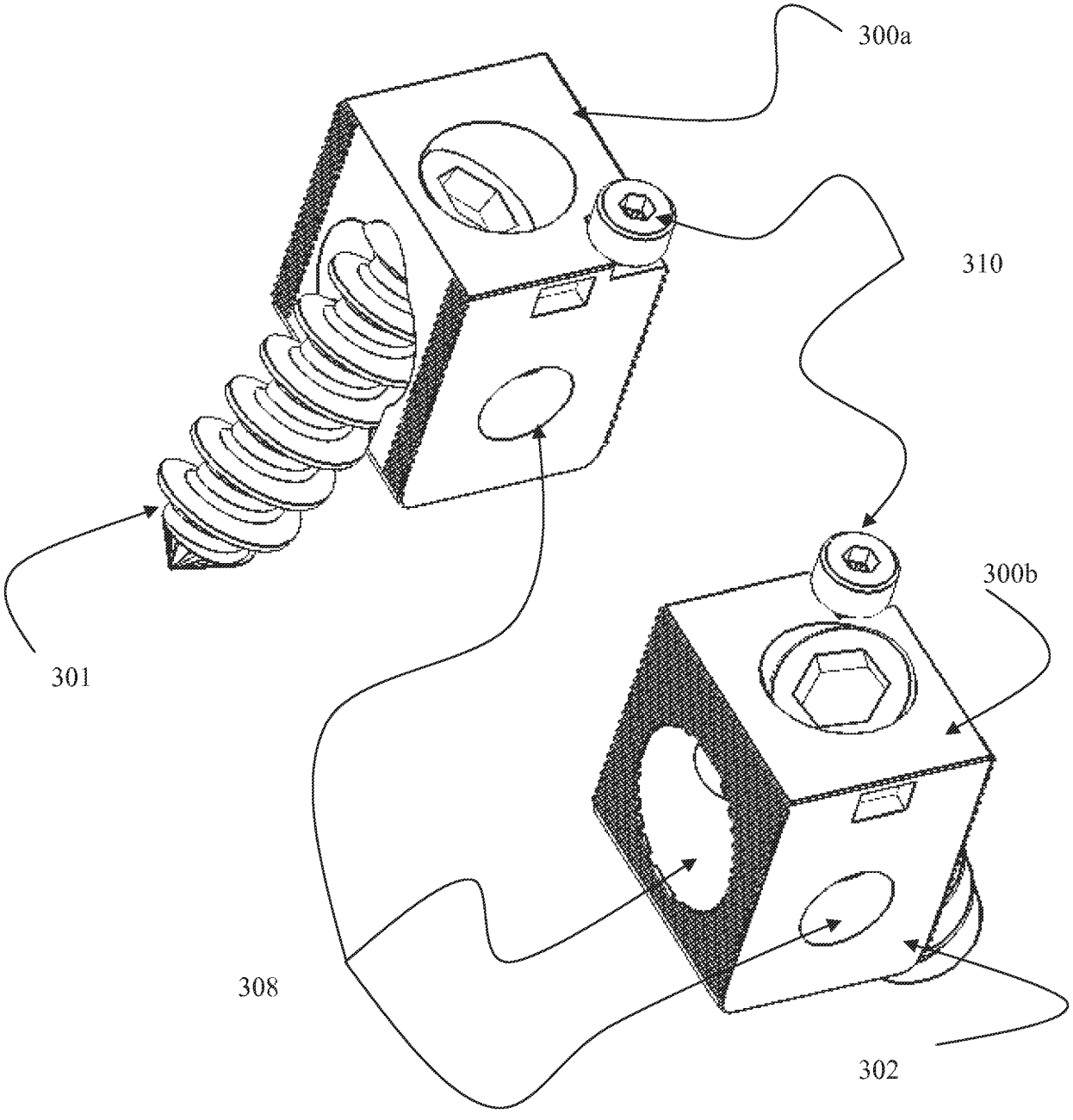


Fig. 3

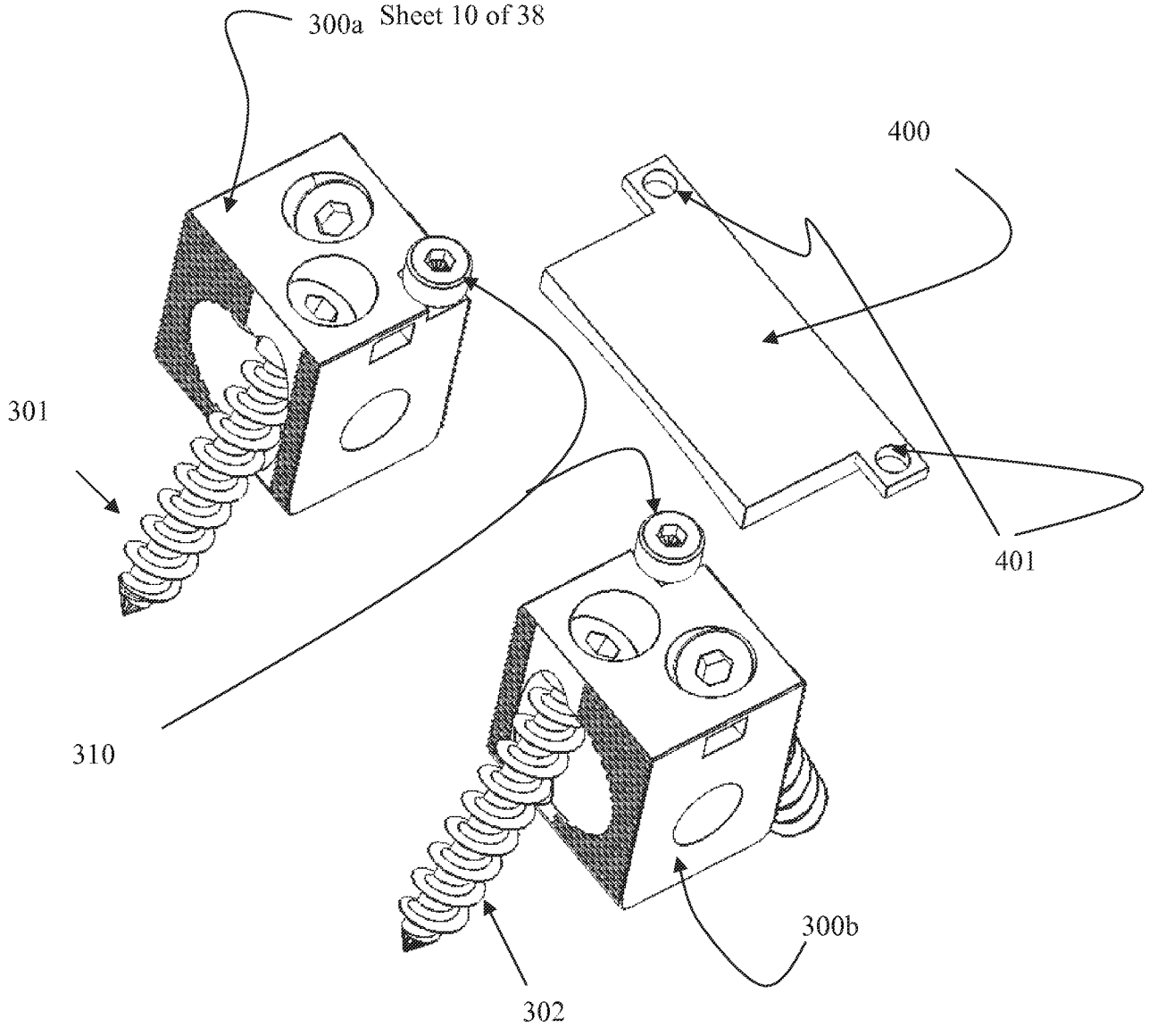


Fig. 4A

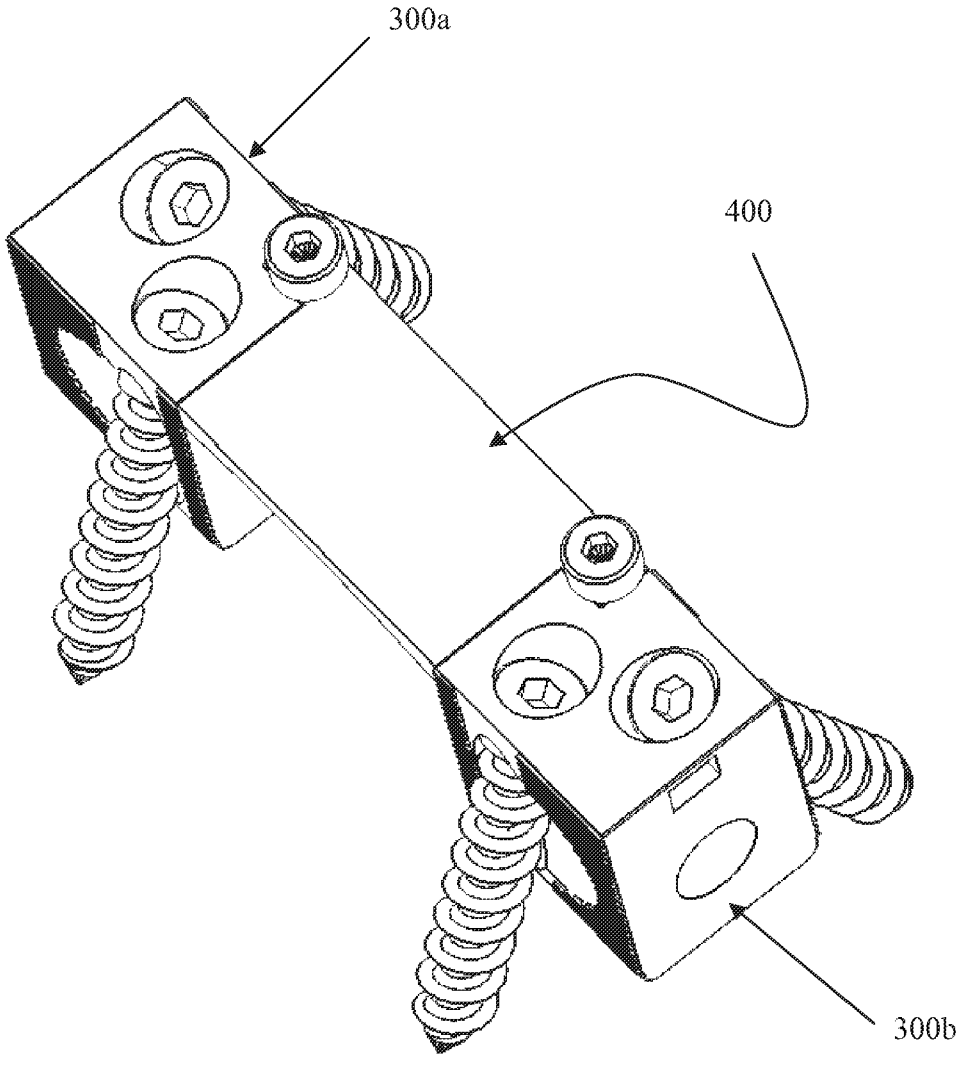


Fig. 4B

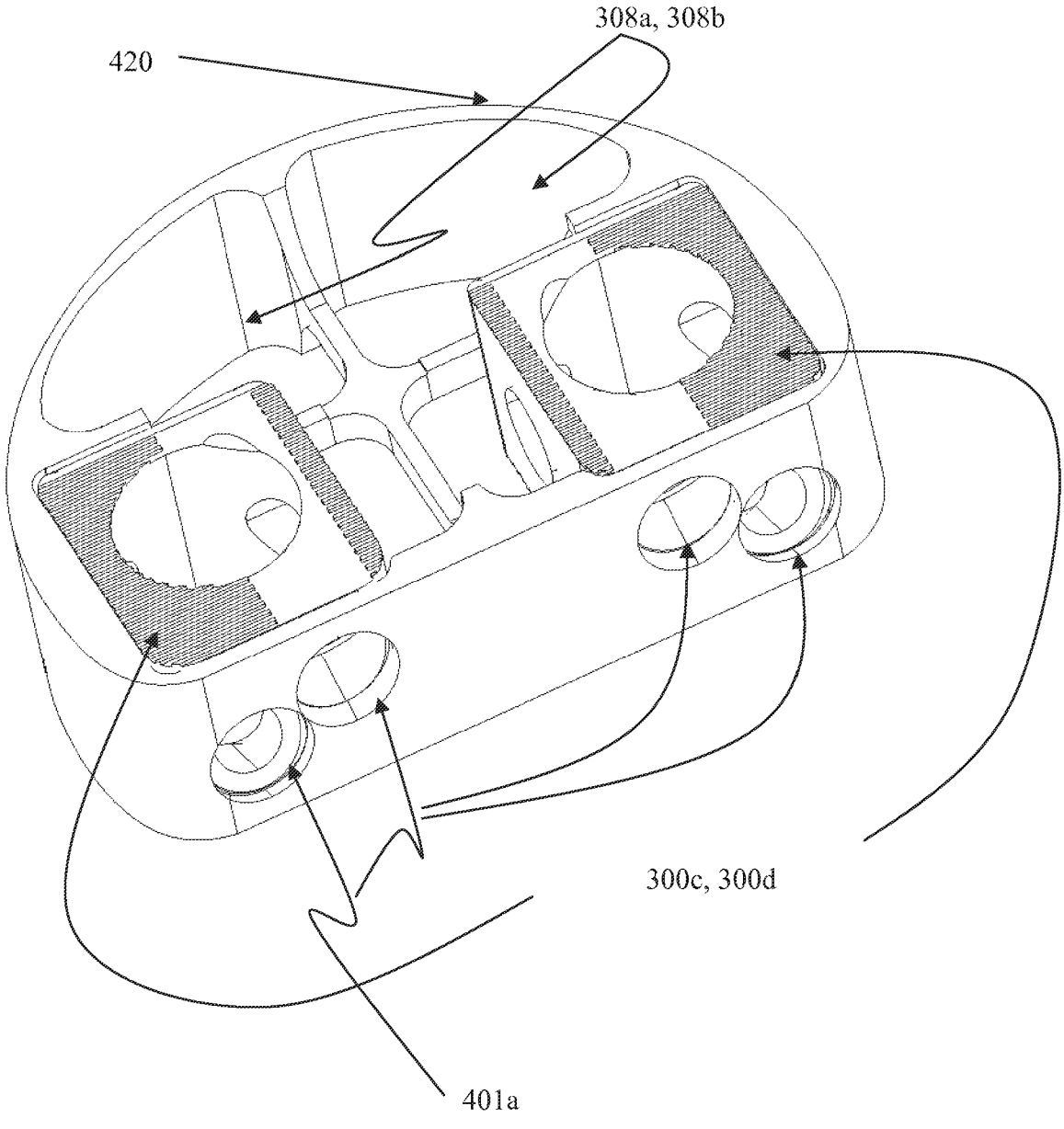


FIG. 4C

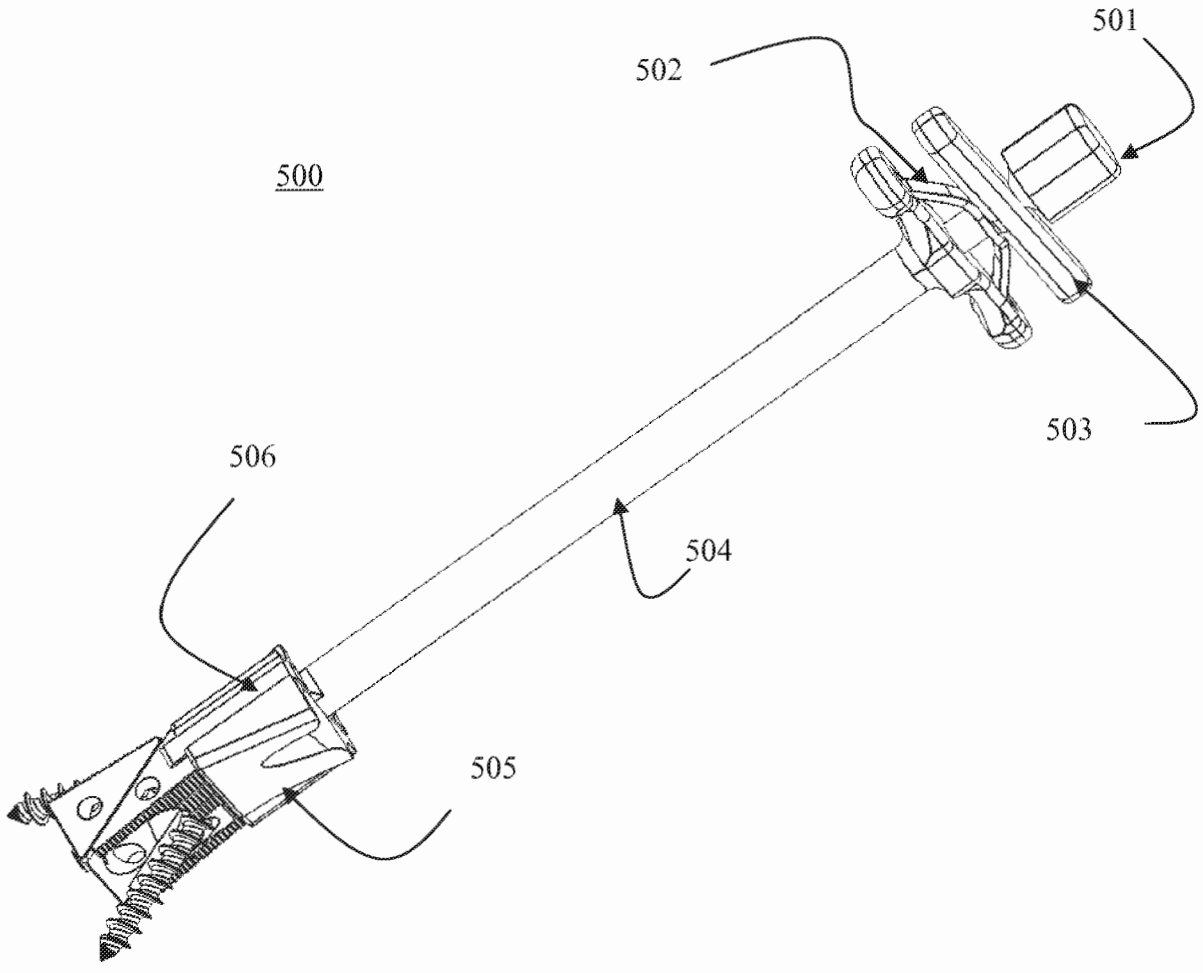


Fig. 5A

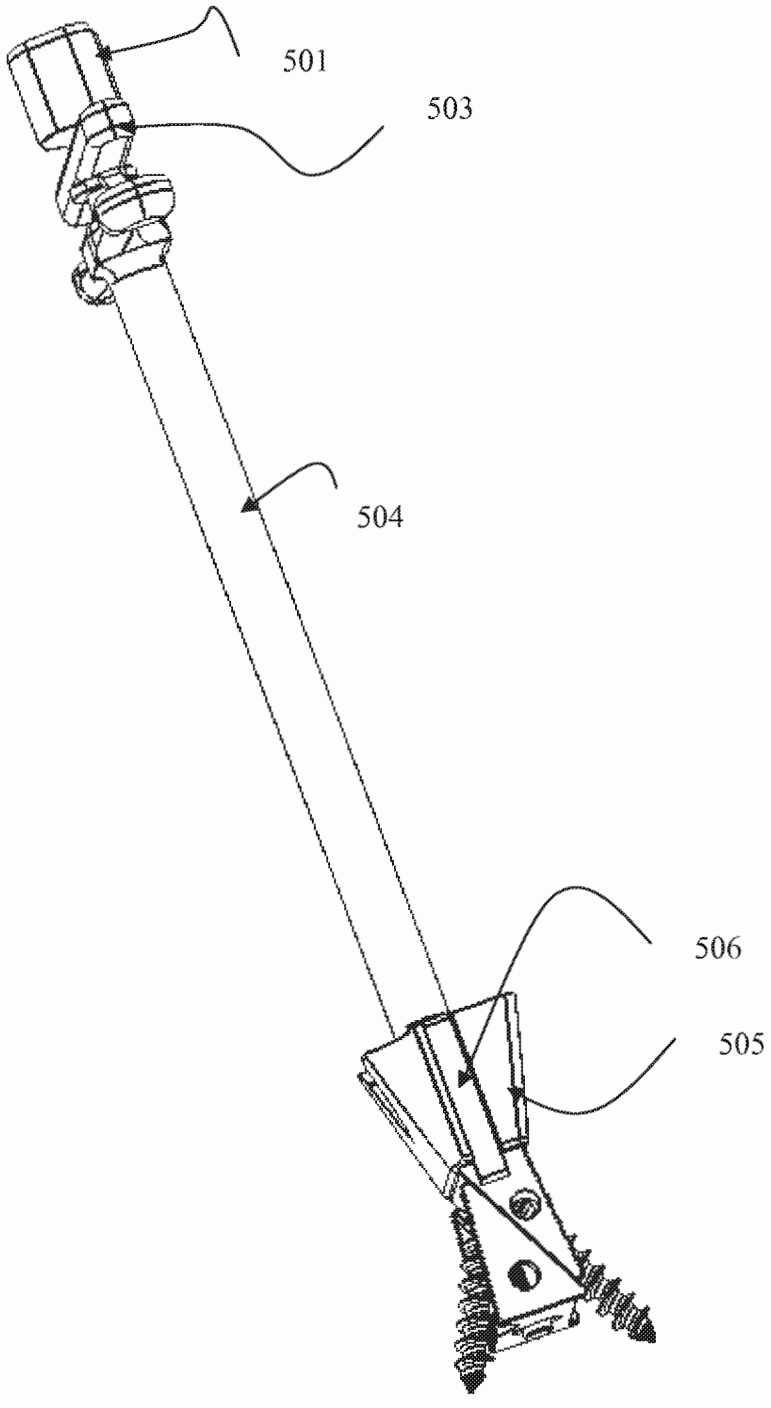


Fig. 5B

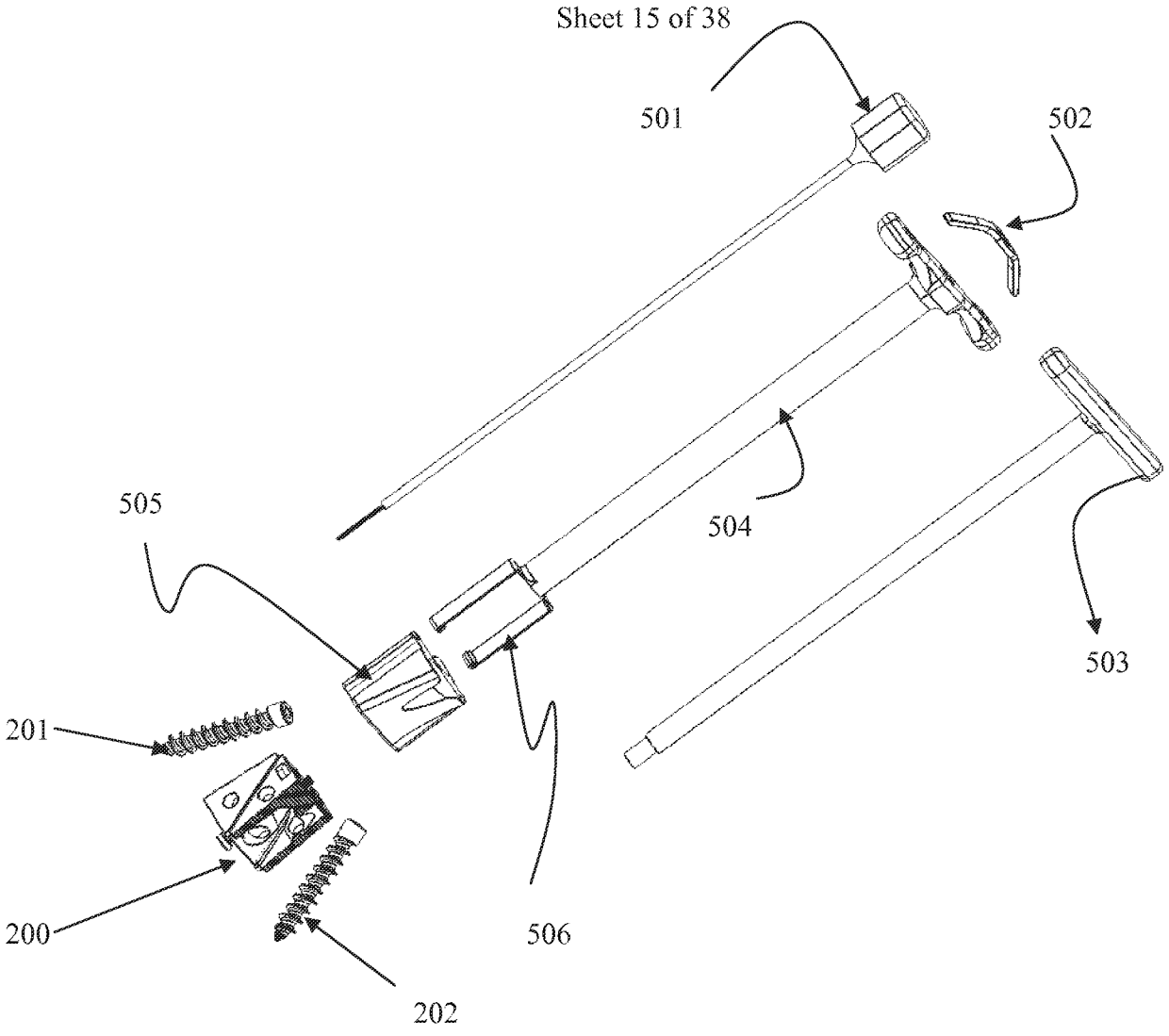


Fig. 5C

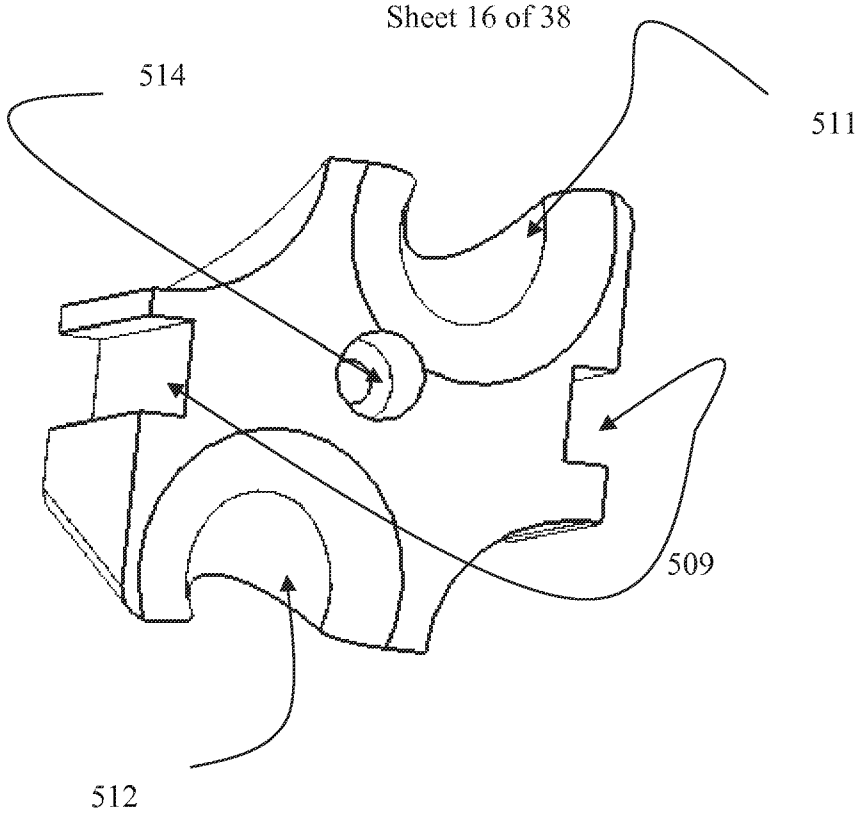


Fig. 5D

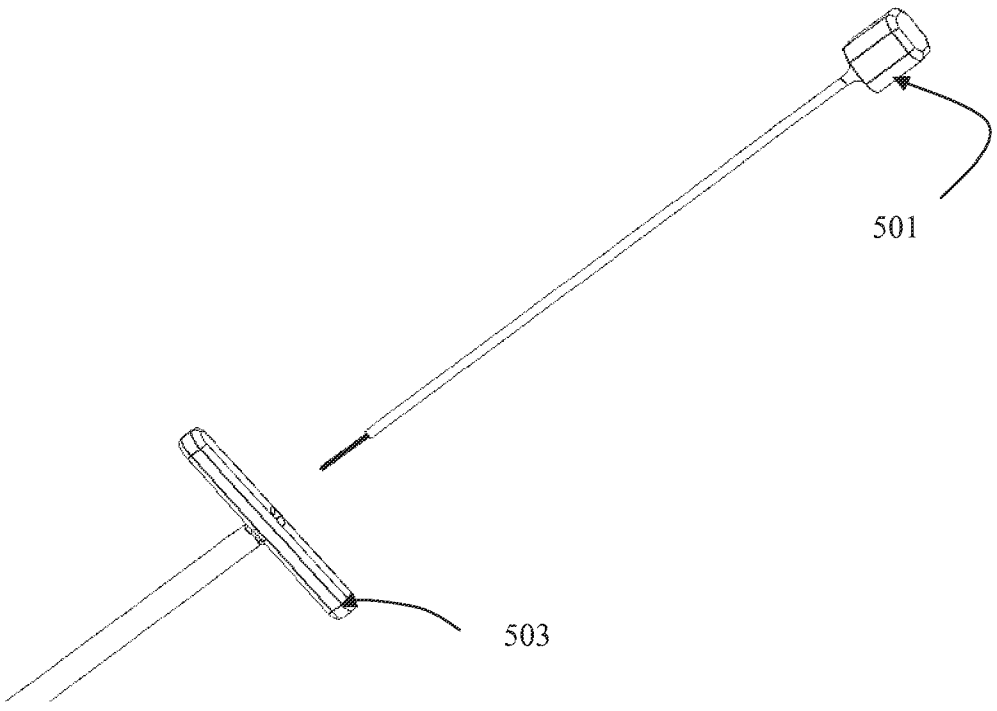


Fig. 5E

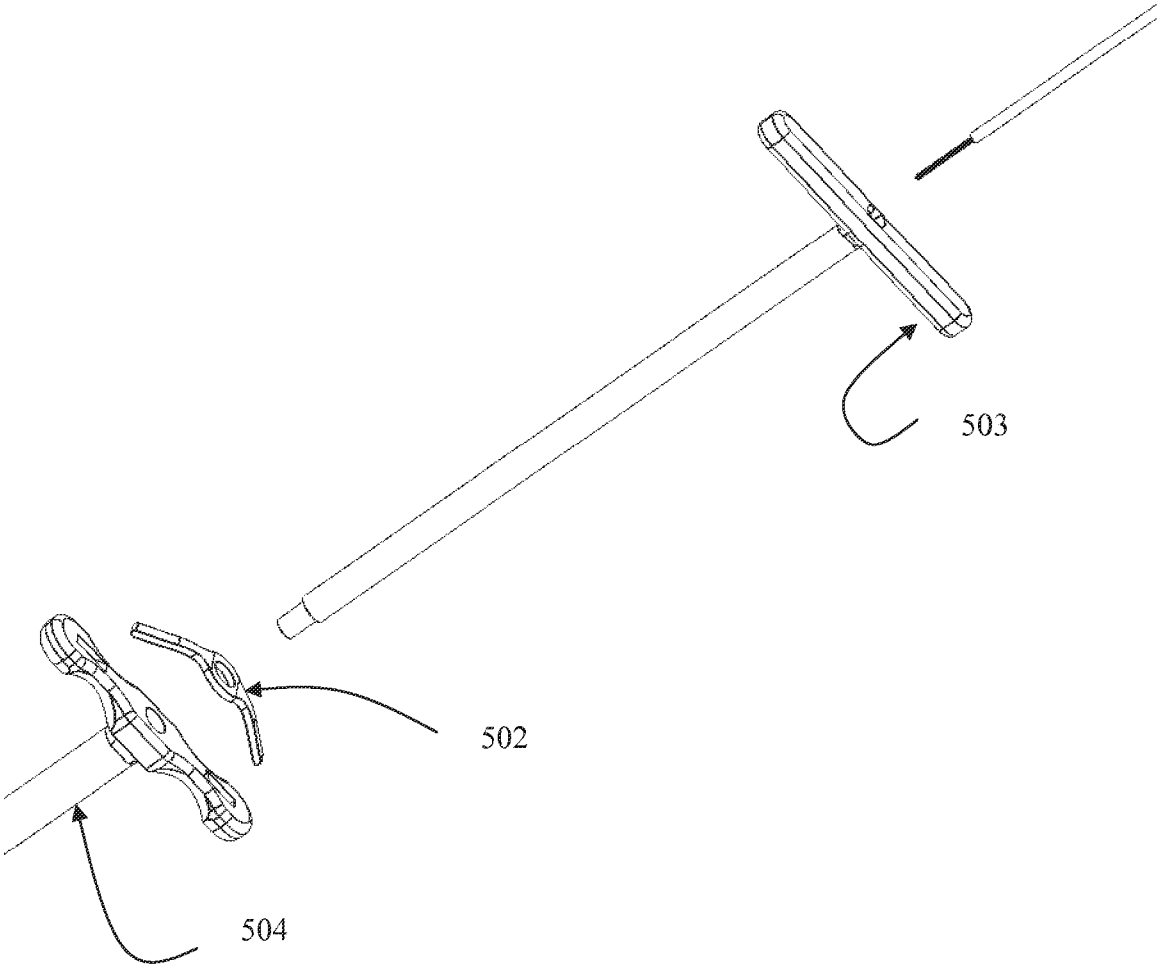


Fig. 5F

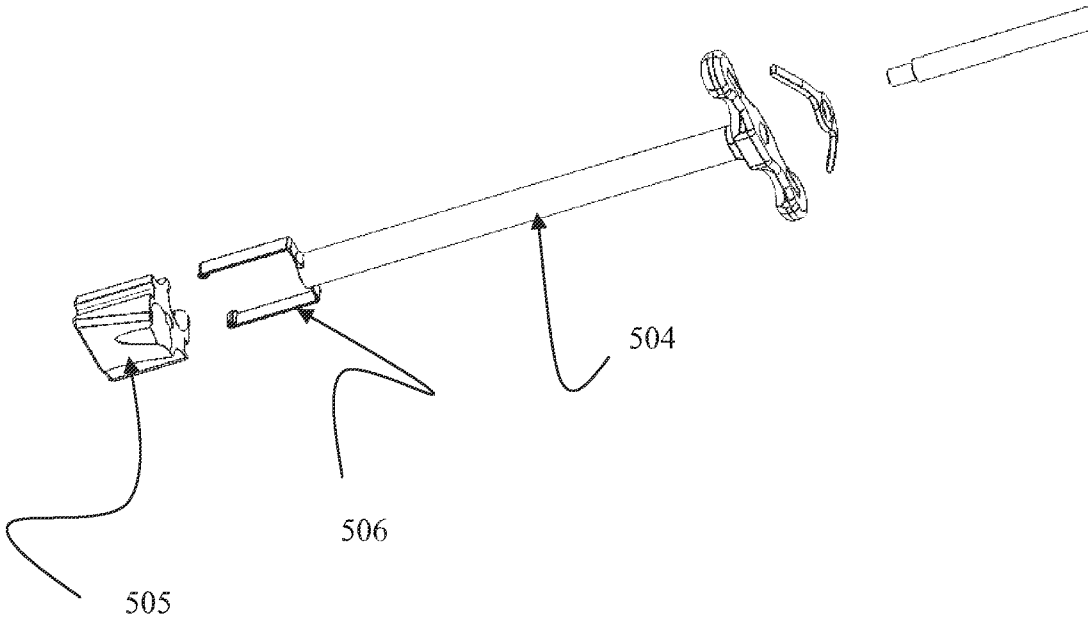


Fig. 5G

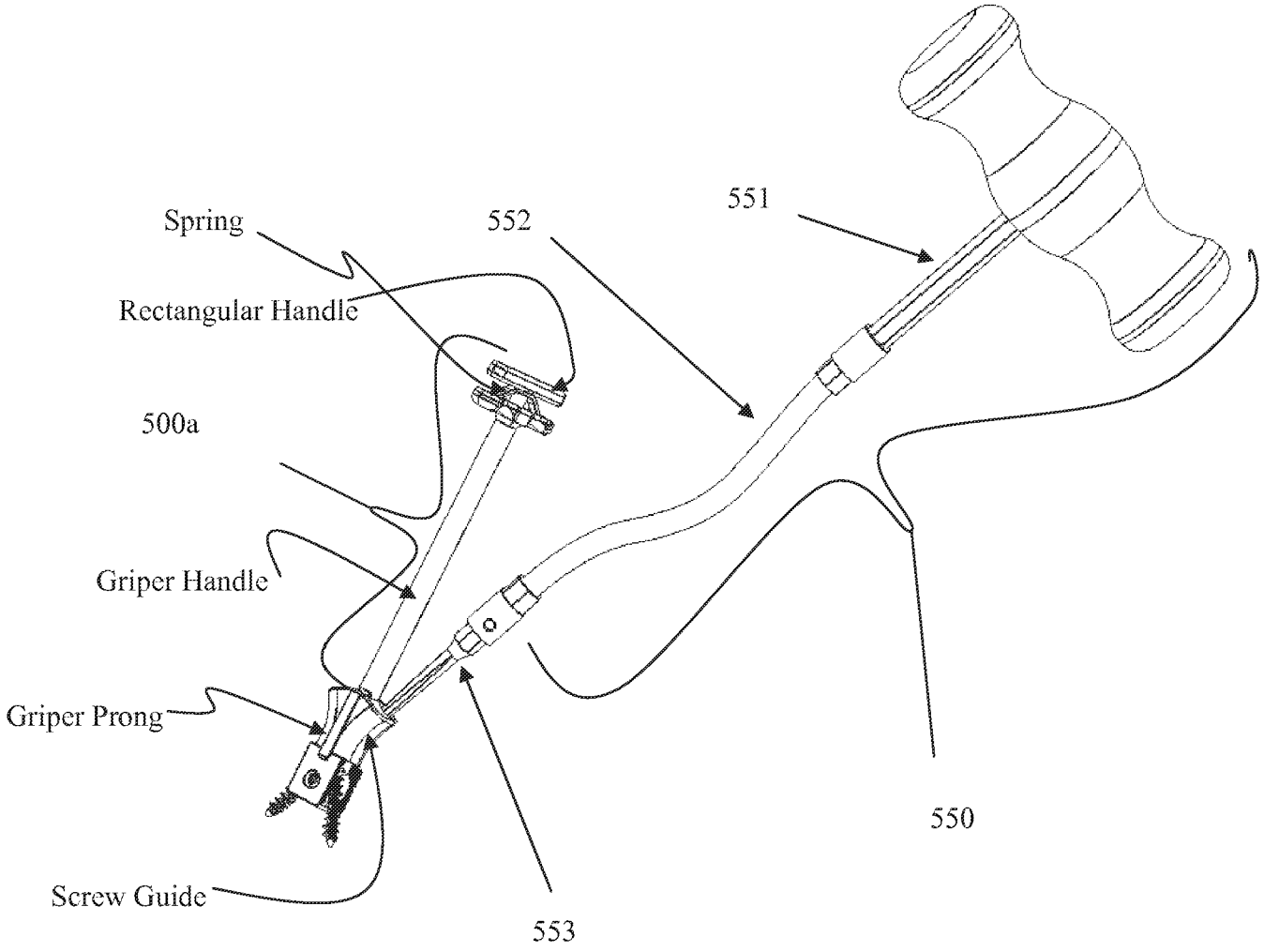

Spring
552
551
Rectangular Handle
500a
Griper Handle
Griper Prong
550
Screw Guide
553

FIG. 5H

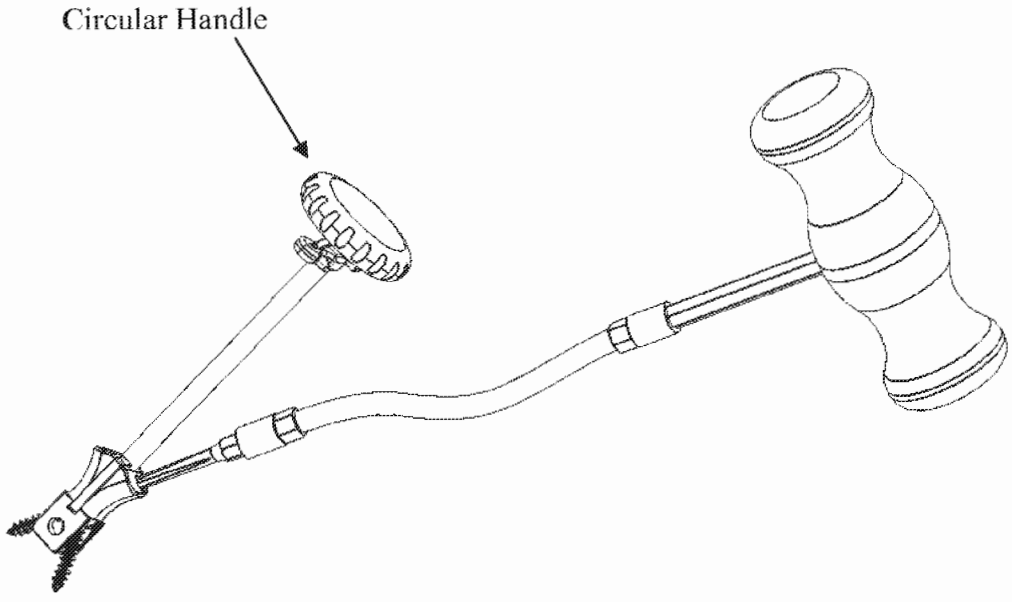


FIG. 5I

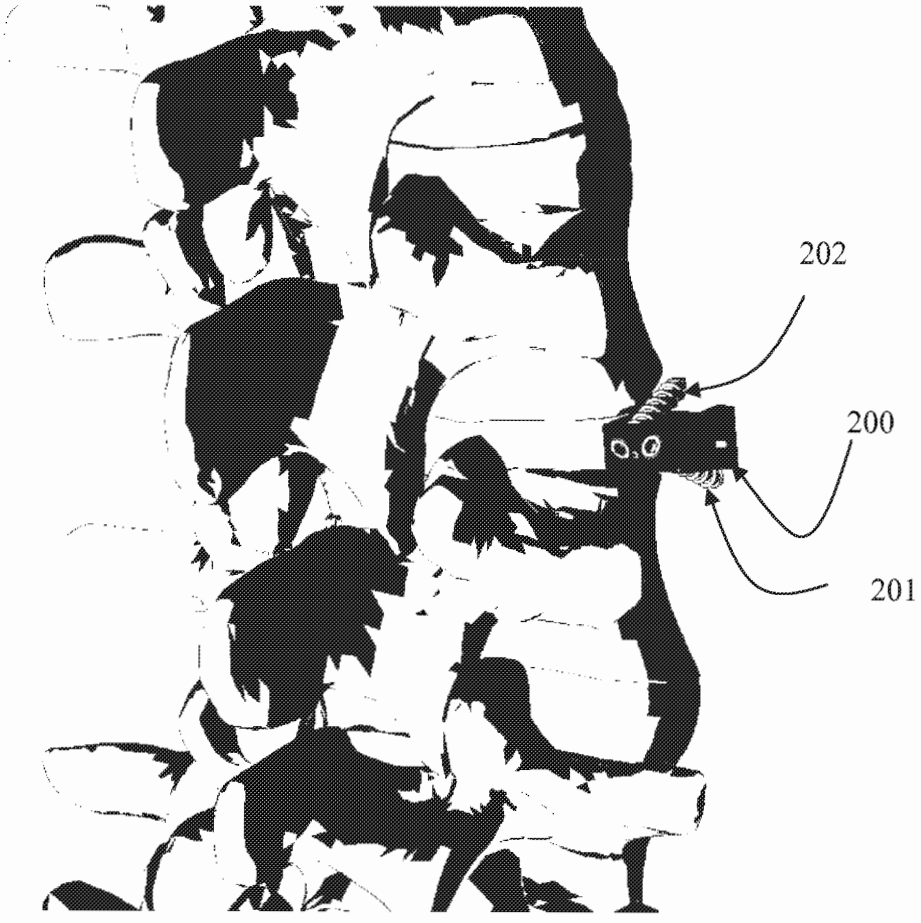


Fig. 6A

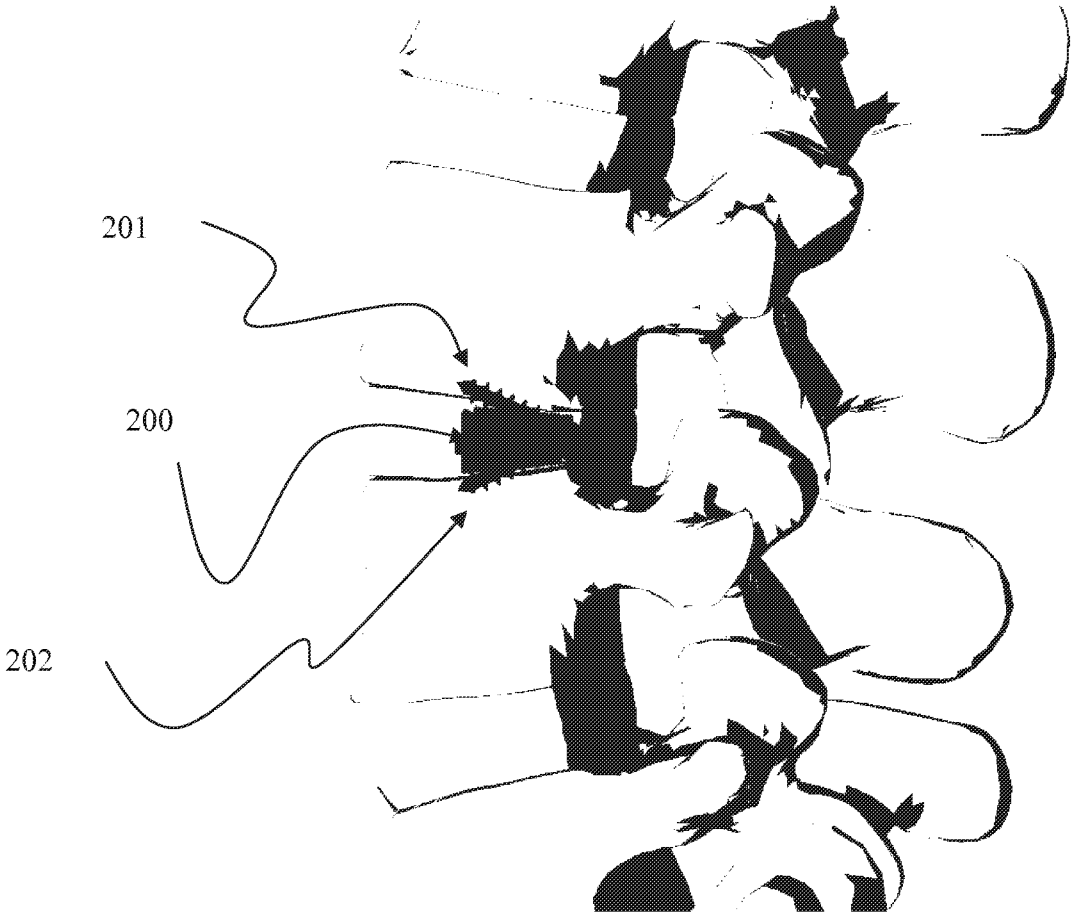


Fig. 6B

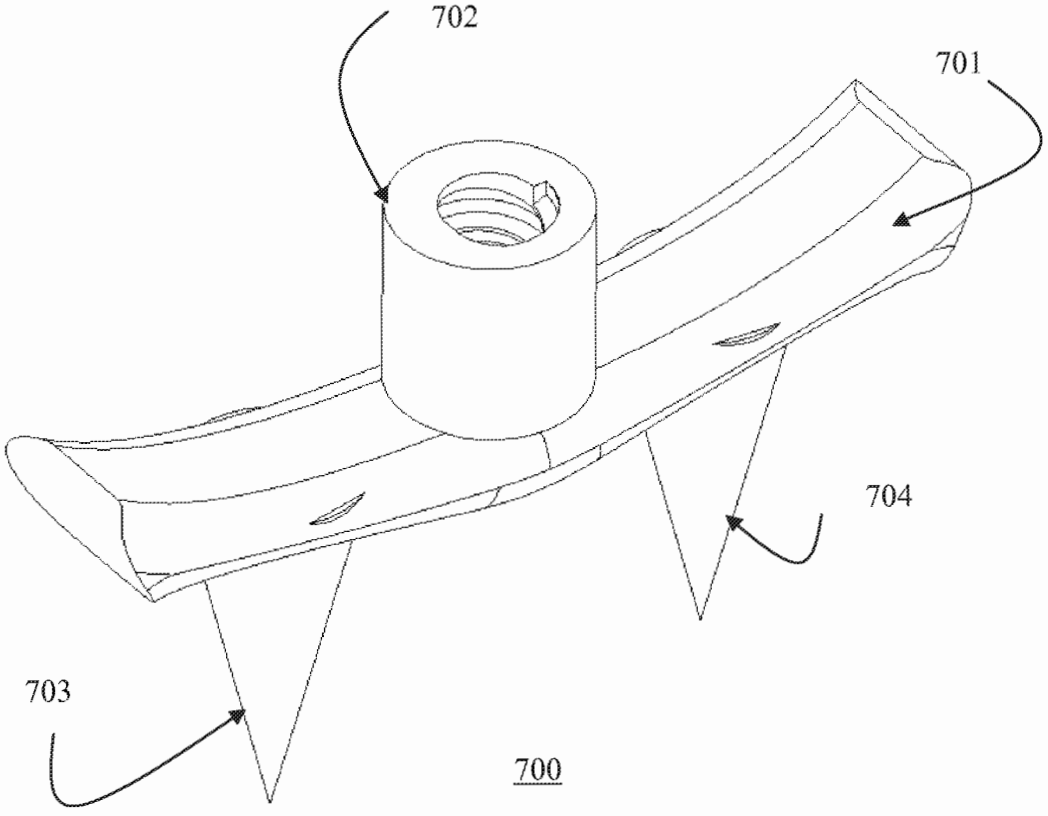
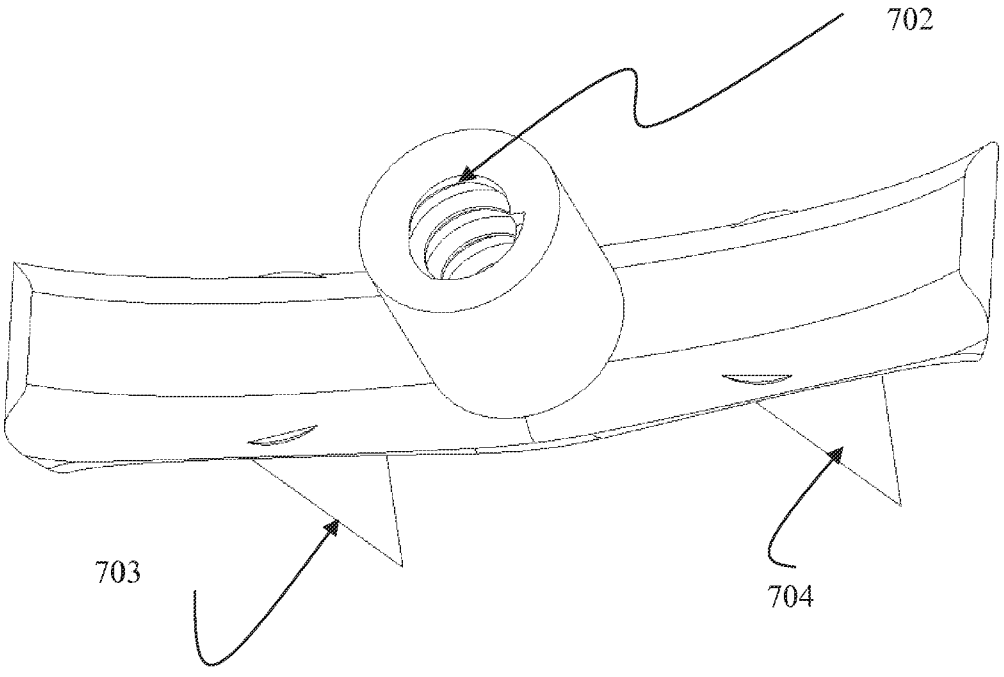


Fig. 7A



700

Fig. 7B

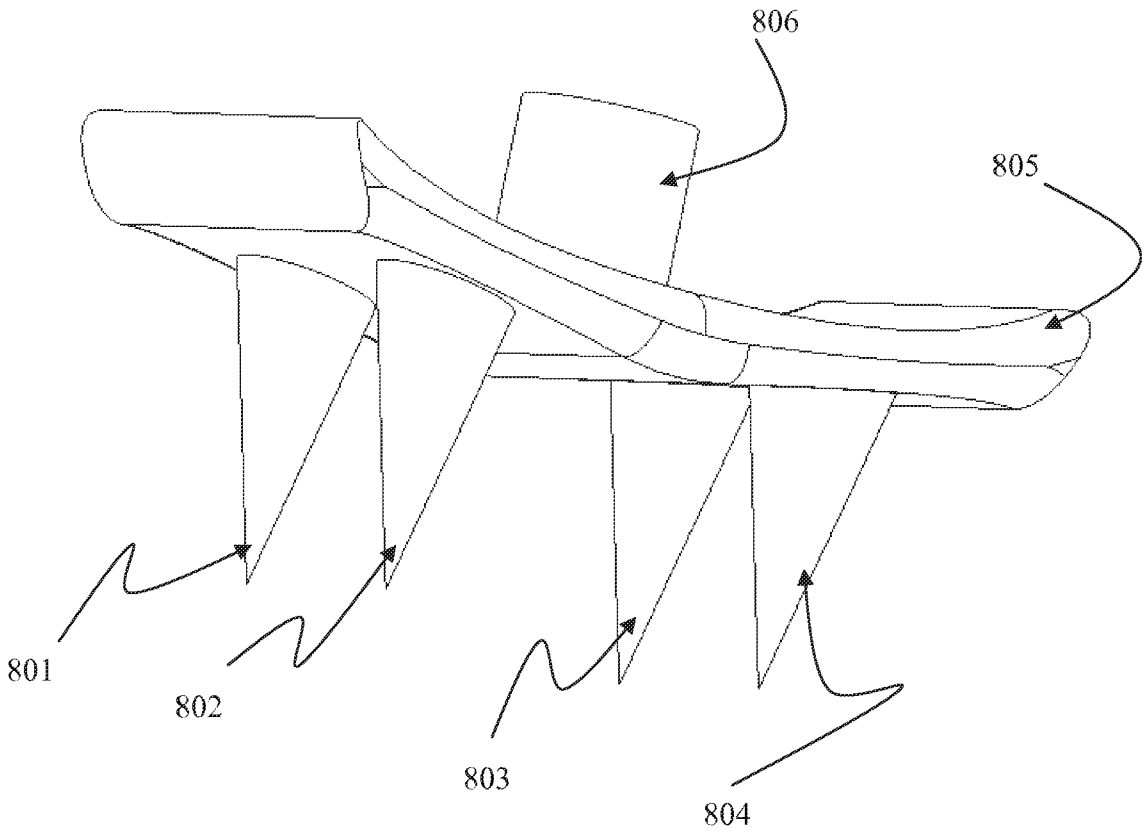


Fig. 8A

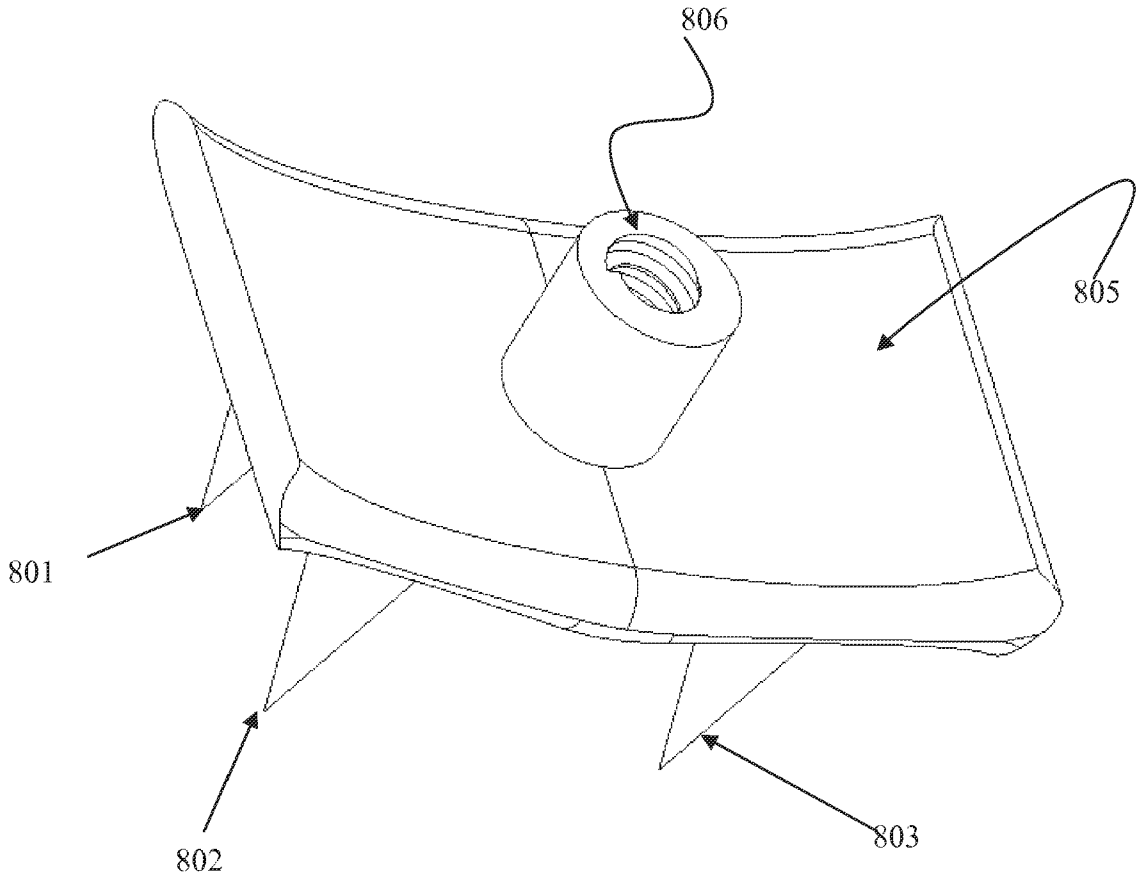
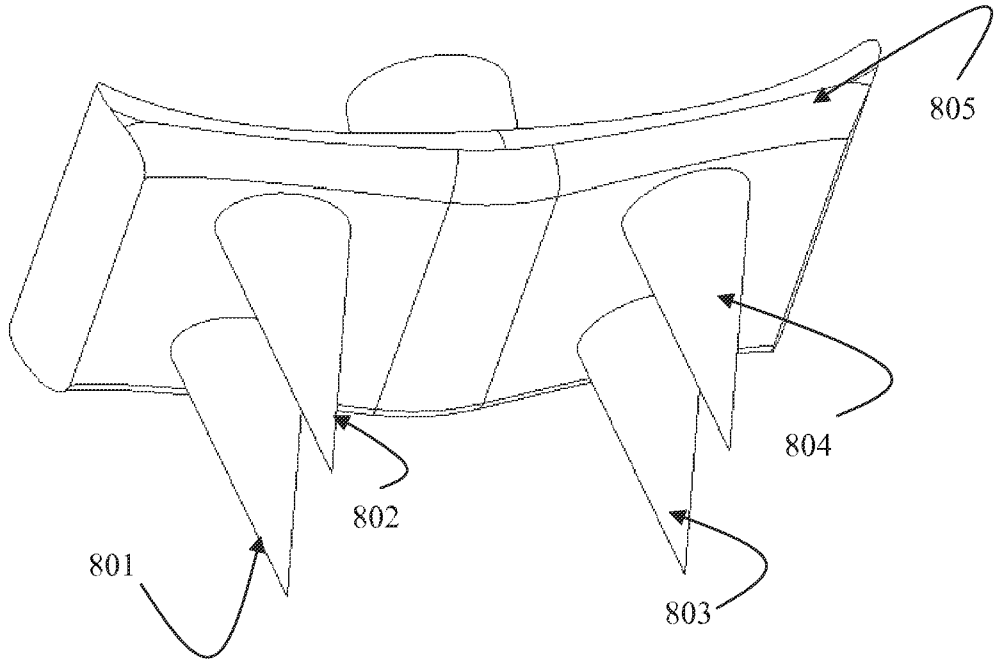


Fig. 8B



800

Fig. 8C

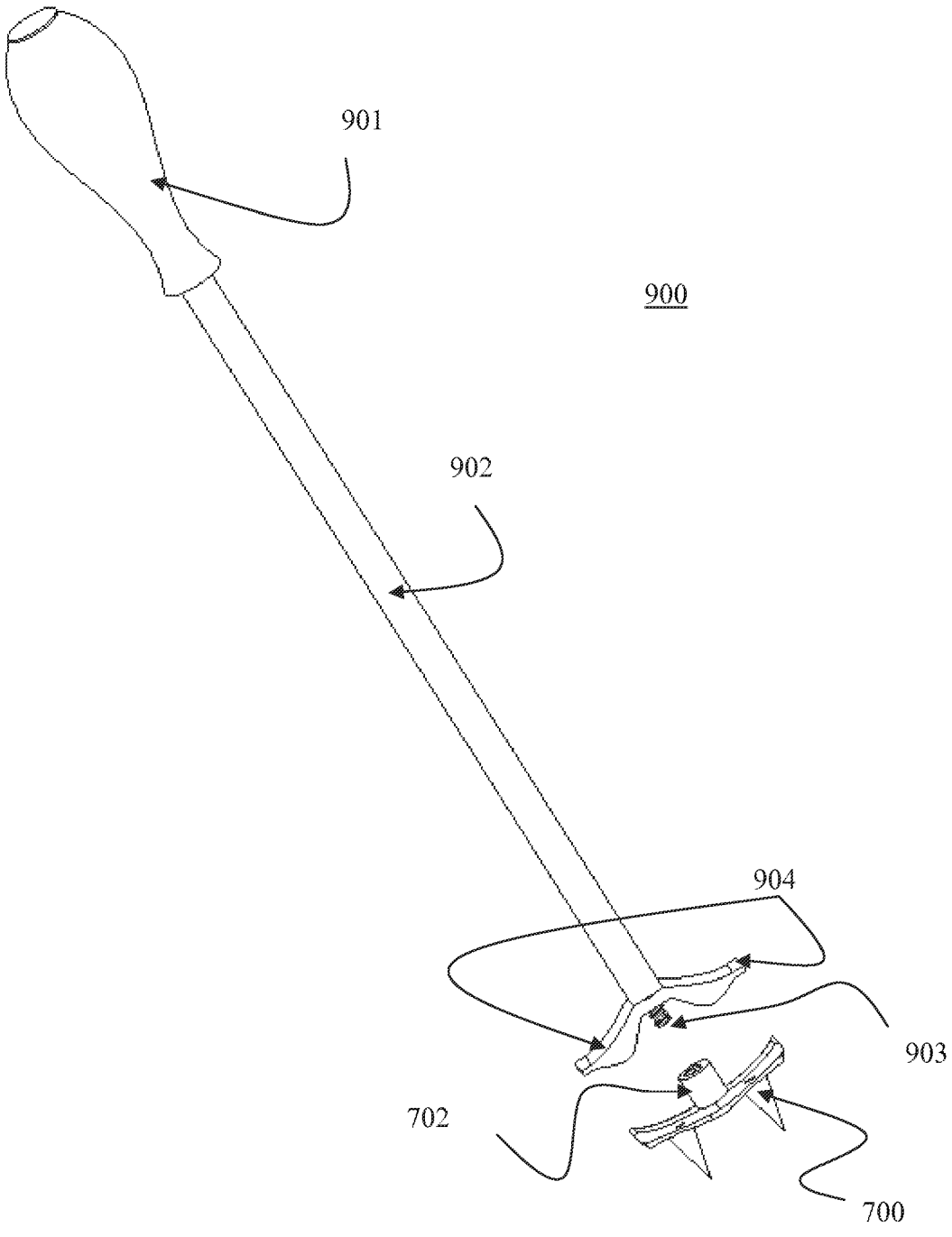


Fig. 9A

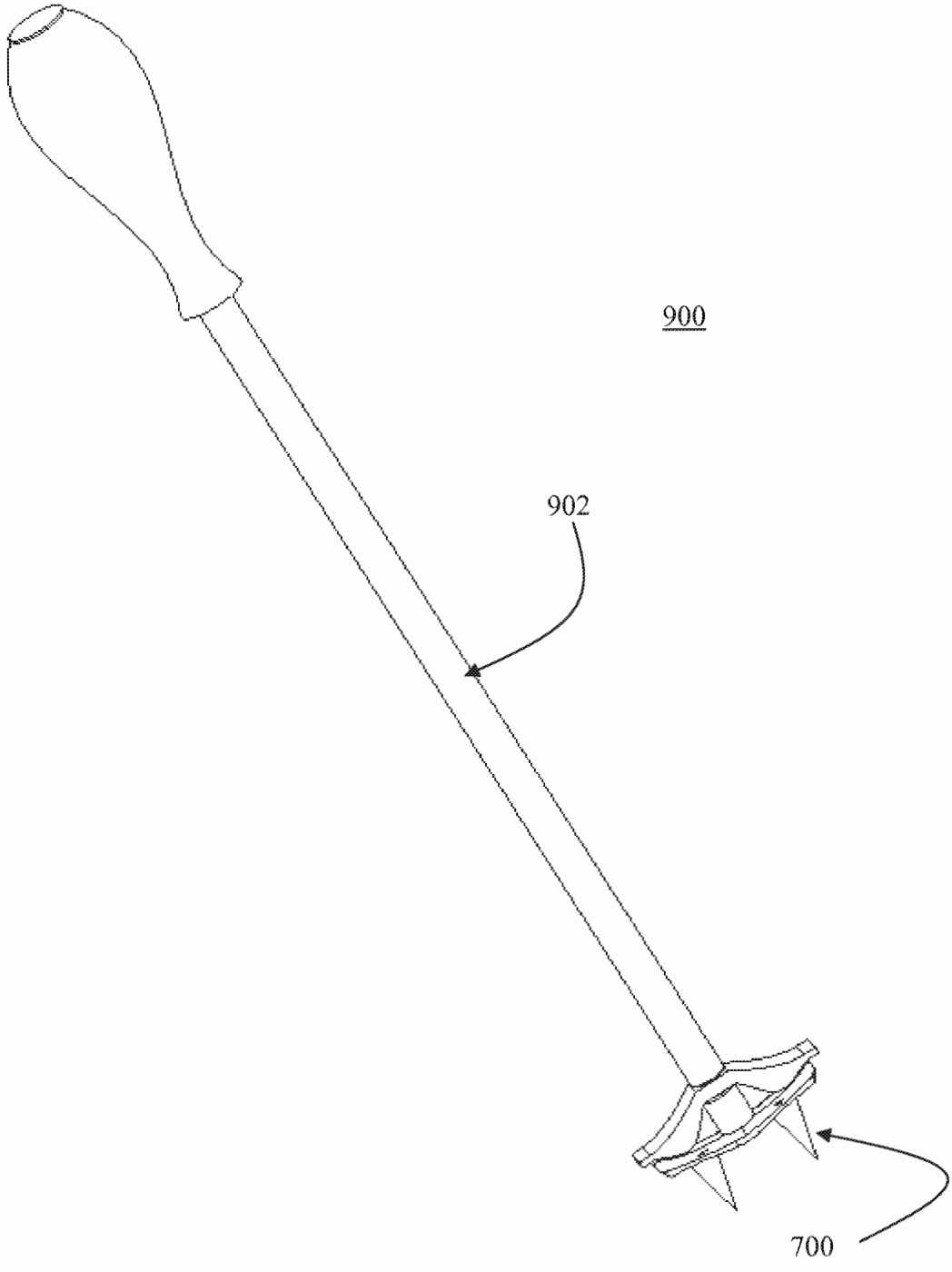


Fig. 9B

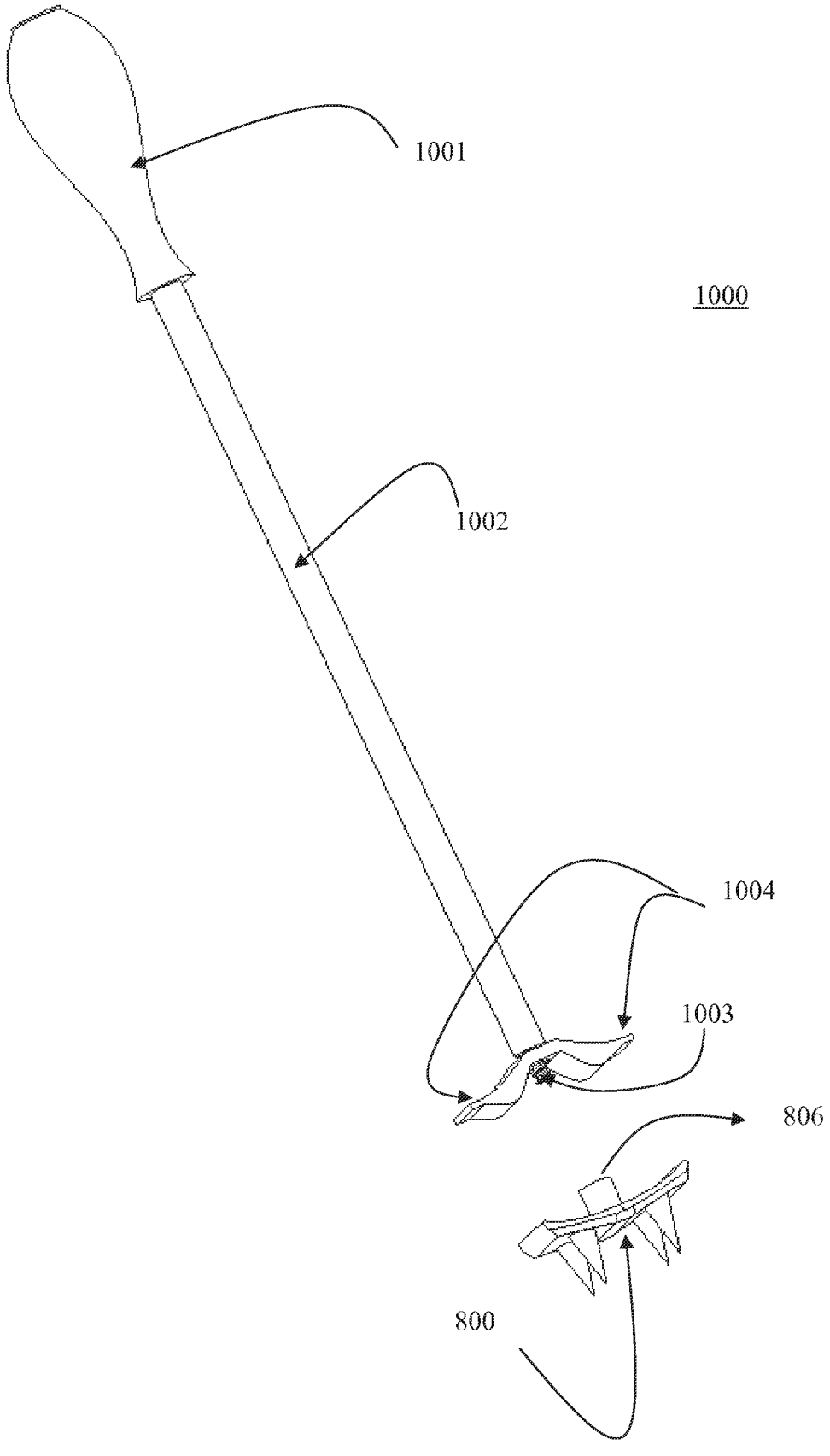


Fig. 10A

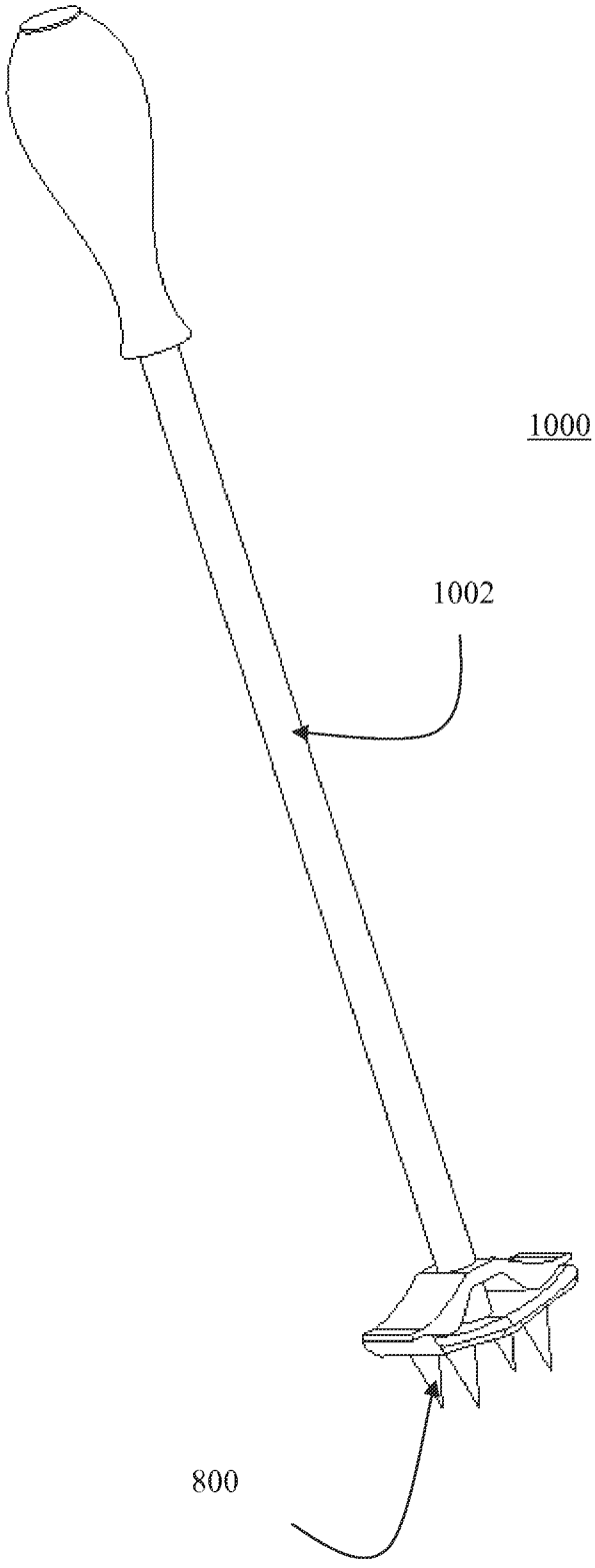


Fig. 10B

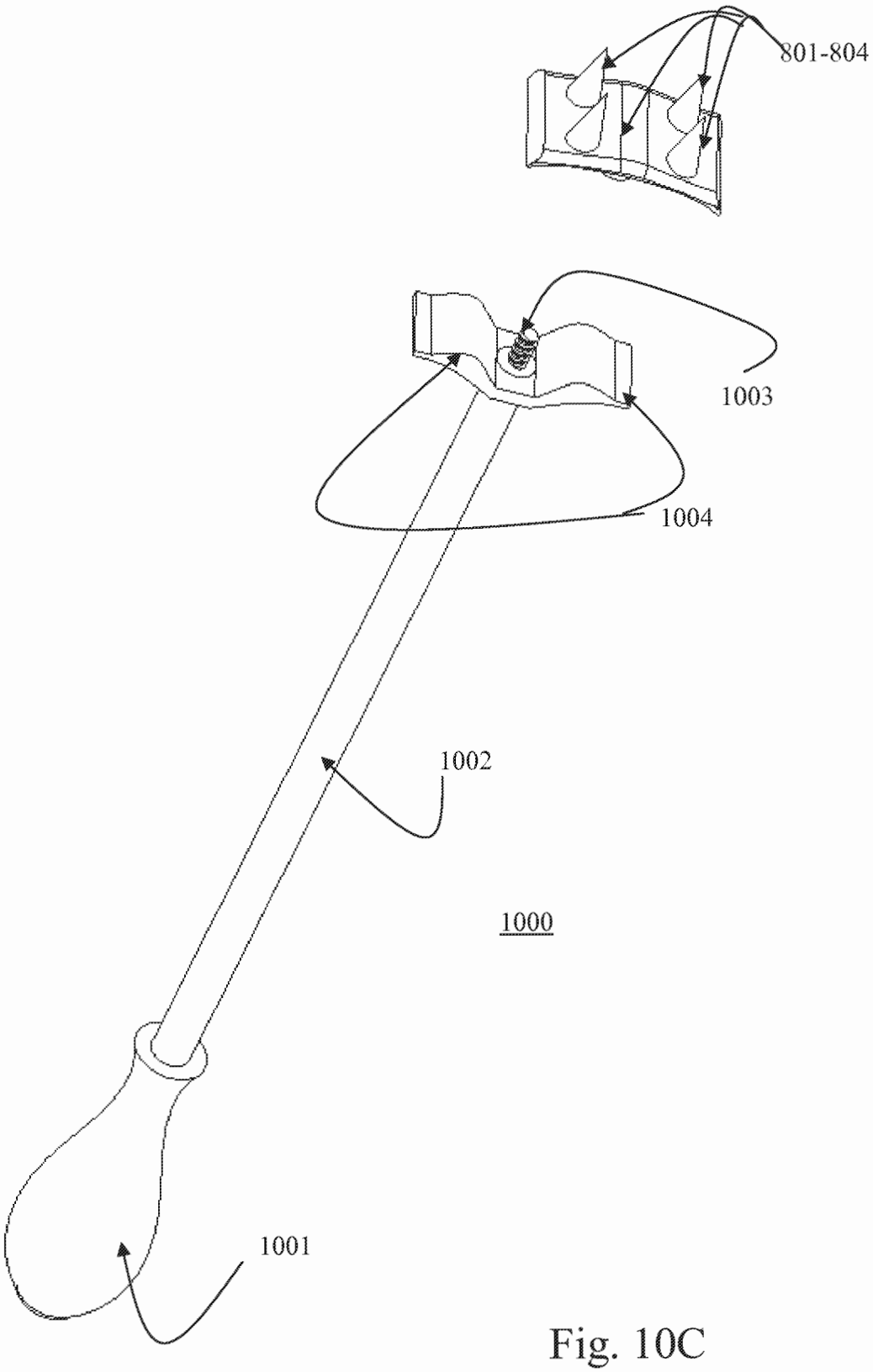


Fig. 10C

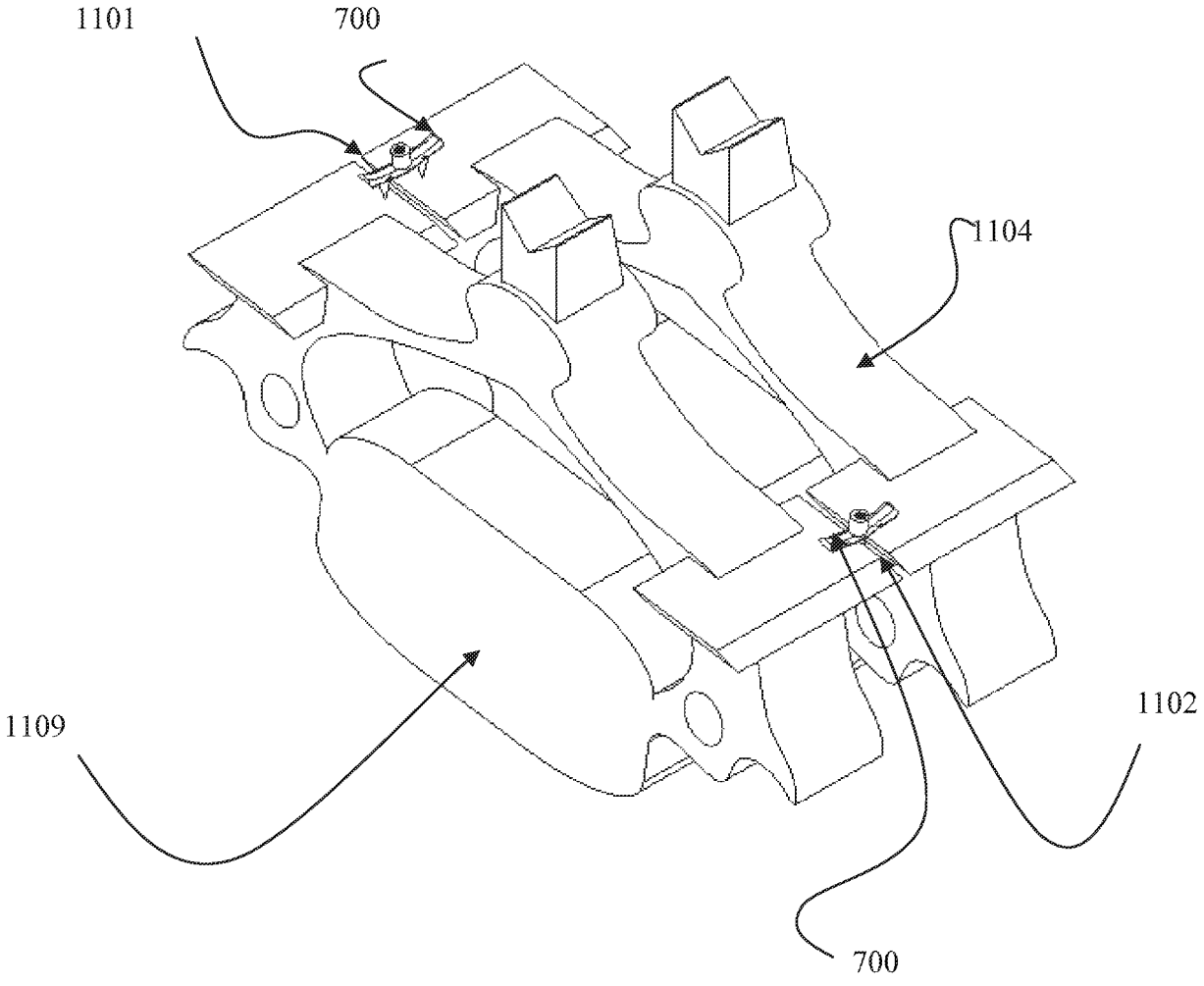


Fig. 11A

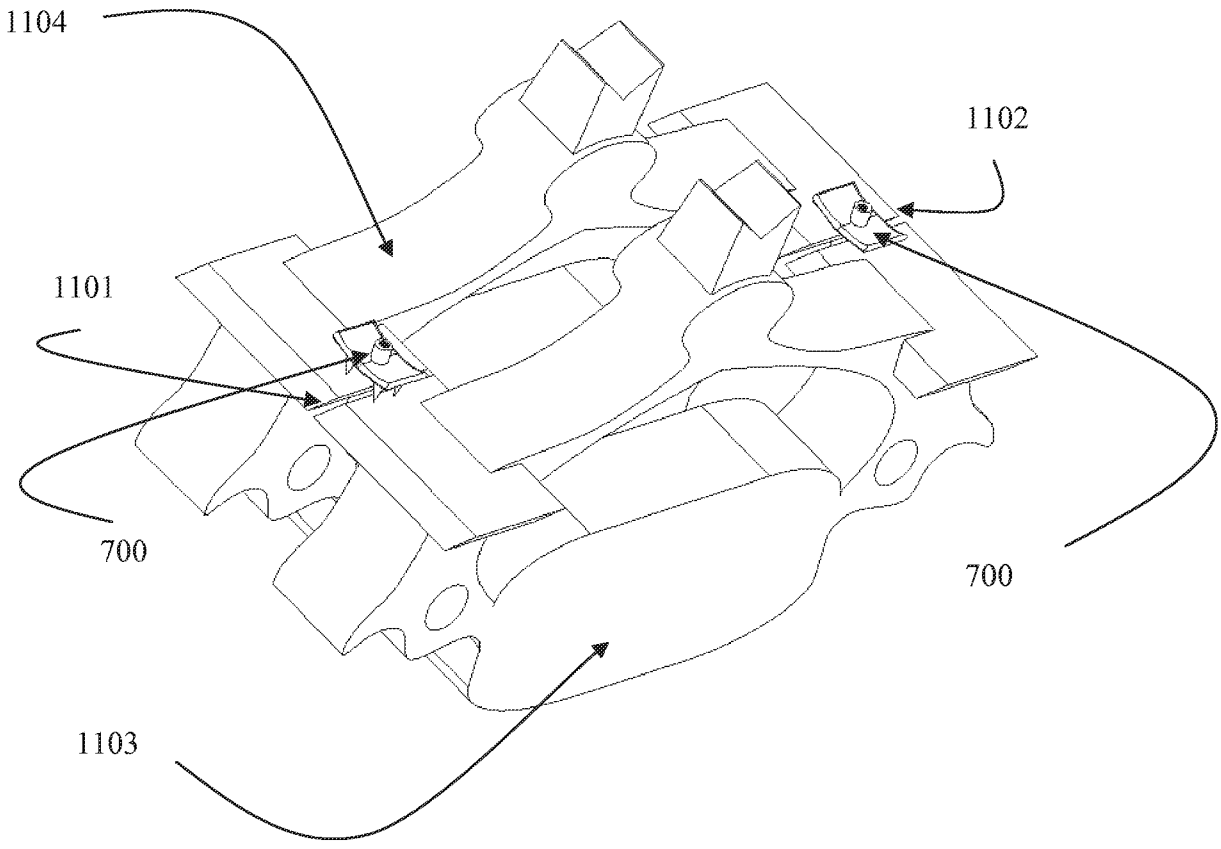


Fig. 11B

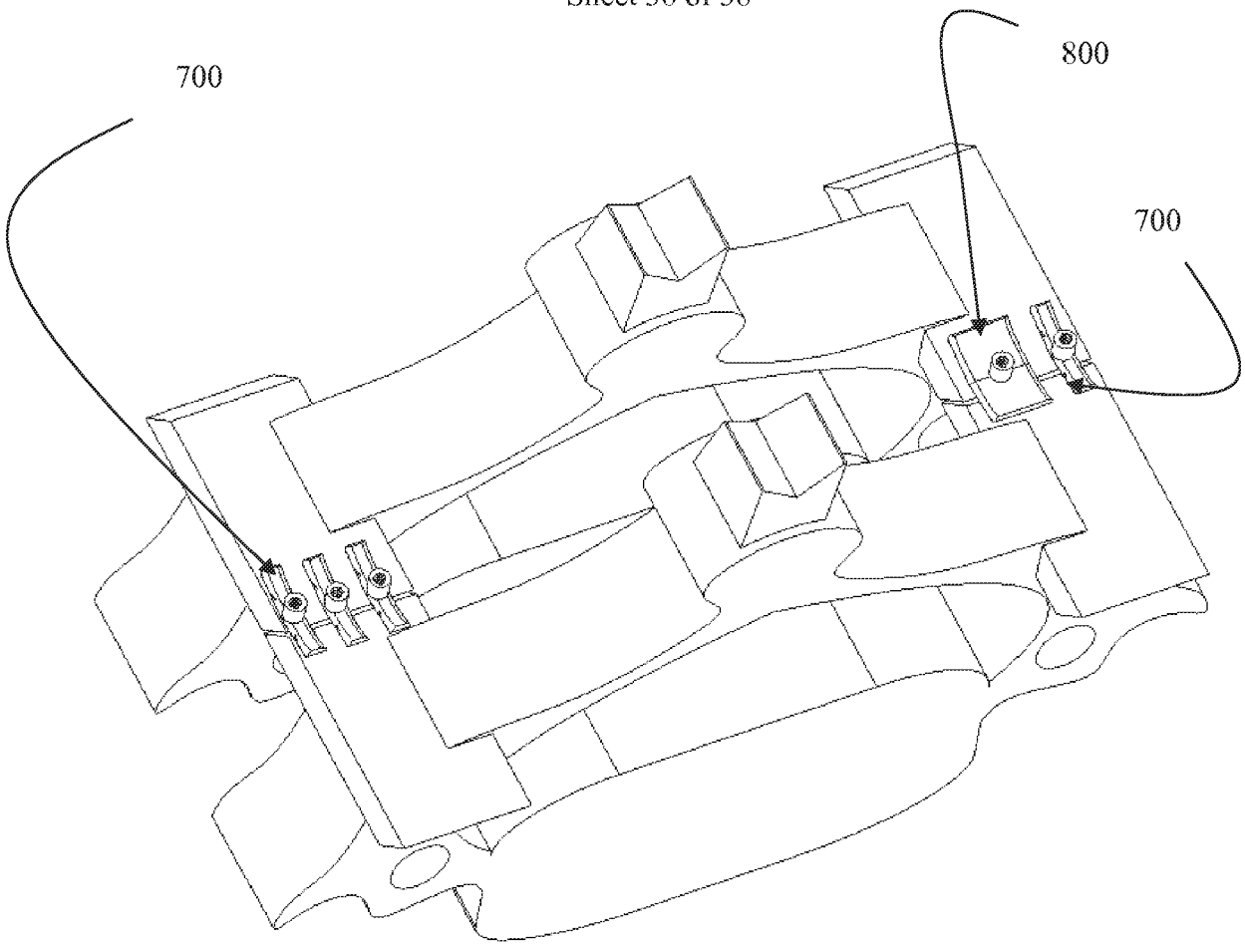


Fig. 11C

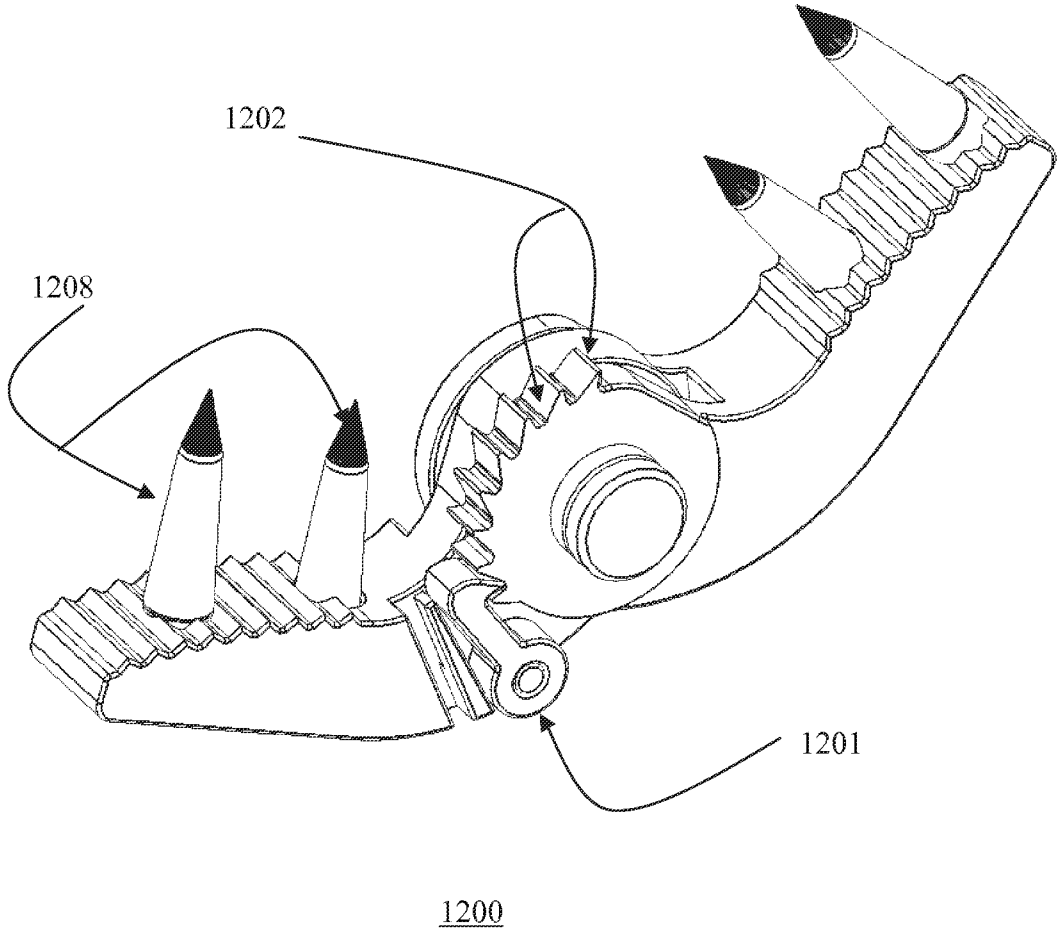


Fig. 12A

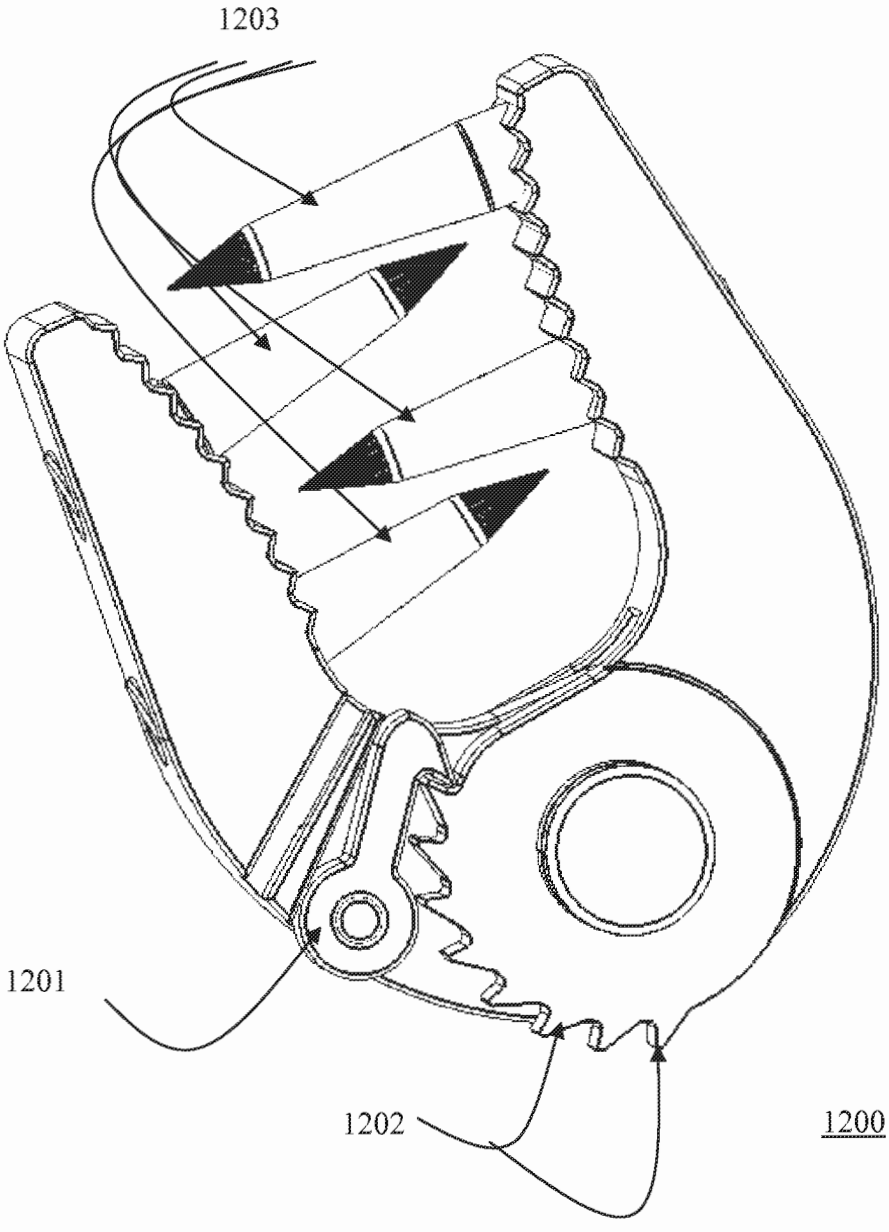


Fig. 12B

PTO/SB/81 (01-09)
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POWER OF ATTORNEY OR REVOCATION OF POWER OF ATTORNEY WITH A NEW POWER OF ATTORNEY AND CHANGE OF CORRESPONDENCE ADDRESS

Application Number	11/842,855
Filing Date	08/21/2007
First Named Inventor	MOSKOWITZ, ET AL.
Title	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL ...
Art Unit	3733
Examiner Name	Philogene, Pedro
Attorney Docket Number	3003/0105PUS1

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

☐ A Power of Attorney is submitted herewith.

OR

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

87409

OR

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

Practitioner(s) Name	Registration Number

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

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

OR

☐ The address associated with Customer Number: 87409

OR

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

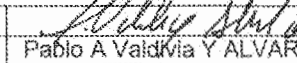
I am the:

☒ Applicant/Inventor.

OR

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

SIGNATURE of Applicant or Assignee of Record

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

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

☒ *Total of 4 forms are submitted.

This collection of information is required by 37 CFR 1.31, 1.32 and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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

PATENT APPLICATION

DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION — **ATTORNEY DOCKET NO.** 3003/0105PUS1

As a below named inventor, I hereby declare that:

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

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

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

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

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

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

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

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

Provisional Application

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

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

U.S. Priority Claim

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

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

POWER OF ATTORNEY:

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

CUSTOMER NO. 60601
Matthew T. Shanley, Reg. No. 47074

Send Correspondence to: CUSTOMER NO. 60601

Matthew T. Shanley, Esq.
McGrath, Geissler, Olds & Richardson, PLLC
PO BOX 1364
Fairfax, VA 22038-1364

Direct Telephone Calls To:

Matthew T. Shanley
1.703.621.7140

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

Full Name of Inventor: Ahmnon D. MOSKOWITZ **Citizenship:** US

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

Post Office Address: Same

Ahmnon D Moskowitz — 8/21/07

Inventor's Signature **Date**

08/21/2007 13:38 3012940721 PAGE 04

MOSKOWITZ-00001986

DECLARATION AND POWER OF ATTORNEY
FOR PATENT APPLICATION (continued)

ATTORNEY DOCKET NO. 3003/0103PUS1

Full Name of Inventor: Pablo A Valdivia Y ALVARADO Citizenship: BOLIVIA

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

Post Office Address: Same

P. Valdivia y Alvarado 8/21/07

Inventor's Signature Date

Full Name of Inventor: Mosheh T. MOSKOWITZ Citizenship: US

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

Post Office Address: Same

Inventor's Signature Date

Full Name of Inventor: Nathan C. MOSKOWITZ Citizenship: US

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

Post Office Address: Same

Inventor's Signature Date

DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION (continued)	ATTORNEY DOCKET NO. [redacted]

Full Name of Inventor: Pablo A. Valbuena Y ALVARADO Citizenship: [redacted]

Residence: [redacted]

Post Office Address: [redacted]

Inventor's Signature [redacted] Date [redacted]

Full Name of Inventor: Marisah T. MOSKOWITZ Citizenship: US

Residence: [redacted]

Post Office Address: [redacted]

Inventor's Signature [redacted] Date 8/21/07

Full Name of Inventor: Yaelisa C. MOSKOWITZ Citizenship: US

Residence: [redacted]

Post Office Address: [redacted]

Inventor's Signature [redacted] Date [redacted]

Full Name of Inventor: Pablo A Valdivia Y ALVARADO Citizenship:

Residence:

Post Office Address: Same

Inventor's Signature Date

Full Name of Inventor: Mosheh T. MOSKOWITZ Citizenship: US

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

Post Office Address: Same

Inventor's Signature Date

Full Name of Inventor: Nathan C. MOSKOWITZ Citizenship: US

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

Post Office Address: Same

Nathan C. Moskowitz 8/21/07

Inventor's Signature Date

08/21/2007 13:38 3012940721 PAGE 03

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:	John Jeremy Dresch
Attorney Docket Number:	3003/0105PUS2

Filed as Small Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Utility filing Fee (Electronic filing)	4011	1	82	82
Utility Search Fee	2111	1	270	270
Utility Examination Fee	2311	1	110	110
Pages:				
Claims:				
Independent claims in excess of 3	2201	3	110	330
Miscellaneous-Filing:				
Late filing fee for oath or declaration	2051	1	65	65

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	857

Electronic Acknowledgement Receipt

EFS ID:	9857386
Application Number:	13084543
International Application Number:	
Confirmation Number:	1305
Title of Invention:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION
First Named Inventor/Applicant Name:	Ahmnon D Moskowitz
Customer Number:	87409
Filer:	John Jeremy Dresch
Filer Authorized By:	
Attorney Docket Number:	3003/0105PUS2
Receipt Date:	11-APR-2011
Filing Date:	
Time Stamp:	23:42:35
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	Preliminary Amendment	30030105PUS2_PREL_AMEND_readyforfiling.pdf	106030 784eade1e5d8d72c73782ee82237c246930f7a2f	no	9

Warnings:	
Information:	

2	Application Data Sheet	30030105PUS2_sb0014_fill_.pdf	1032203 186b0938600e82f93e8e8699d1f1b921b3b681003	no	5
Warnings:					
Information:					
3	Specification	0105PUS2_SPEC_fromparent.pdf	1961732 f38d153b944298ef0596595deea8554b2afcf9a7	no	34
Warnings:					
Information:					
4	Drawings-only black and white line drawings	0105PUS2_Figures_fromparent.pdf	890033 36281887253bf53a76d9cfc7122da7756aa9b5a8	no	38
Warnings:					
Information:					
5	Power of Attorney	30030105PUS1_POA_ahmnon_moskowitz_readyforfiling.pdf	57377 896578bcf16c4d3025becb706ef44a1426c40c14	no	1
Warnings:					
Information:					
6	Power of Attorney	30030105PUS1_POA_mosheh_moskowitz_readyforfiling.pdf	57865 860551ebc6d2b42b017c607c11a0b3fa2f625217	no	1
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Information:					
7	Power of Attorney	30030105PUS1_POA_nathan_moskowitz_readyforfiling.pdf	55715 401543190d7d5ad28c1bd1c3e4f9e7781f8dff4d	no	1
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Information:					
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Information:					
9	Oath or Declaration filed	0105PUS2_DEC_fromparent.pdf	225111 66073142198e5b65d3d964d8c17f2eb5b5c3e4e4	no	4
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Information:					
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Warnings:					
Information:					

Total Files Size (in bytes):	5100907

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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

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POWER OF ATTORNEY OR REVOCATION OF POWER OF ATTORNEY WITH A NEW POWER OF ATTORNEY AND CHANGE OF CORRESPONDENCE ADDRESS

Application Number	11/842,855
Filing Date	08/21/2007
First Named Inventor	MOSKOWITZ, ET AL.
Title	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL ...
Art Unit	3733
Examiner Name	Philogene, Pedro
Attorney Docket Number	3003/0105PUS1

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

☐ A Power of Attorney is submitted herewith.

OR

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

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

Practitioner(s) Name	Registration Number

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

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

OR

☐ The address associated with Customer Number: 87409

OR

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

I am the:

☒ Applicant/Inventor.

OR

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

SIGNATURE of Applicant or Assignee of Record

Signature	Nathan C. Moskowitz	Date	10/28/10
Name	Nathan C. MOSKOWITZ	Telephone	301-879-9232
Title and Company			

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

☒ *Total of 4 forms are submitted.

This collection of information is required by 37 CFR 1.31, 1.32 and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: **Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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CONCLUSION

In view of the above, entry of the present Amendment and allowance of Claims 10-25 are respectfully requested. If the Examiner has any questions regarding this amendment, the Examiner is requested to contact the undersigned.

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

Respectfully Submitted,

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

April 11, 2011

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

04/21/2011 MNGUYEN 00000009 505364 13084543

01 FC:4011 82.00 DA
02 FC:2111 270.00 DA
03 FC:2311 110.00 DA
04 FC:2201 330.00 DA

MOSKOWITZ-00001996

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UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
13/084,543	04/11/2011	3733	792	3003/0105PUS2	16	6

CONFIRMATION NO. 1305

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

FILING RECEIPT

OC00000047321810

Date Mailed: 04/26/2011

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Applicant(s)

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

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

Domestic Priority data as claimed by applicant

This application is a DIV of 11/842,855 08/21/2007
which is a CIP of 11/536,815 09/29/2006 PAT 7,846,188
which is a CIP of 11/208,644 08/23/2005 PAT 7,704,279
which claims benefit of 60/670,231 04/12/2005

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

If Required, Foreign Filing License Granted: 04/20/2011

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 13/084,543**

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

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

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

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

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

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

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

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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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UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
13/084,543	04/11/2011	Ahmnon D. MOSKOWITZ	3003/0105PUS2

CONFIRMATION NO. 1305

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

POA ACCEPTANCE LETTER

OC000000047257075

Date Mailed: 04/26/2011

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 04/11/2011.

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

/llvuong/

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

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 13/084,543

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	82		N/A	
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	270		N/A	
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	110		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	16 minus 20 =	*	x 26 =	0.00	OR		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	6 minus 3 =	* 3	x 110 =	330			
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $270 ($135 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			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	792		TOTAL	

APPLICATION AS AMENDED - PART II

		(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($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT A	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	

		(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($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT B	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	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
13/084,543	04/11/2011	Ahmnon D. MOSKOWITZ	3003/0105PUS2

CONFIRMATION NO. 1305

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

FORMALITIES LETTER

OC000000047321811

Date Mailed: 04/26/2011

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 have a line quality that is too light to be reproduced (weight of all lines and letters must be heavy enough to permit adequate reproduction) or text that is illegible (reference characters, sheet numbers, and view numbers must be plain and legible) see 37 CFR 1.84(l) and (p)(1)); See Figure(s) 6A, 6B.
- A substitute specification excluding claims in compliance with 37 CFR 1.52, 1.121(b)(3), and 1.125 is required. The substitute specification must be submitted with markings and be accompanied by a clean version (without markings) as set forth in 37 CFR 1.125(c) and a statement that the substitute specification contains no new matter (see 37 CFR 1.125(b)). Since a preliminary amendment was present on the filing date of the application and such amendment is part of the original disclosure of the application, the substitute specification must include all of the desired changes made in the preliminary amendment. See 37 CFR 1.115 and 1.215.

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.

Replies should be mailed to:

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

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

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

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

/anguyen/

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Courtesy Reminder for
Application Serial No: 13/084,543

Attorney Docket No: 3003/0105PUS2
Customer Number: 87409
Date of Electronic Notification: 04/26/2011

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

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

mailroom@dreschiplaw.com
jdresch@dreschiplaw.com
john_dresch@hotmail.com

Please verify that these email addresses are correct.

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

ATTORNEY DOCKET NO.: 3003/0105PUS2

UNITED STATES PATENT AND TRADEMARK OFFICE

Application Number:	13/084,543
Filing Date:	04/11/2011
Group Art Unit:	3733
Examiner:	Not yet assigned
Confirmation No.:	1305
Title:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION

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REPLY TO NOTICE TO FILE CORRECTED APPLICATION PAPERS

Sir:

This is in response to a Notice to File Corrected Application Papers under 37 CFR 1.53(b) dated April 26, 2011.

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

(X) Applicant claims small entity status. See 37 CFR 1.27; M.P.E.P. § 509.03.

(X) Applicant respectfully submits Replacement Drawing FIGS. 6A-6B (two (2) total sheets).

(X) Applicant respectfully submits a Substitute Specification (clean version and marked up version). The Substitute Specification does not contain new matter.

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The Substitute Specification includes all of the desired changes made in the preliminary amendment.

(X) Excess Claim Fees $ 806.00 (Small Entity - thirty one (31) excess total claims. (*Applicants previously paid $330.00 for three (3) excess independent claims on April 11, 2011*).

(X) Two (2) Month Extension of Time Fees $ 245.00 (Small Entity)

(X) Total Fees Paid: $ 1,051.00 (X) PTO-2038

CONCLUSION

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

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

Respectfully submitted,

/John J. Dresch/

John J. Dresch
Attorney for Applicant(s)
Registration No. 46,672
August 15, 2011

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MOSKOWITZ-00002006

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	MOSKOWITZ, et al.
Application Number:	13/084,543
Filing Date:	04/11/2011
Group Art Unit:	3733
Examiner:	Not yet assigned
Confirmation No.:	1305
Title:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION

Mail Stop Amendment
Commissioner for Patents
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SECOND PRELIMINARY AMENDMENT

Dear Sir:

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

Please amend the application as follows:

Amendments to the Claims, as reflected in the listing of claims, begin on page 2 of this paper; and

Remarks begin on page 16 of this paper.

IN THE CLAIMS:

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

1-25. (Canceled)

26. (New) A tool for manipulating and inserting a universal, intervertebral combination bone fusion spacer and self-drilling screw apparatus into a disc space between a first vertebral body and a second vertebral body to provide fusion of the first vertebral body to the second vertebral body via biological bone fusion and screw fusion, wherein the apparatus includes an intervertebral cage having a first integral screw guide having a first predetermined angle, and a second integral screw guide having a second predetermined angle, wherein each longitudinal end of the intervertebral cage includes a slot or indentation formed adjacent to an edge of an upper surface of the intervertebral cage,

the tool comprising:

a handle; and

a gripper cooperating with the handle and having a plurality of prongs,

wherein a distal end of each of the plurality of prongs engages a respective slot or indentation of the intervertebral cage.

27. (New) The tool of claim 26, further comprising:

a screw guide for controlling a direction of self-drilling screws that are inserted into the first integral screw guide and the second integral screw guide,

wherein the plurality of prongs engage and hold the screw guide in place.

28. (New) The tool of claim 27, wherein the screw guide includes a slot or indentation for receiving one of the plurality of prongs.

29. (New) The tool of claim 27, wherein the screw guide includes slots or indentations on opposing sides for receiving the plurality of prongs.

30. (New) The tool of claim 27, wherein the screw guide includes an integral trajectory guide that receives and guides one of the self-drilling screws of the universal, intervertebral combination bone fusion spacer and self-drilling screw apparatus.

31. (New) The tool of claim 27, wherein the screw guide includes an opening that receives and guides a key that controls an adjustment device which controls a height of the universal, intervertebral combination bone fusion spacer and self-drilling screw apparatus.

32. (New) The tool of claim 26, further comprising:

a key that controls an adjustment device which controls a height of the universal, intervertebral combination bone fusion spacer and self-drilling screw apparatus.

33. (New) The tool of claim 26, wherein the gripper includes a tubular portion that receives and guides a portion of the handle therein.

34. (New) The tool of claim 32, wherein the handle includes a tubular portion that receives and guides a portion of the key therein.

35. (New) The tool of claim 32, wherein the key is an Allen key.

36. (New) The tool of claim 34, further comprising:

a spring disposed between a portion of an end of the handle and a portion of the key.

37. (New) The tool of claim 36, wherein the spring includes an opening corresponding to an opening in the handle, and

wherein a portion of the key extends through the opening of the spring and the opening of the handle.

38. (New) The tool of claim 32, wherein an end of the handle includes a rectangular handle portion.

39. (New) The tool of claim 32, wherein an end of the handle includes a circular handle portion.

40. (New) The tool of claim 26, further comprising:

a driver assembly, the driver assembly including:

a driver handle;

a drive bit portion; and

a flexible drive shaft extending between the driver handle and the drive bit portion for manipulating one of the self-drilling screws of the universal, intervertebral combination bone fusion spacer and self-drilling screw apparatus.

41. (New) A tool assembly comprising:

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

an intervertebral cage including:

a first integral screw guide having a first predetermined angle;

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

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

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

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

a tool for manipulating and inserting the universal, intervertebral combination bone fusion spacer and self-drilling screw apparatus into the disc space between the first vertebral

body and the second vertebral body to provide fusion of the first vertebral body to the second vertebral body via biological bone fusion and screw fusion, the tool comprising:

a handle; and

a gripper cooperating with the handle and having a plurality of prongs,

wherein a distal end of each of the plurality of prongs engages a respective slot or indentation of the intervertebral cage.

42. (New) The tool assembly of claim 41, further comprising:

a screw guide for controlling a direction of the first screw member and the second screw member that are inserted into the first integral screw guide and the second integral screw guide,

wherein the plurality of prongs engage and hold the screw guide in place.

43. (New) The tool assembly of claim 42, wherein the screw guide includes a slot or indentation for receiving one of the plurality of prongs.

44. (New) The tool assembly of claim 42, wherein the screw guide includes slots or indentations on opposing sides for receiving the plurality of prongs.

45. (New) The tool assembly of claim 42, wherein the screw guide includes an integral trajectory guide that receives and guides one of the first screw member and the second screw member of the universal, intervertebral combination bone fusion spacer and self-drilling screw apparatus.

46. (New) The tool assembly of claim 42, wherein the screw guide includes an opening that receives and guides a key that controls an adjustment device which controls a height of the universal, intervertebral combination bone fusion spacer and self-drilling screw apparatus.

47. (New) The tool assembly of claim 42, further comprising:

a key that controls an adjustment device which controls a height of the universal, intervertebral combination bone fusion spacer and self-drilling screw apparatus.

48. (New) The tool assembly of claim 41, wherein the gripper includes a tubular portion that receives and guides a portion of the handle therein.

49. (New) The tool assembly of claim 47, wherein the handle includes a tubular portion that receives and guides a portion of the key therein.

50. (New) The tool assembly of claim 47, wherein the key is an Allen key.

51. (New) The tool assembly of claim 49, further comprising:

a spring disposed between a portion of an end of the handle and a portion of the key.

52. (New) The tool assembly of claim 51, wherein the spring includes an opening corresponding to an opening in the handle, and

wherein a portion of the key extends through the opening of the spring and the opening of the handle.

53. (New) The tool assembly of claim 47, wherein an end of the handle includes a rectangular handle portion.

54. (New) The tool assembly of claim 47, wherein an end of the handle includes a circular handle portion.

55. (New) The tool assembly of claim 41, further comprising:

a driver assembly, the driver assembly including:

a driver handle;

a drive bit portion; and

a flexible drive shaft extending between the driver handle and the drive bit portion and manipulating one of the first screw member and the second screw member of the universal, intervertebral combination bone fusion spacer and self-drilling screw apparatus.

56. (New) The tool assembly of claim 41, wherein each of the first internal screw guide and the second internal screw guide is angled to orient the first screw member and the second screw bi-directionally in opposite directions.

57. (New) The tool assembly of claim 41, wherein the first screw member is a self-tapping and self-drilling screw member having a tapered end and a threaded body, and

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

58. (New) The tool assembly of claim 41, further comprising:

a bone graft cavity for receiving bone packing material for bone fusion between the first vertebral body and the second vertebral body.

59. (New) The tool assembly of claim 41, wherein the intervertebral cage includes a side having a plurality of ridges.

60. (New) The tool assembly of claim 41, wherein the first integral screw guide and the second integral screw guide are adjacent to each other and at an angulation with respect to a wall having the first integral screw guide and the second integral screw guide.

61. (New) The tool assembly of claim 60, wherein a first angulation of the first integral screw guide is opposed to a second angulation of the second integral screw guide.

62. (New) The tool assembly of claim 41, wherein the first integral screw guide and the second integral screw guide are adjacent to each other along a longitudinal extent of a wall having the first integral screw guide and the second integral screw guide, and

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

63. (New) The tool assembly of claim 62, wherein a part of the first integral screw guide overlaps a part of the second integral screw guide along the longitudinal extent of the wall having the first integral screw guide and the second integral screw guide.

64. (New) The tool assembly of claim 62, wherein the first integral screw guide and the second integral screw guide are at an angulation with respect to the wall having the first integral screw guide and the second integral screw guide.

65. (New) The tool assembly of claim 64, wherein a first angulation of the first integral screw guide extends in a first direction from the wall having the first integral screw guide and the second integral screw guide toward a first side of the intervertebral cage,

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

wherein the first side is opposed to the second side.

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

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

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

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

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

wherein one of:

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

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

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

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

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

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

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

wherein one of:

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

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

68. (New) The tool of claim 26, wherein the intervertebral cage includes a wall having an entry opening of the first integral screw guide and an entry opening of the second integral screw guide, the wall including a first corner and a second corner, the first corner being

arranged at an opposite side of the wall and an opposite end of the wall with respect to the second corner,

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

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

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

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

71. (New) The tool assembly of claim 41, wherein the first integral screw guide and the second integral screw guide are at an angulation with respect to a wall having the first integral screw guide and the second integral screw guide.

72. (New) The tool assembly of claim 41, wherein the first integral screw guide and the second integral screw guide diverge from each other.

73. (New) The tool assembly of claim 41, wherein the first integral screw guide and the second integral screw guide diverge from each other and at an angulation with respect to a wall having the first integral screw guide and the second integral screw guide.

74. (New) A method of inserting a universal, intervertebral combination bone fusion spacer and self-drilling screw apparatus into a disc space between a first vertebral body and a

second vertebral body using a tool for manipulating and inserting the universal, intervertebral combination bone fusion spacer and self-drilling screw apparatus into the disc space between the first vertebral body and the second vertebral body,

wherein the universal, intervertebral combination bone fusion spacer and self-drilling screw apparatus includes:

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

wherein the tool includes:

a handle; and

a gripper cooperating with the handle and having a plurality of prongs,

wherein a distal end of each of the plurality of prongs engages a respective slot or indentation of the intervertebral cage,

the method comprising:

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

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

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

engaging each slot or indentation of the intervertebral cage with the distal end of each of the plurality of prongs;

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

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

75. (New) A method of inserting a universal, intervertebral combination bone fusion spacer and self-drilling screw apparatus into a disc space between a first vertebral body and a second vertebral body and fusing the first vertebral body to the second vertebral body via biological bone fusion and screw fusion using a tool for manipulating and inserting the universal, intervertebral combination bone fusion spacer and self-drilling screw apparatus into the disc space between the first vertebral body and the second vertebral body,

wherein the universal, intervertebral combination bone fusion spacer and self-drilling screw apparatus includes:

an intervertebral cage including:

a first integral screw guide having a first predetermined angle;

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

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

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

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

wherein the tool includes:

a handle; and

a gripper cooperating with the handle and having a plurality of prongs,

wherein a distal end of each of the plurality of prongs engages a respective slot or indentation of the intervertebral cage,

the method comprising:

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

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

selecting the universal, intervertebral combination bone fusion spacer and self-drilling screw apparatus based on the measured dimension of the disc space and based on the

determination of the disc space being the posterior lumbar disc space, the anterior-lateral lumbar disc space, the anterior lumbar disc space, or the anterior cervical disc space;

engaging each slot or indentation of the intervertebral cage with the distal end of each of the plurality of prongs;

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

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

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

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

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

76. (New) A tool assembly comprising:

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

an intervertebral cage including:

a first integral screw guide having a first predetermined angle;

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

a bone graft cavity for receiving bone packing material for bone fusion between the first vertebral body and the second vertebral body;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

wherein one of:

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

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

a tool for manipulating and inserting the universal, intervertebral combination bone fusion spacer and self-drilling screw apparatus into the disc space between the first vertebral body and the second vertebral body to provide fusion of the first vertebral body to the second vertebral body via biological bone fusion and screw fusion, the tool comprising:

a handle; and

a gripper cooperating with the handle and having a plurality of prongs,

wherein a distal end of each of the plurality of prongs engages a respective slot or indentation of the intervertebral cage.

REMARKS

Claims 1-25 were previously pending in the application.

This Amendment cancels claims 1-25 and adds new claims 26-76. Claims 26, 41, and 74-76 are independent.

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

Early and favorable prosecution on the merits is respectfully requested.

In view of the above, entry of the present Amendment and allowance of Claims 26-76 are respectfully requested. If the Examiner has any questions regarding this amendment, the Examiner is requested to contact the undersigned.

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

Respectfully Submitted,

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August 15, 2011

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Electronic Patent Application Fee Transmittal

Application Number:	13084543
Filing Date:	11-Apr-2011
Title of Invention:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION
First Named Inventor/Applicant Name:	Ahmnon D. MOSKOWITZ
Filer:	John Jeremy Dresch
Attorney Docket Number:	3003/0105PUS2

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Utility under 35 USC 111(a) Filing Fees

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Claims:				
Claims in excess of 20	2202	31	26	806
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

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Extension - 2 months with $0 paid	2252	1	245	245
Miscellaneous:				
			Total in USD ($)	**1051**

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Application Number:	13084543
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Title of Invention:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION
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1	Drawings-only black and white line drawings	30030105PUS2_Replacement_Figures.pdf	170369 771fd2a2fe295d3f2cdb16cfba89e7c2c7db2407	no	2
Warnings:					
Information:					
2	Specification	30030105PUS2_substitute_spec_clean_version.pdf	103179 34ad7a646bdd384e5aad97756b1a7bfb810820f0	no	25
Warnings:					
Information:					
3	Specification	30030105PUS2_substitute_spec_markedup_version_READYFORFILING.pdf	172788 ed2f82bcf9be2c6a6bdaf82a04ba5eeb6e0bc082	no	23
Warnings:					
Information:					
4	Applicant Response to Pre-Exam Formalities Notice	30030105PUS2_ReplyToNTFMP_readyforfiling.pdf	115057 b1837874aa98487a12bd2cc6ea6a110a5582f272	no	2
Warnings:					
Information:					
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Warnings:					
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		Total Files Size (in bytes):	706402		

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

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

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

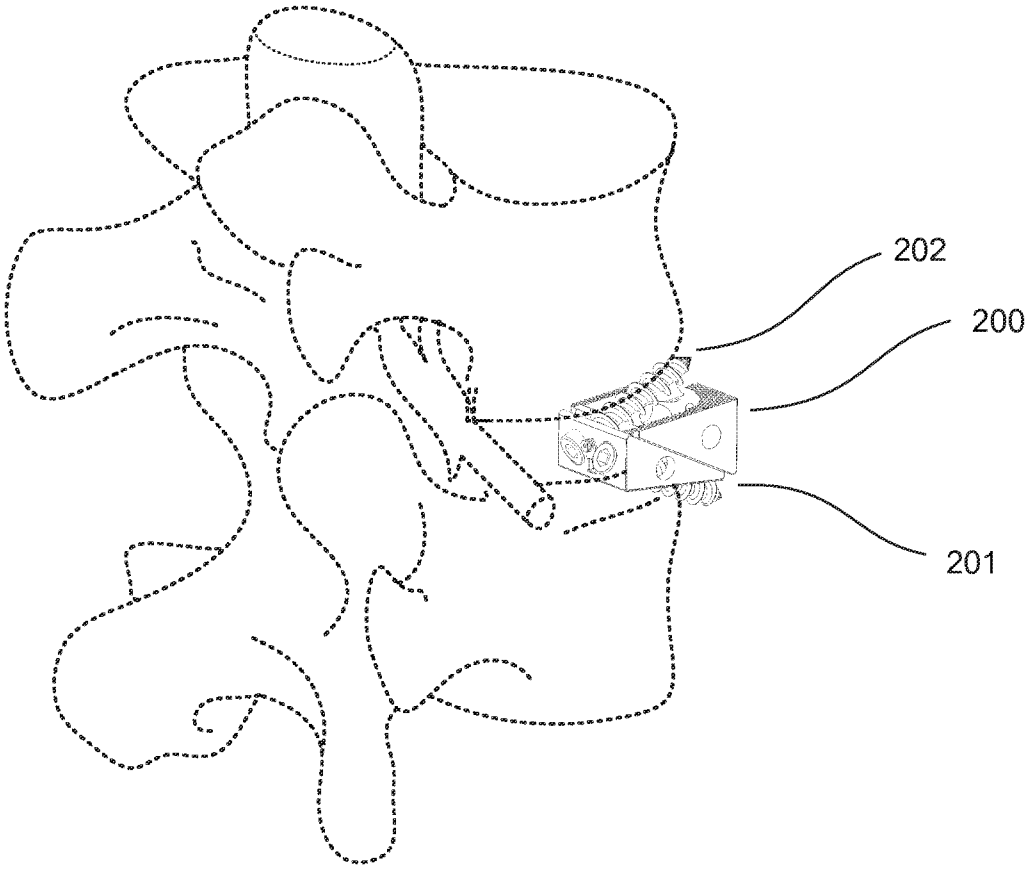


Fig. 6A

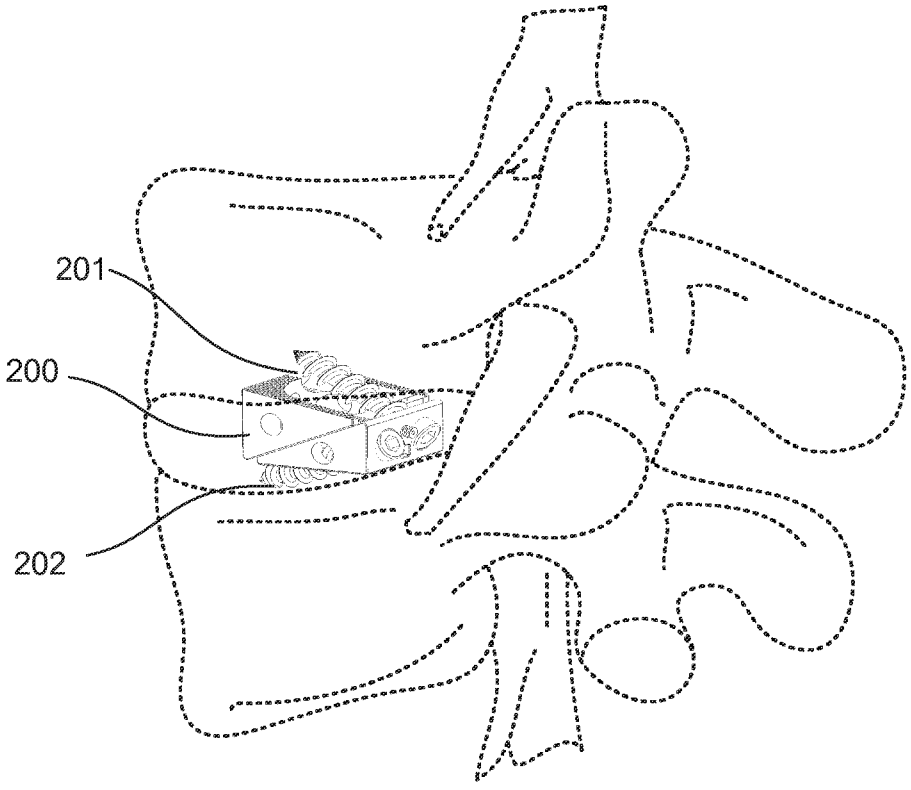


Fig. 6B

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

CROSS-REFERENCE TO RELATED APPLICATIONS

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

BACKGROUND OF THE INVENTION

FIELD OF INVENTION

[0002] The present invention relates to a unique universal bidirectional screw (BDS) system, and in particular its application to the spine, also referred to as bi-directional fixating transvertebral (BDFT) screws which can be used as a stand-alone intervertebral device which combines the dual functions of an intervertebral spacer which can be filled with bone fusion material(s), as well as a transvertebral bone fusion screw apparatus. In the posterior lumbosacral

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and thoracic spine, BDFT screw/box constructs can be used independently or supplemented with a novel horizontal mini-plate which prevents upward bone graft intrusion into the thecal sac and nerves. In the anterior lumbosacral spine BDFT screw box constructs can be inserted into and supplemented by a circumferential cage. These posteriorly and anteriorly placed stand-alone intervertebral body fusion constructs may obviate the need for supplemental pedicle screw fixation.

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

DESCRIPTION OF THE RELEVANT ART

[0004] The history and evolution of instrumented spinal fusion in the entire human spine has been reviewed in our two prior copending applications Ser. No. 11/536,815, filed on Sep. 29, 2006, and Ser. No. 11/208,644, filed on Aug. 23, 2005, the related contents of which are hereby incorporated by reference. Currently the majority of posterior cervical and almost all anterior and posterior lumbosacral and thoracic fusion techniques are typically supplemented with pedicle screw placement. Complications of pedicle screw placement in cervical, thoracic and lumbar spine include duration of procedure, significant tissue dissection and muscle retraction, misplaced screws with neural and/or vascular injury, excessive blood loss, need for transfusions, prolonged recovery, incomplete return to work, and excess rigidity leading to adjacent segmental disease requiring further fusions and re-operations. Recent advances in pedicle screw fixation

including minimally invasive and image-guided technology, and the development of flexible rods, imperfectly address some but not all of these issues.

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

SUMMARY

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

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

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

[0009] To achieve safe, effective and minimally invasive segmental spinal fusion, applicants propose the use of novel bi-directional fixating transvertebral (BDFT) screws which can be strategically inserted via anterior or posterior surgical spinal approaches into the anterior and middle columns of the 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 spine, these screws can be capped with a horizontal mini-plate which will prevent bony growth into the thecal sac and nerves. We refer to this as a two-in-one device, i.e. two screw boxes/BDFT screws combined with one horizontal mini-plate. This is an entirely novel concept in posterior lumbar spinal surgery. In yet another embodiment two BDFT screw boxes can be combined with a circumferential cage (also 2 in 1) to be placed anteriorly into the lumbar spine.

[0015] It is believed that BDFT-screw constructs provide as strong or stronger segmental fusion as pedicle screws without the complications arising from pedicle screw placement which include screw misplacement with potential nerve and/or vascular injury, violation of healthy facets, possible pedicle destruction, blood loss, and overly rigid fusions. By placing screws across the intervertebral space from vertebral body to vertebral body, engaging anterior and

middle spinal columns, and not the vertebral bodies via the 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] FIGS. 1A-D illustrate the Lumbar intervertebral screw box with one lateral oriented BDFT screw and one medially oriented BDFT screw (Embodiment IA) in sagittal-

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oblique (FIG. 1A), superior perspective (FIG. 1 B), inferior perspective (FIG. 1C) and exploded (FIG. 1 D) views.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

DETAILED DESCRIPTION OF THE INVENTION

[0060] 1. The Medical Device

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

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

[0063] The expandable box 100 consists of top and bottom triangular sliding bases 103, 104 (FIG. 1-D). The superior and inferior segments of the height/depth adjusting screw 105 are integrated and connected to the two separate top and bottom triangular bases 103, 104, respectively. By turning this adjusting screw 105 back and forth i.e. clock-wise, and counter clockwise, the sliding rails 106 of the top triangular base 103 (FIG. 1D) slide up and down the

rail inserts 107 on the bottom triangular base 104 (FIG. 1D). This action will simultaneously alter the intervertebral height and depth of the screw box 100 allowing individualized custom fitting of the screw box 100 conforming to the dimensions of the disc space.

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

[0065] FIGS. 2A-C illustrate three-dimensional views of the Lumbar intervertebral non-expandable screw box 200 with two BDFT screws 201, 202 (Embodiment II). Screws 201 and 202 perforate and orient in opposing, superior and inferior directions. There are holes 208 and hollow spaces allowing packaging with bone. There are also holes which allow the traversal of screws. The superior and inferior edges include ridges 207 to facilitate integration and fusion with superior and inferior vertebral bodies. The expandable screw box 200 may include a screw insert 209 to attach a horizontal mini-plate (not shown). The self-contained internalized drill guides are at a 25 degree angle. The screw boxes can be designed with the internalized drill guides with different angles and/or different positions within the box.

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

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

[0068] FIG. 4C illustrates two screw boxes 300c, 300d within a circumferential cage 420 (2 in 1) construct which is designed for anterior placement into the lumbar spine. There are slots 308a, 308b for bone graft placement, both outside and inside the boxes. The circumferential cage 420 has perforations 401a for the placement of transvertebral screws (not shown).

[0069] FIGS. 5A-C illustrate three-dimensional views of the external drill/screw guide-box expander 500 which assists in screw trajectory and box expansion (embodiments IA-B). For

embodiments II and III, the same instrument is utilized; however, an expanding Allen key component is not used.

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

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

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

[0073] FIGS. 5H-I illustrate three-dimensional views of a positioning tool 500a for impaction and placement of two transvertebral screws 201, 202 in the non-expandable screw box 200. The driver assembly 550 consists of a screw driver 551, a flexible shaft 552 and a square recess bit 553. This facilitates turning the screws 201, 202 into the bone. The flexible shaft 552 facilitates the avoidance of spinous processes which might hinder the screw driving if the shaft 552 were straight. The positioning tool 500a can have a rectangular handle, Embodiment I (FIG. 5H), or a circular handle, Embodiment II (FIG. 5I). This serves to position the screw box within

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

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

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

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

[0077] FIGS. 8A-C illustrate three-dimensional views of the four-pronged cervical facet staple 800 (Embodiment II). Likewise it has a staple base 805 contoured specifically for the surface of the facet joint. It also has an impactor insert 806. The insertion of a device with four prongs 801-804 instead of two prongs further limits the degrees of motion of the joint hence making the fusion more rigid.

[0078] FIGS. 9 A-B illustrate a three-dimensional view of the two-pronged cervical staple impactor 900. It has a handle 901, a stem 902, and a screw insert 903 which can be

screwed into the threaded staple insert. The impactor has two wings 904 which keep the staple base edges in place facilitating staple impaction. The handle 901 of the impactor 900 is broad in order to allow impaction by a mallet.

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

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

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

[0082] FIG. 11C illustrates the concept of modularity and incremental diminution of movement of the joint by the modular placement of different combinations and permutations of varying numbers of two and four pronged cervical facet staples 700, 800. If one wishes to have the most flexible (least rigid) fusion, one would place a unilateral two pronged staple 700. One can increase i.e. calibrate increasing degrees of rigidity by increasing the number of prongs penetrating the facet joints bilaterally. In FIG. 11C each facet joint is fused using a total number of six prongs. One side this is accomplished by using three two pronged staples 700, and on the other side using one four pronged staple 800 and one two pronged staple 700. These two embodiments can be mixed and matched unilaterally or bilaterally to vary the degree of rigidity

and conversely flexibility of fusion. The most flexible fusion at one level would be accomplished by one staple 700 (2 prongs). The highest level of rigidity would be achieved by placing two four pronged staples 800 on both sides totaling sixteen prongs. Intermediate degrees of relative joint motion can be modulated by insertion into the cervical facet joints staples in two-four prong increments from 2-16. Each additional prong further limits the degree of facet joint motion hence increasing rigidity, and conversely decreasing flexibility. Thus the novel modular use of these embodiments heralds an era of flexible cervical spine fusion.

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

[0084] 2. The Surgical Method

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

[0086] The posterior lumbar spine implantation of all the screw box 100, 200, 300 embodiments, with BDFT screws, and horizontal mini-plate 400 can be implanted via previously described posterior lumbar interbody fusion (PLIF) or posterior transforaminal lumbar interbody

fusion (TLIF) procedures. The procedures can be performed open, microscopic, closed tubular or endoscopic. Fluoroscopic guidance can be used with any of these procedures.

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

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

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

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

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

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

[0093] The anterior thoracic and lumbar spine implantation of one, two or three screw box constructs 100, 200, 300 and BDFT screws can be performed in a similar manner to the posterior application. Likewise, a horizontal mini-plate 400 can be used to cap two or three screw box constructs 100, 200, 300 (one placed midline deeply, one placed left and one placed right, forming a triangulation). Alternatively two screw box constructs may be placed into a circumferential ring for anterior placement. Anterior placement of these devices can be performed into the L4/5 and L5/S1 spaces on the supine anesthetized patient via previously described open microscopic or endoscopic techniques. Once the disc space is exposed and discectomy and space preparation are performed, placement of one, two or three screw box embodiments 100, 200, 300 (I-III) or a 2 in I construct can be placed. The screw placement is facilitated by the internal screw guides, and different positioning tools ((FIG. 5). A right angled screw driver and/or ratchet could alternatively be employed A capping mini-plate 400 may be

applied if desirable. The mechanism of screw placement and mini-plate 400 attachment are identical to what was described above.

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

[0095] For posterior placement of cervical facet staple 700, 800 embodiments, after adequate induction of anesthesia the patient is flipped prone and his head and neck secured. A single midline or two para-median incisions are made for unilateral or bilateral or multilevel placement of staples. Ultimately the facet joint is exposed. Alternatively and preferably this can be performed percutaneously under fluoroscopic guidance with intravenous sedation. The staple 700, 800 (Embodiments I or II) is loaded into the impactor 900, 1000. The staple 700, 800 is placed on the two articulating cervical facets, and then impacted into the joint. To achieve modular calibrated fusion different combinations and permutations of cervical facet stales can be inserted ranging from a single unilateral two pronged staple providing a high degree of flexibility to a total of four bilaterally placed four pronged staples 800 (16 prongs) leading to the highest degree of rigidity. Additional bone may or may not be placed in its vicinity to facilitate permanent and solid fusion. This procedure can be performed open, closed, percutaneously, tubulary, endoscopically or microscopically. FIGS. 11A-C illustrates placement of the staples 700, 800 in the cervical spine.

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

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

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

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

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

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

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

BACKGROUND OF THE INVENTION

FIELD OF INVENTION

~~**Field of Invention**~~

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

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

DESCRIPTION OF THE RELEVANT ART

~~**Description of the Relevant Art**~~

[0004] The history and evolution of instrumented spinal fusion in the entire human spine has been reviewed in our two prior copending applications Serial No. 11/536,815, filed on September, 29, 2006, and Serial No. 11/208,644, filed on August 23, 2005, the related contents of which are hereby incorporated by reference. Currently the majority of posterior cervical and almost all anterior and posterior lumbosacral and thoracic fusion techniques are typically supplemented with pedicle screw placement. Complications of pedicle screw placement in cervical, thoracic and lumbar spine include duration of procedure, significant tissue dissection and muscle retraction, misplaced screws with neural and/or vascular injury, excessive blood

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loss, need for transfusions, prolonged recovery, incomplete return to work, and excess rigidity leading to adjacent segmental disease requiring further fusions and re-operations. Recent advances in pedicle screw fixation including minimally invasive and image-guided technology, and the development of flexible rods, imperfectly address some but not all of these issues.

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

SUMMARY

~~**Summary**~~

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

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

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

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

[0015] It is believed that BDFT- screw constructs provide as strong or stronger segmental fusion as pedicle screws without the complications arising from pedicle screw placement which include screw misplacement with potential nerve and/or vascular injury, violation of healthy facets, possible pedicle destruction, blood loss, and overly rigid fusions. By placing screws across the intervertebral space from vertebral body to vertebral body, engaging anterior and middle spinal columns, and not the vertebral bodies via the transpediclar route, the

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healthy facet joints, if they exist, are preserved. Because this technique accomplishes both anterior and middle column fusion, without rigidly fixating the posterior column, it in essence creates a flexible fusion. This device therefore is a flexible fusion device because the preserved posterior facet joints retain their function achieving at least a modicum of mobility and hence a less rigid (i.e. a flexible) fusion.

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

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

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

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

[0020] Previous improvements included a novel calibrated lumbar /thoracic facet stapling device which staples the inferior articulating facet of the superior segment to the superior articulating facet of the caudal

vertebral segment unilaterally or bilaterally, which may minimize motion until interbody fusion occurs. In the present patent application we introduce a new design of the staple enhancing its calibrating capability.

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

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

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

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

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

[0026] Implementations of this aspect may include one or more of the following features. For example, the first and second screw members may be medially aligned. At least one of the first and second screw members may be laterally aligned. The first and second screw members are laterally aligned. One of the first and second screw members is laterally aligned and the other

screw member is laterally aligned. The first and second sliding boxes may be substantially triangularly shaped. The triangularly shaped first and second sliding boxes may include a sliding rail and ridged surfaces. The triangularly shaped first and second sliding boxes may include holes for bone grafts. The adjuster may include a screw.

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

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

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

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

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

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

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

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

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

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

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

BRIEF DESCRIPTION OF DRAWINGS

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

~~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 1 D) 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).

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[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-111) 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 51)

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

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

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

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

DETAILED DESCRIPTION OF THE INVENTION

1. THE MEDICAL DEVICE

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

[0061] Figures 1A-D illustrate three-dimensional views of the Lumbar intervertebral expandable screw box 100 with two BDFT screws 101, 102; one lateral and one medially

oriented (Embodiment IA). Figure 1E illustrates a sagittal-oblique view of the lumbar intervertebral expandable screw box 120 with two lateral oriented BDFT screws 121, 122 (Embodiment IB).

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

[0063]Transvertebral screw 101 penetrates the top base 103, and transvertebral screw 102 traverses the bottom base 104 of the screw box 100. The two screws 101, 102 traverse the screw box 100 in opposing directions, bi-directionally (whether they are lateral or medially oriented). The external edges of the triangular bases 103, 104 in contact with vertebral body surfaces include ridges 107. This facilitates the screw box's 100 incorporation into and fusion with the superior and inferior vertebral bodies (Figures 1A-E). Both top and bottom screw box bases 103, 104 are perforated with holes 108 to allow bone placement for fusion. The entire construct, furthermore, is hollow to allow bone filling. Hence this device functions as both an intervertebral bone fusion spacer and bidirectional transvertebral screw fusion device.

[0064] Figures 2A-C illustrate three-dimensional views of the Lumbar intervertebral non-expandable screw box 200 with two BDFT screws 201, 202 (Embodiment II). Screws 201 and 202 perforate and orient in opposing, superior and inferior directions. There are holes 208 and

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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).

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

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

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

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

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

[0072] Figures 5H-1 illustrate three-dimensional views of a positioning tool 500a for impaction and placement of two transvertebral screws 201, 202 in the non- expandable screw box 200. The

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driver assembly 550 consists of a screw driver 551, a flexible shaft 552 and a square recess bit 553. This facilitates turning the screws 201, 202 into the bone. The flexible shaft 552 facilitates the avoidance of spinous processes which might hinder the screw driving if the shaft 552 were straight. The positioning tool 500a can have a rectangular handle, Embodiment I (FigureSH), or a circular handle, Embodiment II (Figure 51). This serves to

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

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

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

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

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

[0077] Figures 9 A-B illustrate a three-dimensional view of the two-pronged cervical staple impactor 900. It has a handle 901, a stem 902, and a screw insert 903 which can be screwed into the threaded staple insert. The impactor has two wings 904 which keep the staple base edges in place facilitating staple impaction. The handle 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 11 B illustrates a three-dimensional view of placement of the four pronged cervical facet staple 800 into a cervical spine pre and post impaction.

[0081] Figure 11C illustrates the concept of modularity and incremental diminution of movement of the joint by the modular placement of different combinations and permutations of varying numbers of two and four pronged cervical facet staples 700, 800. If one wishes to have the most flexible (least rigid) fusion, one would place a unilateral two pronged staple 700. One can increase i.e. calibrate increasing degrees of rigidity by increasing the number of prongs penetrating the facet joints bilaterally. In Figure 11C each facet joint is fused using a total number of six prongs. One side this is accomplished by using three two pronged staples 700, and on the other side using one four pronged staple 800 and one two pronged staple 700. These two embodiments can be mixed and matched unilaterally or bilaterally to vary the degree of rigidity

and conversely flexibility of fusion. The most flexible fusion at one level would be accomplished by one staple 700 (2 prongs). The highest level of rigidity would be achieved by placing two four pronged staples 800 on both sides totaling sixteen prongs. Intermediate degrees of relative joint motion can be modulated by insertion into the cervical facet joints staples in two-four prong increments from 216. Each additional prong further limits the degree of facet joint motion hence increasing rigidity, and conversely decreasing flexibility. Thus the novel modular use of these embodiments heralds an era of flexible cervical spine fusion.

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

2. THE SURGICAL METHOD

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

[0084] The posterior lumbar spine implantation of all the screw box 100, 200, 300 embodiments, with BDFT screws, and horizontal mini-plate 400 can be implanted via previously described posterior lumbar interbody fusion (PLIF) or posterior transforaminal lumbar

interbody fusion (TLIF) procedures. The procedures can be performed open, microscopic, closed tubular or endoscopic. Fluoroscopic guidance can be used with any of these procedures.

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

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

[0087]Then one screw box 100, 200, 300 of either embodiments I-III is placed on either right, left or both sides. Then another screw box of embodiments 100, 200, 300 I-III is placed on the contralateral side. For embodiment I the external screw guide 505/ box expander is attached to the screw box (Figures 5A-H). First the Allen key 501 is screwed until the box conforms perfectly to the height and depth of the space. Then a pilot hole can be drilled or an awl can start a pilot hole in the vertebral bodies. Then a transvertebral screw is screwed into the vertebral body via the built- in box screw guides 505. For difficult angles, an angled screw driver can be employed.

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

[0089]If bilateral constructs have been inserted, bone is packed into the intervertebral space, as well as within the device. Then the horizontal intervertebral zero profile mini-plate 400 is slid beneath the thecal sac and is secured to both left and right screw boxes with

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small mini-plate screws 210 (Figures 4A-B). This prevents bone intrusion into the thecal sac and hence possible nerve root compression.

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

[0091] The anterior thoracic and lumbar spine implantation of one, two or three screw box constructs 100, 200, 300 and BDFT screws can be performed in a similar manner to the posterior application. Likewise, a horizontal mini-plate 400 can be used to cap two or three screw box constructs 100, 200, 300 (one placed midline deeply, one placed left and one placed right, forming a triangulation). Alternatively two screw box constructs may be placed into a circumferential ring for anterior placement. Anterior placement of these devices can be performed into the L4/5 and L5/S1 spaces on the supine anesthetized patient via previously described open microscopic or endoscopic techniques. Once the disc space is exposed and discectomy and space preparation are performed, placement of one, two or three screw box embodiments 100, 200, 300 (I-111) or a 2 in I construct can be placed. The screw placement is facilitated by the internal screw guides, and different positioning tools ((Figure 5). A right angled screw driver and/or ratchet could alternatively be employed A capping mini-plate 400 may be applied if desirable. The mechanism of screw placement and mini-plate 400 attachment are identical to what was described above.

[0092] The posterior placement of screw box constructs 100, 200, 300 alone or combined with horizontal mini-plates 400 into the thoracic spine can be performed via previously described transpedicular approaches; open or endoscopic. The anterior placement into the thoracic spine can be accomplished via a trans-thoracic approach. Once the disc space is exposed via either approach, any combination of the

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above mention Embodiments (I-111) can be inserted. Engagement of the devices is identical to what was mentioned above.

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

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

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

[0096] The speed and simplicity of placement of cervical and lumbar facet staples, and placement of Lumbar screw box —BDFT constructs far exceeds that of current pedicle screw technology. Furthermore, these

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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

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 13/084,543

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	82		N/A	
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	270		N/A	
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	110		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	51 minus 20 =	* 31	x 26 =	806	OR		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	5 minus 3 =	* 2	x 110 =	220			
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $270 ($135 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			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	1488		TOTAL	

APPLICATION AS AMENDED - PART II

		(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($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT A	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	

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE($)	ADDITIONAL FEE($)	OR	RATE($)	ADDITIONAL FEE($)
AMENDMENT B	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".

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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**

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Domestic Priority data as claimed by applicant

This application is a DIV of 11/842,855 08/21/2007 PAT 7,942,903
which is a CIP of 11/536,815 09/29/2006 PAT 7,846,188
which is a CIP of 11/208,644 08/23/2005 PAT 7,704,279
which claims benefit of 60/670,231 04/12/2005

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

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The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 13/084,543**

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** **SMALL ENTITY** **

Title

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

Preliminary Class

606

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

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

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

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

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

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

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

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

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

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

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United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
13/084,543	04/11/2011	Ahmnon D. MOSKOWITZ	3003/0105PUS2

CONFIRMATION NO. 1305

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

PUBLICATION NOTICE

OC000000051241851

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

Publication No.US-2011-0295327-A1
Publication Date:12/01/2011

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 Office of Public Records. The Office of Public Records can be reached by telephone at (703) 308-9726 or (800) 972-6382, by facsimile at (703) 305-8759, by mail addressed to the United States Patent and Trademark Office, Office of Public Records, 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 http://pair.uspto.gov/. 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

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/084,543	04/11/2011	Ahmnon D. MOSKOWITZ	3003/0105PUS2	1305

87409 7590 12/19/2011

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

EXAMINER
PHILOGENE, PEDRO

ART UNIT	PAPER NUMBER
3733	

NOTIFICATION DATE	DELIVERY MODE
12/19/2011	ELECTRONIC

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

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

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@dreschiplaw.com
jdresch@dreschiplaw.com
john_dresch@hotmail.com

Office Action Summary	Application No.	Applicant(s)	
	13/084,543	MOSKOWITZ ET AL.	
	Examiner	Art Unit	
	PEDRO PHILOGENE	3733	

-- 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* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 April 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *26-76* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *26-76* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

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) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

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 obviousness-type 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); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 26-76 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 26-93 of copending Application No. 13/108,982. Although the conflicting claims are not identical, they are not patentably distinct from each other because it is clear that all the elements of claims of the copending application are to be found in claims of the application. The difference between claims of the application and claims of the copending application lies in the fact that the application claims include many more elements and are thus much more specific. Thus the invention of claims of the application is in effect a "species" of the "generic" invention of claims of the copending application. It has been held that the generic invention is "anticipated" by the "species". See in re Goodman, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claims of the copending application are anticipated by claims of the application, they are not patentably distinct.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 66-69, 76 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the

invention. Applicant fails to teach the wall having four quadrants delineated by a first axis and second axis each lying in a plane of the wall, and the first axis is at a right angle with respect to the second axis, wherein the four quadrants includes a first quadrant, a second quadrant, a third quadrant, and a fourth quadrant, wherein the first quadrant and the fourth quadrant are opposed to the second quadrant and the third quadrant with respect to the first axis, and the first quadrant and the second quadrant are opposed to the third quadrant and the fourth quadrant with respect to the second axis, wherein the first quadrant is diagonally opposed to the third quadrant, and the second quadrant is diagonally opposed to the fourth quadrant. Therefore, the claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 26, 32-35, 38, 39, 41-48, 56-76 are rejected under 35 U.S.C. 102(e) as being anticipated by Michelson (7,442,209).

Michelson discloses a tool (172) for manipulating and inserting a universal, intervertebral combination bone fusion spacer and self-drilling screw apparatus into a disc space between a first vertebral body and a second vertebral body to provide fusion of the first vertebral body to the second vertebral body via biological bone fusion and a screw fusion; as best seen in FIGS.5, 6, wherein the apparatus includes an intervertebral cage (100) having a fist integral screw guide (126) having a first predetermined angle; as best seen in FIGS.1-11, and a second integral screw guide (126) having a second predetermined angle, wherein the each longitudinal end of the intervertebral cage includes a lot or indentation formed adjacent to an edge of an upper surface of the intervertebral cage; as set forth in column 9, lines 32-56; the tool comprising a handle (155); and a gripper (178) cooperating with the handle and having a plurality of prongs (174) wherein a distal end of each of the plurality of prongs engages a respective slot or indentation of the intervertebral cage (100). A first screw member (128) disposed in the first integral screw guide at the first predetermined angle and at least partially within the intervertebral cage; as best seen in FIG.8; a second screw member (128) disposed in the second integral screw guide at the second predetermined angle and at least partially within the intervertebral cage, as best seen in FIG.8; the intervertebral cage includes (as understood) a wall having an entry opening of the first integral screw guide and an entry opening of the second integral screw guide; as best seen in FIG.8; the wall having four quadrants delineated by a first axis and second axis each lying in a plane of the wall, and the first axis is at a right angle with respect to the second axis, wherein the four quadrants includes a first quadrant, a

second quadrant, a third quadrant, and a fourth quadrant, wherein the first quadrant and the fourth quadrant are opposed to the second quadrant and the third quadrant with respect to the first axis, and the first quadrant and the second quadrant are opposed to the third quadrant and the fourth quadrant with respect to the second axis, wherein the first quadrant is diagonally opposed to the third quadrant, and the second quadrant is diagonally opposed to the fourth quadrant; as best seen in FIG.8, and wherein one of a majority of an area of the entry opening of the first integral screw guide is in the first quadrant and a majority of an area of the entry opening of the second integral screw guide is in the third quadrant; and the majority of the area of the entry opening of the first integral screw guide is in the second quadrant and the majority of the area of the entry opening of the second integral screw guide is in the fourth quadrant (if a Cartesian coordinate system is drawn in the center of FIG.8). A key (154) that controls an adjustment device which controls a height of the universal intervertebral combination bone fusion spacer and the self-drilling screw apparatus.

With respect to the method claims, the method steps, as set forth would have been inherently carried out in the operation of the device, as set forth above and as best seen in FIGS.1-11

Claim Rejections - 35 USC § 103

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

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

Claims 40, 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson (7,442,209).It is noted that Michelson discloses a driver assembly including a driver handle, a drive bit portion and a drive shaft (184)as claimed by applicant. However, it is also noted that Michelson does not teach of a flexible drive shaft, as claimed by applicant. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a preferred material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the the wall having four quadrants delineated by a first axis and second axis each lying in a plane of the wall, and the first axis is at a right angle with respect to the second axis, wherein the four quadrants includes a first quadrant, a second quadrant, a third quadrant, and a fourth quadrant, wherein the first quadrant and the fourth quadrant are opposed to the second quadrant and the third quadrant with respect to the first axis, and the first quadrant and the second quadrant are opposed to the third quadrant and the fourth quadrant with respect to the second axis, wherein the first quadrant is diagonally opposed to the third quadrant, and the second quadrant is diagonally opposed to the fourth quadrant must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Conclusion

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

6,972,019	12-2005	Michelson
7,959,675	6-2011	Gately
7,887,591	2-2011	Aebi et al.
7,862,616	1-2011	Lechmann et al
7,618,456	11-2009	Mathieu et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PEDRO PHILOGENE whose telephone number is (571)272-4716. The examiner can normally be reached on Monday to Friday 8:00 AM to 4:30 PM.

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

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

/Pedro Philogene/
Primary Examiner, Art Unit 3733
December 13, 2011

Notice of References Cited	Application/Control No. 13/084,543	Applicant(s)/Patent Under Reexamination MOSKOWITZ ET AL.	
	Examiner PEDRO PHILOGENE	Art Unit 3733	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-7,618,456	11-2009	Mathieu et al.	623/17.11
*	B	US-7,862,616	01-2011	Lechmann et al.	623/17.11
*	C	US-7,887,591	02-2011	Aebi et al.	623/17.15
*	D	US-7,959,675	06-2011	Gately, Nicholas V.	623/17.11
*	E	US-6,972,019	12-2005	Michelson, Gary K.	606/86A
*	F	US-7,442,209	10-2008	Michelson, Gary K.	623/17.11
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

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BIB DATA SHEET

CONFIRMATION NO. 1305

SERIAL NUMBER	FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
13/084,543	04/11/2011 RULE	606	3733	3003/0105PUS2

APPLICANTS

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 DIV of 11/842,855 08/21/2007 PAT 7,942,903
which is a CIP of 11/536,815 09/29/2006 PAT 7,846,188
which is a CIP of 11/208,644 08/23/2005 PAT 7,704,279
which claims benefit of 60/670,231 04/12/2005

**** FOREIGN APPLICATIONS ***************************

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED **** ** SMALL ENTITY **
04/20/2011

Foreign Priority claimed	☐ Yes ☑ No	☐ Met after Allowance	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
35 USC 119(a-d) conditions met	☐ Yes ☑ No		MD	38	51	5
Verified and Acknowledged	/PEDRO PHILOGENE/ Examiner's Signature	Initials				

ADDRESS

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

TITLE

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

FILING FEE RECEIVED		
1598	FEES: Authority has been given in Paper No._____ to charge/credit DEPOSIT ACCOUNT No._____ for following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13084543	MOSKOWITZ ET AL.
	Examiner	Art Unit
	PEDRO PHILOGENE	3733

SEARCHED

Class	Subclass	Date	Examiner
606	86A, 251, 246, 301, 247, 250, 252, 99, 248, 279	12/13/11	/P.P./
623	17.11, 17.15, 17.16		

SEARCH NOTES

Search Notes	Date	Examiner
EAST search enclosed	12/13/11	/P.P./

INTERFERENCE SEARCH

Class	Subclass	Date	Examiner

	/PEDRO PHILOGENE/ Primary Examiner.Art Unit 3733

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13084543	MOSKOWITZ ET AL.
	Examiner	Art Unit
	PEDRO PHILOGENE	3733

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

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

CLAIM		DATE								
Final	Original	12/13/2011								
	1	-								
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	36	✓								

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13084543	MOSKOWITZ ET AL.
	Examiner	Art Unit
	PEDRO PHILOGENE	3733

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

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

CLAIM		DATE								
Final	Original	12/13/2011								
	37	✓								
	38	✓								
	39	✓								
	40	✓								
	41	✓								
	42	✓								
	43	✓								
	44	✓								
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Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13084543	MOSKOWITZ ET AL.
	Examiner	Art Unit
	PEDRO PHILOGENE	3733

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

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

CLAIM		DATE								
Final	Original	12/13/2011								
	73	✓								
	74	✓								
	75	✓								
	76	✓								

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	12	moskowitz near ahmnon.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2011/12/13 10:46
L2	2	moskowitz near ahmnon.in. & tool & bone near fusion near spacer & screw & intervertebral near cage & screw near guide & angle & (slot or indentation) & handle & gripper & prongs	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2011/12/13 11:02
L3	2	tool & bone near fusion near spacer & screw & intervertebral near cage & screw near guide & angle & (slot or indentation) & handle & gripper & prongs	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2011/12/13 11:03
L4	584	606/86A	USPAT	OR	OFF	2011/12/13 11:04
L5	73	606/251	USPAT	OR	OFF	2011/12/13 11:22
L6	792	606/246	USPAT	OR	OFF	2011/12/13 11:24
L7	236	606/301	USPAT	OR	OFF	2011/12/13 11:33
L8	281	606/247	USPAT	OR	OFF	2011/12/13 11:35
L9	267	606/250	USPAT	OR	OFF	2011/12/13 11:40
L10	120	606/252	USPAT	OR	OFF	2011/12/13 11:43
L11	1770	606/99	USPAT	OR	OFF	2011/12/13 11:45

L12	267	606/248	USPAT	OR	OFF	2011/12/13 12:13
L13	663	606/279	USPAT	OR	OFF	2011/12/13 12:14
L14	2001	623/17.16	USPAT	OR	OFF	2011/12/13 12:20
L15	138	("20010001129" | "20010005796" | "20010010021" | "20010016777" | "20010031254" | "20010039456" | "20010041941" | "20020010511" | "20020022843" | "20020029084" | "20020082597" | "20020091447" | "20020099376" | "20020106393" | "20020111680" | "20020147450" | "20020169508" | "20030125739" | "20040210314" | "20050033433" | "2621145" | "4135506" | "4501269" | "4512038" | "4627853" | "4678470" | "4717115" | "4858603" | "4904261" | "4936851" | "4950296" | "4961740" | "4994084" | "5026373" | "5053049" | "5062850" | "5084051" | "5112354" | "5192327" | "5211664" | "5281226" | "5284655" | "5298254" | "5314476" | "5348788" | "5405391" | "5423817" |	US-PGPUB; USPAT; USOCR	OR	OFF	2011/12/13 12:34

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L16	1338	623/17.15	US-PGPUB; USPAT	OR	OFF	2011/12/13 12:49
L17	3159	623/17.11	US-PGPUB; USPAT	OR	OFF	2011/12/13 12:56

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

Courtesy Reminder for
Application Serial No: 13/084,543

Attorney Docket No: 3003/0105PUS2
Customer Number: 87409
Date of Electronic Notification: 12/19/2011

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

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

mailroom@dreschiplaw.com
jdresch@dreschiplaw.com
john_dresch@hotmail.com

Please verify that these email addresses are correct.

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

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/084,543	04/11/2011	Ahmnon D. MOSKOWITZ	3003/0105PUS2	1305

87409 7590 03/19/2012

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

EXAMINER	
PHILOGENE, PEDRO	
ART UNIT	PAPER NUMBER
3733	

NOTIFICATION DATE	DELIVERY MODE
03/19/2012	ELECTRONIC

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

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

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@dreschiplaw.com
jdresch@dreschiplaw.com
john_dresch@hotmail.com

Applicant-Initiated Interview Summary	Application No.	Applicant(s)	
	13/084,543	MOSKOWITZ ET AL.	
	Examiner	Art Unit	
	PEDRO PHILOGENE	3733	

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

(1) *PEDRO PHILOGENE*.

(2) *John J Dresch*.

(3) *Nathan C. Moskowitz*.

(4) *Mosheh T. Moskowitz*.

Date of Interview: *12 March 2012*.

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

Exhibit shown or demonstration conducted: ☒ Yes ☐ No.
If Yes, brief description: *Applicant demonstrated how the device works*.

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: *26*.

Identification of prior art discussed: *Michelson (7,442,209)*.

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...)

Applicant's arguments seem to overcome the rejection over Michelson, since Michelson does not teach, wherein a distal end of each of the plurality of prongs engages a respective slot or indentation of the intervertebral cage. The examiner agrees with applicant. Also, applicant must amend the specification and drawings to show the quadrants as claimed. In addition, the dependent claims with a claimed key that controls an adjustment device must be corrected since there is no adjustment device in the cage as claimed. Applicant will send in the amendment and the examiner will conduct an update search .

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

/Pedro Philogene/ Primary Examiner, Art Unit 3733	

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.

ATTORNEY DOCKET NO.: 3003/0105PUS2

UNITED STATES PATENT AND TRADEMARK OFFICE

Application Number:	13/084,543
Filing Date:	04/11/2011
Group Art Unit:	3733
Examiner:	PHILOGENE, PEDRO
Confirmation No.:	1305
Title:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION

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

AMENDMENT UNDER 37 C.F.R. § 1.111
AND
STATEMENT OF THE SUBSTANCE OF THE INTERVIEW

Dear Sir:

This Amendment responds to the Office Action dated October December 19, 2011, having a response due date of April 19, 2012, and is accompanied by a fee for one (1) excess independent claim and a one-month extension of time fee.

Please amend the application as follows:

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

Amendments to the Drawings begin on page 5 of this paper;

Amendments to the Claims, as reflected in the listing of claims, begin on page 6 of this paper; and

Remarks begin on page 23 of this paper.

MOSKOWITZ-00002108

AMENDMENTS TO THE SPECIFICATION:

At paragraph [0038], please amend the specification as follows:

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

At paragraph [0040], please amend the specification as follows:

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

After paragraph [0047], please insert the following new paragraph into the specification as follows:

-- FIG. 5J illustrates another superior oblique perspective view of the positioning tool/drill guide/box expander component with gridlines. --

At paragraph [0065], please amend the specification as follows:

FIGS. 2A-2E [[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. As shown in Figures 2A and 2B, each longitudinal end of the screw box 200 can include a slot or indentation 12 formed adjacent to an edge of an upper surface of the screw box 200 for engaging a protuberant extension of a tool (as shown in Figures 5A-5J).

At paragraph [0070], please amend the specification as follows:

The key components of this device include an Allen key 501, a spring 502, a handle 503, a griper 504 and a screw guide 505. The Allen key 501 when inserted in the insertion 514 and turned, turns the screw adjuster (FIG. 5C) which in turn regulates top and bottom triangular screw box base sliding, and hence box 200 width and depth. The griper 504 has griper prongs 506 which insert into grooves of the screw guide 505. The griper prongs 506 include medially oriented male protuberant extensions 506a that engage the slot or indentation 12 of ~~and~~ the screw box 200 (FIGS. 5A-D) thus perfectly aligning them.

At paragraph [0071], please amend the specification as follows:

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

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

[0073] FIGS. 5H-I illustrate three-dimensional views of a positioning tool 500a for impaction and placement of two transvertebral screws 201, 202 in the non-expandable screw box 200. The driver assembly 550 consists of a screw driver 551, a flexible shaft 552 and a square recess bit 553. This facilitates turning the screws 201, 202 into the bone. The flexible shaft 552 facilitates the avoidance of spinous processes which might hinder the screw driving if the shaft 552 were straight. The positioning tool 500a can have a rectangular handle, Embodiment I (FIG. 5H), or a circular handle, Embodiment II (FIG. 5I). This serves to position the screw box within the intervertebral space, and screws 201, 202 within the screw box. Once positioned, the screw box can be impacted by tapping the handle with a mallet (not shown). The positioning tool's 500a griper handle inserts into the screw guide and the box, which maintains alignment.

AMENDMENTS TO THE DRAWINGS:

This Amendment is accompanied by Replacement Drawing Figures 2A, 2B, and 5C (Three (3) Total Replacement Sheets 6/41, 7/41, and 15/41) and New Drawing Figures 2D, 2E, and 5J (Three (3) Total New Sheets 39/41, 40/41, and 41/41).

The Replacement Drawing Sheets add reference numeral 12 and a corresponding lead line identifying the slot on the intervertebral cage (shown in the original drawings) and reference numeral 506a and a corresponding lead line identifying the protuberant extension of the gripper prong 506 of the tool (shown in the original drawings).

The New Drawing Sheets show the quadrants in response to the drawing objections and rejection under 35 U.S.C. § 112, first paragraph.

This Amendment does not add new matter. See, e.g., original Figures 2A-2C and 5A-5I; and paragraphs [0065] and [0069]-[0073].

IN THE CLAIMS:

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

1-25. (Canceled)

26. (Previously presented) A tool for manipulating and inserting a universal, intervertebral combination bone fusion spacer and self-drilling screw apparatus into a disc space between a first vertebral body and a second vertebral body to provide fusion of the first vertebral body to the second vertebral body via biological bone fusion and screw fusion, wherein the apparatus includes an intervertebral cage having a first integral screw guide having a first predetermined angle, and a second integral screw guide having a second predetermined angle, wherein each longitudinal end of the intervertebral cage includes a slot or indentation formed adjacent to an edge of an upper surface of the intervertebral cage,

the tool comprising:

a handle; and

a gripper cooperating with the handle and having a plurality of prongs,

wherein a distal end of each of the plurality of prongs engages a respective slot or indentation of the intervertebral cage.

27. (Previously presented) The tool of claim 26, further comprising:

a screw guide for controlling a direction of self-drilling screws that are inserted into the first integral screw guide and the second integral screw guide,

wherein the plurality of prongs engage and hold the screw guide in place.

28. (Previously presented) The tool of claim 27, wherein the screw guide includes a slot or indentation for receiving one of the plurality of prongs.

MOSKOWITZ-00002113

29. (Previously presented) The tool of claim 27, wherein the screw guide includes slots or indentations on opposing sides for receiving the plurality of prongs.

30. (Previously presented) The tool of claim 27, wherein the screw guide includes an integral trajectory guide that receives and guides one of the self-drilling screws of the universal, intervertebral combination bone fusion spacer and self-drilling screw apparatus.

31-32. (Canceled)

33. (Previously presented) The tool of claim 26, wherein the gripper includes a tubular portion that receives and guides a portion of the handle therein.

34-37. (Canceled)

38. (Previously presented) The tool of claim 32, wherein an end of the handle includes a rectangular handle portion.

39. (Previously presented) The tool of claim 32, wherein an end of the handle includes a circular handle portion.

40. (Previously presented) The tool of claim 26, further comprising:

a driver assembly, the driver assembly including:

a driver handle;

a drive bit portion; and

a flexible drive shaft extending between the driver handle and the drive bit portion for manipulating one of the self-drilling screws of the universal, intervertebral combination bone fusion spacer and self-drilling screw apparatus.

41. (Previously presented) A tool assembly comprising:

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

an intervertebral cage including:

a first integral screw guide having a first predetermined angle;

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

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

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

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

a tool for manipulating and inserting the universal, intervertebral combination bone fusion spacer and self-drilling screw apparatus into the disc space between the first vertebral body and the second vertebral body to provide fusion of the first vertebral body to the second vertebral body via biological bone fusion and screw fusion, the tool comprising:

a handle; and

a gripper cooperating with the handle and having a plurality of prongs,

wherein a distal end of each of the plurality of prongs engages a respective slot or indentation of the intervertebral cage.

42. (Previously presented) The tool assembly of claim 41, further comprising:

a screw guide for controlling a direction of the first screw member and the second screw member that are inserted into the first integral screw guide and the second integral screw guide,

wherein the plurality of prongs engage and hold the screw guide in place.

43. (Previously presented) The tool assembly of claim 42, wherein the screw guide includes a slot or indentation for receiving one of the plurality of prongs.

44. (Previously presented) The tool assembly of claim 42, wherein the screw guide includes slots or indentations on opposing sides for receiving the plurality of prongs.

45. (Previously presented) The tool assembly of claim 42, wherein the screw guide includes an integral trajectory guide that receives and guides one of the first screw member and the second screw member of the universal, intervertebral combination bone fusion spacer and self-drilling screw apparatus.

46-47. (Canceled)

48. (Previously presented) The tool assembly of claim 41, wherein the gripper includes a tubular portion that receives and guides a portion of the handle therein.

49-52. (Canceled)

53. (Previously presented) The tool assembly of claim 47, wherein an end of the handle includes a rectangular handle portion.

54. (Previously presented) The tool assembly of claim 47, wherein an end of the handle includes a circular handle portion.

55. (Previously presented) The tool assembly of claim 41, further comprising:

a driver assembly, the driver assembly including:

a driver handle;

a drive bit portion; and

a flexible drive shaft extending between the driver handle and the drive bit portion and manipulating one of the first screw member and the second screw member of the universal, intervertebral combination bone fusion spacer and self-drilling screw apparatus.

56. (Previously presented) The tool assembly of claim 41, wherein each of the first internal screw guide and the second internal screw guide is angled to orient the first screw member and the second screw bi-directionally in opposite directions.

57. (Previously presented) The tool assembly of claim 41, wherein the first screw member is a self-tapping and self-drilling screw member having a tapered end and a threaded body, and

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

58. (Previously presented) The tool assembly of claim 41, further comprising:

a bone graft cavity for receiving bone packing material for bone fusion between the first vertebral body and the second vertebral body.

59. (Previously presented) The tool assembly of claim 41, wherein the intervertebral cage includes a side having a plurality of ridges.

60. (Previously presented) The tool assembly of claim 41, wherein the first integral screw guide and the second integral screw guide are adjacent to each other and at

an angulation with respect to a wall having the first integral screw guide and the second integral screw guide.

61. (Previously presented) The tool assembly of claim 60, wherein a first angulation of the first integral screw guide is opposed to a second angulation of the second integral screw guide.

62. (Previously presented) The tool assembly of claim 41, wherein the first integral screw guide and the second integral screw guide are adjacent to each other along a longitudinal extent of a wall having the first integral screw guide and the second integral screw guide, and

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

63. (Previously presented) The tool assembly of claim 62, wherein a part of the first integral screw guide overlaps a part of the second integral screw guide along the longitudinal extent of the wall having the first integral screw guide and the second integral screw guide.

64. (Previously presented) The tool assembly of claim 62, wherein the first integral screw guide and the second integral screw guide are at an angulation with respect to the wall having the first integral screw guide and the second integral screw guide.

65. (Previously presented) The tool assembly of claim 64, wherein a first angulation of the first integral screw guide extends in a first direction from the wall having the first integral screw guide and the second integral screw guide toward a first side of the intervertebral cage,

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

wherein the first side is opposed to the second side.

66. (Previously presented) The tool of claim 26, wherein the intervertebral cage includes a wall having an entry opening of the first integral screw guide and an entry opening of the second integral screw guide,

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

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

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

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

wherein one of:

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

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

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67. (Previously presented) The tool of claim 26, wherein the intervertebral cage includes a wall having an entry opening of the first integral screw guide and an entry opening of the second integral screw guide,

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

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

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

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

wherein one of:

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

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

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

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

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

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

70. (Previously presented) The tool of claim 26, wherein the intervertebral cage includes an arcuate wall.

71. (Previously presented) The tool assembly of claim 41, wherein the first integral screw guide and the second integral screw guide are at an angulation with respect to a wall having the first integral screw guide and the second integral screw guide.

72. (Previously presented) The tool assembly of claim 41, wherein the first integral screw guide and the second integral screw guide diverge from each other.

73. (Previously presented) The tool assembly of claim 41, wherein the first integral screw guide and the second integral screw guide diverge from each other and at an angulation with respect to a wall having the first integral screw guide and the second integral screw guide.

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74. (Currently amended) A method of inserting a universal, intervertebral combination bone fusion spacer and self-drilling screw apparatus into a disc space between a first vertebral body and a second vertebral body using a tool for manipulating and inserting the universal, intervertebral combination bone fusion spacer and self-drilling screw apparatus into the disc space between the first vertebral body and the second vertebral body,

wherein the universal, intervertebral combination bone fusion spacer and self-drilling screw apparatus includes:

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

wherein the tool includes:

a handle; and

a gripper cooperating with the handle and having a plurality of prongs,

wherein a distal end of each of the plurality of prongs engages a respective slot or indentation of the intervertebral cage,

the method comprising:

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

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

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

engaging each slot or indentation of the intervertebral cage with the distal end of each of the plurality of prongs;

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

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

75. (Currently amended) A method of inserting a universal, intervertebral combination bone fusion spacer and self-drilling screw apparatus into a disc space between a first vertebral body and a second vertebral body and fusing the first vertebral body to the second vertebral body via biological bone fusion and screw fusion using a tool for manipulating and inserting the universal, intervertebral combination bone fusion spacer and self-drilling screw apparatus into the disc space between the first vertebral body and the second vertebral body,

wherein the universal, intervertebral combination bone fusion spacer and self-drilling screw apparatus includes:

an intervertebral cage including:

a first integral screw guide having a first predetermined angle;

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

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

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

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

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wherein the tool includes:

a handle; and

a gripper cooperating with the handle and having a plurality of prongs,

wherein a distal end of each of the plurality of prongs engages a respective slot or indentation of the intervertebral cage,

the method comprising:

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

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

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

engaging each slot or indentation of the intervertebral cage with the distal end of each of the plurality of prongs;

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

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

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

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

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

76. (Previously presented) A tool assembly comprising:

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

an intervertebral cage including:

a first integral screw guide having a first predetermined angle;

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

a bone graft cavity for receiving bone packing material for bone fusion between the first vertebral body and the second vertebral body;

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

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

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

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

wherein each of the first internal screw guide and the second internal screw guide includes a tunnel that permits only a predetermined angled trajectory

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of the first screw member and the second screw member, and the predetermined angled trajectory of the first internal screw guide is different than the predetermined angled trajectory of the second internal screw guide,

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

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

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

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

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

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

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

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

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

wherein one of:

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

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

a tool for manipulating and inserting the universal, intervertebral combination bone fusion spacer and self-drilling screw apparatus into the disc space between the first vertebral body and the second vertebral body to provide fusion of the first vertebral body to the second vertebral body via biological bone fusion and screw fusion, the tool comprising:

a handle; and

a gripper cooperating with the handle and having a plurality of prongs,

wherein a distal end of each of the plurality of prongs engages a respective slot or indentation of the intervertebral cage.

77. (New) A tool assembly comprising:

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

an intervertebral cage including:

a plurality of internalized screw guides, wherein each of the plurality of internalized screw guides includes a proximal screw head recess that is entirely encased within an upper surface of the intervertebral cage, wherein each of the

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plurality of internalized screw guides includes a tunnel-guide that projects into the intervertebral cage from the proximal screw head recess, the tunnel-guide including a proximal tunnel-guide portion that is entirely encased by walls of the intervertebral cage and a distal tunnel-guide portion that is partially encased by the walls of the intervertebral cage, the distal tunnel-guide portion being contiguous with and exiting into a bone cavity of superior and inferior walls of the intervertebral cage, and wherein a surface of each longitudinal wall of the intervertebral cage includes a slot or indentation formed adjacent to an edge of the upper surface of the intervertebral cage; and

a screw member disposed in each of the plurality of internalized screw guides at a predetermined angle and at least partially within the intervertebral cage; and

a tool for manipulating and inserting the universal, intervertebral combination bone fusion spacer and self-drilling screw apparatus into the disc space between the first vertebral body and the second vertebral body to provide fusion of the first vertebral body to the second vertebral body via biological bone fusion and screw fusion, the tool comprising:

a handle; and

a gripper cooperating with the handle and having a plurality of prongs each having a distal end,

wherein the distal end of each of the plurality of prongs respectively engages the slot or indentation of the intervertebral cage on the surface of each longitudinal wall of the intervertebral cage.

78. (New) The tool assembly of claim 77, wherein the distal tunnel-guide portion that is partially encased by the walls of the intervertebral cage is parabola shaped.

79. (New) the tool assembly of claim 78, wherein the screw member extends through one of the plurality of internalized screw guides via the proximal screw head recess that is entirely encased within a top plane of the intervertebral cage, into the

proximal tunnel-guide portion that is entirely encased by the walls of the intervertebral cage, into the parabola shaped distal tunnel-guide portion that is partially encased by the walls of the intervertebral cage, and then exits from the bone cavity of the superior and inferior walls.

80. (New) The tool assembly of claim 58, wherein the bone graft cavity is accessible through an opening formed in a lateral wall of the intervertebral cage, a perimeter of the opening including an indentation through which one of the first screw member and the second screw member passes from the bone graft cavity to an exterior of the intervertebral cage.

81. (New) The tool assembly of claim 77, wherein the bone cavity is accessible through an opening formed in a lateral wall of the intervertebral cage, a perimeter of the opening including an indentation through which the screw member passes from the bone cavity to an exterior of the intervertebral cage.

REMARKS

Claims 26-76 were previously pending in the application. This Amendment amends claims 74 and 75, cancels claims 31, 32, 34-37, 46, 47, and 49-52 without prejudice or disclaimer, and adds new claims 77-81. Claims 26, 41, 74, 75, 76, and 77 are independent.

Statement of the Substance of the Interview

Applicant's representative thanks Examiner Pedro Philogene for the courtesies extended during the personal interview conducted on March 12, 2012, with Applicants' Attorney, John J. Dresch, Reg. No. 46672, and inventors Dr. Nathan C. Moskowitz and Mosheh T. Moskowitz.

An Interview Summary was mailed on March 19, 2012. Applicant submits this Statement to comply with the requirements of M.P.E.P. § 713.04.

In the interview, the following was discussed:

A. Identification of claim discussed:

Claims 26-76

B. Identification of prior art discussed:

Michelson (U.S. Patent No. 7,442,209)

C. Identification of principal proposed amendments:

Applicants' representative discussed clarifications to the specification and drawings to show the claimed quadrants, as explained below. This Amendment encloses New Drawing Sheets and amends the specification.

D. Brief Identification of principal arguments:

The Prior Art Rejections

Applicants argued that Michelson does not teach a tool comprising a gripper cooperating with the handle and having a plurality of prongs, wherein a distal end of each of the plurality of prongs engages a respective slot or indentation of the intervertebral cage, as recited in claim 26.

Michelson does not teach a tool assembly comprising:

> an intervertebral cage [...] wherein a surface of each longitudinal end of the intervertebral cage includes a slot or indentation formed adjacent to an edge of an upper surface of the intervertebral cage for receiving a distal end of a prong of an implantation tool; and
>
> a tool [...] comprising [...] a gripper cooperating with the handle and having a plurality of prongs, wherein a distal end of each of the plurality of prongs engages a respective slot or indentation of the intervertebral cage, as recited in claim 41.

The alleged prongs 174 of Michelson do not engage any slots (openings 118) on the side of the cage 100. Instead, the slots (openings 118) are for bone growth material. See, col. 6, lines 10-18. No part of either of the prongs 174 engages the openings 118 of the implant 100.

Thus, Michelson does not anticipate at least claims 26 and 41.

Instead, Michelson teaches that the driver 172 holds the implant 100 using alignment pegs 154 that engage alignment holes 150, 152 and a threaded driver 155 that engages the threaded hole 153 of the implant.

Contrary to the assertion in the Office Action, Applicants respectfully argued that the alignment pegs 154 are not comparable to the claimed key that controls an adjustment device, as recited in claims 31-35. Applicants respectfully argued that the Office Action

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does not cite any support in the Michelson reference for the screw guide, as recited in claims 27-31.

The Rejection under 35 U.S.C. § 112, first paragraph

Applicants argued that these claims merely characterize the structural elements and spatial relationships of those elements depicted in the original drawings as will be understood by one of ordinary skill in the art. Therefore, these claims are enabled by the original drawings.

The Drawing Objections

Applicants propose to submit new drawings depicting only the original features of the drawings with the quadrants drawn thereon. The proposed Amendment does not add new matter. The proposed drawings are intended merely to describe the structural and spatial relationship of the features illustrated in the original drawings.

E. Results of the Interview:

Applicants gratefully acknowledge the agreement in the Interview Summary that the arguments seem to overcome the rejection over Michelson, since Michelson does not teach, wherein a distal end of each of the plurality of prongs engages a respective slot or indentation of the intervertebral cage and the Examiner's kind indication that the Examiner agrees with Applicant.

Applicants agreed to submit amendments to the specification and drawings to show the quadrants, as claimed. This Amendment encloses Replacement Drawing Sheets and amends the specification to show the quadrants in accordance with the agreement in the Interview.

The Examiner stated that the dependent claims with a claimed key that controls an adjustment device must be corrected since there is no adjustment device in the cage as claimed.

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The Examiner kindly stated that an updated search will be conducted upon receipt of the Amendment.

The Provisional Double Patenting Rejection

Claims 26-76 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 26-93 of copending Application No. 13/108,982.

Since this is a provisional rejection and the claims of the present application or the copending application may be amended during prosecution, which may obviate the double patenting rejection, Applicants respectfully reserve the right to file a Terminal Disclaimer at such time when the conflicting claims have in fact been patented.

The Rejection under 35 U.S.C. § 112, first paragraph

Claims 66-69, 76 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. Applicants respectfully traverse this rejection.

Applicants respectfully submit that these claims merely characterize the structural elements and spatial relationships of those elements depicted in the original drawings as will be understood by one of ordinary skill in the art. Therefore, these claims are enabled by the original drawings. See M.P.E.P. § 2163.02.

This Amendment encloses New Drawing Sheets and correspondingly amends the specification to show the quadrants in accordance with the agreement in the Interview.

Applicants respectfully request withdrawal of this rejection.

The Rejection under 35 U.S.C. § 102

Claims 26, 32-35, 38, 39, 41-48, and 56-76 are rejected under 35 U.S.C. § 102(e) as being anticipated by Michelson (7,442,209).

Applicants respectfully traverse this rejection.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. [...] The

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identical invention must be shown in as complete detail as is contained in the ... claim." M.P.E.P. § 2131.

Applicants respectfully submit that Michelson does not teach a tool comprising "a gripper cooperating with the handle and having a plurality of prongs, wherein a distal end of each of the plurality of prongs engages a respective slot or indentation of the intervertebral cage," as recited in claim 26.

Applicants respectfully submit that Michelson also does not teach a tool assembly comprising:

> an intervertebral cage [...] wherein a surface of each longitudinal end of the intervertebral cage includes a slot or indentation formed adjacent to an edge of an upper surface of the intervertebral cage for receiving a distal end of a prong of an implantation tool; and
>
> a tool [...] comprising [...] a gripper cooperating with the handle and having a plurality of prongs, wherein a distal end of each of the plurality of prongs engages a respective slot or indentation of the intervertebral cage,

as recited in claim 41.

The alleged prongs 174 of Michelson do not engage any slots (openings 118) on the side of the cage 100. Instead, the slots (openings 118) are for bone growth material. See, col. 6, lines 10-18. No part of either of the prongs 174 engages the openings 118 of the implant 100.

Thus, Applicants respectfully submit that Michelson does not anticipate at least claims 26 and 41. Instead, Michelson teaches that the driver 172 holds the implant 100 using alignment pegs 154 that engage alignment holes 150, 152 and a threaded driver 155 that engages the threaded hole 153 of the implant.

Applicants gratefully acknowledge the agreement in the Interview Summary that the arguments seem to overcome the rejection over Michelson, since Michelson does not teach, wherein a distal end of each of the plurality of prongs engages a respective slot or

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indentation of the intervertebral cage and the Examiner's kind indication that the Examiner agrees with Applicant.

Independent claims 74, 75, and 76 recite similar features as claims 26 and 41 and are patentable over Michelson for the same reasons.

Claims 27-39, 42-54, and 56-73 are patentable by virtue of their dependency from claims 26 and 41, as well as for the additional features recited therein.

Applicants respectfully request withdrawal of this rejection.

Additionally, this Amendment amends method claims 74 and 75 to define more clearly the features of the invention.

The Rejection under 35 U.S.C. § 103

Claims 40 and 55 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Michelson. Applicants respectfully traverse this rejection.

Claims 40 and 55 are patentable by virtue of their dependency from claims 26 and 41, as well as for the additional features recited therein.

Moreover, M.P.E.P. § 2144.04 states that, if the applicant has demonstrated the criticality of a specific limitation, it would not be appropriate to rely solely on case law as the rationale to support an obviousness rejection. In the present application, the disclosure explains the criticality of the claimed features. See, e.g., paragraph [0073], lines 4-6. Thus, Applicants respectfully submit that it is not appropriate to rely solely on case law as the rationale to support this rejection

Applicants respectfully request withdrawal of this rejection.

The Drawing Objections

The drawings are objected to as failing to comply with 37 C.F.R. § 1.83(a) as failing to show the wall having four quadrants as claimed.

In accordance with the agreement in the personal interview, this Amendment encloses New Drawing Figures 2D, 2E, and 5J (Three (3) Total New Sheets 39/41, 40/41, and 41/41) depicting only the original features of the drawings with the geometric

quadrants drawn thereon, thereby obviating this objection. This Amendment does not add new matter. See, e.g., original Figures 2A-2C and 5A-5I; and paragraphs [0069]-[0073].

The New Drawing Sheets are intended merely to provide geometric means for referring to the structural and spatial relationship of the features illustrated in the original Figures in response to the drawing objections and rejection under 35 U.S.C. § 112, first paragraph.

The specification correspondingly is amended to reference the Replacement Drawings.

Applicants respectfully request withdrawal of this objection.

The New Claims

This Amendment adds new claims 77-81. This Amendment does not add new matter. See, e.g., Figures 2A-2C; paras. [0065], [0089], and [0090].

None of the applied references discloses or suggests the subject matter defined by claims 77-81 for at least the same reasons as the independent claims above, as well as for the additional features recited therein.

Applicants respectfully request allowance of these claims.

CONCLUSION

In view of the above, entry of the present Amendment and allowance of Claims 26-30, 33, 38-45, 48, and 53-81 are respectfully requested. If the Examiner has any questions regarding this amendment, the Examiner is requested to contact the undersigned. If an extension of time for this paper is required, petition for extension is herewith made. Please charge Deposit Account No. 505364 for any deficiency or overpayment.

Respectfully Submitted,

/ John J. Dresch /
John J. Dresch
Attorney for Applicant(s)
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March 21, 2012

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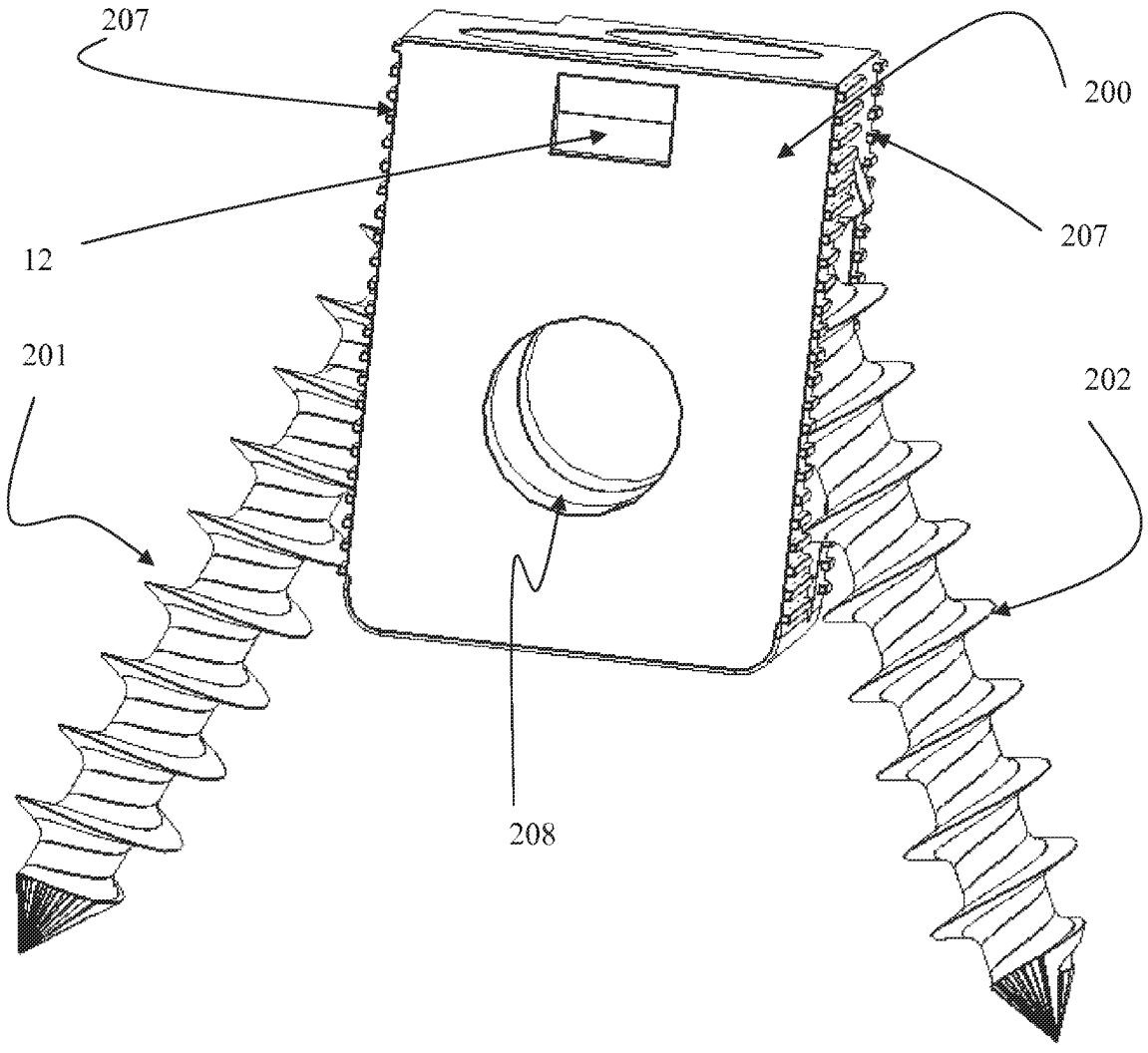


Fig. 2A

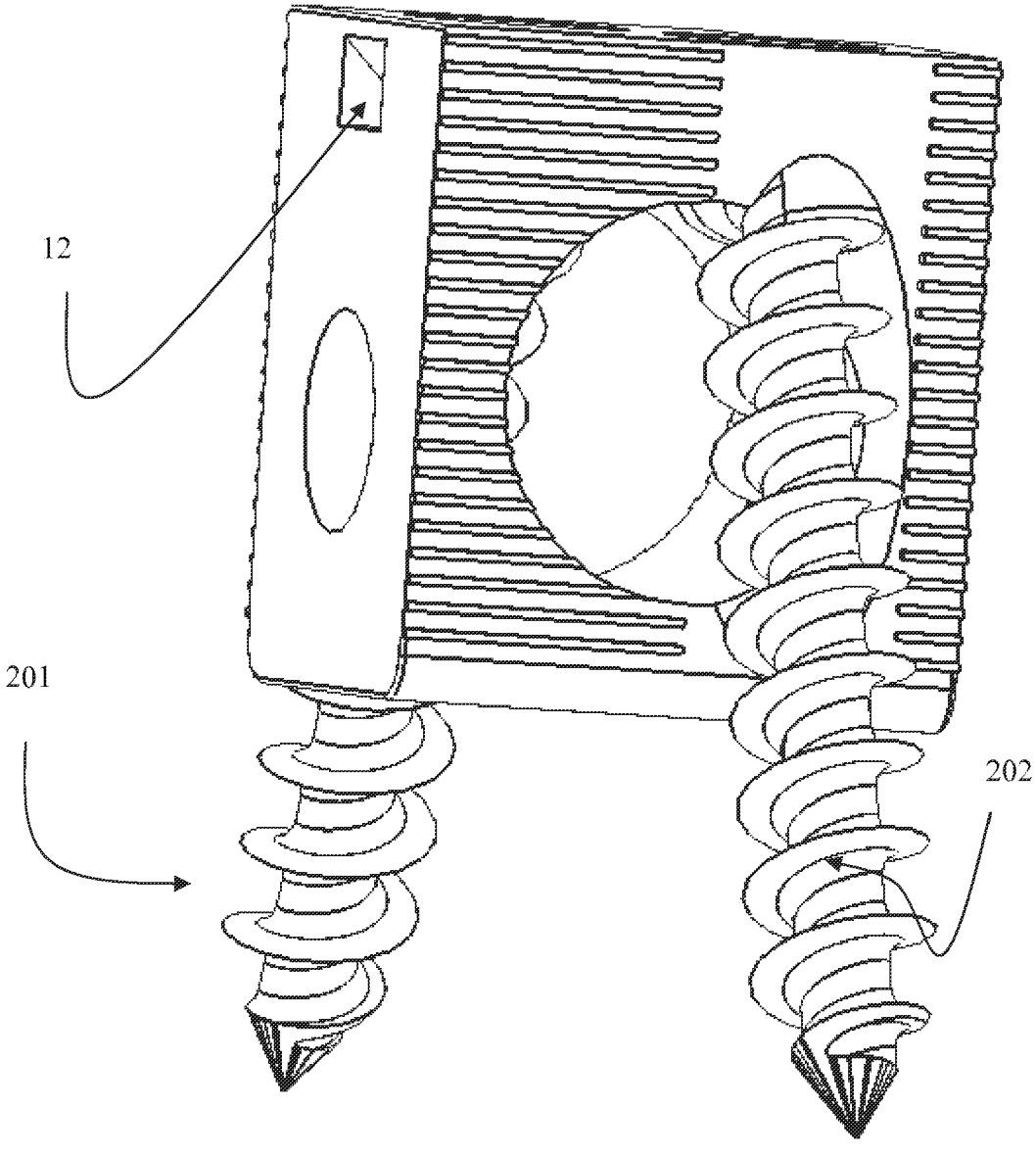


Fig. 2B

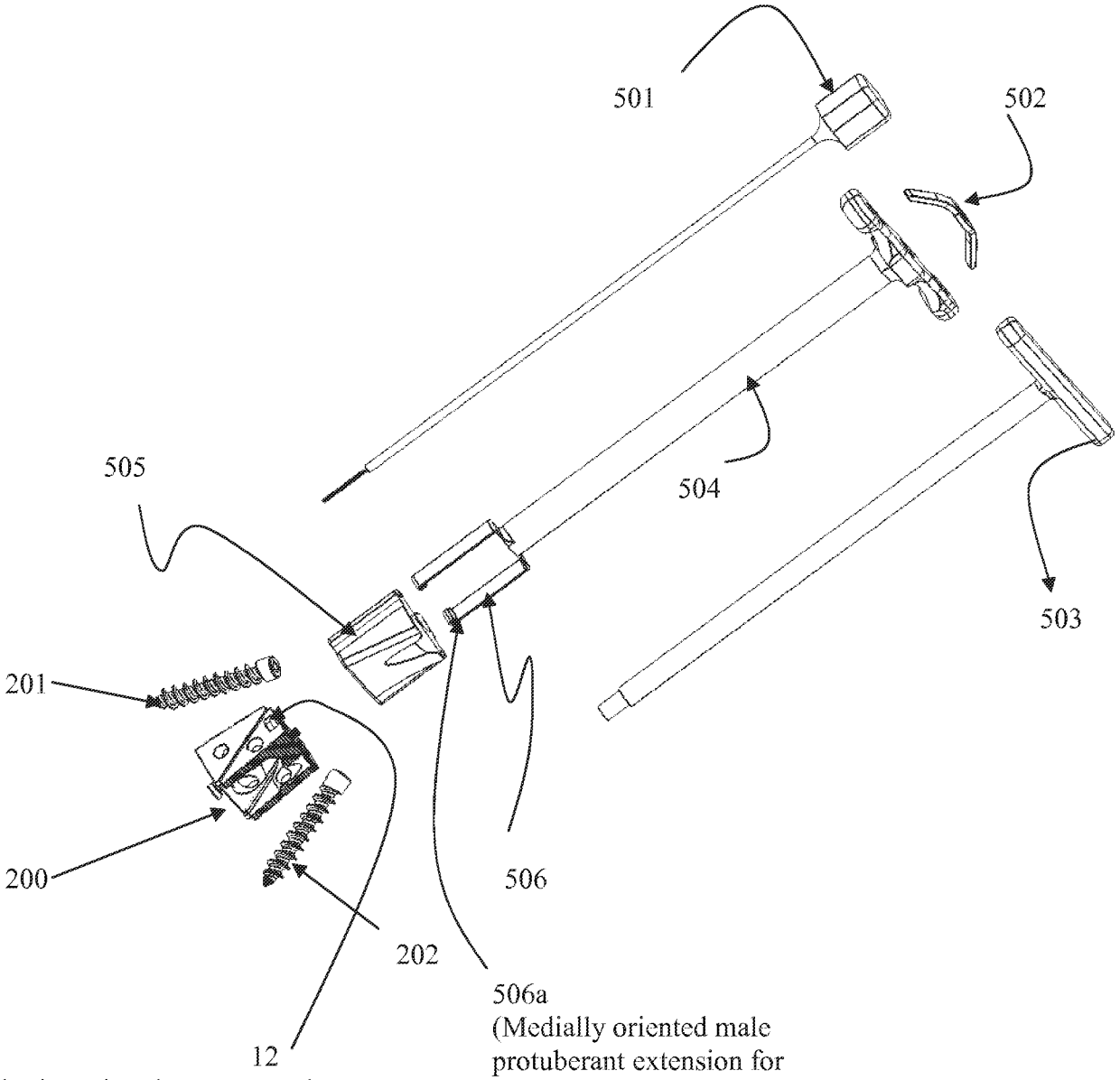

501
502
504
505
503
201
200
506
202
506a
(Medially oriented male protuberant extension for insertion into lateral cage slot.)
12
(Slot insertion that engages the medially oriented male protuberant extension of the lateral gripper prong.)

Fig. 5C

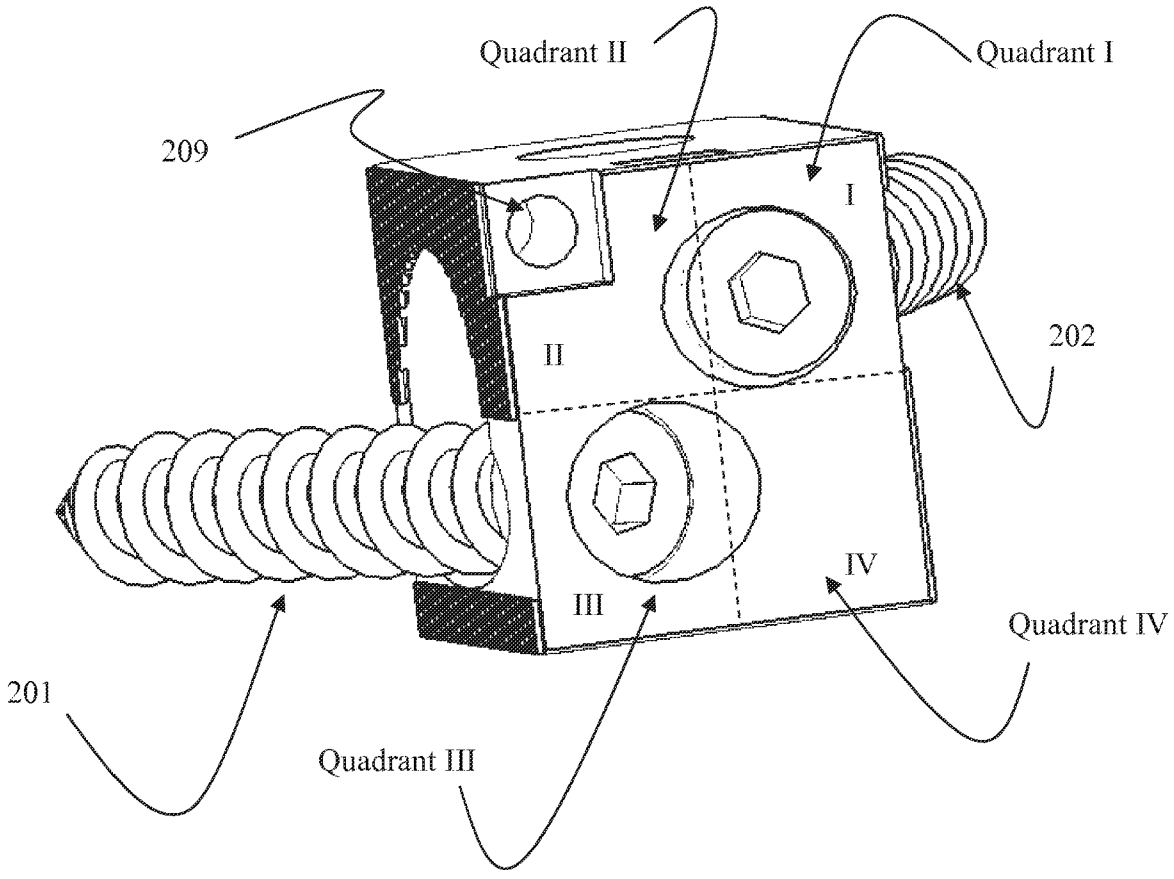

Quadrant II
Quadrant I
209
I
202
II
IV
III
Quadrant IV
201
Quadrant III
200

Fig. 2D

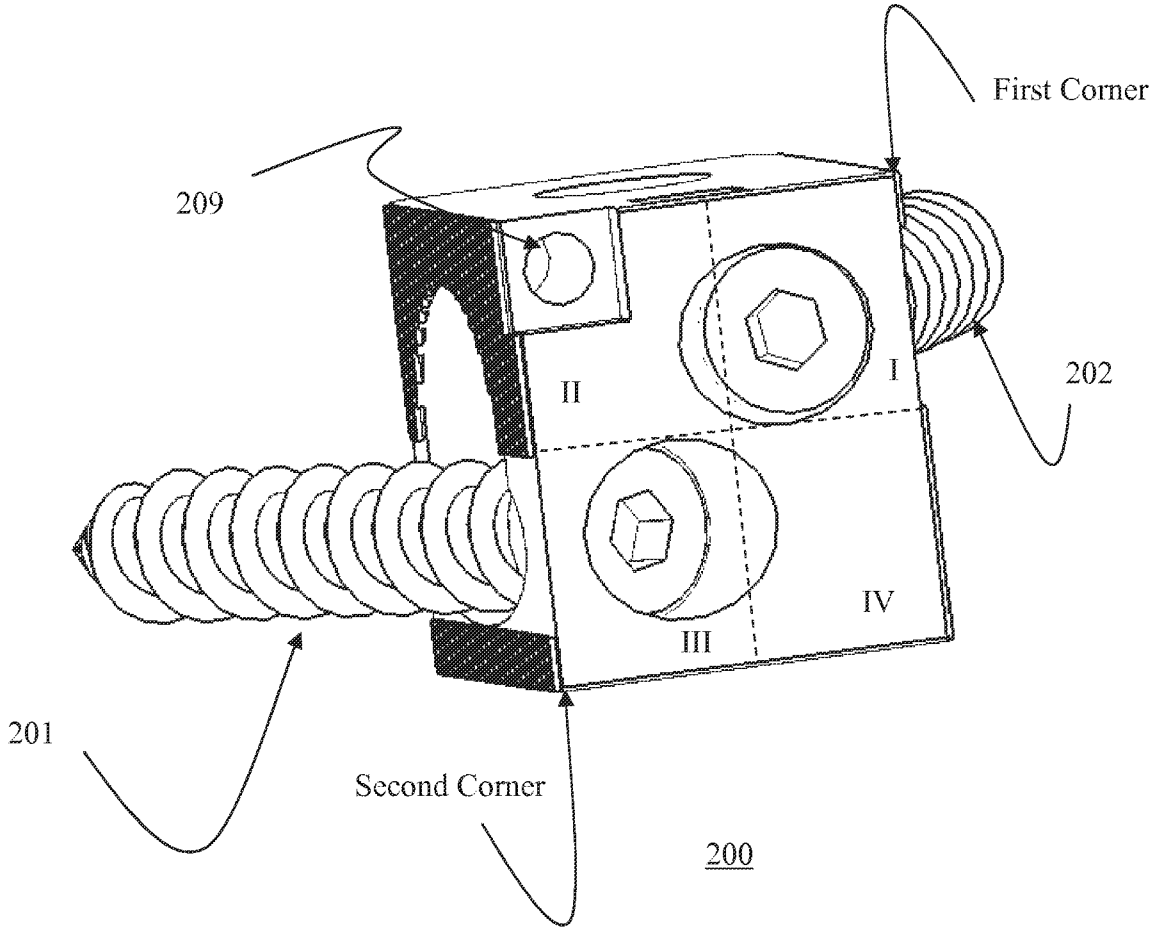


Fig. 2E

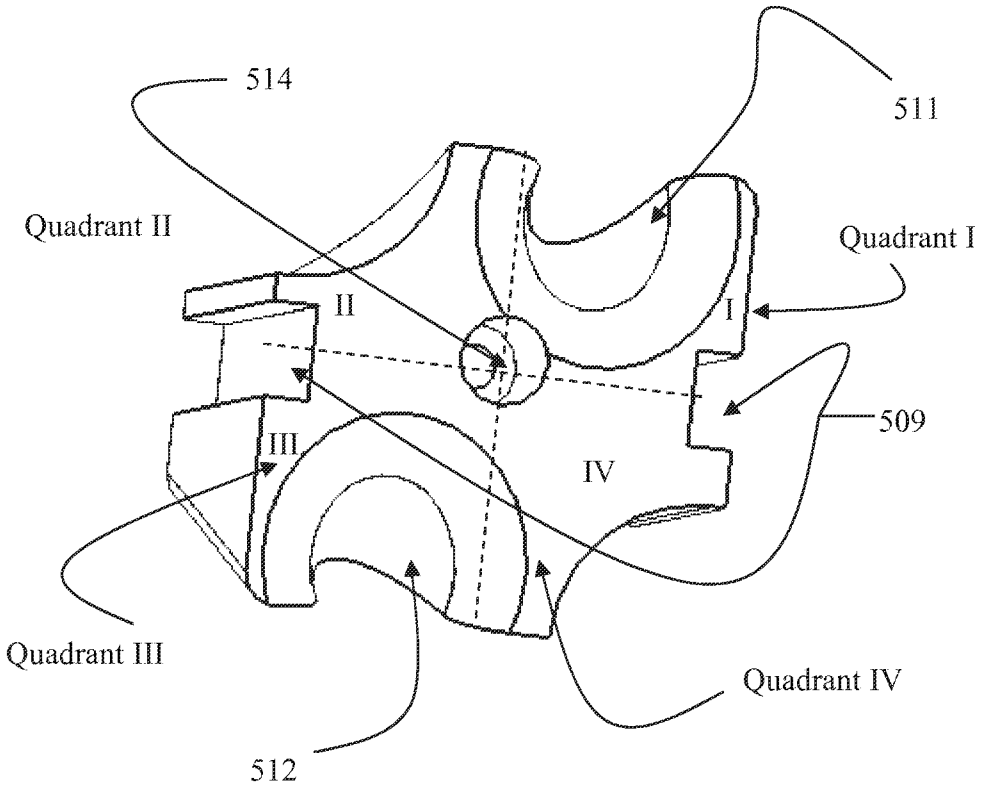

514
511
Quadrant II
Quadrant I
II
I
509
III
IV
Quadrant III
Quadrant IV
512

Fig. 5J

Electronic Patent Application Fee Transmittal

Application Number:	13084543
Filing Date:	11-Apr-2011
Title of Invention:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION
First Named Inventor/Applicant Name:	Ahmnon D. MOSKOWITZ
Filer:	John Jeremy Dresch
Attorney Docket Number:	3003/0105PUS2

Filed as Small Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Independent claims in excess of 3	2201	1	125	125
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension - 1 month with $0 paid	2251	1	75	75
Miscellaneous:				
			Total in USD ($)	**200**

Electronic Acknowledgement Receipt

EFS ID:	12363888
Application Number:	13084543
International Application Number:	
Confirmation Number:	1305
Title of Invention:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION
First Named Inventor/Applicant Name:	Ahmnon D. MOSKOWITZ
Customer Number:	87409
Filer:	John Jeremy Dresch
Filer Authorized By:	
Attorney Docket Number:	3003/0105PUS2
Receipt Date:	21-MAR-2012
Filing Date:	11-APR-2011
Time Stamp:	22:39:54
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$200
RAM confirmation Number	7632
Deposit Account	
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)

1	Amendment/Req. Reconsideration-After Non-Final Reject	30030105PUS2_Amendment_A_v02_readyforfiling.pdf	145382 7266c9cee7248c151b81479af4604af35b6f832e	no	30
Warnings:					
Information:					
2	Drawings-only black and white line drawings	30030105PUS2_Replacement_and_New_Drawing_Sheets_20120319_readyforfiling.pdf	195575 893ecac0792ec2954b39174596d50c0e4bf841f4	no	6
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	32335 4b614abdb46b8a6d2c9c3cd48177f1c5a6b0cd5c	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	373292		

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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.

PTO/SB/06 (07-06)
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PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
13/084,543	04/11/2011	

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			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 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			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT 03/21/2012	(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))	* 44	Minus	** 51	= 0	X $30 =	0	OR	X $ =	
Independent (37 CFR 1.16(h))	* 6	Minus	***5	= 1	X $125 =	125	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	125	OR	TOTAL ADD'L FEE	

AMENDMENT	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)		RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =		OR	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =		OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ 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 number found in the appropriate box in column 1.

Legal Instrument Examiner:
/MARGARET BYARS/

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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PTO/SB/08a (07-05)
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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet	1	of	8

Complete if Known	
Application Number	13/084,543
Filing Date	April 11, 2011
First Named Inventor	MOSKOWITZ et al.
Art Unit	3733
Examiner Name	Unknown
Attorney Docket Number	3003/0105PUS2

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number: Number - Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	AA	US-5,123,926	06-23-1992	Pisharodi	
	AB	US-5,514,180	05-07-1996	Heggeness et al.	
	AC	US-6,368,350	04-09-2002	Erickson et al.	
	AD	US-6,419,704	07-16-2002	Ferree	
	AE	US-6,458,159	10-01-2002	Thalgott	
	AF	US-6,527,804	03-04-2003	Gauchet et al.	
	AG	US-6,533,818	03-18-2003	Weber et al.	
	AH	US-6,579,318	06-17-2003	Varga et al.	
	AI	US-6,582,468	06-24-2003	Gauchet	
	AJ	US-6,719,794	04-13-2004	Gerber	
	AK	US-6,733,532	05-11-2004	Gauchet et al.	
	AL	US-6,764,491	07-20-2004	Frey et al.	
	AM	US-6,770,094	08-03-2004	Fehling et al.	
	AN	US-6,572,653	06-03-2003	Simonson	
	AO	US-5,782,832	07-21-1998	Larsen et al.	
	AP	US-6,641,614	11-04-2003	Wagner et al.	
	AQ	US-6,126,689	10-03-2000	Brett	
	AR	US-6,375,682	04-23-2002	Fleischmann et al.	
	AS	US-6,723,126	04-20-2004	Berry	
	AT	US-2004/0088054	05-06-2004	Berry	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document: Country Code[3] - Number[4] - Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours 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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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 8

Complete if Known	
Application Number	13/084,543
Filing Date	April 11, 2011
First Named Inventor	MOSKOWITZ et al.
Art Unit	3733
Examiner Name	Unknown
Attorney Docket Number	3003/0105PUS2

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	BA	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.	
	BB	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.	
	BC	Richard D. GUYER et al., "Intervertebral Disc Prostheses," SPINE JOURNAL, Volume 28, Number 15S, Supp. To 8/1/03, pages S15-S23.	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[1]Applicant's unique citation designation number (optional). [2]Applicant is to place a check mark here if English language Translation is attached.
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 3 of 8

Complete if Known	
Application Number	13/084,543
Filing Date	April 11, 2011
First Named Inventor	MOSKOWITZ, et al.
Art Unit	3733
Examiner Name	Unknown
Attorney Docket Number	3003/0105PUS2

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number: Number - Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	CA	US-5,960,522	10-05-1999	Boe	
	CB	US-5,660,188	08-26-1997	Groiso	
	CC	US-4,960,420	10-02-1990	Goble et al.	
	CD	US-4,636,217	01-13-1987	Ogilvie et al.	
	CE	US-4,554,914	11-26-1985	Kapp et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document: Country Code[3] - Number[4] - Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

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Sheet	4	of	8

Complete if Known	
Application Number	13/084,543
Filing Date	April 11, 2011
First Named Inventor	MOSKOWITZ et al.
Art Unit	3733
Examiner Name	Unknown
Attorney Docket Number	3003/0105PUS2

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	DA	DIETER GROB et al., "Clinical Experience With the Dynesys Semirigid Fixation System for the Lumbar Spine," SPINE, Vol. 30, No. 3, 2005, pp. 324-331.	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
[1]Applicant's unique citation designation number (optional). [2]Applicant is to place a check mark here if English language Translation is attached.
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet	5	of	8

Complete if Known	
Application Number	13/084,543
Filing Date	April 11, 2011
First Named Inventor	MOSKOWITZ, et al.
Art Unit	3733
Examiner Name	Unknown
Attorney Docket Number	3003/0105PUS2

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number: Number - Kind Code[2] (*if known*)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	EA	US 5667472	09-07-1997	Finn et al.	
	EB	US 6955671	10-18-2005	Uchikubo	
	EC	US 7037258	05-02-2006	Chatenever et al.	
	ED	US 6904308	06-07-2005	Frisch et al.	
	EE	US 7097615	08-29-2006	Banik et al.	
	EF	US 7030904	04-18-2006	Adair et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document: Country Code[3] - Number[4] - Kind Code[5] (*if known*)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

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PTO/SB/08a (07-05)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet	6	of	8

Complete if Known	
Application Number	13/084,543
Filing Date	April 11, 2011
First Named Inventor	MOSKOWITZ, et al.
Art Unit	3733
Examiner Name	Unknown
Attorney Docket Number	3003/0105PUS2

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number: Number - Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	FA	US 20050273170	12-08-2005	Navarro et al.	
	FB	US 20040177531	09-16-2004	DiBenedetto et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document: Country Code[3] - Number[4] - Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet	7	of	8

Complete if Known	
Application Number	13/084,543
Filing Date	April 11, 2011
First Named Inventor	MOSKOWITZ, et al.
Art Unit	3733
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U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number: Number - Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	GA	US 20050278026 A1	12-15-2005	Gordon, et al.	
	GB	US 20050216084 A1	09-29-2005	Fleischmann	
	GC	US 20050027362 A1	02-03-2005	Williams et al.	
	GD	US 20050049590 A1	03-03-2005	Alleyne et al.	
	GE	US 20040254644 A1	12-16-2004	Taylor	
	GF	US 4,997,432 A	03-05-1991	Keller	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document: Country Code[3] - Number[4] - Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

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Sheet 8 of 8

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NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	HA	International Search Report (ISR) and Written Opinion of the International Searching Authority, 03 December 2007, International Application No. PCT/US 07/05005.	

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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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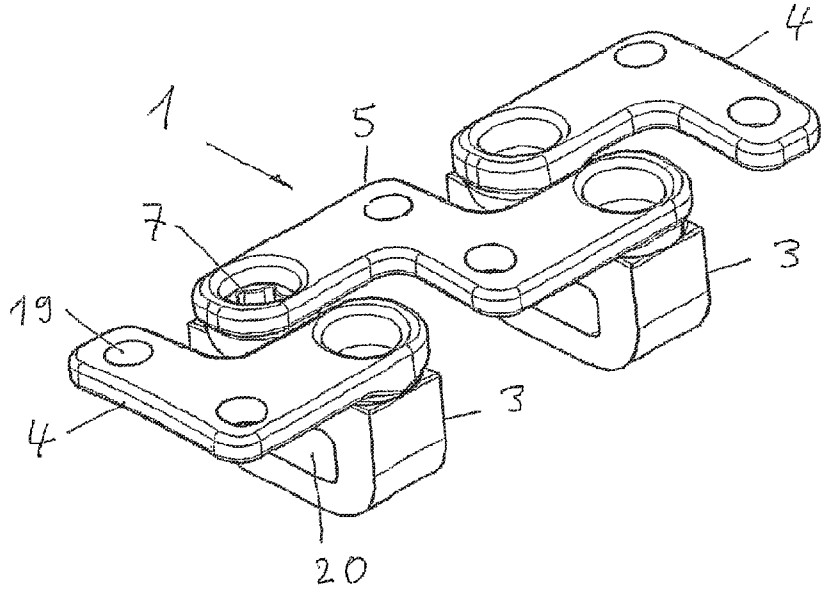
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[Fortsetzung auf der nächsten Seite]

(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.

MOSKOWITZ-00002158

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.

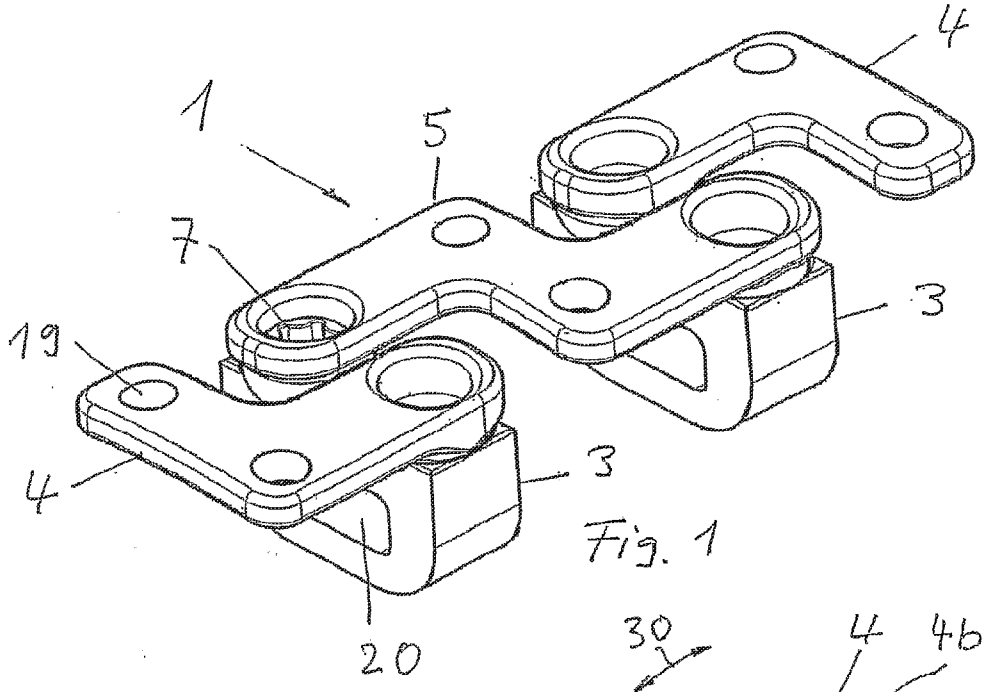


Fig. 1

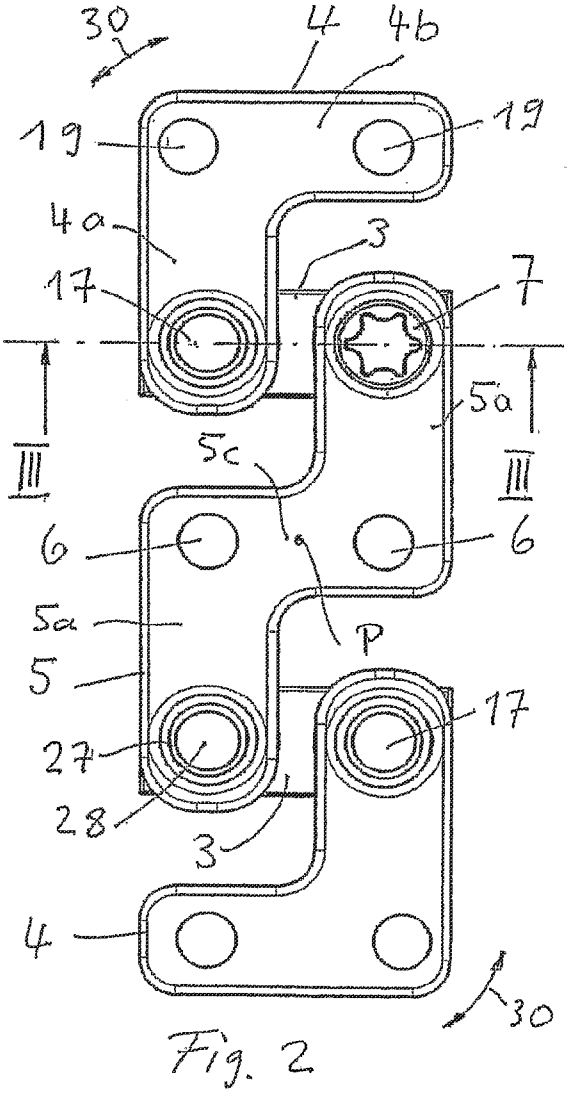


Fig. 2

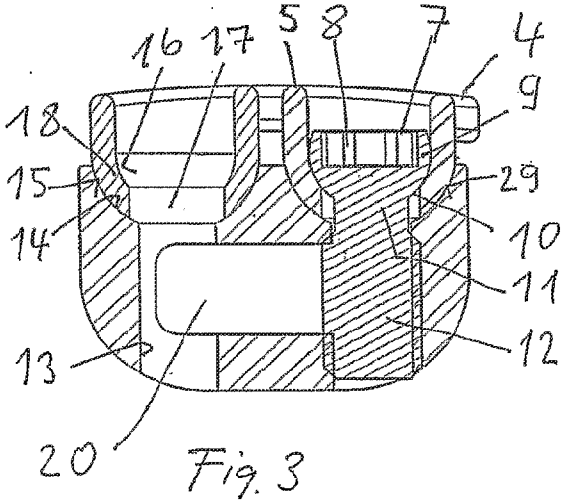


Fig. 3

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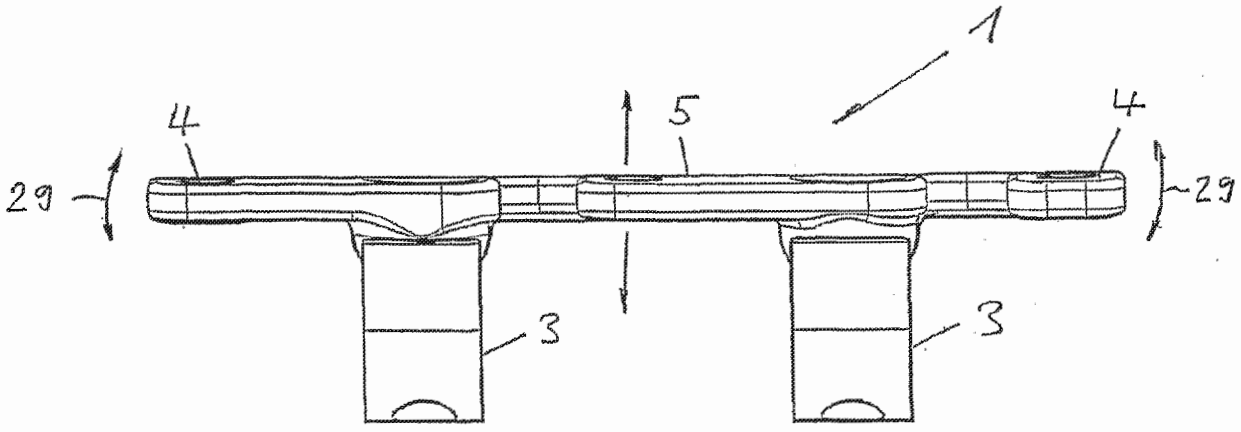


Fig. 4

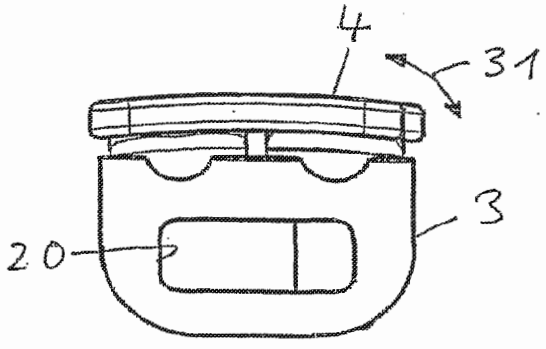


Fig. 5

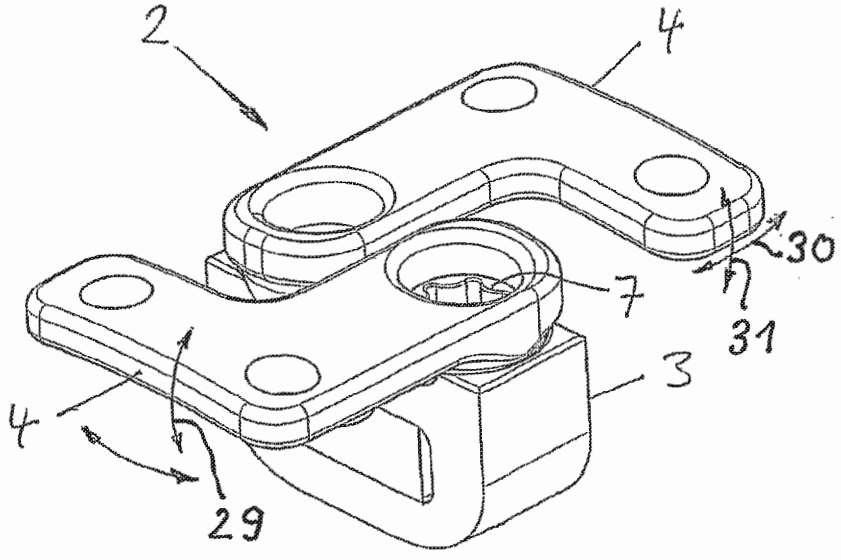


Fig. 6

ERSATZBLATT (REGEL 26)

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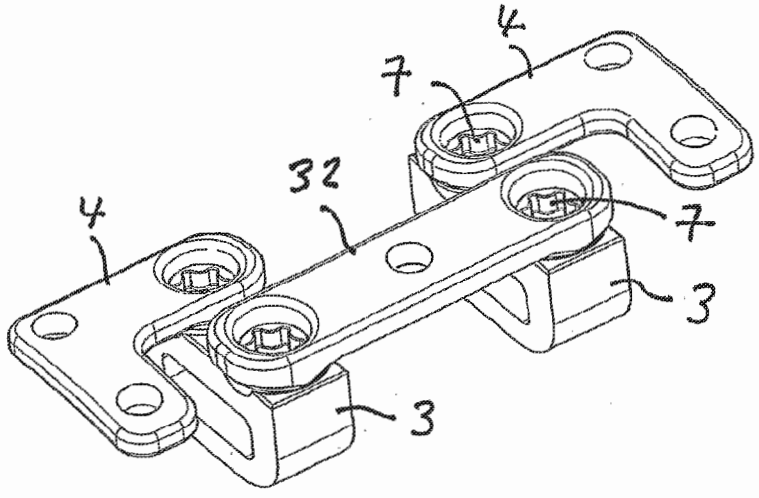


Fig. 7

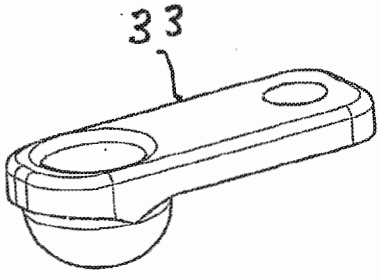


Fig. 8

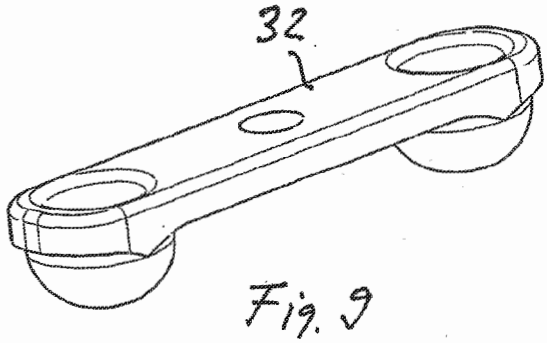


Fig. 9

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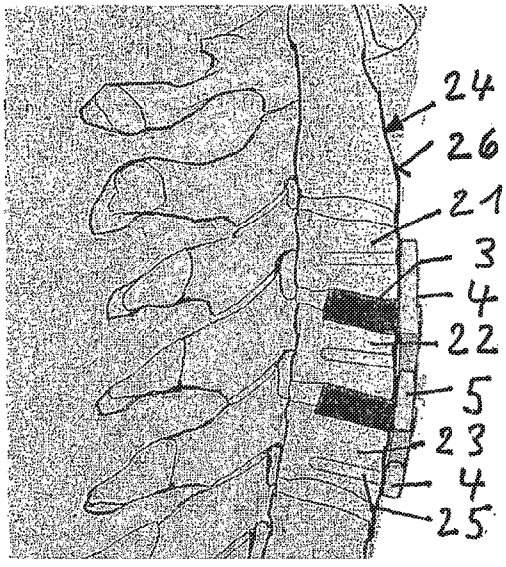


Fig. 10

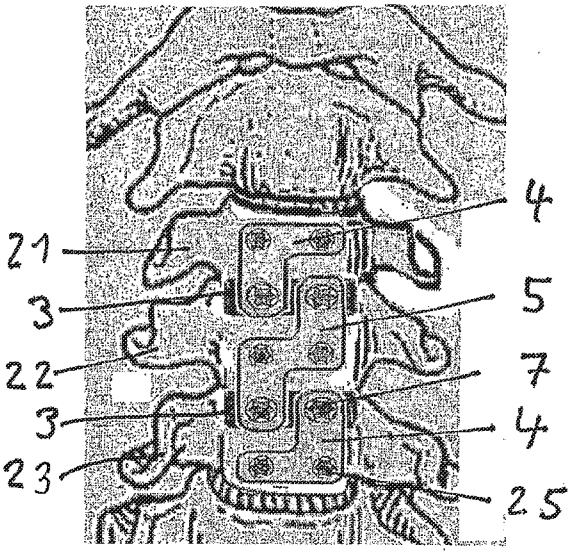


Fig. 11

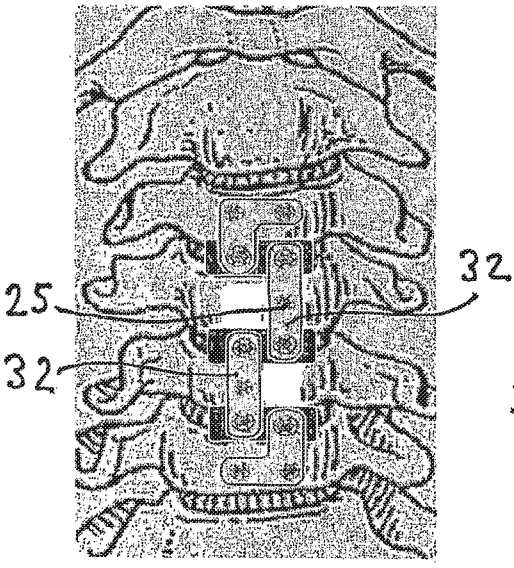


Fig. 12

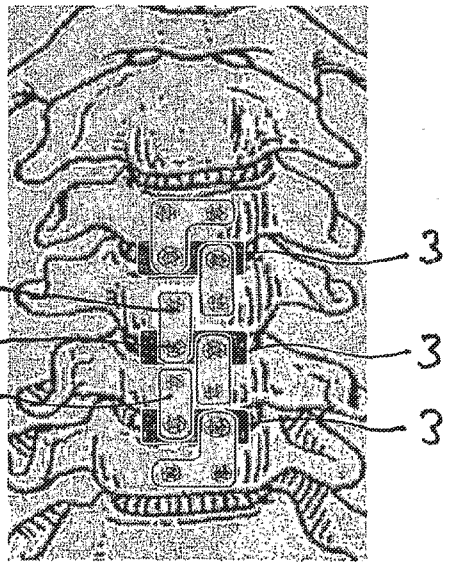


Fig. 13

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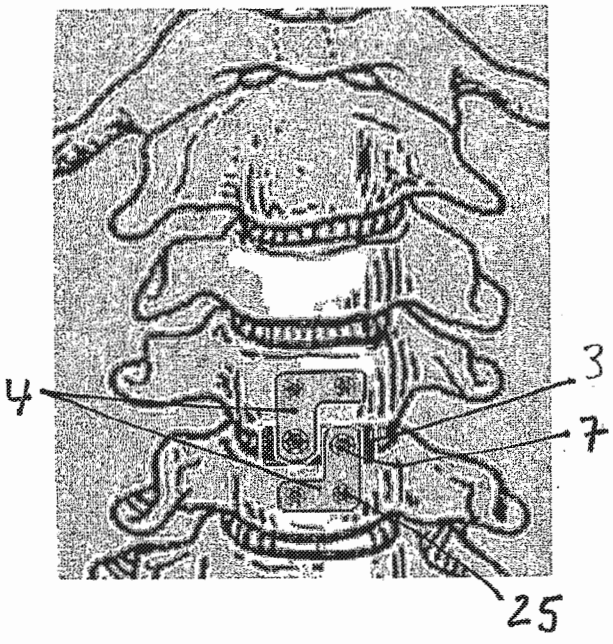


Fig. 14

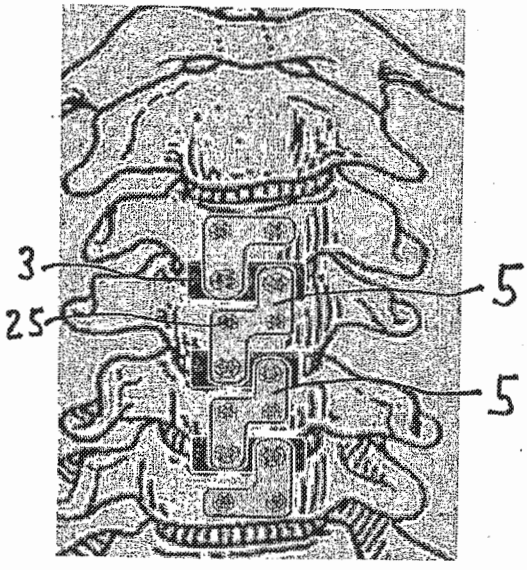


Fig. 15

MOSKOWITZ-00002185

INTERNATIONAL SEARCH REPORT

onal 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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INTERNATIONAL SEARCH REPORT

nal Application No
PCT/CH2004/000244

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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INTERNATIONAL SEARCH REPORT

formation on patent family members

>nal 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)
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Recherchierte aber nicht zum Mindestprüfstoff gehörende Veröffentlichungen, soweit diese unter die recherchierten Gebiete fallen

Während der internationalen Recherche konsultierte elektronische Datenbank (Name der Datenbank und evtl. verwendete Suchbegriffe)
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C. ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie°	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
X	US 5 360 430 A (LIN CHIH-I) 1. November 1994 (1994-11-01) in der Anmeldung erwähnt Anspruch 1; Abbildungen 1,2A-2H,2L-3	1,2,7, 11,12
Y		8
A		13,16
X	US 5 443 515 A (COHEN ROBERT C ET AL) 22. August 1995 (1995-08-22) in der Anmeldung erwähnt Abbildungen 1-5 Spalte 7, Zeile 12 - Zeile 48	1,2,7, 11,12
A		13,16

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[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
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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
A	US 6 306 136 B1 (BACCELLI CHRISTIAN) 23. Oktober 2001 (2001-10-23) Abbildungen 3,7,8	1,2,7,8, 13
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A	GB 1 243 353 A (LUMB WILLIAM) 18. August 1971 (1971-08-18) Abbildungen 5,7 Seite 2, Zeile 91 - Zeile 124 Seite 3, Zeile 50 - Zeile 105	1,2,10, 11
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INTERNATIONALER RECHERCHENBERICHT

Angaben zu veröffentlichungen, die zur selben Patentfamilie gehören

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			JP	2002523128 T	30-07-2002
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(71) Applicant *(for all designated States except US)*: **TIMKEN US CORPORATION** [US/US]; 59 Field Street, Torrington, Connecticut 06790 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **SHATTUCK, Charles, W.** [US/US]; 138 Allyn Road, West Goshen, Connecticut 06756 (US). **TORLAI, David, R.** [US/US]; 120 Wedgewood Drive, Torrington, Connecticut 06790 (US). **MURPHY, Richard, F.** [US/US]; 187 Hodges Hill Road, Torrington, Connecticut 06790 (US).

(74) Agents: **SMITH, David, D.** et al.; MICHAEL BEST & FRIEDRICH LLP, 100 East Wisconsin Avenue, Suite 3300, Milwaukee, Wisconsin 53202-4108 (US).

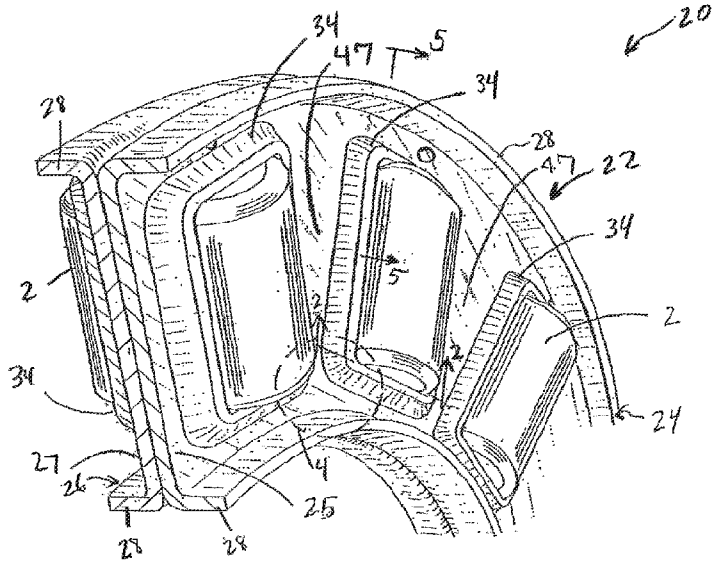
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, 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).

Published:
— *with international search report*

[Continued on next page]

(54) Title: THRUST BEARING ASSEMBLY



(57) Abstract: A thrust bearing assembly (20) generally includes a cage (22) and a plurality of rolling elements (2). The cage (22) has first and second cage halves (24,26) with each cage half having a respective radial segment (25,27) with a plurality of circumferentially spaced openings (30,32). Each opening has an opening perimeter. The cage halves (24,26) are interconnected with portions of the radial segments (25,27) circumferentially between the plurality of openings (30,32) abutting along a given plane and the respective openings (30,32) aligned to defined rolling element pockets. The rolling elements (2) are positioned in the rolling element pockets such that a centerline of each rolling element (2) lies in or in proximity to the given plane (P). A flange (34) extends along at least a portion of each opening perimeter to retain the rolling elements (2) within a respective one of the rolling element pockets.

WO 2006/091503 A1

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— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

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;

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[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.

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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

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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

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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

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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.

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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.

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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.

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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.

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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.

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Fig. 1

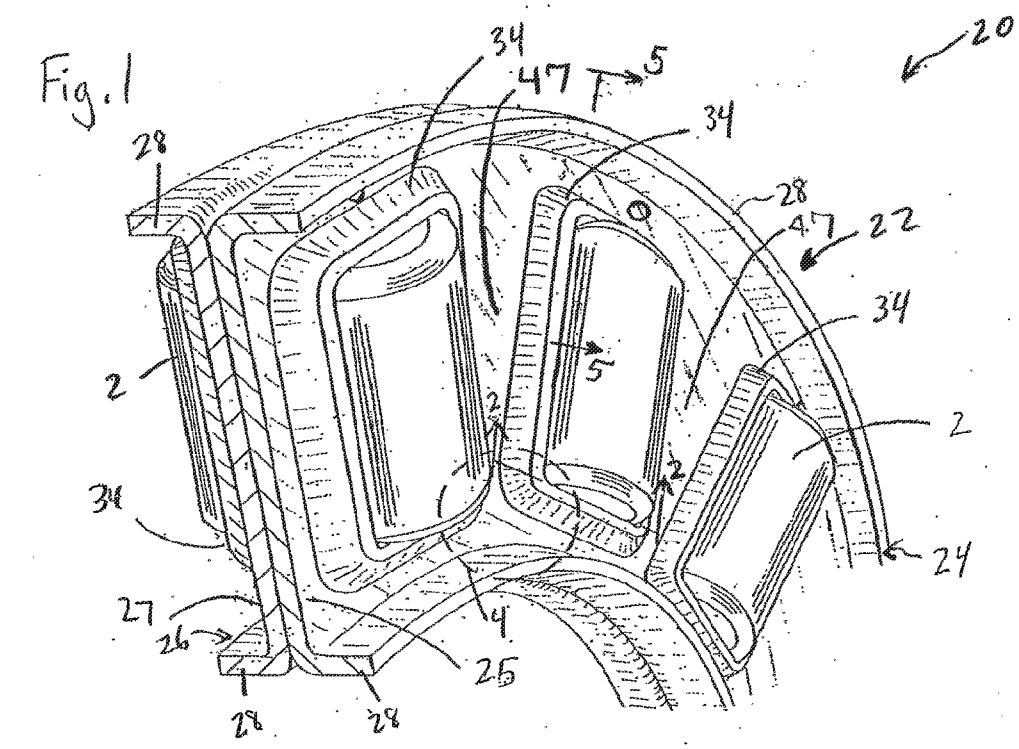


Fig. 2

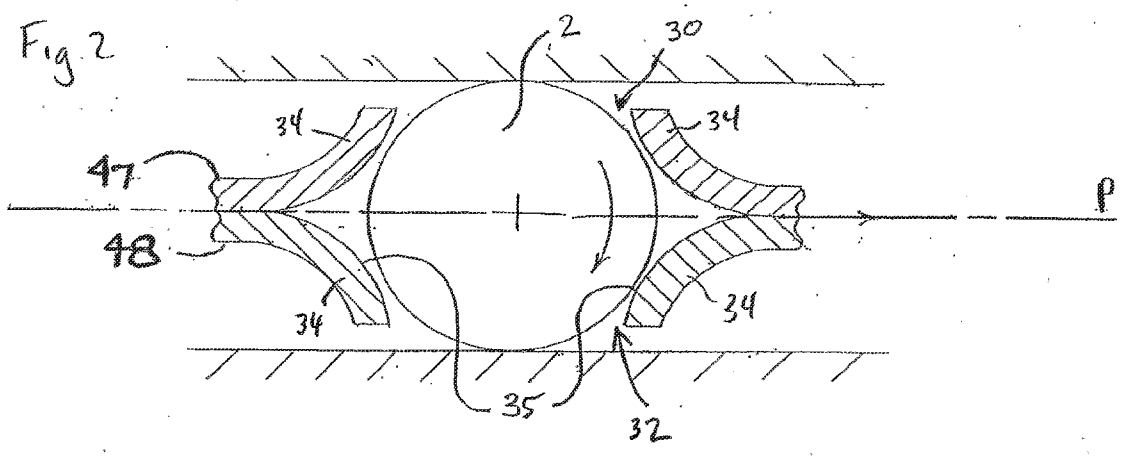
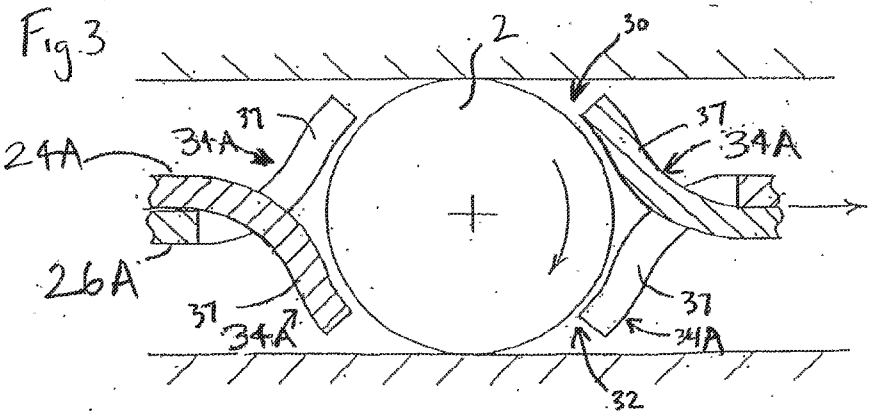
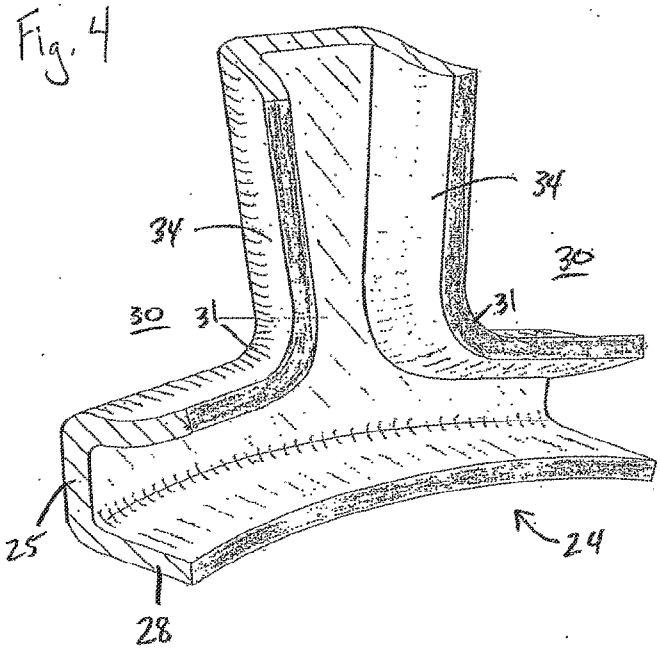


Fig. 3



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Fig. 4



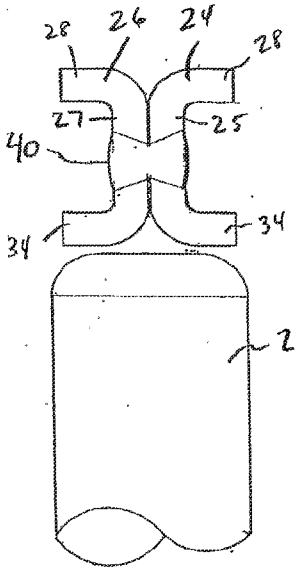


Fig. 5

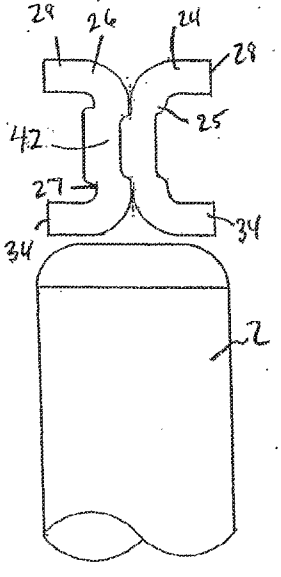


Fig. 6

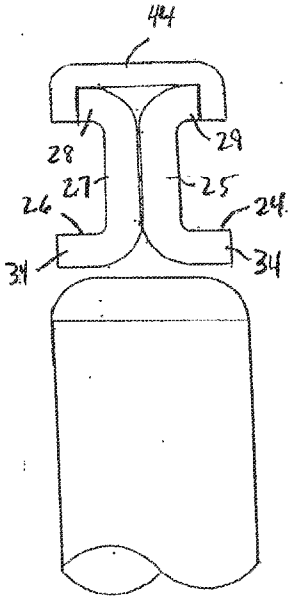


Fig. 7

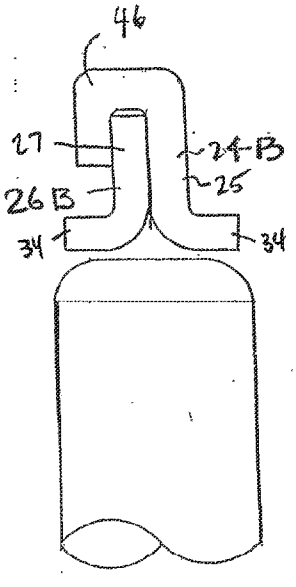


Fig. 8

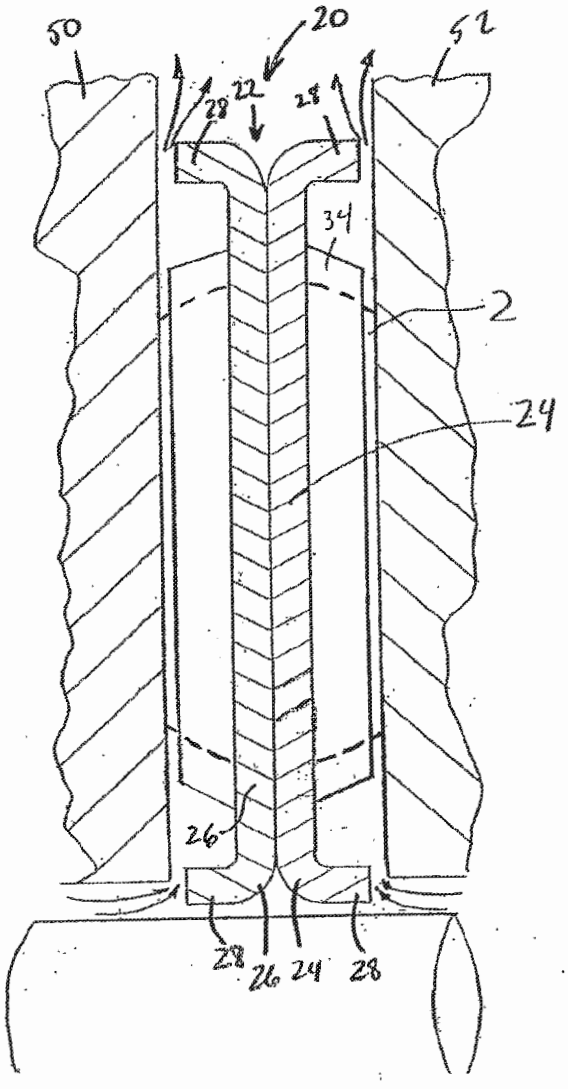


Fig. 9

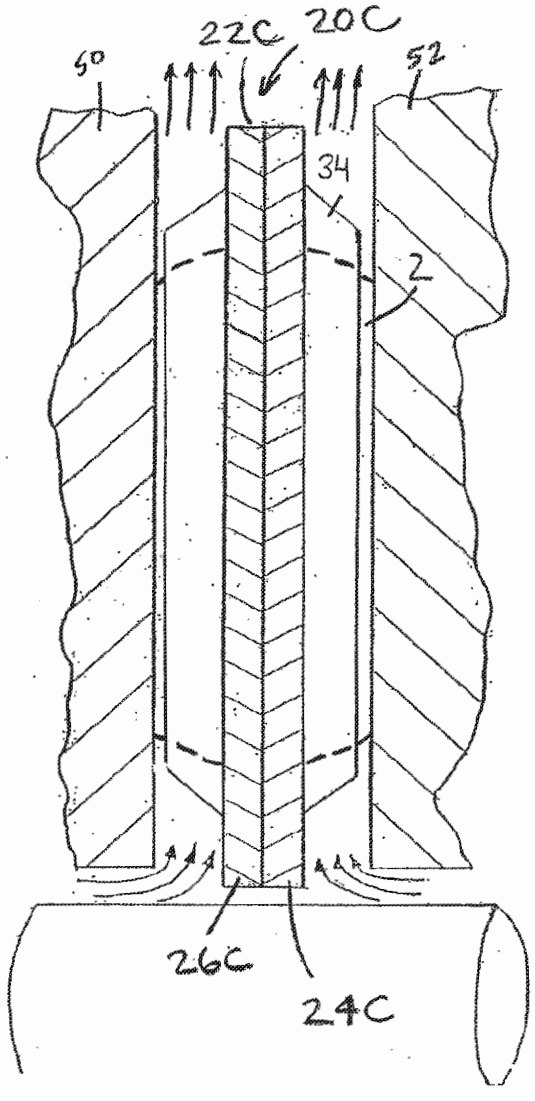


Fig. 10

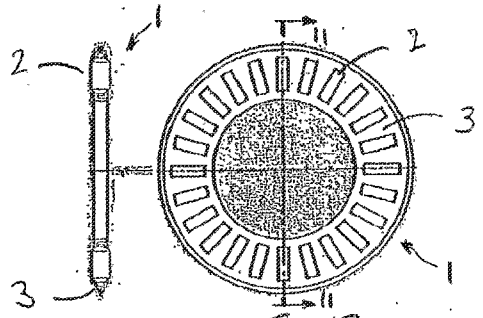


Fig. 11 (Prior Art)

Fig. 12 (Prior Art)

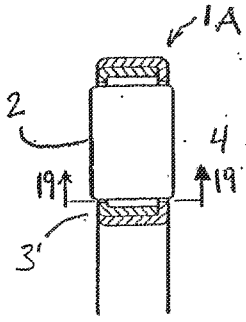


Fig. 13 (Prior Art)

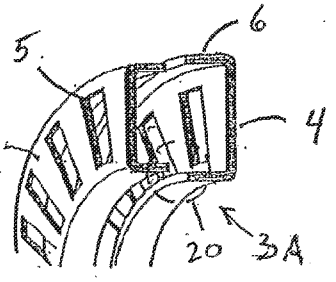


Fig. 14 (Prior Art)

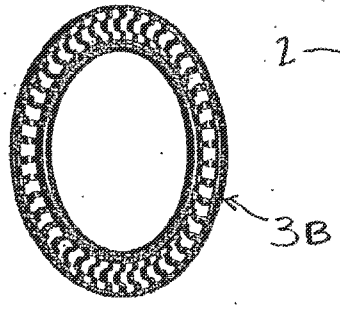


Fig. 15 (Prior Art)

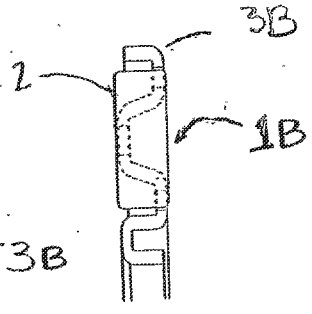


Fig. 16 (Prior Art)

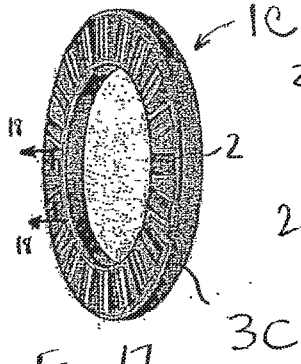


Fig. 17 (Prior Art)

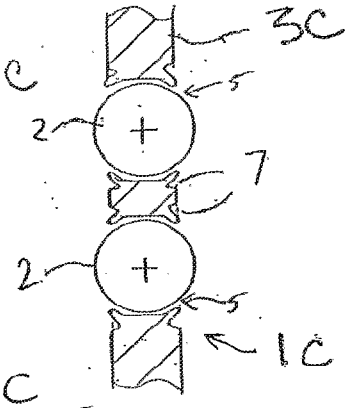


Fig. 18 (Prior Art)

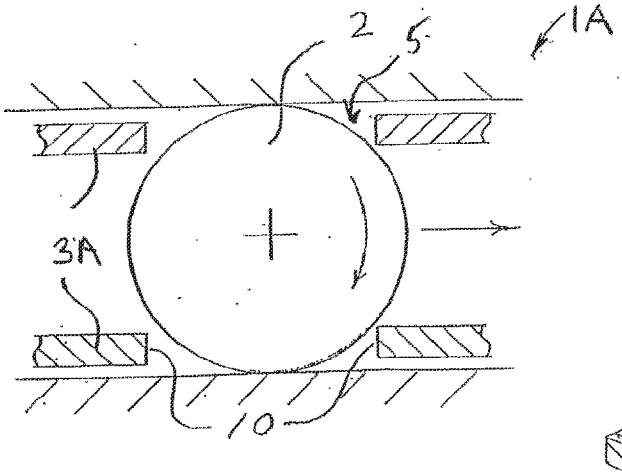


Fig. 19 (Prior Art)

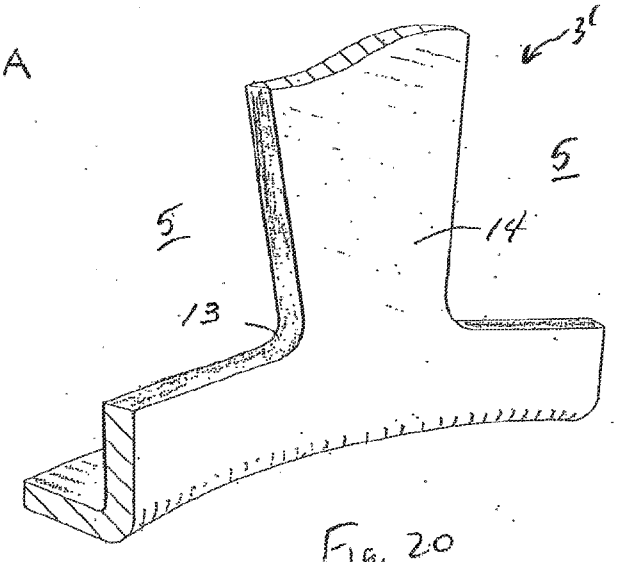


Fig. 20 (Prior Art)

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
"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
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)

MOSKOWITZ-00002209

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)

MOSKOWITZ-00002210

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	

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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

ENTERED
CFS 5/23/08
MT

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

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.

MOSKOWITZ-00002215

International application No.
PCT/US2007/021015

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	US 4,636,217 A (OGILVIE et al) 13 January 1987 (13.01.1987) entire document	1-8, 11
Y		9-10, 12-14
Y	US 2002/0143338 A1 (ORBAY et al) 03 October 2002 (03.10.2002) entire document	10
Y	WO 2004/093749 A1 (MAGERL et al) 04 November 2004 (04.11.2004) entire document	9-10
Y	WO 2006/091503 A1 (SHATTUCK et al) 31 August 2006 (31.08.2006) entire document	12-14

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	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	FOR FURTHER ACTION
30030104PW02	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:

MOSKOWITZ-00002219

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

MOSKOWITZ-00002220

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)

MOSKOWITZ-00002221

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.

MOSKOWITZ-00002222

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
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

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.

MOSKOWITZ-00002227

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 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, 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	FOR FURTHER ACTION
30030105pwo1	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:

MOSKOWITZ-00002230

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

MOSKOWITZ-00002231

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.

MOSKOWITZ-00002232

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.

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the manufacturer of the medications mentioned.

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CHAPTER

9

Prosthetics and Biologics: The Wave of the Future

VINCENT C. TRAYNELIS, M.D.

This review will address the next wave of technology as it pertains to the treatment of spinal spondylosis. Spinal surgery currently consists of two basic treatment options: decompression and fusion. These may be performed separately or in a combined fashion. The coming decade will witness the addition of a number of prosthetic alternatives, all of which are focused on the maintenance of motion and stability. Additionally, specific biologic factors will improve the success of arthrodesis when that treatment is necessary. Genetic research has tremendous potential in terms of prevention and treatment of degenerative spinal disorders; however, such therapies probably will not reach the clinical arena for at least 10 years.

SPINAL PROSTHESES

Multiple factors must be addressed to produce an effective prosthetic disc. Maintenance of motion, normal alignment, and stability as well as preservation of intervertebral height and durability constitute the most basic requirements. Natural discs also act as shock absorbers, which may be an important quality to incorporate into the design of a prosthesis, particularly those devices being developed for multilevel lumbar reconstruction. Ease and safety of implantation, minimal imaging distortion, and revisability are also significant issues.

Currently, segmental spinal restoration can be divided into two categories: nucleus replacement and total disc replacement. The addition of these two classes of prosthetic devices will double our treatment options. In the future, simple disc herniations, particularly free fragments, may be treated solely with a decompression. A nucleus replacement may be appropriate for a more marked disturbance, such as a recurrent disc herniation with a significant component of axial pain. Total joint arthroplasty has the capability of restoring intervertebral height and represents a potential option for patients with dis-

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ease more advanced than that of the previous example. Finally, arthrodesis will still be necessary in patients with overt instability, deformity, or complete absence of segmental motion.

NUCLEUS REPLACEMENTS

Nucleus replacements may be considered in situations with significant nuclear degeneration but a relatively healthy annulus and supporting fibers. Contraindications to nuclear disc arthroplasty include an interspace height of less than 5 mm, spondylolisthesis, and Schmorl's nodes.

The most extensively evaluated nucleus replacement is the Prosthetic Disc Nucleus (PDN; Raymedica, Bloomington, MN), and more than 500 patients have received this implant. The implant closely replicates the physiologic function of the nucleus and can restore some disc space height (1). The PDN device consists of a hydrogel core constrained within a woven polyethylene jacket (*Fig. 9.1*). It has been evaluated with mechanical and in vitro testing. The results have been favorable, and the early clinical results are promising (2–4).

Compression and hydration of the hydrogel core and insertion of platinum-iridium wire markers before implantation minimizes the size of the PDN and allows for radiographic identification of the device.



FIG. 9.1 Prosthetic Disc Nucleus.

The permeable, tightly woven, ultrahigh-molecular-weight polyethylene (UHMWPE) jacket is flexible but inelastic. These properties constrain expansion upon hydration yet permit the core to deform and reform in response to compressive forces. Once implanted, the hydrogel immediately begins to absorb fluid, and within 4 to 5 days, maximum expansion is achieved. Currently, the PDN is the only nucleus replacement that can effectively distract the interspace. Because of this distraction capability, it can be implanted into segments as small as 5 mm, whereas the nondistracting nucleus replacements probably will function best in disc spaces that have maintained a height of at least 10 mm.

Several other nucleus replacements are currently under development. No significant volume of clinical data exist concerning the outcomes of patients receiving these implants, making it impossible to present relevant patient outcomes at this time.

Aquarelle (Stryker Howmedica, Rutherford, NJ) is a hydrogel-based nuclear replacement constructed with polyvinyl alcohol (PVA). This viscoelastic material exerts a uniform pressure across the end plates. Biomechanically, the Aquarelle device has performed well in fatigue testing up to 40 million cycles, and extensive cadaveric studies have demonstrated that the device does not extrude. There has been no evidence of local or systemic toxicity to the PVA or its particles in a baboon study (5). Aquarelle is inserted through a 4- to 5-mm, tapered cannula that may access the disc space from either a lateral or posterior avenue.

Newcleus (Sulzer Spine-Tech, Edina, MN) is a spinal nuclear implant constructed with a polycarbonate urethane elastomer (Sulene PCU). Sulene PCU is biocompatible and has been used in multiple cardiovascular applications. The Newcleus device is manufactured in a specific manner that causes it to curl up into a spiral in its natural state. This property enables Newcleus to completely fill the intervertebral space and, potentially, to exert lateral tension on the annulus. Functionally, it probably acts as a spacer with some shock-absorbing capabilities. Newcleus is implanted using the same approach as that for a microdiscectomy, but in the future, it may be possible to introduce the implant percutaneously.

At least two other nuclear replacements are being developed that consist of polymers cured in situ. The ability to insert these implants through a small annular window may be an attractive factor in selected patients, because theoretically, this would allow for implantation via a minimally invasive procedure with minuscule risk of implant migration.

The Prosthetic Intervertebral Nucleus (PIN; Disc Dynamics, Minnetonka, MN) is an in situ curable polyurethane. The PIN is injected

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into a polyurethane balloon through a catheter and polymerizes in minutes, after which the catheter is removed. BioDisc (Cryolife, Kennesaw, GA) is constructed with a protein hydrogel. This in situ curable protein hydrogel is injected into the disc space and also cures within minutes. Very little additional information is available concerning these implants at this time.

TOTAL DISC REPLACEMENT

Lumbar

The Link SB Charite (Waldemar Link GmbH & Co, Hamburg, Germany), now in its third generation, has been the most widely implanted disc prosthesis, and more than 2,000 patients have received this device (6). The Charité III consists of a biconvex UHMWPE spacer encircled by a radiopaque ring for x-ray localization. This core spacer, which is available in different sizes, interfaces with two casted cobalt-chromium-molybdenum (CrCoMO) alloy end plates. The end plates are coated with titanium and hydroxyapatite to promote bone bonding, and they have ventral and dorsal teeth to discourage migration (*Fig. 9.2*). The end plates are available in different sizes and angulations. The unique design of the Charité III allows the implant to provide unconstrained kinematic motion across the treated spinal segment. Although there is great concern regarding wear debris from hip prostheses in which UHMWPE articulates with metal, this does not appear to occur in the Charité III (6). A number of studies assessing clinical outcome have been published, some with 5-year follow-up, and the overall results with the Charité implant have been good (7–9).

The Prodisc (Aesculap AG & Co KG., Tuttlingen, Germany) was developed by Dr. Thierry Marnay. It is constructed with two CrCoMO alloy end plates with vertical wings (*Fig. 9.3*) and a monoconvex polyethylene core inserted into the caudal end plate. The polyethylene core is firmly anchored to the caudal end plate, which results in a kinematic behavior that is best described as "semiconstrained." Good to excellent results have been reported in the majority of patients receiving this implant (10, 11).

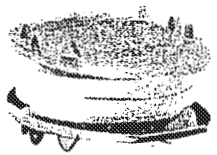


FIG. 9.2 Link SB Charité Disc.

FIG. 9.3 Prodisc.

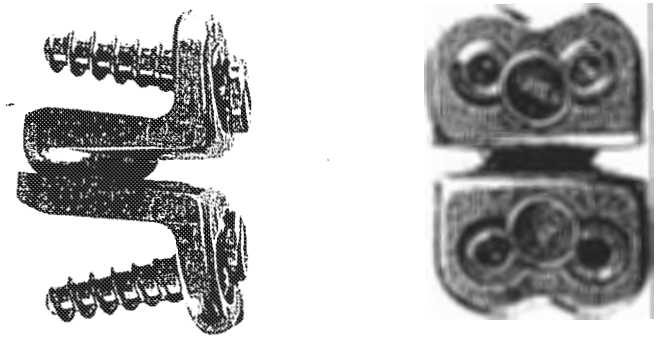


Cervical

At first glance, it may seem a little more difficult to justify arthroplasty in the cervical spine as opposed to the lumbar region. Evidence is mounting, however, that arthrodesis increases stress and, therefore, the rate of disc degeneration in the cervical spine (12–18).

The Bristol cervical disc has the longest follow-up compared to any other current prosthesis, and the clinical outcomes have been good (19). The Bristol disc is the second generation of the Cummins disc. It is a ball-and-trough-type device constructed of stainless steel, which is secured to the vertebral bodies with screws (*Fig. 9.4*). The Bristol disc allows unconstrained motion across the segment (*Fig. 9.5*).

Wigfield et al. (20, 21) have recently reported that the Bristol artificial disc decreases adjacent level motion as compared to an arthrode-



A B

FIG. 9.4 The Bristol disc. (*A*) Lateral view. (*B*) Anterior view.

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FIG. 9.5 The Bristol disc. (*A*) Lateral cervical radiograph in extension.

sis. Theoretically, this will decrease the incidence of adjacent segment disease. Robertson et al. (22) have reviewed the preliminary data for a prospective, randomized trial comparing the Bristol disc to an instrumented arthrodesis for single-level primary cervical disc disease. The 1-year data demonstrate that the arthroplasty patients had a greater improvement than those in the arthrodesis cohort in the Neck Disability Index, visual analog pain scale scores, and the mental and physical component scores of the SF-36. Segmental cervical motion was maintained across the operated segments in all patients.



FIG. 9.5 The Bristol disc. (*B*) Lateral cervical radiograph in flexion.

The Bryan Cervical Disc System (Spinal Dynamics Corporation, Seattle, WA) consists of a polyurethane nucleus that is situated between and articulates with two titanium plates (shells) that are fitted to the vertebral body end plates (*Fig. 9.6*). A pliable polyurethane membrane surrounds the nucleus and is secured to the end plates with a titanium wire. The closed environment deters wear-debris migration and also inhibits the intrusion of connective tissue. The implant allows for unconstrained normal range of motion in flexion/extension, lateral bending, axial rotation, and translation. It also provides some cushioning for axial loads.

The initial clinical experience with the Bryan Total Cervical Disc Prosthesis has been promising. Goffin et al. (23) have reported the results of 60 patients receiving the Bryan disc. Although the follow-up

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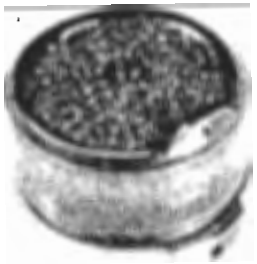


FIG. 9.6 Bryan Cervical Disc Prosthesis.

has only been 1 year, no device failures and no subsidence were found, and motion was maintained at each implanted level. The patient-derived outcomes were excellent.

BONE MORPHOGENETIC PROTEIN

Those patients who require an arthrodesis will benefit from advances in biologic enhancement of the bony healing process. More than 35 years ago, Marshall Urist (24), an orthopedic surgeon, discovered that demineralized bone could induce a cellular response resulting in new bone formation. He later demonstrated that this activity was caused by a protein (or group of proteins) that he named bone morphogenetic protein (BMP) (25, 26). Progress in biochemical techniques and advances in genetic research technology have led to the discovery and purification of numerous specific BMPs. At least a dozen separate BMPs have been detected. The genes or cDNA encoding each of these proteins has been cloned. Analysis of the clones has revealed that the individual proteins are related, and the family of compounds have been named bone morphogenetic proteins. The family consists of dimeric molecules that constitute the largest subgroup of the transforming growth factor-β (TGFβ) superfamily (27).

Bone morphogenetic proteins are local-acting, soluble proteins that bind to specific receptors on the cell surface. These receptors transduce their signal via a group of proteins called Smads, which result in the activation of certain genes. The BMPs act primarily as differentiation factors converting responsive mesenchymal cells into cartilage- and bone-forming cells. The activity of BMPs is controlled at many levels. In the extracellular space, inhibitory proteins may bind BMPs, thereby making them unavailable to the cell-surface receptors; in fact, BMPs may upregulate the activity of these inhibitors, creating a negative-feedback loop. In the intracellular space, BMPs can up-

regulate the expression of inhibitory Smad proteins. Additionally, a number of negative intranuclear BMP regulators are known. The bone induction process is tightly controlled by each of these processes. The end result of these processes is that bone induction is observed only locally at the site of BMP and matrix implantation. The amount of bone formation is determined by the volume of matrix implanted and the time that the BMP is present (28).

It is relatively easy to promote bone formation both in vitro and in rodent models. Likewise, in lower vertebrates such as rabbits and dogs, bone heals more readily than in humans. Physiologic BMP concentrations are adequate for fracture healing and arthrodesis in ideal conditions, but supraphysiologic concentrations are necessary to produce a significant positive effect in the human condition. The presence of powerful inhibitors of BMP is a major reason for this variation (29, 30).

It is imperative that an adequate concentration of BMPs be delivered to and maintained at the appropriate site to be effective. This is accomplished by loading a carrier material with BMPs. The major role for carrier-based delivery systems is to preserve the concentration of osteogenic factors at the fracture site long enough to allow the migration of mesenchymal cells to the area of injury to proliferate and differentiate. The carrier must accomplish these goals without interfering with the healing process. Ideally, the carrier would be porous and rapidly biodegradable to allow for cellular and vascular ingrowth yet, at the same time, produce a minimal inflammatory response. Spinal fusion requires that the carrier serve as an osteoconductive matrix for bone-forming cells while maintaining a three-dimensional space where bone formation can occur. This is particularly important to prevent soft tissues from entering the site and inhibiting the fusion process. Four major categories of carriers have been utilized for the delivery of osteogenic factors: inorganic materials, natural polymers, synthetic polymers, and composites. Each has specific advantages and disadvantages, and the ideal carrier has yet to be identified (30).

Currently, four BMPs show promise for clinical application in the arena of spinal fusion. These include recombinant human BMP (rhBMP)-2; rhBMP-7, which is also known as osteogenic protein (OP)-1; bovine bone-derived BMP extract; and growth and differentiation factor-5.

Recombinant human bone morphogenetic protein-2 has been evaluated in several human studies of lumbar fusion (31). The most important was one in which rhBMP-2 was compared to autograft in an open anterior lumbar interbody fusion study using titanium cages (INFUSE, LT Cage; Medtronic Sofamor Danek, Memphis, TN). The car-

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rier for the rhBMP-2 was a collagen sponge. This study enrolled 279 patients, and more than 90% completed their 2-year follow-up. Demographically, the two groups were similar. The operative time and blood loss were significantly less in the investigational group (rhBMP-2). In the autograft group, 32% of the patients had some degree of donor site pain at 2 years following surgery. The two groups did not differ in terms of back pain and Oswestry scores. The successful fusion rates at 2 years were 94.5% and 88.7% for the rhBMP-2 and autograft groups, respectively. The U.S. Food and Drug Administration granted permission for an additional arm to be added to the above study in which rhBMP-2-filled cages were inserted laparoscopically. Although only 12-mo data are available from this study, the results are encouraging. Currently, rhBMP-2 is approved for the performance of lumbar fusions with the LT Cage.

Recombinant human OP-1 (rhOP-1; Stryker Biotech, Hopkinton, MA) has demonstrated efficacy in promoting spinal fusion in animal models, and human trials are currently ongoing (32). The early clinical results show an improved outcome with the use of rhOP-1, although statistical significance has yet to be achieved. These trials have not demonstrated any adverse effects related to the use of rhOP-1. Currently, a trial is ongoing in which patients with lumbar spinal stenosis and degenerative spondylolisthesis are treated with decompression followed by an uninstrumented posterolateral fusion using either iliac crest autograft or rhOP-1 putty. The 6-mo results for 36 patients are notable for a 32% higher clinical success rate in the rhOP-1 group.

While the recombinant forms of BMPs, rhBMP-2 and rhOP-1, are single factors manufactured using cell culture techniques, bovine BMP extract (bBMPx) is a highly purified protein extract from bovine bone. This extract contains BMP-2, BMP-3, BMP-4, BMP-6, BMP-7, TGFβ_1, TGFβ_2, TGFβ_3, fibroblast growth factor 1, and other noncollagenous proteins. The bBMPx product is composed of bBMPx and type I collagen (Ne-Osteo; Sulzer Biologics, Austin, TX) (33). The bBMPx has been demonstrated to be safe and efficacious in a rabbit posterolateral transverse process fusion model and was twice as successful as autograft in producing arthrodesis in a primate study. At this time, a human study of a posterolateral lumbar transverse process fusion is ongoing; one side receives autograft and the other bBMPx so that each patient serves as his or her own control. The results have not been formally published.

A number of viral and nonviral techniques are being employed to transduce cells with a BMP gene so that significant quantities of BMP will be produced. Both direct and ex vivo BMP gene therapy have been effective in animal models. Although BMP gene therapy may possess advantages over direct BMP applications, this field is in its infancy, and no specific vector or treatment technique has been developed enough to consider for evaluation in clinical trials.

LIGAMENTOUS RESTORATION

Finally, at least two spinal implant systems are designed to restore ligamentous function. Although these are distinctly different than disc replacements, they have the same goal: maintenance of motion. Disc cell death has been shown to be a function of the magnitude and duration of applied loads (34). This has led to the hypothesis that degeneration of the posterior supporting structures may predispose an individual to accelerated disc degeneration (35).

The Dynesys device (Sulzer Orthopedics, Ltd., Baar) is a dynamic neutralization system that consists of polyester cords and modular polycarbonate-urethane spacers attached to the lumbar spine with pedicle screws (36). The rigidity of the cord and spacer is comparable to that of the posterior ligaments of the lumbar spine. The cord allows for stabilization in flexion, while the spacer stabilizes extension motion. The cords and spacers are attached to the spine with pedicle screws. Cadaveric studies have demonstrated that the Dynesys device restores normal stiffness to the lumbar spine following destabilization. Additionally, Dynesys neutralizes posterior nuclear and annular pressure variations. The device does not appear to affect pressures in the anterior portion of the disc/annulus complex. Dynesys has been shown to reverse Modic's end plate changes. The clinical results have been good. The major problem with this technique appears to be related to screw loosening. Clinical and radiographic findings consistent with screw loosening have been reported in 9.6% of patients receiving Dynesys; however, this has only been confirmed by reoperation in 1.9% of the implants placed.

The spinal degenerative process leads to an increase in the neutral zone during sagittal plane rotation. The Wallis System (Spine Next, Bordeaux, France), designed by Prof. Senegas, eliminates not only this increase but other spondylotic perturbations in spinal mechanics (37). The Wallis system consists of a plastic interspinous block and woven polyethylene ligaments. The Wallis device unloads the adjacent disc in both extension and flexion. Indeed, the interspinous portion of the implant decreases disc loading by 50% in extension alone. A prospective study was performed using the first generation of the Wallis device from 1988 through 1993. Two groups of patients were studied: those undergoing excision of a recurrent disc (group A) and those undergoing recurrent disc excision and Wallis implantation (group B).

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The improvement in visual pain and Oswestry scores was higher in group B, but the differences did not achieve statistical significance. Perhaps the most fascinating aspect of the Wallis System has been the observation that not only do Modic's changes reverse after implantation of the device but that some patients also develop MR imaging-documented rehydration of their discs.

This is an exciting time to be involved in the management of degenerative spinal disease. Radical new treatments are on the immediate horizon, and these will not only improve patient outcomes but expand our knowledge of degenerative spondylosis.

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Disk Replacement Arthroplasties: Can The Success of Hip and Knee Replacements be Repeated in the Spine?

E.K. Wai, G.P.K. Selmon, and R.D. Fraser

"Revolutionary artificial disc for the spine ... is set to cure disabling pain around the world,"[1] and other similar statements have become common place in newspaper articles, over the Internet, and even peer-reviewed journals. Without doubt, degeneration of the lumbar intervertebral disk is one of the most common forms of spinal pathology encountered. It results in a cascade of events that is claimed to lead to segmental instability with associated back pain and sciatica.[2] Traditional surgical treatments of these conditions address only the specific pathology at the expense of the functional aspects of the disk. Although artificial disk replacement has the potential to overcome this, its use remains in an infancy period. This article will discuss issues related to this.

Disk as a Pain Generator

Although the lumbar intervertebral disk has been the traditional focus of study as the site for initiation of the degenerative process, it shares an intimate relationship with the facet joints.[2] As such, the concept of the functional spinal unit has been promoted.[3] This consists of the disk and its 2 associated facet joints that represent the smallest segment for biomechanical study of spinal characteristics. Regardless, the disk is a critical component of the fuhctional spinal unit. It consists of a tough annulus fibrosus, which contributes significantly to the torsional and tensile stability of the spine.[2,4-6] The annulus is maintained under tension by the viscoelastic nucleus pulposus. The disk is responsible for at least half of the axial compressive load transmitted through the functional spinal unit. In a healthy spine, the 5 lumbar functional spinal units are arranged in a balanced mobile lordosis, which serves to buffer and decrease the apparent applied load transmitted to the individual components.

The degeneration of the disk is considered a natural process of aging. The classical works of Kirkaldy-Willis,[7] Yong-Hing and Kirkaldy-Willis,[8] and Farfan and coworkers[9] have formed the basis for the understanding of this process. Based on detailed anatomic and pathologic studies, 3 sequential phases have been identified. The dysfunctional phase includes annular tears and nuclear degeneration. A second phase of instability is characterized by gross morphologic changes to the disk and reduction of disk height. The final stage involves restabilization with osteophytes and the complete loss of disk height, resulting in increased spinal stiffness.

Numerous studies have shown that pathologic changes seen in the disk may not necessarily equate with clinical findings.[10-13] Acknowledging that there is significant overlap with natural age related changes, pathologic degeneration of the disk may result in symptoms. These have been loosely divided into pain associated with (1) herniation, (2) spinal stenosis, or (3) originating from within the disk itself.[14] Herniation of the disk's nucleus material initiates various mediators that may result in irritation of the adjacent nerve root and radiculopathy. The loss of spinal canal dimensions from an interaction among the degeneration of the disk, facet joints, and ligaments may lead to symptoms of spinal stenosis, including neurogenic claudication. Discogenic pain, the least well understood, is explained by various pathomechanical theories, including peripheral annular tear, focal degeneration resulting in production of local painful inflammatory mediators, and segmental instability.[14,15]

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Current Surgical Treatment

Partial discectomy is considered the standard surgical treatment of radicular pain associated with a disk herniation.[16,17] However, the discectomy procedure itself may accelerate degeneration of the functional spinal unit. Mixter and Barr first described the destabilizing effect of the surgical removal of disk material.[18] Various studies following discectomy have documented a significant number of patients reporting back pain.[19,20] Population based studies have shown an excessive rate of reoperations.[21,22] Although it is apparent that standard procedures for removal of disk material damages supporting structural elements in the spine, it is unclear whether minimally invasive techniques, with higher preservation of supporting structures, reduce the incidence of back pain and repeat surgery.

The initial treatment of back dominant pain associated with degeneration of the lumbar spine is nonoperative, and consists of various forms of treatments, including physical therapy, medication, manipulation, injections, watchful waiting, and other modalities. The vast majority of patients find relief with a nonoperative approach. However, for those patients with continued disabling symptoms, surgical intervention may be required. Lumbar fusion, considered the standard surgical approach, addresses the problem by either removing the pain source or preventing motion of painful joints. However, the use of fusion for treatment of degenerative back pain remains controversial. Although a recent, multicenter, randomized controlled trial has shown the efficacy of fusion,[23] it is generally accepted that the outcomes are not as successful as total hip and knee arthroplasty. Specific disadvantages of spinal fusion for the treatment of discogenic back pain include donor site morbidity, high rates of pseudarthrosis, and the potential for the acceleration of adjacent level degeneration.

Numerous biomechanical studies have shown increased stress transferred to levels adjacent to fusion.[24-26] A number of case series have shown significant rates of reduced disk height, osteophytes, increased segmental mobility, and spinal stenosis in the adjacent levels.[25,27-30] Additionally, cohort series comparing groups of patients with fusion with those without fusions have shown increased rates of adjacent level degeneration.[31,32] However, it is questionable whether the choice of control groups in these studies represents a valid comparison. Furthermore, 2 recent studies, both with more than 10 years of follow-up, have questioned the relationship between adjacent level degeneration and fusion. Penta and coworkers used magnetic resonance imaging (MRI) findings at a minimum of 10 years following anterior lumbar interbody fusion, and showed a similar prevalence of degenerative changes between adjacent and nonadjacent levels.[13] With an average of 22 years of follow-up, Hambly and colleagues showed similar rates of degeneration between fused and nonoperated cases.[33] These investigators have concluded that the increased degeneration changes seen may be more likely related to constitutional factors inherent within the individual as opposed to the increased biomechanical stresses at the adjacent levels.

Rationale for Total Disk Arthroplasty

New technology should only be introduced and used if it overcomes shortcomings of previous procedures. Although controversial, as discussed in the previous section, the shortcomings of the current standard surgical procedures are summarized as follows. Although discectomy is considered a highly successful procedure for the treatment of sciatica caused by lumbar disk prolapse, its use is associated with high rates of recurrence and postoperative back pain. Nucleus replacement devices, which have been developed with the potential to overcome this problem, will be discussed later.

Total disk arthroplasty has been promoted for the treatment of back pain associated with spinal degeneration that previously was treated by spinal fusion. Fusion procedures are limited by (1) relatively poorer functional outcomes, especially when compared with other orthopedic procedures; (2) donor site morbidity; (3) high rates of pseudarthrosis; (4) increased complications associated with instrumentation; and (5) potentially accelerated degeneration of the adjacent level. In theory, total disk arthroplasty is able to restore the range of motion to the functional spinal unit, hence, maintaining a flexible lordosis, with the potential to overcome the shortcomings of fusion.

Principles of Total Disk Arthroplasty

In the 1960s, Charnley introduced low-friction total hip arthroplasty and revolutionized the treat-

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ment of hip arthritis.[34] Since then, total joint arthroplasty has become the standard surgical treatment of various peripheral arthropathies, and, more recently, the concept of arthroplasty has been applied in the treatment of the degenerative spine. For a number of reasons, the focus of efforts in spinal arthroplasty has been the disk. It is the largest structure in the 3 joint functional spinal unit and carries the majority of the load.[2-5] Also, many theories attribute initiation of spinal degeneration and pain generation to the disk.[14] However, the disk is not a synovial joint, and many principles of peripheral joint arthroplasty may not readily apply.

First, it can be argued that the primary reason to restore the range of motion in peripheral joint arthroplasty is to improve function, while in the spine, it is to minimize the transfer of stress to adjacent levels. As such, not only is range of motion important, but so is the viscoelastic shock absorbing capacity of the disk replacement. Second, the functional spinal unit is a 3-joint complex, and disk arthroplasties will not directly address any pathology associated with the facets joints. Moreover, unless kinematics of the disk are completely restored, increased stress may be placed on the facet joints. Along similar lines, the stability of a peripheral joint arthroplasty relies on restoration of joint geometry, supplemented by external ligaments that are often preserved. In contrast, the shape of the disk provides no inherent geometric stability. However, the annulus provides significant soft-tissue stabilization that is lost through its resection, and this results in increased shear and torsional loads on the prosthesis.

Finally, load bearing and wear issues differ between peripheral joints compared with the lumbar disk. The factors that determine wear are (1) the applied load, (2) the number of cycles, (3) the stiffness of materials, (4) the coefficient of friction, and (5) the sliding distance.[35] Significant loads, approximately 2 to 5 times body weight, pass through the lumbar disk and the hip.[35,36] The differences between these 2 joints exist in the range of motion, the direction of forces, and the viscoelastic properties. Although abrasive polyethylene wear is a major concern in total hip and knee arthroplasty, it may not be a significant problem for disk arthroplasty. The lumbar disk undergoes significantly less range of motion than peripheral joints. As such, it may be less susceptible to abrasive wear. However, because the disk is smaller than other large weight bearing joints, the materials used in disk arthroplasty will be thinner, resulting in reduced stiffness, and the subsequent inability to withstand fatigue wear and creep. The increased shear stress that is placed on an artificial disk confounds this. Because a disk prosthesis may be expected to withstand more than 100 million cycles in its lifetime and none of the current models have been this extensively challenged, valid concerns over this type of wear have been raised.[36]

Indications for Total Disk Arthroplasty

It is emphasized that for any spinal operation, including total disk arthroplasty, the selection of patients requires a careful consideration of a multitude of factors. Success depends on precise correlation of the patient's history, physical examination, and radiographic investigations, as well as consideration of the psychosocial and medical backgrounds. With this in mind, the indications that we have used for a trial of the AcroFlex (DePuy AcroMed, Raynham, MA) Lumbar Disc Prosthesis consisted of patients with 1 or 2-level symptomatic disk degeneration at either L4-5 or L5-1.[37] Disabling back pain, with or without referral type leg pain, must have been present for a minimum of 12 months and have been refractory to conservative, nonoperative treatment for patients to qualify for the trial. Furthermore, there had to be radiographic correlation of the degenerative level as determined by provocative diskography. The diskogram was performed by the treating surgeon and showed (1) internal disk disruption at the target level, (2) reproduction of the patient's typical pain, and (3) failure to reproduce typical pain at levels adjacent to the target level (control levels). Patients between the ages of 30 and 55 were included.

Contraindications can be divided into technical and patient selection considerations. A history of previous lumbar infection or an active infection elsewhere should exclude patients from disk arthroplasty. Because disk arthroplasty does not address posterior element pathology, patients with spondylitic spondylolisthesis, significant facet arthritis, lateral recess stenosis, or central stenosis should be considered as having a contraindication. Technical considerations that make disk arthroplasty difficult or impossible include

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patients with a steep lumbosacral angle at the target level, osteopenia, previous abdominal radiation or vascular graft, or morbid abdominal obesity. Finally, patient factors, such as significant medical comorbidity, psychiatric illness, ongoing litigation or compensation issues, substance abuse, or the presence of 3 or more Waddell nonorganic signs,[38] may be the major determinants of eventual outcomes and should be considered contraindications to surgical intervention.

Although it has been suggested that disk replacement may be an eventual solution to multilevel degeneration or degeneration adjacent to a fused segment, this has not been considered an ideal indication. Furthermore, given the increased stresses placed on the prosthesis in this situation and its relatively unproven track record, patients with structural scoliosis or adjacent level fusions are also considered as having relative contraindications.

Bertagnoli and Kumar attempted to correlate preoperative clinical findings to outcome to formulate appropriate indications for disk replacement.[39] A retrospective review of 108 patients who underwent total disk arthroplasty with the ProDisc prosthesis (Spine Solutions, New York, NY) was performed. Patients were divided into those who had "prime," "good," "borderline," or "poor" indications for surgery. "Prime" indications were (1) > 4 mm remaining disk height, (2) no facet joint arthritis, (3) no adjacent level degeneration, and (4) intact posterior elements. Patients with adjacent level fusions were considered to have borderline indications. Although no statistical analyses were performed, it appears that there is a gradient of improved successful outcomes in patients with better indications. However, it would also appear that patients with "better indications" were also those with minimal disease and, as such, may be predisposed to better outcomes no matter what form of treatment was used.

Disk Prosthetic Designs

Since Fernstrom implanted an SKF metal ball to recreate the "ball joint" mechanism of the disk in the late 1950s,[40] more than 100 different prosthesis designs have been patented or published.[41] These have been broadly divided into those that (1) replace the nucleus material, while preserving the annular and ligamentous support; (2) reconstruct the viscoelastic properties; and (3) reconstruct the motion characteristics of the disk. Relative to the number of designs that exist, only a handful of devices have been used clinically.

Nucleus Replacements

Numerous biochemical and histologic studies have characterized the degenerative changes that occur in the nucleus.[6,14,42,43] It is theorized that restoration of the annular tension and viscoelastic properties of the nucleus would stop the degenerative cascade that affects the entire functional spinal unit.[42] The potential for such materials to be inserted via a relatively minimally invasive or potentially percutaneous approach increases the attractiveness of this technique. Furthermore, the replacement of the nucleus is a potential strategy to slow the degenerative process associated with the removal of disk material during discectomy.

The nucleus replacement with the most clinical experience in humans is the Prosthetic Disc Nucleus (PDN) (Raymedica, Minneapolis, MN), developed by Klara and Ray.[44] It consists of a hyaluronic acid (hydrogel) within a semipermeable membrane, which is enclosed in a woven jacket. The hydrogel has hydrophilic properties, and is able to absorb fluid and expand. Initial trials during the mid 1990s showed a high migration rate, with 38% of subjects requiring revision. The PDN shape and surgical protocol has since been modified to minimize the extrusion rate, and clinical trials are in progress. Reports of the PDN claim encouraging results, although in each article, the description of the methodology is brief and does not allow for critical review.[44-46] Other nuclear replacements implanted clinically include the Aquarelle (Stryker-Howmedica, Rutherford, NJ), a polyvinyl alcohol, and the Newcleus (Sulzer Spine-Tech, Edina, MN), a polycarbonate urethane elastomer, although there are no published results for these devices.

Assuming that the technical aspects of nucleus replacement have been adequately addressed, the strategy of nucleus replacement does not address pathology related to the annulus or end plate, both of which are considered important sites in the pathogenesis of disk degeneration and also potential pain generators. Nuclear re-

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placements work in conjunction with an annulus to restore biomechanical function to the disk. However, an annular lesion must be created or already exist to insert any device. Although the phase IV trials of the PDN use special dilators to minimize annular damage, it is unclear whether damage caused exceeds the benefits of the nuclear replacement.

Mechanical Disk Replacements

Mechanical disk replacements attempt to recreate the normal kinematics of the intervertebral disk. Using principles similar to the low-friction polyethylene on metal articulations of total hip and knee arthroplasty, 2 disk prostheses have been designed and used in clinical trials. In general, these prostheses replace almost the entire disk, are inserted using an approach similar to an anterior lumbar interbody fusion, and rely on bony ingrowth for stability against the vertebral end plates.

The Link SB Charite (Waldemar Link GmbH & Co., Hamburg, Germany) was developed by Schellneck and Buttner-Janz in the 1980s.[47] It consists of a biconvex polyethylene spacer articulating with 2 concave cobalt-chromium alloy end plates, allowing rotation in all 3 planes. The polyethylene core is able to slide, similar to mobile bearing total knee replacements, allowing for changing centers of rotation. Over the years, it has undergone 2 revisions in design. The latest model has been in use since 1987 and has the most clinical experience of any disk prosthesis. More than 2,000 prostheses have been implanted, with the largest series of 105 patients being reported as a generally successful procedure.[48]

The ProDisc was developed by Marnay and coworkers in the 1990s. It consists of a polyethylene cap articulating with 2 titanium alloy end plates. In contrast to the Link SB Charite, the metal-polyethylene-metal articulation is a cap over cup design, which also allows for motion in all 3 planes. The only published article is by Bertagnoli and Kumar, who reported on a series of 108 patients with a follow-up ranging between 3 months and 2 years.[39] The overall success rate was 90.8%. However, it was 98% in patients considered having "prime" indications.

Viscoelastic Disk Replacements

The previous 2 disk prostheses use polyethylene as articulations surface because of its low friction and excellent wear characteristics. However, polyethylene lacks elasticity and cannot replicate the normal compressive stiffness of the natural disk. The mechanical type of prostheses relies on the restoration of a mobile lordosis to absorb load across the lumbar spine, as opposed to within the disk itself.[48] Steffee designed the AcroFlex artificial prosthesis that used a polyolefin-based rubber core vulcanized between 2 titanium end plates. The rubber core allows for not only the range of motion but is also able to replicate normal disk elasticity. Theoretically, this design should allow for better absorption of loads. However, the trade-off is in the use of materials, with potentially inferior wear characteristics as shown by the relatively high rates of failure. In the original series of 6 patients, 2 were reported as having failures due to fracture of the rubber core.[49] A second-generation device using a silicone core instead of rubber was implanted in 8 patients with one mechanical failure. All failures occurred at levels with increased stress, either due to adjacent fusion levels or scoliosis. The AcroFlex is now in its third generation of design, reverting back to the rubber core optimized with improved processing and bonding techniques, and refined indications for surgery. Although functional outcomes following implantation have been generally satisfactory, further trials with the third generation prosthesis have been halted because of the detection of early failure of the rubber core on fine-cut computerized tomography (CT).[37]

The fine-cut CT used in the AcroFlex study identified a significant number of patients with periprosthetic heterotopic ossification. This may be another potential source of failure for any disk replacement by limiting the range of motion. Future studies should incorporate the use of fine-cut CT and report on any loss in the range of motion.

Critical Review of The Literature

Any critical assessment of the evidence related to a medical treatment should begin with an assembly of published peer-reviewed literature.[50,51] As such, a thorough search of both the PubMed and

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Ovid Medline databases up to October 2002 has been performed, and articles relevant to the current clinical use of disk prostheses are summarized in Table 1. It has been divided into the assessment of outcomes that are considered important to disk replacement: (1) complications, (2) overall clinical function, (3) restoration of disk function, and (4) preservation of adjacent levels.

Given the relatively recent introduction of the disk replacements into clinical practice, there is a commendably reasonable follow-up, with an average for of all articles of just less than 2 years. Although 2 years represents a minimum standard of follow-up for surgical articles, the reader should bear in mind that the conclusions of many of these articles are based on patients with significantly less follow-up and that standard follow-up for mechanical arthroplasties should be much longer. This is especially true when assessing the safety of these implants. Given their relatively large size, proximity to vital structures, and difficulty with anterior low-lumbar revision surgery, complications related to mechanical failure can be disastrous.

Various and often ill-defined definitions of clinical functional success have been used in the articles, with reported success rates ranging from 63% to 95%. Although it is hard to make comparisons because of different case-mix, these results are comparable with case series reports for spinal fusion, and various forms of nonoperative care.[23,56-66] Clearly, randomized controlled trials using validated and independent assessments of function and safety are required to determine the efficacy of disk replacement relative to the current standard of care. However, given the large variability in function related to factors other than disk pathology, a substantial effect from the disk replacement would be required to show statistically significant differences. Using baseline results and variance from a recent randomized controlled trial on fusion for back pain, it is estimated that more than 500 patients are required to determine a 10% improvement in success rates, assuming a 2:1 study design with a power of 0.8.[23]

Although the short-term clinical differences between fusion and replacement may be small, disk replacement has a theoretic advantage of restoring disk function and, hence, preserving adjacent level disease. Nearly all reported studies have shown restoration of disk height and range of motion following implantation of prosthesis. However, restoration of load bearing and buffering function has yet to be shown in vivo. Given the importance of preservation of adjacent levels as a rationale for disk replacement, only 3 studies have evaluated adjacent levels. Cinotti and coworkers performed MRI on 10 patients from their original cohort of Link SB Charit, III prostheses and have shown no adjacent level degeneration.[52] However, it is difficult to make any conclusions because more than 75% of their original cohort have not been investigated. Bertagnoli and Kumar have shown that radiographic evidence of adjacent level degeneration developed in 4.6% of patients within 3 to 24 months of implantation of the ProDisc.[39] However, with short follow-up, it is unclear if this represents the natural history of disk degeneration in this patient population and whether it is significantly less than would have occurred if they had undergone a lumbar fusion. Many studies of adjacent level disease following fusion use MRI and/or have longer follow-up.[14,20,32,67] The closest methodologically to Bertagnoli and Kumar's[39] study was the study by Kumar and coworkers, which showed an 8% incidence of radiographically determined adjacent level disease at a much longer follow-up of 5 years following lumbar fusion with a normal sagittal alignment.[68]

Of concern to disk replacement's ability to preserve the adjacent levels is a study by Zeegers and coworkers, which reported 24% of patients requiring an operation at the adjacent level within 2 years of implantation of a SB Charit, III prosthesis.[53] This number is significantly higher than any reported for lumbar fusion. However, it may represent a failure to exclude adequately adjacent level pathology before proceeding with the index procedure. Regardless, there is no evidence to date that disk replacement protects against adjacent level degeneration.

Food and Drug Administration Status

To date, the Food and Drug Administration (FDA) in the United States has not cleared disk replacements for routine marketing. As such, any use of these devices is considered investigational. The manufacturer must show to the FDA's satisfaction that its prosthesis is as substantially equivalent (ie, as safe and effective) to a device

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Table 1. Summary of Published Peer-Reviewed Clinical Articles on Disk Replacement Arthroplasty

Author (yr)	*Disk*	*Sample Size (No. of disks)*	*No. of Follow-Up mo (range)*	*Study Quality*	*Restoration of Normal Mechanics*	*Preservation of Adjacent Levels*	*Clinical Success*	*Complications*
Enker et al (1993)[49]	Acroflex	6	40	—	8° avg. ROM	N/A	66% Success	33% Implant failure
Griffith et al (1994)	Charite SB III	93 (139)	12 (1-37)	—	N/A	N/A	65% Improvement in back pain	4.3% Migration/dislocation 1% core failure
Cinotti et al (1996)[52]	Charite SB III	46 (56)	38 (48-60)	IR, NC	12° avg. ROM	No degeneration on MRI for 10 patients	63% Good or excellent, 17% required eventual fusion	26% Placed too anterior-ROM affected if malpositioned,
Lemaire et al (1997)[48]	Charite SB III	105	51	NC	7° avg. ROM, >50% restoration of disk height and lordosis	N/A	79% Excellent	2.9% Related to implant (1 subsidence, 2 ossification)
Zeegers et al (1999)[53]	Charite SB III	46 (75)	48	NC	74% Good technical radiographic result	24% Required adjacent level oR	70% Improved	1 Required conversion to fusion
Sott et al (2000)[54]	Charite SB III	15	48 (18-68)	NC	N/A	N/A	80% Good or fair results	None related to implant
Bertagnoli and Kumar (2002)[39]	ProDisc	108 (134)	(3-48)	VQ, NC	10° avg. ROM	4.6% Adjacent level degeneration	90.8% Excellent	None related to implant
Hopf et al (2002)	Charite SB III	35	15	NC	Correction of avg. lordosis by 7°	N/A	80% Reduction in pain medication	None related to implant
Bertagnoli and Schonmayr(2002)[45]	PDN - Phase III trials	168	6 (3-24)	VQ	Preservation of disk height	N/A	88% Success	26% Required revision for migration
Hochshuler et al (2002)[55]	Charite SB III	22	12	VQ	N/A	N/A	40% Improvement in Oswestry	None related to implant
Klara and Ray (2002)[44]	PDN - All phases	423	Up to 48†	VQ	Increase in disk height by an avg. of 1.8 mm reported in 7 patients*	N/A	43.7% Improvement of Oswestry scores reported in 7 patients	10% Overall explant rate
Link (2002)[47]	Charite SB III	20	46 (6-156)	VQ	7° avg. ROM	N/A	95% Reduction in pain	None related to implant

Abbreviations: IR, reported that outcomes assessed independently; NA, not applicable; NC, no conflict of interest stated; ROM, range of motion; VQ, validated questionnaire (eg, SF36, Oswestry) used in clinical assessment.

*Not clearly stated for radiographic details but implied because 7 patients reported for Oswestry.

†Clinical results of patients with shorter follow-up not reported.

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already on the market. More specific guidelines related to the device's indications, in vivo biomechanical testing, and clinical results have been published for spinal implants.[69]

Currently, 2 separate multicenter, randomized controlled clinical trials are being performed in the United States under the FDA's Investigational Device Exemption. The ProDisc is being compared with combined anterior and posterior fusion using pedicle screws and an interbody fusion construct, while the SB Charit, III is being compared with anterior interbody fusion using a B.A.K. Cage (Sulzer Spine-Tech, Edina, MN).[69] Both trials expect to recruit between 300 and 500 patients, and the manufacturers hope to achieve FDA approval within a few years.

The PDN has been given approval by the Canadian Therapeutic Directorate to begin a clinical trial. Three Canadian centers are recruiting patients for a prospective evaluation of the PDN.[44] The initiation of a FDA approved trial in the United States is pending. An international, multicenter prospective trial of the Acroflex Lumbar Disc Prosthesis has been halted because of an unacceptable high incidence of failure of the rubber elastomer.

Ultimately, these trials will address short-term safety issues related to the prostheses and whether the clinical efficacy is similar to fusion. However, as discussed previously, unless there is a large clinical effect, these studies may not have sufficient power to detect a difference with fusion. Long-term follow-up will be required to determine the overall safety of these implants and their ability to protect adjacent levels.

Future Directions

Developers in the field of artificial disk replacement have been trying to translate the success of peripheral joint arthroplasty to the spine. There is no question that the current prostheses are able to restore range of motion to the disk, at least in the short term. However, this does not necessarily result in pain relief or improved function. Not only is there an incomplete understanding of the differences between pathologic disk degeneration, and natural wear and tear aging, the current "gold-standard" tests for the diagnosis of discogenic back pain, MRI, and diskography have significant high false-positive rates.[12] As such, there is a large potential for misdiagnosis and operations for pain not originating from the disk, hence, the poor results often reported for treatment of discogenic back pain.

Combined anterior and posterior fusion has often been thought of as a "shotgun approach" to the treatment of back pain because it deals with many different potential pain generators, including not only the disk but also the ligaments and facets. In contrast, disk arthroplasty targets only the disk. As such, it is more vulnerable to the effects of misdiagnosis, and potential for replacing a nonpainful disk and not dealing with other pain generators. This is countered by the restoration of the functional spinal unit's range of motion. However, it is unclear whether the extra few degrees in range of motion offered by a disk replacement over fusion is functionally significant, especially given the motion available at adjacent levels and hips. Future generations of spinal arthroplasty will no doubt replicate the viscoelastic properties of the disk, while maintaining excellent wear characteristics, and also will attempt to address facet and other painful pathologies. Only time and carefully controlled, long-term trials will determine whether or not there exists a satisfactory technological solution for discogenic low back pain.

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Focus Issue

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Intervertebral Disc Prostheses

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Study Design. This article is based on a comprehensive review of the literature related to intervertebral disc prostheses.

Objective. To compile an overview of the results and complications related to various types of lumbar and cervical disc replacements.

Summary of Background Data. A functional disc prosthesis has been sought since the 1950s. Although there were a few early attempts, disc replacement did not become a viable therapy until the late 1980s. Devices that were used in Europe at that time are now being evaluated in the United States in clinical trials. Cervical disc replacements are currently in the early stages of development and evaluation.

Methods. A thorough literature search was conducted to identify articles published on intervertebral disc prostheses. Proceedings from conferences were reviewed as well. Articles were classified by topics, including lumbar total disc replacement, disc nucleus replacement, and cervical disc replacement.

Results. Results of total disc replacement are favorable, with 63–85% of patients having a good outcome. As with any procedure, issues related to patient selection, operative technique, and device size selection were learned from the early experiences with these devices. There has been only one disc nucleus replacement used in an appreciable number of patients. This has yielded good results, but there have been problems related to device displacement. There are increasing reports on the use of cervical disc replacements, but they are still in the early evaluation phases. However, as with the lumbar counterparts, new designs are being evaluated.

Discussion. Although still in the early phases of development, functional disc replacement will become a part of the spine surgeon's armamentarium for the treatment of patients with disc-related pain unresponsive to nonoperative care. The future in this area is exciting and bright with the introduction of new materials and new designs for implants. However, as with any new technology, there must be careful consideration of the safety of the devices, and their effectiveness will only be determined in long-term follow-up studies. [Key words: artificial disc, spinal arthroplasty, lumbar spine, cervical spine, review article]
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In most areas of orthopedics, fusion of joints was abandoned in favor of joint replacement decades ago. For the treatment of patients with pain originating from the intervertebral disc, the move to spinal arthroplasty has been extremely slow. There were attempts at disc replacements as early as the 1950s. Although these attempts apparently did no harm, there was either no benefit or the benefit may have been only short term. Not until the late 1980s and early 1990s did viable disc prostheses become a reality. Now the field has suddenly caught fire with many new prostheses for the back and the neck being developed. The purpose of this article is to review the current experience with these devices.

Traditionally, the operative treatment for patients with persistent back pain unresponsive to nonoperative therapy has involved spinal fusion. The techniques used have varied greatly, including anterior interbody fusion, posterior interbody fusion, posterolateral fusion with or without internal fixation, and various combinations of these approaches. Similarly, the type of bone graft used for spinal fusion traditionally was autogenous iliac crest. Problems with donor site pain and other problems led to the use of allograft of various types and sizes and bone morphogenetic proteins (BMPs). The role of the BMPs is still under investigation. However, even with these many variations of spinal fusion procedures available, the results are far from perfect. Also, there is a great deal of difficulty in determining if a solid fusion was achieved. In many studies, there has been a good clinical outcome in 70–75% of patients. Although this is acceptable, there is certainly room for improvement.

In the management of many orthopedic problems, the goal is to restore the injured or painful joint to normal function. The spine is no exception. Replacing fusion with a therapy that restores the spine to a more normal state intuitively is very desirable. This parallels what had been experienced with hips and knees, *i.e.*, progressing from fusing a painful joint to replacing the affected joint with an implant that allows motion. In the spine, there are many issues to consider in the design and use of such a device. There is the potential for injury to major vascular and neural structures during device placement, unanticipated device displacement or fracture, and wear debris. One must also consider the impact of a disc replacement on the facet joints and the adjacent vertebral segments.

Disc Replacement Designs

The goal of disc replacement is to implant a device that is safe, durable, and that functions similar to a normal intervertebral disc. Also, the prosthesis must be designed so that it can be implanted safely. Additionally, the ideal device would allow a safe revision. This is particularly important considering the relative small disc space and the proximity of the cauda equina, nerve roots, sympathetic chain, and major vascular structures.

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The device(s)/drug(s) that is/are the subject of this manuscript is/are being evaluated as part of an ongoing FDA-approved investigational protocol (IDE) or corresponding national protocol. No funds were received in support of this work. Although one or more of the author(s) have received benefits (e.g., honoraria, gifts, consultancies) for personal or professional use from a commercial party related directly or indirectly to the subject of this manuscript, benefits will be directed solely to a research fund, foundation, educational institution, or other nonprofit organization which the author(s) has/have been associated.
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Special attention must also be paid to the fact that if there is implant fracture or wear debris, these structures are at risk of injury. Currently, there are two basic types of disc designs: total disc replacements and disc nucleus replacements. The results and complications reported for the various implants that have been used clinically will be discussed.

Metal Spheres. The first disc replacement used in a large number of patients was a stainless steel ball. In 1966, Fernström[1] reported his results with this device, which he had implanted into the disc spaces of 125 patients after lumbar discectomy. Based on the results at follow-up evaluation, ranging from 6 to 30 months after implantation, he reported that the results were better than those achieved from discectomy alone. There were very few complications, consisting of one displaced device (0.7%) and one case of temporary paresis (0.7%). He also reported that there was motion at the levels receiving the spheres.

Another report on the use of metal spheres, implanted in 40 patients, was published in 1972.[2] The author noted that the devices had not subsided into the vertebral bodies and that there was motion at the implanted levels. The same author later reported on the long-term follow-up evaluation of 67 patients in whom the metal spheres were implanted.[3] The follow-up period ranged from 10 to 20 years. Good to excellent results were noted in 83% of patients who underwent surgery for sciatica and in 75% of patients with disc degeneration or postlaminectomy syndrome and who were initially considered fusion candidates. Results for patients who underwent surgery for spondylolisthesis or facet arthritis were not as positive. In only one patient the sphere required removal. Eight patients eventually had a spinal fusion. Four patients developed discitis. The authors suspected that this was less likely related to the spheres and probably related to discography being performed by inexperienced radiologists or the use of overhead radiographic imaging intraoperatively.

Acroflex Disc. One of the few one-piece total disc replacements made of a combination of metal and plastic, the Acroflex disc (Acromed, Raynham, MA), was implanted in six patients during the late 1980s.[4] This was a one-piece device consisting of two metal plates with a rubber core adhered between them. Among the six patients, four had acceptable results, one patient had a poor result related to failure of the device, and the remaining patient had a poor result but the device had remained intact. This device ceased being used because of concerns about a possible carcinogenic agent in the rubber. Recently, there has been some testing of this device, but it appears that there are problems with failure of the rubber component in this totally constrained device.

SB Charité. The disc that has emerged as the most commonly used disc prosthesis was created in Germany in the early 1980s.[5] The Link SB Charité III (Waldermar Link, Hamburg, Germany), the third generation of design, has been used since 1987 with more than 5000 implanted worldwide to date. The Charité consists of two metal (cobalt-chrome) endplates with a sliding polyethylene core between them. There is a metal wire around the circumference of the core to aid in imaging. The device is anchored to the adjacent vertebral bodies by teeth on the surfaces of the endplates and bony ingrowth surfaces (available everywhere except in the US Investigational Device Exemptions [IDE] study). It is a nonconstrained device that attempts to mimic normal disc biomechanics by permitting translation and rotation. The rate of favorable results achieved with the device ranges from 63% to 85%, with most studies reporting good results in more than 70% of patients.[6–9] The length of the follow-up period in these studies ranged from 18 months to more than 5 years, with several studies having a mean follow-up period of more than 3 years. One of the longest follow-up studies has been reported by Lemaire,[7] whose study had a mean follow-up period of 51 months. Of 105 patients, 79% had a good outcome, and an additional 6% had a satisfactory outcome. The return to work rate was 87%.

Table 1. Summary of Reported Complications Related to the SB Charité III

Complication	N Patients	N Events	%	
Neurological:				
Temporary[31]	50	7	14.0%	
Permanent[31]	50	3	6.0%	
Sympathetic disturbance[27,31]	65	12	18.5%	
Painful or numb scar[31]	50	5	10.0%	
Hematoma[31]	50	12	24.0%	
Visceral dysfunction[31]	50	1	2.0%	
Retroperitoneal hematoma[31]	50	1	2.0%	
Abdominal pain[31]	50	1	2.0%	
New pain or pain progression (temporary)[31]	50	5	10.0%	
Micturation disturbance[31]	50	1	2.0%	
Urinary tract infection[31]	50	4	8.0%	
Retrograde ejaculation[19,31]	93	2	2.2%	(of males)*
Deep vein thrombosis[31]	50	1	2.0%	
Phlebitis[19]	105	2	1.9%	
Pulmonary embolism[19]	105	2	1.9%	
Acute leg ischemia[19]	105	1	0.9%	
Infection of prosthesis[31]	50	0	0.0%	

* In the Zeegars' study,[31] the number of males was not reported. For this table, it was estimated that 50% of the 50 patients in his study were male. (The table was based on only the studies which reported the presence or absence of each specific complication. Similar data has not been published for other devices.)

Complications related to the use of the Charité III disc are similar to those encountered with anterior lumbar interbody fusion and are generally related to the approach to the disc space. Complications related to the use of the Charité III have been reported in several studies and are summarized in Table 1.[7–9] (Similar data are not currently available for other devices.) As with reviewing complications encountered with any surgical procedure, the process is difficult because of the variation in the criteria each author uses to define a complication. We calculated the percentage based on the number of patients in the studies that reported the complication or noted that the complication did not occur. This may result in the percentages being greater than the actual rate because of authors not commenting on complications that were not encountered.

Device placement-related complications have also been reported. In a series of 96 patients, David[6] reported 10 reoperations, including one case of bone migration resulting in fusion surgery, one device removal and fusion, and eight patients who underwent fusion leaving the disc prosthesis in place. In an additional five patients, there was complete ossification around the implant. In a series of 50 patients published by Zeegers *et al*,[31] six patients underwent reoperation to address posterior element abnormalities. Perhaps the most pertinent complication reported in the series was the great difficulty encountered when attempting to reoperate to reposition the prosthesis. This

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resulted in converting the procedure to a fusion, and the patient eventually required three additional vascular surgeries on the aorta. This case highlights the difficulty with any type of revision anterior spine surgery and the increased risk of vessel damage. As these authors noted, this series included their first 50 [illegible] represented the learning curve associated with any procedure. Lemaire[7] reported reoperations and radiographic findings in a series of 105 patients. One patient underwent revision surgery because of posterior joint instability resulting in L5 paralysis, and another patient underwent surgery to address an endplate fracture requiring fusion. There was one case of subsidence into an osteoporotic vertebral body, and ossification around the prosthesis was noted in two patients. Another author noted asymptomatic subsidence of a device into a vertebral body.[8]

[illegible] current SB Charité III, there have been no published reports of device failure or displacement from the spinal column. There has been concern about the possibility of wear debris from the sliding polyethylene core in the Link disc and a similar concern with the polyethylene core in the ProDisc. However, to date, there have been no data from laboratory studies or clinical cases to suggest that this is a problem. This is particularly impressive because the discs have been in clinical use for more than 10 years.

[illegible]ently, the US IDE study, which began in March 2000 and [illegible] enrollment in December 2001, is awaiting the 2-[illegible]-up completion of the study and consideration by the Food and Drug Administration (FDA) for release for general use. This was a randomized Charité to BAK study of 2:1 for single-level L4–L5 or L5–S1 disease in which 375 patients were enrolled. Two hundred seventy-six patients (including 71 nonrandomized patients) received the Charité disc and 96 received the BAK. A second arm of continued access is ongoing presently. Preliminary results from one of the study centers were [illegible] published and were promising.[10] The authors reported [illegible] visual analog scale (VAS) score assessing pain improved 52.7% at the 6-week follow-up visit compared with the preoperative score. The improvement was maintained during 12 months. The Oswestry disability score improved 39.4% at 6 weeks, and the improvement was also maintained during the 12-month follow-up period. As the authors noted, these preliminary results are encouraging, but longer-term follow-up evaluation with more patients is needed.

ProDisc, another disc replacement that has been used in Europe since 1990 is the ProDisc (Spine Solutions, New York, New York). It consists of three pieces: two metal endplates and a polyethylene core that is fixed to the inferior endplate when the device is implanted. It is a semiconstrained device. The inventor of the device, Marnay,[11] recently reported on the results of using ProDisc. The study was based on the 8- to 10-year follow-up evaluation of 70 patients. An excellent or good result was achieved in 78% of patients. Complications reported in the study included one iliac vein injury that was repaired intraoperatively, [illegible] of appendicitis with peritonitis, and a disc herniation [illegible] level above an ankylosis of the prosthesis resulting from calcification. There were no cases of device failure, and none of the devices required removal.

Mayer *et al*[12] published the early results of the ProDisc in a group of 34 patients of whom 26 patients had undergone surgery at least 3 months previously. The mean follow-up period for the entire group was 5.8 months. There were three complications: one case of nerve root irritation resulting from compression by nucleus material (this was managed successfully with injections), one patient underwent reoperation to replace the device because the core was not completely fixed to the inferior device endplate at the initial surgery, and there was one case of retrograde ejaculation. The authors reported promising clinical results, and Wiechert *et al*[13] reported 6-month follow-up evaluation of a subgroup of 16 of these patients. The mean VAS score improved from 7.0 to 1.9, and the Oswestry scores improved from 23.3 to 10.2. Although the authors are enthusiastic about the results, it must be noted that the follow-up period is very short.

Bertagnoli and Kumar[14] published the results of ProDisc implanted in 108 patients with a follow-up period of 3–24 months. They reported that 91% of the patients had an excellent outcome, 8% a good outcome, 1% a fair outcome, and none had a poor outcome. Unfortunately, the authors did not provide information concerning the criteria used to make the outcome classification. The authors reported only one complication, which was systemic septicemia that was managed successfully with antibiotics. The ProDisc is being studied in a US IDE study that began in October 2001. It is a randomized study, in which patients receive the ProDisc or an anteroposterior fusion with pedicle screw fixation either unilateral or bilateral in a 2:1 ratio. One or two of the three lowest lumbar levels can be implanted. As of this writing, more than 300 patients have been enrolled, and the single replacement arm will be complete in the first quarter of 2003. A 2-year follow-up evaluation will be needed before its consideration for release to the US market.

Other Total Disc Replacements. There are several other discs that have been designed and are in various stages of testing. The Maverick disc (Medtronic Sofamor Danek, Minneapolis, MN) is a metal-on-metal design with anchoring keels similar to the ProDisc and is being tested in Europe. Clinical trials have not yet been initiated in the United States.

The Flexcore is another disc that uses a unique biomechanical design involving seven preassembled pieces that include a conical internal specialized spring. This disc is still in its developmental stages, although it is hoped that clinical testing will start in the near future.

An additional disc replacement with a unique design has been evaluated in laboratory and animal studies.[15] It is made of a triaxial three-dimensional fabric woven from a high molecular weight polyethylene fiber. The inferior and superior surfaces are coated with a bioactive material to allow bony ingrowth to anchor the device. The authors reported that the disc produced promising results in their early investigations. However, as with any new device, long-term investigation is needed. For this particular device, this is especially important to determine if bony ingrowth eventually occurs through the implant producing a fusion.

Disc Nucleus Replacements. Although we currently think of disc replacements as fusion alternatives, nucleus replacement devices have the same advantage but may also be viewed as postdiscectomy augmentations. This use of artificial discs parallels those practiced in the 1950s and 1960s. With respect to replacing spinal fusion, nucleus replacements may be useful for the treatment of patients with early symptomatic disc disruption. This application may address pain related to the chemical irritation of neural tissue induced by neurotoxic agents leaking from the disc nucleus. In the future, these procedures may be

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performed at the time of discectomy to maintain normal anatomy and biomechanics of the spine. As with many new techniques, long-term studies will determine their place in the treatment armamentarium for patients with spine disorders.

When considering the functions of a normal disc nucleus, it appears natural that investigators were drawn to the use of hydrogels. Intuitively, such materials should closely mimic the functions of a normal nucleus. They absorb water to increase in size and fill the disc space. Their high water content potentially mimics the hydrostatic load-bearing and load distribution characteristics of an intact nucleus.

The most widely used nucleus replacement is the PDN (prosthetic disc nucleus; Raymedica, Minneapolis, MN). The device is made of a hydrogel core encased in a polyethylene jacket. The hydrogel absorbs water and expands to fill the nuclear cavity. The jacket prevents the hydrogel from expanding too much. Two of the devices are implanted at each operated level.

There have been presentations by Ray[17] and Schrönmayr[17] at recent conferences involving approximately 300 patients who received the PDN device. There was a dramatic improvement in Oswestry disability scores from 50 to less than 10. The pain scores also improved dramatically from 7 to less than 2. Although the clinical outcome reported with the PDN is good, there have been problems with device displacement. The operative technique has been changed, but the occurrence of this problem is still relatively high, at approximately 6%. In a recent publication dealing with the PDN, Klara and Ray reviewed the history of the device.[18] They reported that in a group of 51 patients, the Oswestry disability scores improved from 52 to a score of 10 at the 2-year follow-up evaluation, and the score was 8.3 at the 4-year follow-up evaluation; however, the number of patients for whom the follow-up data were derived was not clearly reported. The authors also noted that since 1996, 423 patients have received the devices. The PDN has been explanted in 10% of patients.

Korge *et al*[19] reported a nucleus replacement made of polycarbonate urethane that is a memory coiling spiral called the Newcleus® (Centerpulse, Sulzer SpineTech, Minneapolis, MN). This device has undergone laboratory testing and evaluation in animals and has been implanted into five humans with radicular pain caused by disc herniation. Two years after the implantation, there were no complications, the facet joints were completely functional, there was clinical improvement indicated by improvement in VAS and Oswestry scores, and the patients reported being satisfied with their results. The authors reported that an international multicenter study has been initiated. Several other companies are working on nucleus replacements that are in varying stages of development and clinical studies. With the goal of mimicking the natural disc nucleus, Mathys Medical Ltd (Bettlach, Switzerland) has designed a hydrogel memory coiling material.[20] The material is inserted through a tube and coils in the cavity. It then hydrates to fill the height of the disc space. Stryker Howmedica Osteonic (Allendale, New Jersey) produced the Aquarelle® Hydrogel Nucleus made of a polyvinyl alcohol; Disc Dynamics (Eden Prairie, MN) made a polyurethane balloon-like implant that is injected into the disc space; CryoLife BIODISC® (Kennesaw, GA) developed a protein hydrogel that is also injected into the disc, which then sets into a firm weightbearing substance; Disc Augmentation Technology has a thermopolymer nucleus replacement.

Range of Motion. One of the problems with lumbar fusion is the loss of motion at the operated segment and the subsequent adjacent level degeneration or what is now termed the "transition syndrome." Artificial discs are designed with a goal of allowing motion at the operated segment. Not only should this allow patients to engage in a more normal lifestyle, it should also reduce the chances of future pain originating from the adjacent motion segments. There have been few reports on range of motion after disc replacement.

Lemaire *et al*[7] and Cinotti *et al*[21] reported on results after the implantation of the SB Charité disc and noted very similar results. At the L4–L5 level, the mean motion was approximately 15° and 9° at the L5–S1 level. Cinotti *et al*[21] investigated factors related to amount of motion present at follow-up evaluation. They found that the amount of motion was related to device size, device positioning within the disc space, and the patient's postoperative treatment program. Range of motion was greatest at segments where the prosthesis covered 80% or more of the vertebral endplate. Greater motion was also associated with the prosthesis being implanted slightly posterior to the center of the disc space in the anteroposterior view than if the disc was positioned more anteriorly. This finding was recently supported in a biomechanical study using finite element analysis and a different design of artificial disc.[22] Results of these studies emphasize the importance of the details of intraoperative device placement for maximizing the clinical results achieved with disc replacement. The motion of the replaced segment among patients who wore a corset for 3 months after surgery was only half of that seen in patients who began exercising 1 week after the disc implantation surgery. Use of the artificial disc fits well with a philosophy promoting early and active postoperative rehabilitation.

A recent study of the ProDisc reported that among 54 patients who were followed more than 1 year, the average range of motion after disc replacement was 9° at L5–L1 and 10° at L4–L5 and L3–L4.[14] These results were much more favorable than those recently reported at a conference on the ProDisc I design.[23] The authors reported that at a mean follow-up period of 8.6 years, ranging from [illegible] to 10 years, the mean range of motion was 3.2° at L5–L1, 4.5° at L4–L5, and 4.0° at L3–L4. One cannot determine if the decreased range of motion in the study with a longer follow-up period is related to a decrease in the performance of the device, differences in the design between the current disc and the first design, or possibly changes in the operative technique or postoperative treatment protocol.

Postoperative Rehabilitation. As with any spine surgical intervention, treatment does not end with the operation. Postoperative rehabilitation is critical to achieving a good treatment outcome. From the standpoint of indications and operative technique, total disc replacement is very similar to anterior interbody fusion. However, the postoperative rehabilitation is very different. After arthrodesis, patients typically wear a brace and avoid motion. This allows the fusion mass to incorporate during the ensuing 3–12 months. Patients are discouraged long-term from activities that require much bending or rotation to prevent the accelerated degeneration of the disc adjacent to the fused segment. Spinal arthroplasty requires a different approach. Patients need to participate in a rehabilitation program encouraging controlled, progressive motion of the spine. Typically, flexion exercises are initiated first. Extension is avoided in the early postoperative period to allow healing of the anterior wound incision. Rotation is introduced after flexion, and

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when extension is allowed. As suggested by Cinotti *et al*,[23] failure to engage in spinal motion exercises early in the postoperative rehabilitation program is likely to result in reduced motion at the operated segment in the long-term follow-up period. As with most postoperative patients, general physical reconditioning is needed. Most spine surgery patients have been [illegible] pain patients and have reduced or eliminated activities because of their pain.

Indication and Contraindications. Indications for total disc replacement are similar to those for anterior interbody fusion. Before considering disc replacement, the patient should have failed to improve after an appropriate course of nonoperative care, including active rehabilitation, activity modification, medication, and, in some cases, spinal injections. The patient should have pain related to disc disruption or degeneration. If there are concerns about a strong behavioral component to the patient's pain, preoperative screening by a qualified psychologist should be sought.[24] Computed tomography (CT) and discography are helpful in determining if the disc is the pain generator and similarly which level(s) should be replaced.

Use of the current total disc replacements in patients with more than a few millimeters of slip is ill advised because of the inherent malalignment of the metallic endplates, which would occur in such patients, and the lack of posterior element support. There are several possible applications for artificial discs that have yet been investigated. These include the level adjacent to a previously fused segment and painful disc levels in patients with scoliosis.

One contraindication for the total disc replacements with metal endplates is osteoporosis. The concern is a potential increased risk of endplate subsidence into the vertebral bodies. Routine bone density scanning on all patients is likely not necessary. However, one may desire to screen the patient's family history, smoking status, and personal characteristics that are related to osteoporosis (fair hair, fair skin, small frame), and if risk factors for osteoporosis are identified, a bone density scan may be obtained.

Facet joint abnormality is considered a contraindication for disc replacement. The effect of an articulating disc on the facet joints is not known, but there is concern that pain originating from the facets is not addressed, and there may be increased risk for the development of joint hypertrophy resulting in painful stenosis.

In [illegible] reporting indications and outcomes when using the [illegible] Bertagnoli and Kumar[14] defined four indication criteria categories based on disc height, condition of the facet joints, number of levels operated, degeneration of other spinal segments, and condition of the posterior elements. They defined a "prime" candidate for the procedure to be a patient with a disc height of more than 4 mm, no facet joint changes, single-level disc problem, no adjacent segment degeneration, and intact posterior elements. Among patients in this group, 98% of patients were satisfied with their operative result. Results in the "marginal" and "borderline" indication groups indicated [illegible] satisfaction. No patients with "poor" indications [illegible] disc replacement surgery. Although the patient satisfaction rate was high in the three groups, it should be noted that the study follow-up period was in the range of 3–24 months, which is not long enough to truly determine outcome and its relationship to indications.

The use of nucleus replacements still needs more investigation to identify appropriate indications. In the data presented at conferences, indications for these devices have been described as chronic degenerative pain unresponsive to nonoperative treatment, and one study also included patients with recurrent disc herniation.[7,8,17] In a recent article, Klara and Ray[13] described the indications for the PDN device to be back pain, with or without leg pain, related to degenerative disc disease that is refractory to nonoperative treatment. Patients with a disc space height of less than 5 mm are excluded because of the difficulty of implanting the device in such a narrowed disc space. The authors also noted that annular defects might exclude a patient from receiving a nucleus replacement because the device applies tension to the anulus. It appears that such implants may be useful to manage the very early stages of symptomatic disc disruption. They will probably have a role as an adjunct to discectomy to maintain disc space height and motion at the operated level. These proposed indications need future clinical investigation.

Cervical Disc Replacements. The pursuit of cervical disc replacements has not been as vigorous as for their lumbar counterparts. Although the design of lumbar disc replacements is difficult and there is a risk of potential complications, the risks are even greater in the cervical spine. One may think of cervical disc replacements as miniature versions of lumbar prostheses, but the biomechanics of the cervical spine are different and must be considered when designing a cervical prosthesis.

Cummings *et al*[25] reported on the use of a two-piece stainless steel disc replacement called the Bristol Disc (Cummins, UK) in a series of patients described as having spondylosis with myelopathy, and 19 of the 20 patients had previous surgical or congenital fusion. Motion occurs through articulation between concave and convex surfaces. Each piece of the device is L-shaped with a concave or convex surface in the disc space and an exrension that is attached by screws to the anterior portion of the vertebral body. The authors reported on a series of 20 patients, of whom 18 were available for follow-up evaluation. Fourteen of the patients had previously undergone cervical fusion at an adjacent segment, and a congenital fusion was noted at the segment adjacent to the replaced level in four others. Postoperative radiographs showed motion of the joint in 16 patients. In the remaining two patients, disc space distraction at device implantation was great enough to separate the facet joints. With regard to clinical results, 16 of the 20 patients reported improvement. In the first five patients in the series, only one screw was put into the anterior portion of the device. Among these patients, three had a partial screw pullout, one had a broken screw, and there was one joint subluxation. After this experience, the technique was changed so that two screws were used to attach each component of the device to the vertebral bodies. This resulted in two cases of partial screw pullout, one broken screw, and one joint subluxation associated with persistent dysphagia. To address these problems, in the remaining 15 patients, two screws were placed into the anterior portion of each piece of the device. Among these patients, there were two partial screw pullouts, one broken screw, one transient hemiparesis (caused by drill injury), three patients with mild persistent dysphasia, and one reoperation to remove a device that was loose. The authors acknowledged the rather high complication rate and noted that the causes were primarily the result of the use of a uniform sized device, not adaptable to individual patient anatomy, and the high profile of the device probably caused the dysphagia.

In a recent study, Wigfield *et al*[26] reported the results of a

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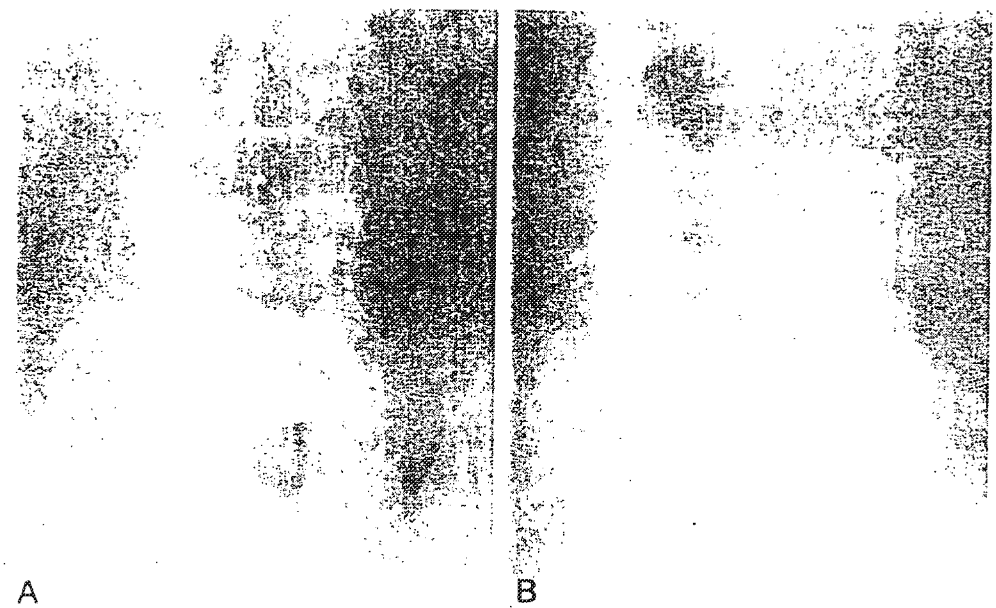


Figure 1. Radiographic (A) anteroposterior and (B) lateral views of a Link Charité disc implanted at the L disc space.

prior study involving a new Frenchay cervical disc, which is a modification of the Bristol disc. They enrolled 15 patients with radiculopathy or myelopathy with evidence of compression in the presence of a congenital fusion or a previous surgical fusion. The 24-month follow-up data indicated a 46% improvement in arm pain and a 45% improvement in neck pain. The authors noted that joint motion was maintained in all cases except one patient from whom the device was removed. Complications encountered in the series included one patient who experienced the breakage of the two anchoring screws, one patient underwent removal of the device and a fusion procedure that also failed to relieve her symptoms, two patients had hoarseness that resolved, one patient had recurrent brachialgia that was treated with foraminotomy at the adjacent level, one patient had brachialgia that resolved, and two patients had progressive myelopathy. The authors attributed the need to remove one of the devices was the result of removal of too much bone during the operation.

Another study involving cervical disc replacement reported on a group of 10 patients described as having cervicobrachial pain for more than 3 months and magnetic resonance imaging (MRI) demonstrating small disc herniations.[7] The author used a metal L-shaped device with a carbon convex piece attached to it. Motion occurred through articulation between this convex carbon component and the concave endplate of the superior vertebral body. There were only 10 patients in the series. Eight of the patients had an acceptable clinical result, but radiographs demonstrated no motion at the operated level. The device was removed and a fusion was performed in one patient with persistent pain. The patient went on to have a good result. The other patient had ongoing pain but did not undergo reoperation.

The Bryan Cervical Disc (Spinal Dynamics Corp., Seattle, WA) is a low-friction, wear-resistant, elastic nucleus that is sandwiched between two titanium plates. It has been implanted in patients in [illegible] and reported [illegible] [illegible] [illegible] the disc replacement [illegible] [illegible] disease [illegible] [illegible] [illegible] at 24 [illegible]

nation. Based on Odum's criteria, at 12 months 70% of the patients had excellent results, 4% had good results, 13% had fair results, and 13% had poor results. At 24-month follow-up evaluation, the figures were similar. Clinical studies are expected to begin in the United States in the near future.

There several other discs that are being developed that mimic the present lumbar disc replacements. They are in varying stages of testing, and no clinical studies have been started yet.

The Future. We are likely seeing only a glimpse of the horizon of spinal arthroplasty. Artificial discs are now a reality. In the next few years, we will likely see many more designs of disc replacements made of new materials and incorporating new design concepts. Nucleus replacements will also be developed that potentially will become a routine part of lumbar discectomy procedures, restoring and maintaining disc space height and mimicking the load-bearing properties of a normal disc nucleus.

The future will bring more designs of total disc and disc nucleus replacements. Currently, total disc replacements yield good results in approximately 75% of patients. These results include patients who received the implants early in their development. As with any procedure, this initial experience has resulted in better knowledge of patient selection, selection of device size, details of ideal device placement within the disc space, and postoperative rehabilitation and activities.

Discussion

The results of current disc prostheses are promising. Total disc replacements have now been used in Europe for almost two decades and have performed well with regard to the lack of device fracture or displacement. Many new designs and new materials for disc prostheses are being tested. Some of these will probably [illegible] in the next few years. [illegible] generation beyond the current mechanical disc replacements, it is likely that materials that aid healing of disc [illegible] will be developed, and genetic engineering and [illegible] will [illegible]

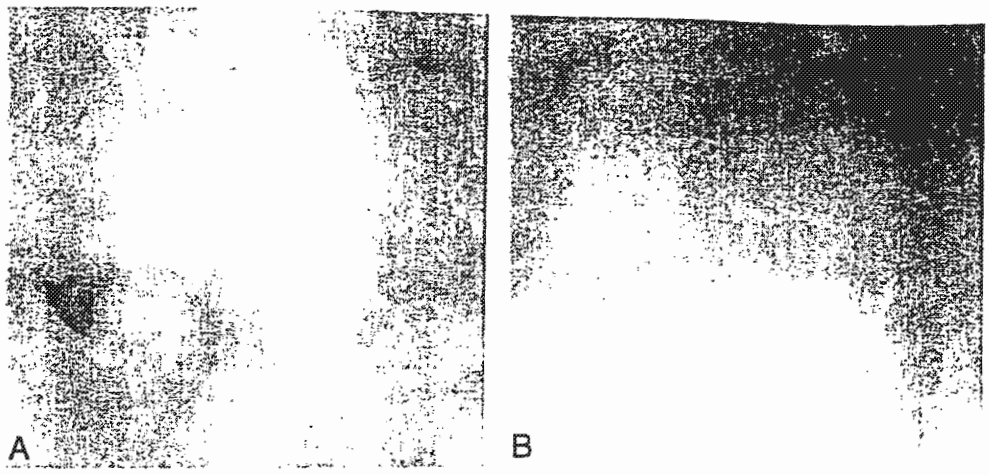


Figure 2. Radiographic (A) anteroposterior and (B) lateral views of a ProDisc implanted at L disc space.

using new alternatives. For now, we have already learned much from the pioneers of disc replacement technology with regard to the importance of device size selection and placement within the disc space. These details not only prevent complications but also are related to achieving an optimal clinical outcome long term.

Although there is a great deal of enthusiasm over disc replacements, there are also concerns that must be considered before such technology is fully embraced. As with any metallic spine implant, one must consider the relationship between the implant and the vertebral bodies. As we age, our vertebrae become less dense, which may lead to osteoporosis. With respect to spinal implants, there is concern that aging will result in subsidence of the devices into the vertebral bodies. Subsidence was a problem with the first designs of the SB Charité disc. This problem was addressed by enlarging the endplate so that load was disseminated to the stronger cortical bone of the vertebral body rather than concentrated on the less dense cancellous bone in the center of the vertebrae. Such design factors may help reduce the risk of subsidence, but the possibility of long-term problems related to decreasing bone density associated with aging remains to be addressed. This will only be addressed fully when those patients who first received the devices become old enough to have developed significant osteoporosis. The potential for device subsidence into osteoporotic bone is currently addressed by not implanting devices into patients with low bone density. However, many patients undergoing surgery for the treatment of disc-related pain are relatively young, and changes in density have not yet occurred. Not only is subsidence a possibility but also there may be a risk of fracture at the operative levels in patients who develop osteoporosis. How whether the fracture rate is any greater in patients with osteoporosis and implants compared with those with osteoporosis and no implants remains to be determined. Vigilant monitoring and aggressive medical treatment may best address the potential problems related to device implantation in persons who develop osteoporosis.

Another potential long-term difficulty with the devices is the development of facet joint hypertrophy, which may result in painful spinal stenosis. In some patients undergoing spinal fusion, facet hypertrophy develops at the fused segment or adjacent segments. By more closely mimicking the natural disc, this problem may be reduced with artificial discs; however, the problem may be similar to that seen in fusion patients if normal motion is not preserved. As with the potential difficulty posed by the development of osteoporosis, only time will reveal the effects of disc implants.

Currently, disc prostheses are viewed primarily as replacements for fusion performed to manage pain related to disc degeneration. Although the clinical results of spinal fusion vary greatly, the overall rate of favorable outcome is approximately 70%. This number varies greatly with surgical technique, factors related to patient selection, diagnosis, length of follow-up period, and other variables that have not been explored; however, there is certainly room for improvement. One concern with spinal fusion that may lead to unfavorable results in some patients is the development of future problems in the spine. The altered loading and motion patterns created by fusing a segment may force additional stresses onto the adjacent segments, accelerating their degeneration. The exact incidence of this potential problem is not known, and its occurrence likely varies with the type of fusion and operative technique, the number of levels involved, the length of follow-up period, and the level of patient activity after surgery. As with any spinal surgery, a long-term follow-up evaluation is needed to determine the true results and shortcomings. However, the difficulty of performing long-term follow-up studies with significant numbers of patients has limited the quantity and quality of this type of information. There have been few reports with follow-up periods of 10 or more years. One article with a follow-up period of 21–52 years reported a 45% occurrence rate of instability at a segment above a fused segment.[39] However, the authors noted that these changes were not significantly correlated to symptoms, although the sample size was relatively small. There have

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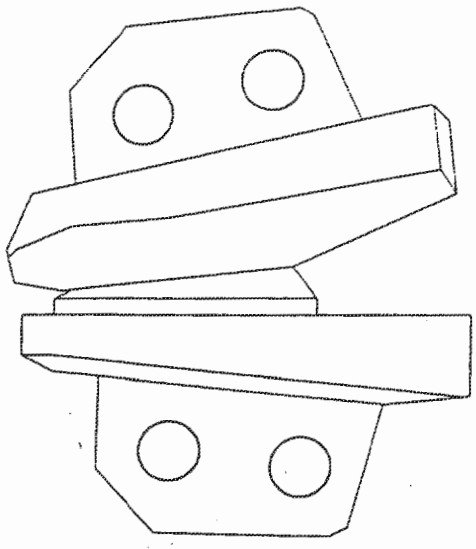


Figure 3. Schematic of the Maverick total disc replacement.

been two recent studies comparing the occurrence of changes at the adjacent segment in patients undergoing fusion with those treated with spinal arthroplasty methods.[23,31] In the study by Kanayama *et al*,[31] the level above the treated level, either by posterolateral fusion or the Graf artificial ligament, was studied a minimum of 5 years after surgery. Deterioration of the segment adjacent to the treated segment occurred in 25–43%, varying by intervertebral level, of the discs next to a fused segment. This was noted in only 6–18% of the patients with the Graf device. In the fusion group, 18.5% of patients underwent subsequent surgery to manage pain related to the adjacent segment compared with 5.6% in the Graf group. In a recent study presenting the long-term follow-up evaluation, mean of 8.6 years (range, 7–10 years), of the ProDisc I, a relationship between the range of motion at the implanted level and the condition of the adjacent segment was identified.[23] The authors noted that among the 34 junctional levels studied, 9 (26%) were degenerated. The range of motion of the implanted level below a degenerated disc was only 1.4°, which was significantly less ($P < 0.015$) than the 5° of motion noted at the implanted levels below a nondegenerated adjacent segment. These results indicate that the motion achieved with a functional disc replacement is related to degeneration at an adjacent segment, supporting the idea that artificial discs have a role in preventing adjacent segment breakdown. Although the results of both of these studies

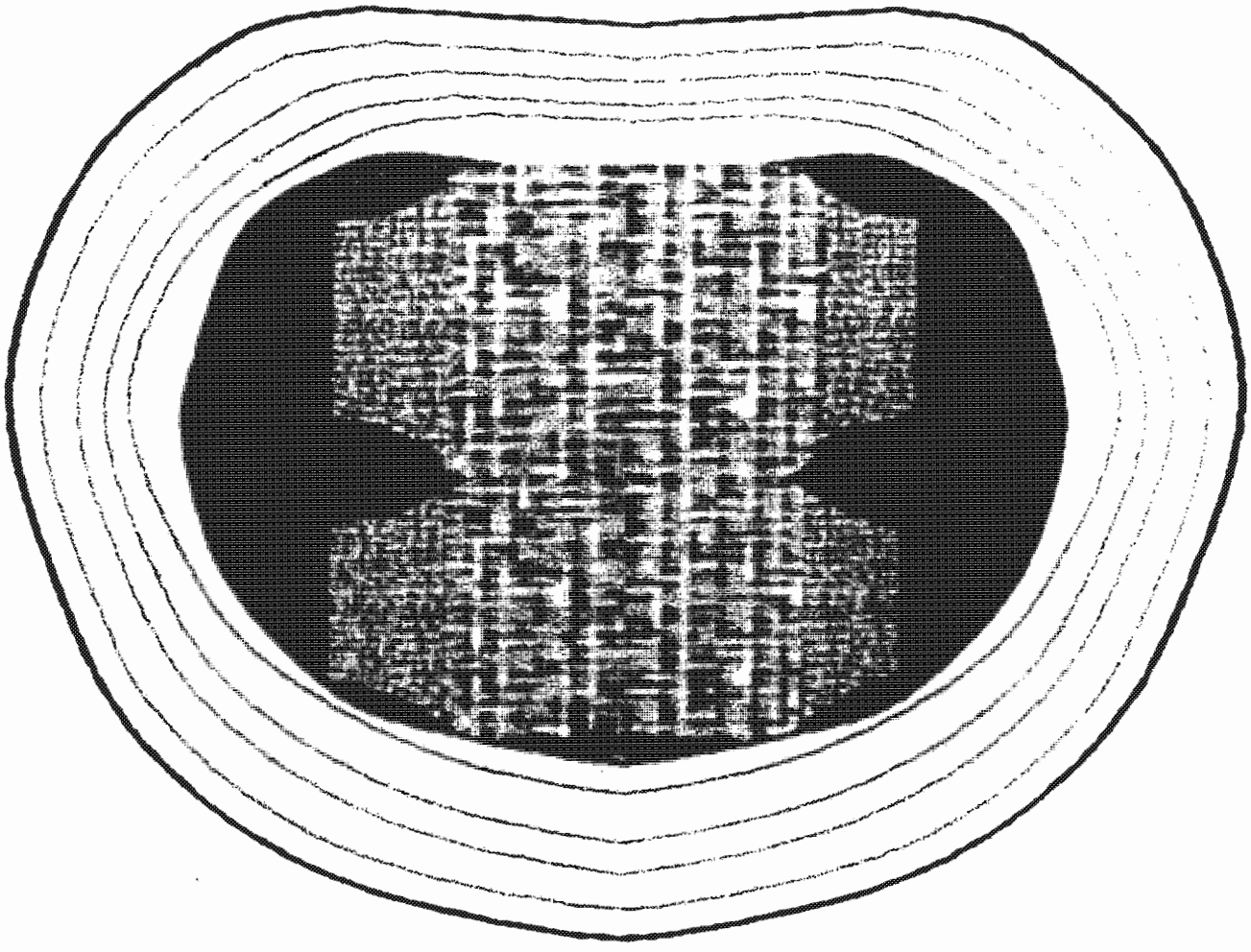


Figure 4. Schematic of the Ray PDN disc nucleus replacement.

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suggest that the use of devices designed to allow motion of an operated spinal segment reduces the occurrence of deterioration of the adjacent segment, more studies involving greater numbers of patients are needed to confirm these findings.

The technology of spinal arthroplasty holds much promise; however, like many new advances, physicians and patients cannot view it as a "cure-all." It must be looked on as another treatment modality along a continuum from nonoperative treatment through fusion. There will be newer advances beyond disc replacement, such as disc regeneration, but for now it offers a truly anatomic alternative rather than the salvage procedure of a fusion. It can only be effective if patients meet well-defined selection criteria. As the number of options increases for spinal arthroplasty, the type of disc treatment used will have to be matched with the patient's abnormality. Surgeons must be trained in applying patient selection criteria for individual devices and for the appropriate technique of device implantation. Only if these basic concepts are addressed can the promise that artificial discs hold be fulfilled. (Figures 1–4)

Key Points

- Artificial disc replacement has been used in Europe for more than 10 years with acceptable results reported.
- Care must be taken to carefully evaluate new devices.
- Although there is great enthusiasm over evolving technologies, factors of appropriate patient selection and operative technique remain key to achieving favorable outcome.
- The future of intervertebral disc arthroplasty is promising.

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Clinical Experience With the Dynesys Semirigid Fixation System for the Lumbar Spine

Surgical and Patient-Oriented Outcome in 50 Cases After an Average of 2 Years

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Study Design. Retrospective study on a consecutive series of patients.

Objectives. To examine patient-oriented outcome after Dynesys implantation.

Summary of Background Data. The dynamic neutralization system for the spine, Dynesys, is a nonfusion pedicle screw stabilization system, which was developed in an attempt to overcome the inherent disadvantages of rigid instrumentation and fusion. Although the system has been in clinical use for more than 5 years, no studies from disinterested research groups have reported on patient-oriented outcome after surgery with Dynesys.

Methods. A total of 50 consecutive patients instrumented with Dynesys over the preceding 40 months were invited to complete a postal, patient-oriented follow-up questionnaire. The data from 31 of 31 of these, with at least 2 years' follow-up, were analyzed (mean age, 50 years; SD, 13 years; 20 women, 11 men). The primary indication for surgery was degenerative disease (disc/stenosis) with associated "instability"; 11 of 31 (35%) patients had had prior spinal surgery. In 32% cases, 1 level was instrumented, in 52% 2 levels, 13% 3 levels, and 3% 4 levels. Thirteen of 31 (42%) patients underwent additional decompression.

Results. Within the 2-year follow-up period, 6 of 31 (19%) patients had required or were scheduled for a further surgical intervention. At follow-up, mean (SD) back and leg pain (0–10 VAS) were 4.7 (3.2) and 3.8 (3.6), respectively. The following global outcomes were reported: back symptoms, 67% improved, 30% same, 3% worse; leg symptoms, 64% improved, 21% same, 14% worse; ability to do physical activities/sports, 40% improved, 33% same, 27% worse; quality of life, 50% improved, 37% same, 13% worse; how much the operation helped, 29% helped a lot, 23% helped, 10% only helped a little, 35% didn't help, 3% made things worse.

Conclusion. The results of the present study indicate that both back and leg pain are, on average, still moderately high 2 years after instrumentation with the Dynesys system. Only half of the patients declared that the operation had helped and had improved their overall quality of life; less than half reported improvements in functional capacity. The reoperation rate after Dynesys was relatively high. The results provide no support for the notion that semirigid fixation of the lumbar spine results in better patient-oriented outcomes than those typical of fusion.

Key words: semirigid instrumention, Dynesys, fusion, patient-oriented outcome, degenerative disorders, back pain, leg pain. **Spine 2005;30:324–331**

Fusion is a widespread and accepted treatment for painful degenerative conditions of the lumbar spine. However, the inconsistent results reported in the literature indicate a basic lack of understanding regarding the exact mechanism of pain relief. Overall, the outcome after fusion appears to be quite inconsistent: a systematic review of mainly retrospective case series reported that satisfactory clinical outcomes ranged from just 16% to as high as 95%, with an average of around 68%.[1] Although technical errors and inaccurate indications might be responsible for failure in some instances, there is some suggestion that additional factors may play a role in governing the outcome.

In the course of the degenerative process, during which the segment undergoes various anatomic alterations, there are significant changes in both the motion characteristics of, and the load distribution across, the affected (and possibly also neighboring) segments.[2] The loading pattern and motion are to a certain extent interdependent, and alterations in either (or both) may contribute to the generation of pain.[3] The concept of spinal fusion originally arose from the notion that a degenerated motion segment is often "unstable" or shows "movement abnormalities," and that accordingly, the elimination of motion in the affected segment would prevent it from undertaking the movements associated with the generation of pain. Recent thinking, however, suggests that the prevention of movement per se may not be the most important factor accounting for the success of fusion.

For a long time, solid fusion was thought to be a requirement for a successful outcome: however, the results of many recent studies have challenged this concept by showing that patients' self-rated improvements in pain and function after surgery are unrelated to the attainment of solid fusion.[4–8] It is now well accepted that degeneration of the spine is often, but not invariably, associated with pain. It has been noted that back pain is

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primarily related to position or posture, rather than movement of the lumbar spine, and it has thus been hypothesized that it is the abnormal pattern of loading associated with degeneration, rather than the abnormal movement itself, which accounts for disc degeneration causing back pain in some patients.[3] The fact that, in a given patient, the precise position that provokes an abnormal loading pattern is rarely known may explain why the results of fusing the spine in one position appear to be somewhat "random" as regards clinical success.[3]

The dynamic neutralization system for the spine (Dynesys) is a nonfusion pedicle screw stabilization system, which was developed more than 10 years ago.[9] In view of the arguments presented above, and the suggestion that prevention of all movement within fused segments may not only be detrimental to sagittal balance and overall function, but may also elicit accelerated degenerative changes in neighboring segments, "soft stabilization" was developed. Although the system has now been in clinical use for almost a decade, there are few studies in the literature that report on patient-oriented outcome after Dynesys implantation. A recent report from the originators of the system reported marked reductions in average pain and disability in a group of 73 patients, approximately 3 years after Dynesys instrumentation.[9] However, neither the proportion of patients declaring a successful global outcome nor the proportion attaining a clinically relevant change in pain or Oswestry disability was reported. Furthermore, the complications reported with the 3-year period were quite considerable. To date, only one study from a disinterested research group has been published in the peer-reviewed literature.[10] In this small, retrospective study, patient-oriented outcomes after dynamic stabilization (n = 10) were compared with those of historical controls (n = 10) who had undergone dorsoventral fusion. Before surgery, all patients had radiographically demonstrable "instability," defined as antelisthesis or retrolisthesis of 2 to 5 mm recorded in sagittal images.[10] Similar improvements in Oswestry disability scores and generic health status (SF-36) were recorded in each group after an average 15 months, suggesting that the Dynesys showed promise as an alternative to fusion. However, by the authors' own admission, because of the small sample size (and consequent lack of any statistical analyses) and the retrospective nature of the study, it was difficult to draw any firm conclusions from this work.

The aim of the present study was to examine patient-oriented outcomes in a group of 50 patients in whom the Dynesys system had been implanted over the preceding 40 months; in 31 patients, the system had been implanted at least 2 years earlier. The study was primarily retrospective, as far as the patient-oriented outcome was concerned, but the clinical data documented before surgery were used to examine whether certain preoperative factors bore any association to the later outcome.

Materials and Methods

Patients. A total of 50 consecutive patients (from the Spine Unit of the authors' hospital), who had undergone semirigid fixation of the lumbar spine with the Dynesys system between September 1999 and January 2003, took part in the study. The main results are presented for the first 31 patients with at least 2 years follow-up (and the results for the whole group of 50 patients (regardless of follow-up duration) are briefly described at the end of the results section).

Three surgeons were involved, although one of them carried out the majority of the operations (surgeon 1, 71% cases; surgeon 2, 26%; surgeon 3, 3%). The mean age of the patients at operation was 50 years (SD, 13 years; range, 30–80 years); there were 20 women and 11 men.

The primary indication for surgery was degenerative disease (disc/stenosis/spondylosis) resulting in some form of instability associated with neurogenic or radicular pain and/or chronic back pain. The main diagnosis was in 7 of 31 cases (23%) stenosis, in 11 of 31 (35%) spondylosis, in 7 of 11 (23%) disc degeneration, in 4 of 11 (13%) failed back surgery, 1 of 31 (3%) degenerative listhesis, and 1 of 31 (3%) extradural tumor. For 20 of 31 (65%) patients, the Dynesys fixation was their first spinal operation. Eleven of 31 (35%) patients had previously undergone decompression of the same or neighboring segments and/or fusion of neighboring segments: 8 of 31 (26%) patients had had 1 previous operation, 2 of 31 (6%) had had 2 prior operations, and 1 of 31 (3%) had had 3 prior operations.

Preoperative Evaluation. Preoperative evaluation included patient history, imaging, and clinical and neurologic evaluation by the treating surgeon. On admission to the hospital for the surgery, the patients underwent reexamination by one of the Spine Unit residents; a summary of the findings and the clinical history were then documented on a standardized evaluation form and entered into the hospital's computerized patient-records system. The results of these examinations are shown in Table 1.

Surgery. The dynamic neutralization system claims to restabilize unstable segments keeping them mobile within a controlled range. The system consists of pedicle screws made of Ti-Al-Nb forge alloy Protasul 100. The screws are connected with a polyethylene terephthalate cord (Sulene PET) that runs in the center cylindrical spacer made of a polycarbonate urethane (Sulene PCU). By tethering the cord and selecting the appropriate length of the spacer between the screws, segmental distraction or compression may be applied (Figure 1).

The procedure was performed in the prone position. A midline approach, with dissection of the erector spinae muscles, provided access to the bony anatomy of the lumbar spine. If indicated, decompression of the spinal canal was performed first. Insertion of the pedicle screws was carried out under radiographic control using a C-arm, or with computer assistance (in 12 of 50 patients, 24%). The polycarbonate urethane spacer was cut according the measured distance between the screws, with the length being chosen to compensate any existing lordosis or kyphosis. The central cord and the spacer were then locked within the screw heads. A soft brace was administered after surgery until wound healing had occurred (Figure 2).

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Table 1. Clinical Findings Before Surgery

	N*				
Duration of symptoms	25	4% (0–6 wk)	8% (7 wk to 6 mo)	84% (6–12 mo)	4% (1–3 yr)
Frequency of pain: back	31	0% never	3% occasional	49% often	48% constant
Frequency of pain: leg	26	4% never	27% occasional	42% often	27% constant
Pain at rest	28	11% no	89% yes		
Pain on movement	28	7% no	93% yes		
Pain 0–10 VAS (back) [mean (SD)]	29	7.0 (2.1)			
Pain 0–10 VAS (leg) [mean (SD)]	22	6.6 (2.4)			
Sensory deficits	30	77% no	23% yes		
Claudication	30	50% none	13% yes > 1000 m	24% yes 100–1000 m	13% yes <100 m
Pseudoradicular pain	25	60% no	40% yes		
Radicular pain	25	68% no	32% yes		
Fingertip-floor distance > 10 cm	23	48% no	52% yes		
Lasegue test	29	90% negative	10% positive		

* N < 31 for some tests, as not all were carried out/documented in every patient.

In 33% cases, 1 level was instrumented; in 52%, 2 levels; in 13%, 3 levels; and in 3%, 4 levels. The most frequently performed instrumentation (39% of all cases) was of both L4–L5 and L5–S1. A total of 42% of patients underwent decompression surgery in addition to Dynesys instrumentation.

Short-term Radiologic and Clinical Follow-up. The first postsurgical radiographs, taken 4 to 6 days after surgery, were examined by one of the surgeons and rated in terms of the presence or absence of "technical errors" (such as loose or misplaced screws). Any other early complications were also documented. All this information was entered into the hospital's computerized patient-records system.

Questionnaire Follow-up Assessment. In April 2003, all the patients were contacted by letter and invited to complete a short questionnaire (to be returned in the post) regarding their perceptions of the outcome of surgery. The questionnaire enquired about: pain intensity (0–10 VAS) in the preceding week (separate scales for back pain and leg pain); changes in overall back symptoms and leg symptoms as a result of the operation (categorized in each case as "much improved," "improved," "no change," "worse"); reoperations undergone since the Dynesys implantation (number and nature of operation); removal of the Dynesys system (yes, no, don't know); change in work status, quality of life, and ability to perform free-time/sporting activities as a result of the operation (in each case, "much improved," "improved," "same," "worse"); global outcome after surgery (categorized as "helped a lot," "helped," "helped a little," "no change," "made things worse"); and whether, in hindsight, the same decision would be made to undergo surgery (yes, no). Our pilot studies (as yet unpublished) have shown that the results of the global outcome questionnaire correlate significantly with prospectively collected changes in pain and Roland Morris disability.

Data Analysis. Descriptive and frequency analyses were used to describe the baseline patient characteristics and categorical outcomes; relationships between categorical variables were examined using contingency tables with χ^2/Fishers exact text (for 2 × 2 categories). The Mann Whitney U test was used to examine differences between two main outcome groups (good/bad). Statistical significance was accepted at the $P < 0.05$ level.

■ Results

Complications/Technical Errors

There were four intraoperative/immediate-postoperative complications. One patient developed pleural effusion, following an allergic reaction to the pain medication. In another patient, prolonged hospitalization was required due to transitory postoperative mental confusion. One patient required treatment due to postoperative cardiac insufficiency. In another patient, a dural tear required suturing and sealing with fibrinogenic material. Examination of the first postoperative radiographs in relation to positioning of the Dynesys screws revealed 4 cases of "technical error": in 1 case, the screws were positioned extrapedicularly; in 2 cases, too far laterally (in both these cases, computer assistance had been used); and in 1 case, the screws on the right-hand side showed loosening. None of these technical errors per se caused significant symptoms or necessitated reintervention.

Late Complications/Repeat Surgery

A total of 6 of 31 (19%) patients either required reintervention in the 2-year follow-up or were undergoing further investigative tests with a view to reoperation in the near future. Three patients required revision surgery at the same spinal level with removal of the system: in 2 of these, a rigid fusion was carried out due to implant loosening (after 6 months and 18 months); and in the third,



Figure 1. In the Dynesys system, pedicle screws are connected with a system of a central cord and cylindrical shaped spacers.

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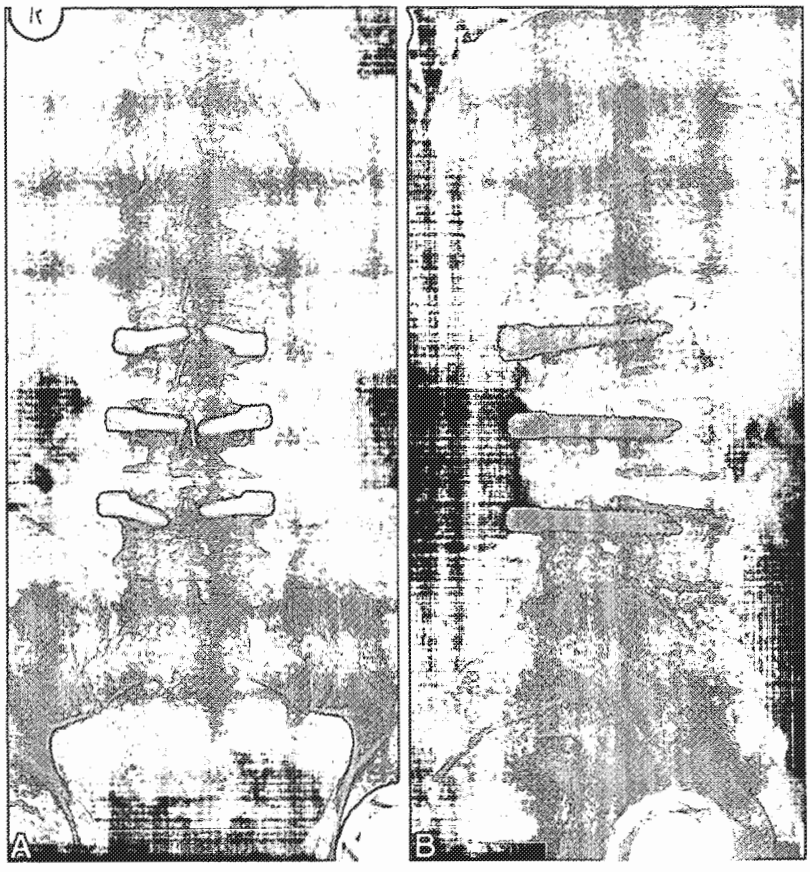


Figure 2. Radiograph with Dynesys of the lumbar spine. In the radiographs, only the pedicle screws are visible.

the Dynesys instrumentation was removed on one side due to infection (after 8 months). One further patient required a morphine pump, 12 months after the Dynesis instrumentation. At the time of the present follow-up study, a further 2 patients with signs of screw loosening were undergoing consultation, with a view to possible revision; both underwent reoperation shortly after (Dynesys removal and fusion).

The findings for all 31 patients are given according to an "intention to treat" analysis, *i.e.*, for all patients in whom the system was implanted. The corresponding data for only those patients in whom the Dynesys was still in place were also analyzed, but as the results were not appreciably different from those for the whole group, only the latter are presented.

Patient-Oriented Outcome Measures After Minimum 2 Years

A total of 30 of 31 (97%) patients completed and returned the patient-oriented follow-up questionnaire. The remaining patient, from whom no questionnaire was received, was contacted by telephone; she explained that she was unwilling to send the questionnaire back because she was most disappointed with the results of the surgery. She did, however, agree to answer the two most important questions concerning the global outcome after surgery and the decision in hindsight to undergo surgery again (last two in the list above, in Methods), and to answer the question about intervening surgical treatment. The average questionnaire follow-up duration was 2.8 (SD 0.5) years (range, 2.0–3.6 years; median, 2.7 years).

The patients' mean (SD) preoperative pain intensity, as documented on the preoperative clinical evaluation form during the initial consultation, was 7.0 (2.1) for back pain and 6.6 (2.4) for leg pain. However, as this preoperative evaluation had been completed by the physician in consultation with the patient (rather than the patient completing it independently), it was decided not to make any direct statistical comparison with the results from the patient-self-rated pain at follow-up. At follow-up, the mean (SD) patient self-rated pain intensity was 4.7 (3.2) for back pain and 3.8 (3.6) for leg pain. The values were almost identical when only those patients were considered who still had the implant in place.

In the follow-up questionnaire, the proportions of patients that declared that their back symptoms had resolved, improved, were unchanged, or were worse were 20%, 47%, 30%, and 3%, respectively; the corresponding figures for self-rated leg symptoms were 32%, 32%, 21%, and 14%, respectively.

At the time of follow-up, the patients' self-rated ability to carry out physical activities (sport/hobbies) had "improved" as a result of the operation in 40% patients, was "unchanged" in 33%, and was "worse" in 27%. Overall quality of life had "improved" in 50%, was "unchanged" in 37%, and was "worse" in 13%.

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Table 2. Difference in Outcome Between Patients Receiving Only Dynesys and Those Receiving Dynesys and Decompression

Outcome Variable (and significance [*P* value] of the Difference in Distribution of Answers in the Two Subgroups, Dynesis Only and Dynesis With Decompression)		Dynesys Only (n = 18) (%)	Dynesys and Decompression (n = 13) (%)
Did the operation help? ($P = 0.36$)	Helped/helped a lot	39	69
	Helped a little	17	0
	No change/made things worse	44	31
Would you, in hindsight, make the same decision to undergo the operation again? ($P = 0.13$)	Yes	56	85
	No	44	15
Quality of life after operation? ($P = 0.10$)	Better	35	69
	Same	53	16
	Worse	12	15
Capacity to do physical activity after operation? ($P = 0.33$)	Better	30	54
	Same	35	31
	Worse	35	15

In response to a question enquiring as to whether the patients were in the same job now as before the operation, the following replies were recorded: 23% were in the exact same job as before; 20% were in the same job but only able to work part-time; 3% had changed jobs for personal reasons or due to changes in the job market; 13% had retired on the grounds of age; 27% had gone onto a disability pension due to back problems; and 13% had a different employment status for other reasons.

The patients' overall self-rating of the global outcome, *i.e.*, how much the operation had helped, was as follows: 29% helped a lot, 23% helped, 10% only helped a little, 35% didn't help, 3% made things worse; 68% declared that they would, in hindsight, make the same decision to undergo surgery, while the remaining 32% reported that they would not.

Comparison of Outcome in Patients Undergoing Just Dynesys Versus Dynesys and Decompression

Approximately 40% patients underwent decompression in addition to the Dynesys instrumentation, making it somewhat difficult to separate out the relative effects of the decompression and those of the stabilization on the patients' self-ratings of pain, disability, quality of life, *etc.* measured at follow-up. Thus, the various outcome variables were compared between the patients who received Dynesys intrumentation only (D) and those who received Dynesys in addition to decompression (DDec). There was an overall trend for poorer results in the D group compared with the DDec group, with the differences for some of the variables (change in quality of life after the operation; and "would you, in hindsight, make the same decision again to undergo the operation?") approaching statistical significance, even with the small numbers involved (Table 2).

Association Between Outcome and Various Baseline Variables

To examine factors that were associated with the global outcome, the answer to the question "would you make the same decision to undergo surgery" was used to dichotomize the outcomes as "good" (= yes, would make the same decision) and "poor" (= no, would not make the same decision). In general, this classification tended to correspond to the same groupings as for "operation helped a lot, helped, helped little" (= good) *versus* "no change/worse" (= poor) on the 5-point Likert scale (Table 3), although interestingly, 27% of the patients who declared that the operation "didn't help" reported that they would still, in retrospect, make the same decision to undergo this surgery again.

Only few of the variables recorded and documented before surgery showed any notable association with the global outcome. Those patients with a "good" global outcome after surgery (n = 21) did not differ from those with a "poor" outcome (n = 10) in terms of gender, age at surgery, or number of previous spine operations. Outcome tended to be better in patients who had no neurogenic claudication before surgery (Fisher's exact test, $P = 0.005$) and in whom only 1 or 2 levels had been instrumented ($P = 0.29$).

Whole-Group Analysis

None of the results for the patient self-rated outcomes were notably different from those reported in the preceding sections, when the whole group of 50 patients was examined (mean [SD] follow-up duration, 25 [13]

Table 3. Relationship Between the Answers to the Questions "How Much Did the Operation Help?" and "Would You, in Retrospect, Make the Same Decision to Undergo Surgery?"

How much did the operation help?	No. in Each Answer Category	Would You, in Retrospect, Make the Same Decision to Undergo Surgery?	
		Yes	No
Helped a lot	9	9/9 (100%)	0/9 (0%)
Helped	7	7/7 (100%)	0/7 (0%)
Only helped little	3	2/3 (67%)	1/3 (33%)
Didn't help	11	3/11 (27%)	8/11 (73%)
Made things worse	1	0/1 (0%)	1/1 (100%)
Total	31	21/31 (68%)	10/31 (32%)

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months; range, 3–43 months; median, 27 months), as opposed to only those with a minimum 2-year follow-up. There was no association between outcome and duration of follow-up ($P = 0.8$).

Discussion

Fusion is generally considered to be the treatment of choice for painful degenerative conditions of the lumbar spine that have proven unresponsive to nonoperative therapy. The results reported in the literature for the outcome after fusion vary according to patient selection and indication; satisfactory results have been reported to range from 16% to 95%, with an average of about 68%.[1] More recent, large-scale studies confirm these figures (57% good/excellent;[12] 63% patients "better" or "much better"[7]). For a long time, good results were thought to be dependent on radiologically confirmed solid fusion, although recent studies in which patients with pseudarthrosis showed the same clinical outcome as patients with solid fusion[4,8,11,12] have challenged this notion. It might therefore be hypothesized that it is the reduction in (rather than the elimination of) segmental motion —brought about by partial fusion, or perhaps even simply by an alteration of the structure of the spinal tissues, induced by the surgery itself —that results in the alleviation of pain. As pain relief represents one of the most important outcomes in achieving a good result after surgery for degenerative spinal disorders, it would thus appear that solid fusion no longer represents a prerequisite for achieving this goal. If this were so, it would present several advantages, including a reduction in the extensiveness of surgery required and the number of complications, as well as the elimination of undesirable late side effects of fusion, such as adjacent segment degeneration[13,14] and consequent hypermobility.[15,16]

It was on this basis that "nonfusion" concepts for treating painful degenerative disorders of the lumbar spine were developed. Initial *in vitro* studies were able to confirm the potential biomechanical advantages of a "dynamic neutralization system" (Dynesys) for the spine: bending angles and horizontal translations were significantly reduced, although not abolished, while vertical translations were increased and bulging of the posterior anulus was reduced.[17] Clinical use of the Dynesys semirigid instrumentation began in 1994. Since then, various individual case studies have been presented, showing restoration of disc height and improvements in Modic changes after Dynesys (Dubois, personal communication, 2003[18]), and the clinical results from some case series have been evaluated and presented at local research meetings.[19,20] Based on promising preliminary findings, the system now enjoys wide clinical application in Europe, despite the fact that its mechanism of action is still far from clear.

The present study represents the first published report on patient-rated outcomes after Dynesys from a disinterested research group, and the generally rather poor results may well serve to dampen current enthusiasm for the system. Overall, approximately two thirds of the patients reported some improvement in their leg/back pain. However, only 40% reported an improvement in their ability to perform physical activities and just 50% an improvement in their quality of life.

Only 52% declared that the operation had helped or helped a lot. In an analysis of the results of a group of 347 historical controls, who had undergone fusion in our hospital and were followed up an average 3 years later (74% follow-up rate), approximately 70% declared that the operation had helped/helped a lot.[21] It could be argued that there is a bias for patients with a better outcome to respond to such questionnaires, *i.e.*, that in the study of Dvorak *et al*,[21] the 26% who did not respond were more likely to have had a poorer outcome. In an attempt to address this issue, we analyzed separately the data from the first 74% questionnaires to be returned in the present study (mostly those individuals who did not need a second or third reminder): 51% reported that the operation helped/helped a lot, more or less the same proportion as in the whole group. Thus, we tentatively suggest that the results after Dynesys were no better, and possibly even worse than those of historical controls undergoing fusion for similar indications within our own hospital. Naturally, randomized controlled trials would be necessary to investigate this with the scientific rigor required to make definitive statements about the relative merits of the two techniques.

In our patient series, the average preoperative leg and back pain VAS scores (recorded by the clinician in consultation with the patient) were similar to those reported by Stoll *et al*.[9] However, the back and leg pain intensities reported in the present study 2 years after surgery were 1 to 2 U higher than those reported by Stoll *et al*[9] and most likely accounted for the generally poor global outcomes.

The better results of Stoll *et al*[9] may have been a reflection of the greater proportion of patients undergoing the (typically more successful) procedure of decompression in their study (68%, compared with 42% in the present study). Notably, in the present study, when the patients who underwent decompression in addition to Dynesys were compared with those who only received Dynesys, the results were generally more favorable for the former group. In the face of such potential confounding factors, caution must be exercised in attributing the results to the Dynesys per se. A further difference between the present study and that of Stoll *et al*[9] was the greater number of unisegmental instrumentations performed in their study (66% *vs.* just 32% in the present study; see later for discussion of the effects of multilevel instrumentation). The proportion of patients who had previously undergone lumbar spine surgery was similar in the two studies (35%–40%).

Although the group results presented here are not very favorable, there are some patients who clearly benefited

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from the surgery. No previous studies have identified predictors of success for the Dynesys implant system, either in relation to the surgical indication or to other baseline factors (such as age, gender, diagnostics used, previous operations, baseline pain levels, *etc.*). The sample size in the present study was not large enough to carry out meaningful multivariate analyses to accurately identify predictor variables. From bivariate analyses, however, there was some suggestion that patients in whom only one or two levels were instrumented had a better outcome, in keeping with the findings for "ordinary" spinal surgery.[22] Further, it was noted that patients with no neurogenic claudication before surgery tended to have a better outcome. Nonetheless, in practice, this does not help to solve the problem of accurately defining indications for the procedure. Further, as "instability" and "movement abnormalities" are vague, poorly defined terms, and the phenomenon evades accurate and clinically meaningful measurement *in vivo*,[23] these are also not suitable as indicators for Dynesys instrumentation. The variable individual outcomes might possibly be related to factors that were not analyzed before and after surgery in the present study, for example, the degree of osteoarthritis of the facet joints or the presence of discogenic pain as determined using discography. Further studies investigating these factors might provide more information in this respect.

Examination of the purported mechanism of action of the Dynesys system may also shed some light on the issue of the varying individual responses to its implantation. When Dynesys first appeared on the market, it was promoted as a device that would allow motion to be "preserved" and "modulated," *i.e.*, movement would be retained, but at a moderated level in relation to the otherwise unphysiologic, hypermobility displayed by the degenerated segment(s). Although precise figures regarding the extent of the residual motion were not proffered, it was expected to be considerably greater than that associated with rigid fixators, in an attempt to circumvent the (suspected) problem of accelerated degeneration in the otherwise overloaded adjacent segment. However, two recent biomechanical studies have shown that, at least *in vitro*, the range of intersegmental motion after Dynesys instrumentation is much lower than expected.[24,25] Independently, both these studies showed that for flexion/extension and lateral bending almost identical ranges of motion were observed for Dynesys instrumentation and a rigid internal fixator. Only in axial rotation did the Dynesys allow a significantly greater range of motion compared with rigid fixation. These findings appear to contradict those from *in vivo* testing,[26] in which 4° to 5° of intersegmental motion in the sagittal plane was recorded in patients instrumented with the device. This could be the result of *in vitro* tests failing to accurately simulate the conditions *in vivo* (although it seems unlikely that this would result in less movement in the *in vitro* situation, since *in vivo* the posterior structures of the spine (muscles, fascia, *etc.*) can be expected to offer additional resistance to bending over and above that offered by the osteoligamentous spine), or may simply be the consequence of the known, interindividual variation in range of motion coupled with the small sample sizes in each study (*i.e.*, in each experimental situation, insufficient cases were examined to provide an accurate representation of "typical" behavior for the given testing situation). Either way, it seems that the biomechanical effect of instrumentation of the lumbar spine with Dynesys must, at present, be summarized as "the alteration of motion to an extent that is not yet well characterized *in vivo*." Interestingly, as far as the restriction in motion is concerned, Graf ligamentoplasty[27] appears to demonstrate similar results, with least stabilization being provided in axial rotation.[28]

According to Mulholland and Sengupta,[3] pain in association with degenerative disease may arise as a result of high spot-loading associated with the adoption of certain positions, rather than movement per se. In one sense, solid fusion of the unstable segment negates the problem of having to identify which particular positions are painful and why, by eliminating all movement in the painful segment in a "sledge-hammer to crack a nut" approach (being sure to include the painful postures, but at the cost of eliminating those that may not be associated with pain). It would be interesting to hypothesize that the benefits of Dynesys and Graf ligamentoplasty may —paradoxically—lie in their ability to markedly reduce movement in the sagittal and frontal planes (thereby emulating fusion, or at least pseudoarthrosis) but that the systems fail those patients whose pain is typically provoked by rotational movements or the adoption of postures in which the spine is rotated. In this sense, the failure of these systems to sufficiently restrict mobility in the horizontal plane, rather than their inability to sufficiently retain motion in flexion/extension, may indeed be their downfall. Obviously, such a hypothesis remains to be tested and requires considerably more investigation using accurate *in vivo* three-dimensional segmental motion analysis, before and after instrumentation, coupled with corresponding pain measurements. In the meantime, since both the Graf and Dynesys semirigid stabilization systems appear to demonstrate similar clinical and biomechanical results, it might be useful to compare the common effects of both systems using data pooled from the very many studies carried out to date, in an attempt to identify their respective benefits and drawbacks in comparison with conventional fusion procedures. One recent study with Graf ligamentoplasty has shown less adjacent segment disc degeneration compared with posterolateral fusion[29]; no comparable data are currently available for the Dynesys system, but it would seem that such data are urgently required if its continued use is to be advocated; at present, there is no overwhelming evidence to suggest that the system per-

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forms better than traditional fusion as far as the mid-term results are concerned.

■ Key Points

- Semirigid instrumentation of the lumbar spine represents a new alternative to fusion in the treatment of chronic low back pain due to degenerative disorders of the lumbar spine.
- The dynamic neutralization system ("Dynesys") has been in clinical use for more than 5 years, but the associated outcome (patient-oriented) has not been reported by any disinterested research groups.
- A total of 31 of 31 patients answered a follow-up questionnaire 2 years after being instrumented with Dynesys. Improvements in functional capacity and quality of life were only moderate. Only approximately 50% patients declared that the operation "helped" or "helped a lot."
- The overall results are poorer than those for historical controls undergoing fusion for similar indications in our hospital.
- There is still insufficient evidence to suggest that semirigid fixation of the lumbar spine results in better patient-oriented outcomes than does fusion.

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MOSKOWITZ-00002270

RECEIVED
DEC 6 2007
MG-IP Law, PLLC

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: Richard McGrath
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

CF3 12/4/07
SIA

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 CF3

e-mail: pt03.pct@wipo.int

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.

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	FOR FURTHER ACTION
3003/101 PWO2	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:

- [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
- [ ] 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	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:

MOSKOWITZ-00002277

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---

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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---

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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---

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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.

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PTO/SB/08a (01-10)
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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.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13084543
Filing Date	2011-04-11
First Named Inventor	Moskoqitz, et al
Art Unit	3733
Examiner Name	PHILOGENE, PEDRO
Attorney Docket Number	3003/0105PUS2

U.S.PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4904261		1990-02-27	Dove et al.	
	2	7875076		2011-01-25	Mathieu et al.	
	3	7232464		2007-06-19	Mathieu et al.	
	4	7846207		2010-12-07	Lechmann et al.	
	5	7862616		2011-01-04	Lechmann et al.	
	6	5290312		1994-03-01	Kojimoto et al	

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

U.S.PATENT APPLICATION PUBLICATIONS

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear

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Attorney Docket Number	3003/0105PUS2

	1	20100305704		2010-12-02	Messerli et al.	
	2	20050177235		2005-08-11	Baynham et al	
	3	20020068977		2002-06-06	Jackson	

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

FOREIGN PATENT DOCUMENTS

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

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NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	International Search Report (ISR) and Written Opinion of the International Searching Authority, 09 July 2008, International Application No. PCT/US07/021013.	☐

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

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13084543
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Art Unit	3733
Examiner Name	PHILOGENE, PEDRO
Attorney Docket Number	3003/0105PUS2

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13084543
Filing Date	2011-04-11
First Named Inventor	Moskoqitz, et al
Art Unit	3733
Examiner Name	PHILOGENE, PEDRO
Attorney Docket Number	3003/0105PUS2

CERTIFICATION STATEMENT

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

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

OR

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

☐ See attached certification statement.

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

☒ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/John J. Dresch/	Date (YYYY-MM-DD)	2012-04-18
Name/Print	John J. Dresch	Registration Number	46672

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

Privacy Act Statement

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

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

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

ATTORNEY DOCKET NO.: 3003/0105PUS2

UNITED STATES PATENT AND TRADEMARK OFFICE

Application Number:	13/084,543
Filing Date:	04/11/2011
Group Art Unit:	3733
Examiner:	PHILOGENE, PEDRO
Confirmation No.:	1305
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

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

I. This Information Disclosure Statement is submitted:
(check at least one box A, B, or C)

A. ☐ (1) Within three months of the filing date of a national application (other than a continued prosecution application);
(2) Within three months of the date of entry of the national stage in an international application;
(3) Before the mailing of a first Office action on the merits; or
(4) Before the mailing of a first Office action after the filing of a request for continued examination.

B. ☒ after the period specified in (A), provided that the information disclosure statement is filed before the mailing date of any of a final action, a notice of allowance, or an action that otherwise closes prosecution in the application, and it is accompanied by one of:

(1) ☐ A statement that:

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(a) ☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or

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

OR

(2) ☒ a $180.00 IDS fee.

C. ☐ after the period specified in (B) provided that the information disclosure statement is filed on or before payment of the issue fee and is accompanied by:

(1) ☐ A statement that:

(a) ☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or

(b) ☐ no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure

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statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

AND

(2) ☐ a $180.00 IDS fee.

II. LIST OF PATENTS, PUBLICATIONS OR OTHER INFORMATION

The U.S. patent or publication documents, foreign patent or publication documents, and/or non-patent literature submitted for consideration by the Office are listed on the attached PTO/SB/08b or PTO -1449.

III. LEGIBLE COPIES OF DOCUMENTS (check all that apply)

A. ☒ U.S. PATENTS OR PUBLISHED APPLICATIONS
Copies of U.S. Patents or Published Applications are not enclosed. If copies are needed, please contact the undersigned.

B. ☒ DOCUMENTS IN AN INTERNATIONAL SEARCH REPORT
Copies of documents in the International Search Report should already be in the PTO file and are not enclosed. If copies are needed, please contact the undersigned.

C. ☒ DOCUMENTS IN THE ENGLISH LANGUAGE
A legible copy of (i) each foreign patent; (ii) each publication; and (iii) all other information in the English language is enclosed.

The attached patents, publications, or other information in the English language do not require a statement of relevancy.

D. ☐ DOCUMENTS NOT IN THE ENGLISH LANGUAGE
A legible copy of (i) each foreign patent; (ii) each publication; and (iii) all other information NOT in the English language is enclosed

CONCISE EXPLANATION OF THE RELEVANCE
A concise explanation of the relevance of all patents, publications, or other information listed that is NOT in the English language is as follows:
(check all that apply)

MOSKOWITZ-00002289

(1) ☐ Complete English Translation

(2) ☐ English Language Equivalent Publication or Patent that is a Complete Translation

(List any known English language documents corresponding or related to a non-English language document as a separate reference on the attached PTO/SB/08b or PTO-1449.)

(3) ☒ Communication from a foreign office in a counterpart foreign application that indicates the degree of relevance found by the foreign office and that is in the English Language.

(4) ☐ Communication from a foreign office in a counterpart foreign application that indicates the degree of relevance found by the foreign office and that is NOT in the English Language: (check all that apply)

(a) ☐ Complete English Language Translation of the communication

(b) ☐ English Language Translation of Relevant Portion(s) of the communication

(c) ☐ ISR with an "X", "Y", or "A" indication only

(5) ☐ English Language Abstract

(6) ☐ Concise Statement of Relevance, as it is presently understood by an individual most knowledgeable about the content of the information listed that is not in the English language.

IV. It is requested that the information disclosed herein be considered by the Examiner and formally made of record in this application. This citation does not constitute an admission that the reference is relevant or material to the claims. It is only cited as constituting related art of which the applicants are aware.

V. Please charge any shortage in fees due in connection with the filing of this, concurrent and future replies, including extension of time fees, to Deposit Account 505364 and please credit any excess fees to such deposit account.

Respectfully Submitted,

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

April 18, 2012

Dresch IP Law, PLLC
PO BOX 650903
Potomac Falls, VA 20165
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*** **Customer No. 87409** ****

MOSKOWITZ-00002291

Electronic Patent Application Fee Transmittal

Application Number:	13084543
Filing Date:	11-Apr-2011
Title of Invention:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION
First Named Inventor/Applicant Name:	Ahmnon D. MOSKOWITZ
Filer:	John Jeremy Dresch
Attorney Docket Number:	3003/0105PUS2

Filed as Small Entity

Utility under 35 USC 111(a) Filing Fees

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

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
		Total in USD ($)		**180**

Electronic Acknowledgement Receipt

EFS ID:	12564526
Application Number:	13084543
International Application Number:	
Confirmation Number:	1305
Title of Invention:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION
First Named Inventor/Applicant Name:	Ahmnon D. MOSKOWITZ
Customer Number:	87409
Filer:	John Jeremy Dresch
Filer Authorized By:	
Attorney Docket Number:	3003/0105PUS2
Receipt Date:	18-APR-2012
Filing Date:	11-APR-2011
Time Stamp:	02:03:29
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$180
RAM confirmation Number	7335
Deposit Account	
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)

1	Non Patent Literature	PCTUS0721013_ISR_PCT_of_parent.pdf	558777 b218d3c6c8119b4eb61da65140c6f97676ba1cd9	no	7
Warnings:					
Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	0105PUS2_PTOSB08a_IDS_from_parent_app.pdf	346153 49a98489ee98409720efabf4154a485f47f61d64	no	8
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
3		11842855_foreign_refs_in_parent_app_0105PUS1.pdf	8320980 f10d908cdd97002b2ad987980a961d8807b906226	yes	125

Multipart Description/PDF files in .zip description

Document Description	Start	End
Foreign Reference	1	35
Foreign Reference	36	55
Non Patent Literature	56	67
Non Patent Literature	68	78
Non Patent Literature	79	86
Non Patent Literature	87	96
Non Patent Literature	97	106
Non Patent Literature	107	114
Non Patent Literature	115	125

Warnings:					
Information:					
4	Information Disclosure Statement (IDS) Form (SB08)	0105PUS2_PTOSB08a_IDS_20120418_Readyforfiling.pdf	1433688 20676494f8019b564d7635f101ab583b6f027523	no	5
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					

5	Transmittal Letter	30030105PUS2_IDS_transmittal_letter_20120418_readyforfiling.pdf	100136 5f4084457eba2a52c1b8b68c1e69cb22a8833bad	no	5
Warnings:					
Information:					
6	Fee Worksheet (SB06)	fee-info.pdf	30687 829ec98649a53bda357f33d1be92af437ebc6e2b	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	10790421	

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 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	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 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 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, PLLC
PO Box 1364
Fairfax, Virginia 22082

PCT

INVITATION TO PAY ADDITIONAL FEES
AND, WHERE APPLICABLE, PROTEST FEE

(PCT Article 17(3)(a) and Rules 40.1 and 40.2(e))

Date of mailing *(day/month/year)*	APR 30 2008
Applicant's or agent's file reference 30030105pwo1	**PAYMENT DUE** within **ONE MONTH** from the above date of mailing
International application No. PCT/US2007/021013	International filing date *(day/month/year)* 01 October 2007
Applicant MOSKOWITZ, Ahmnon D.	

1. This International Searching Authority

(i) considers that there are 4 *(number of)* inventions claimed in the international application covered by the claims indicated below/on an extra sheet:

See Extra Sheet

(ii) therefore considers that **the international application does not comply with the requirement of unity of invention** (Rules 13.1, 13.2 and 13.3) for the reasons indicated below/on an extra sheet:

See Extra Sheet

(iii) ☐ has carried out a partial international search (see Annex) ☒ will establish the international search report on those parts of the international application which relate to the invention first mentioned in claims Nos.:

1-15 and 24

(iv) will establish the international search report on the other parts of the international application only if, and to the extent to which, additional fees are paid.

2. Consequently, the applicant is hereby **invited to pay**, within the time limit indicated above, additional fees in the amount indicated below:

$1,800	x	3	=	$5,400
Fee per additional invention		number of additional inventions		total amount of additional fees/currency

3. The applicant is informed that, according to Rule 40.2(c), **the payment of any additional fees may be made under protest**, that is, a reasoned statement to the effect that the international application complies with the requirement of unity of invention or that the amount of the required additional fees is excessive, where applicable, subject to the payment of a protest fee.

Where the applicant pays additional fees under protest, the applicant is hereby invited, within the time limit indicated above, to pay a protest fee (Rule 40.2(e)) in the amount of _____ *(amount/currency)*

Where the applicant has not, within the time limit indicated above, paid the required protest fee, the protest will be considered not to have been made and the International Searching Authority will so declare.

4. ☐ Claim(s) Nos. _____ have been found to be unsearchable under Article 17(2)(b) because of defects under Article 17(2)(a) and therefore have not been included with any invention.

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/206 (April 2005)

INVITATION TO PAY ADDITIONAL FEES
AND, WHERE APPLICABLE, PROTEST FEE

International application No.
PCT/US2007/021013

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.

MOSKOWITZ-00002302

INVITATION TO PAY ADDITIONAL FEES
AND, WHERE APPLICABLE, PROTEST FEE

International application No.
PCT/US2007/021013

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.

MOSKOWITZ-00002303

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.
13/084,543	04/11/2011	Ahmnon D. MOSKOWITZ	3003/0105PUS2	1305

87409 7590 04/24/2012

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

EXAMINER	
PHILOGENE, PEDRO	
ART UNIT	PAPER NUMBER
3733	

NOTIFICATION DATE	DELIVERY MODE
04/24/2012	ELECTRONIC

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

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

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@dreschiplaw.com
jdresch@dreschiplaw.com
john_dresch@hotmail.com

Office Action Summary	Application No.	Applicant(s)	
	13/084,543	MOSKOWITZ ET AL.	
	Examiner	Art Unit	
	PEDRO PHILOGENE	3733	

-- 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* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, 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 *18 April 2012*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *26-30,33,38-45,48 and 53-81* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *26-30,33,38-45 and 53-81* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

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) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/18/12, 4/18/12*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

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 obviousness-type 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); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.
Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 26-30,33,38-45, 48, 53-81 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 26-93 of copending Application No. 13/108,982. Although the conflicting claims are not identical, they are not patentably distinct from each other because it is clear that all the elements of claims of the copending application are to be found in claims of the application. The difference between claims of the application and claims of the copending application lies in the fact that the application claims include many more elements and are thus much more specific. Thus the invention of claims of the application is in effect a “species” of the "generic" invention of claims of the copending application. It has been held that the generic invention is “anticipated” by the “species”. See in re Goodman, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claims of the copending application are anticipated by claims of the application, they are not patentably distinct. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Amendment

Applicant’s arguments, see Remarks, filed 4/18/12, with respect to claims 26-76 have been fully considered and are persuasive. The art rejection of claims 26-76 has been withdrawn. However, the Double Patenting rejection is maintained. This action is, therefore, made final.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PEDRO PHILOGENE whose telephone number is (571)272-4716. The examiner can normally be reached on Monday to Friday 8:00 AM to 4:30 PM.

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

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

/Pedro Philogene/
Primary Examiner, Art Unit 3733
April 18, 2012

PTO/SB/08a (01-10)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13084543
Filing Date	2011-04-11
First Named Inventor	Moskoqitz, et al
Art Unit	3733
Examiner Name	PHILOGENE, PEDRO
Attorney Docket Number	3003/0105PUS2

U.S.PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4904261		1990-02-27	Dove et al.	
	2	7875076		2011-01-25	Mathieu et al.	
	3	7232464		2007-06-19	Mathieu et al.	
	4	7846207		2010-12-07	Lechmann et al.	
	5	7862616		2011-01-04	Lechmann et al.	
	6	5290312		1994-03-01	Kojimoto et al	

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U.S.PATENT APPLICATION PUBLICATIONS

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear

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	1	20100305704		2010-12-02	Messerli et al.	
	2	20050177235		2005-08-11	Baynham et al	
	3	20020068977		2002-06-06	Jackson	

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

FOREIGN PATENT DOCUMENTS

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

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NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	International Search Report (ISR) and Written Opinion of the International Searching Authority, 09 July 2008, International Application No. PCT/US07/021013.	☐

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EXAMINER SIGNATURE

Examiner Signature	/Pedro Philogene/	Date Considered	04/18/2012

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

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Art Unit	3733
Examiner Name	PHILOGENE, PEDRO
Attorney Docket Number	3003/0105PUS2

CERTIFICATION STATEMENT

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

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

OR

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

☐ See attached certification statement.

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

☒ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/John J. Dresch/	Date (YYYY-MM-DD)	2012-04-18
Name/Print	John J. Dresch	Registration Number	46672

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

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

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 record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13084543	MOSKOWITZ ET AL.
	Examiner	Art Unit
	PEDRO PHILOGENE	3733

SEARCHED

Class	Subclass	Date	Examiner
606	86A, 251, 246, 301, 247, 250, 252, 99, 248, 279	4/18/2012	/P.P./
623	17.11, 17.15, 17.16		

SEARCH NOTES

Search Notes	Date	Examiner
EAST search enclosed	4/18/2012	/P.P./

INTERFERENCE SEARCH

Class	Subclass	Date	Examiner

	/PEDRO PHILOGENE/ Primary Examiner.Art Unit 3733

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet	1	of	8

Complete if Known	
Application Number	13/084,543
Filing Date	April 11, 2011
First Named Inventor	MOSKOWITZ et al.
Art Unit	3733
Examiner Name	Unknown
Attorney Docket Number	3003/0105PUS2

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number: Number - Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	AA	US-5,123,926	06-23-1992	Pisharodi	
	AB	US-5,514,180	05-07-1996	Heggeness et al.	
	AC	US-6,368,350	04-09-2002	Erickson et al.	
	AD	US-6,419,704	07-16-2002	Ferree	
	AE	US-6,458,159	10-01-2002	Thalgott	
	AF	US-6,527,804	03-04-2003	Gauchet et al.	
	AG	US-6,533,818	03-18-2003	Weber et al.	
	AH	US-6,579,318	06-17-2003	Varga et al.	
	AI	US-6,582,468	06-24-2003	Gauchet	
	AJ	US-6,719,794	04-13-2004	Gerber	
	AK	US-6,733,532	05-11-2004	Gauchet et al.	
	AL	US-6,764,491	07-20-2004	Frey et al.	
	AM	US-6,770,094	08-03-2004	Fehling et al.	
	AN	US-6,572,653	06-03-2003	Simonson	
	AO	US-5,782,832	07-21-1998	Larsen et al.	
	AP	US-6,641,614	11-04-2003	Wagner et al.	
	AQ	US-6,126,689	10-03-2000	Brett	
	AR	US-6,375,682	04-23-2002	Fleischmann et al.	
	AS	US-6,723,126	04-20-2004	Berry	
	AT	US-2004/0088054	05-06-2004	Berry	

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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document: Country Code[3] - Number[4] - Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

Examiner Signature	/Pedro Philogene/	Date Considered	04/18/2012

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Sheet 2 of 8

Complete if Known	
Application Number	13/084,543
Filing Date	April 11, 2011
First Named Inventor	MOSKOWITZ et al.
Art Unit	3733
Examiner Name	Unknown
Attorney Docket Number	3003/0105PUS2

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	BA	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.	
	BB	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.	
	BC	Richard D. GUYER et al., "Intervertebral Disc Prostheses," SPINE JOURNAL, Volume 28, Number 15S, Supp. To 8/1/03, pages S15-S23.	
		ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /P.P./	

Examiner Signature	/Pedro Philogene/	Date Considered	04/18/2012

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Sheet	3	of	8

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Attorney Docket Number	3003/0105PUS2

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	CA	US-5,960,522	10-05-1999	Boe	
	CB	US-5,660,188	08-26-1997	Groiso	
	CC	US-4,960,420	10-02-1990	Goble et al.	
	CD	US-4,636,217	01-13-1987	Ogilvie et al.	
	CE	US-4,554,914	11-26-1985	Kapp et al.	
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	DA	DIETER GROB et al., "Clinical Experience With the Dynesys Semirigid Fixation System for the Lumbar Spine," SPINE, Vol. 30, No. 3, 2005, pp. 324-331.	
		ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /P.P./	

Examiner Signature	/Pedro Philogene/	Date Considered	04/18/2012

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PTO/SB/08a (07-05)
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U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet	5	of	8

Complete if Known	
Application Number	13/084,543
Filing Date	April 11, 2011
First Named Inventor	MOSKOWITZ, et al.
Art Unit	3733
Examiner Name	Unknown
Attorney Docket Number	3003/0105PUS2

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number - Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	EA	US 5667472	09-07-1997	Finn et al.	
	EB	US 6955671	10-18-2005	Uchikubo	
	EC	US 7037258	05-02-2006	Chatenever et al.	
	ED	US 6904308	06-07-2005	Frisch et al.	
	EE	US 7097615	08-29-2006	Banik et al.	
	EF	US 7030904	04-18-2006	Adair et al.	
		ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH.			/P.P./

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3] - Number[4] - Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

Examiner Signature	/Pedro Philogene/	Date Considered	04/18/2012

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(Use as many sheets as necessary)

Sheet	6	of	8

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Art Unit	3733
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Attorney Docket Number	3003/0105PUS2

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	FA	US 20050273170	12-08-2005	Navarro et al.	
	FB	US 20040177531	09-16-2004	DiBenedetto et al.	
		ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /P.P./			

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Examiner Signature	/Pedro Philogene/	Date Considered	04/18/2012

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Sheet	7	of	8

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Examiner Initials*	Cite No.[1]	Document Number: Number - Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	GA	US 20050278026 A1	12-15-2005	Gordon, et al.	
	GB	US 20050216084 A1	09-29-2005	Fleischmann	
	GC	US 20050027362 A1	02-03-2005	Williams et al.	
	GD	US 20050049590 A1	03-03-2005	Alleyne et al.	
	GE	US 20040254644 A1	12-16-2004	Taylor	
	GF	US 4,997,432 A	03-05-1991	Keller	
		ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /P.P./			

FOREIGN PATENT DOCUMENTS

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Examiner Signature	/Pedro Philogene/	Date Considered	04/18/2012

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 8 of 8

Complete if Known	
Application Number	13/084,543
Filing Date	April 11, 2011
First Named Inventor	MOSKOWITZ, et al.
Art Unit	3733
Examiner Name	Unknown
Attorney Docket Number	3003/0105PUS2

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	HA	International Search Report (ISR) and Written Opinion of the International Searching Authority, 03 December 2007, International Application No. PCT/US 07/05005.	
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Examiner Signature	/Pedro Philogene/	Date Considered	04/18/2012

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EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	43	(606/251).CCLS.	USPAT; USOCR	OR	OFF	2012/04/18 16:13
L2	15	moskowitz near ahmnon.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/04/18 16:17
L3	2	moskowitz near ahmnon.in. & tool & bone near fusion near spacer & self near drilling near screw & disc near space & intervertebral near cage & screw near guide & angle & (slot or indentation) & inserting & handle & gripper & prongs	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/04/18 16:25
L4	514	(606/86A).CCLS.	USPAT; USOCR	OR	OFF	2012/04/18 16:31
L5	771	(606/279).CCLS.	USPAT; USOCR	OR	OFF	2012/04/18 16:42
L6	643	(606/99).CCLS.	USPAT; USOCR	OR	OFF	2012/04/18 16:52
L7	1128	(623/17.11).CCLS.	USPAT; USOCR	OR	OFF	2012/04/18 16:59
L8	891	(623/17.16).CCLS.	USPAT; USOCR	OR	OFF	2012/04/18 17:08

4/ 18/ 2012 5:08:39 PM

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	37	(("5123926") or ("5514180") or ("6368350") or ("6419704") or ("6458159") or ("6527804") or ("6533818") or ("6579318") or ("6582468") or ("6719794") or ("6733532") or ("6764491") or ("6770094") or ("6572653") or ("5782832") or ("6641614") or ("6126689") or ("6375682") or ("6723126") or ("5960522") or ("5660188") or ("4960420") or ("4636217") or ("4554914") or ("5667472") or ("6955671") or ("7037258") or ("6904308") or ("7097615") or ("7030904") or ("4997432") or ("4904261") or ("7875076") or ("7232464") or ("7846207") or ("7862616") or ("5290312")).PN.	USPAT; USOCR	OR	OFF	2012/04/18 11:52
L2	1	"20020068977"	US-PGPUB; USPAT	OR	OFF	2012/04/18 11:58
L3	2	"20050177235"	US-PGPUB; USPAT	OR	OFF	2012/04/18 11:58
L4	1	"20100305704"	US-PGPUB; USPAT	OR	OFF	2012/04/18 11:59
L5	1	"20040254644"	USPAT	OR	OFF	2012/04/18 12:02
L6	0	"20050049590"	USPAT	OR	OFF	2012/04/18 12:03
L7	1	"20050049590"	US-PGPUB; USPAT	OR	OFF	2012/04/18 12:03
L8	1	"20050027362"	US-PGPUB; USPAT	OR	OFF	2012/04/18 12:04
L9	2	"20050216084"	US-PGPUB; USPAT	OR	OFF	2012/04/18 12:04
L10	2	"20050278026"	US-PGPUB; USPAT	OR	OFF	2012/04/18 12:07
L11	8	"20040177531"	US-PGPUB; USPAT	OR	OFF	2012/04/18 12:08
L12	5	"20050273170"	US-PGPUB; USPAT	OR	OFF	2012/04/18 12:09
L13	0	intervertebral near cage near (insertor or inserter)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/04/18 12:10
L14	0	vertebral near cage near (insertor or inserter)	US-PGPUB; USPAT; USOCR; FPRS;	OR	ON	2012/04/18 12:11

			EPO; JPO; DERWENT; IBM_TDB			
L15	3	vertebral near implant near (insertor or inserter)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/04/18 12:11
L16	8	intervertebral near implant near (insertor or inserter)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/04/18 12:12

4/ 18/ 2012 12:44:39 PM

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13084543	MOSKOWITZ ET AL.
	Examiner	Art Unit
	PEDRO PHILOGENE	3733

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

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

CLAIM		DATE								
Final	Original	04/18/2012								
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	4	-								
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	24	-								
	25	-								
	26	✓								
	27	✓								
	28	✓								
	29	✓								
	30	✓								
	31	-								
	32	-								
	33	✓								
	34	-								
	35	-								
	36	-								

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CLAIM		DATE								
Final	Original	04/18/2012								
	37	-								
	38	✓								
	39	✓								
	40	✓								
	41	✓								
	42	✓								
	43	✓								
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	70	✓								
	71	✓								
	72	✓								

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	74	✓								
	75	✓								
	76	✓								
	77	✓								
	78	✓								
	79	✓								
	80	✓								
	81	✓								

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First Named Inventor	Moskowitz, et al
Art Unit	3733
Examiner Name	PHILOGENE, PEDRO
Attorney Docket Number	3003/0105PUS2

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	7077864		2006-07-18	Byrd, III et al.	

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	1		☐

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Art Unit	3733
Examiner Name	PHILOGENE, PEDRO
Attorney Docket Number	3003/0105PUS2

CERTIFICATION STATEMENT

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

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

OR

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

☐ See attached certification statement.

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

☐ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/John J. Dresch/	Date (YYYY-MM-DD)	2012-05-04
Name/Print	John J. Dresch	Registration Number	46672

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

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

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 record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Patent Application Fee Transmittal

Application Number:	13084543
Filing Date:	11-Apr-2011
Title of Invention:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION
First Named Inventor/Applicant Name:	Ahmnon D. MOSKOWITZ
Filer:	John Jeremy Dresch
Attorney Docket Number:	3003/0105PUS2

Filed as Small Entity

Utility under 35 USC 111(a) Filing Fees

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

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
		Total in USD ($)		**180**

Electronic Acknowledgement Receipt

EFS ID:	12702989
Application Number:	13084543
International Application Number:	
Confirmation Number:	1305
Title of Invention:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION
First Named Inventor/Applicant Name:	Ahmnon D. MOSKOWITZ
Customer Number:	87409
Filer:	John Jeremy Dresch
Filer Authorized By:	
Attorney Docket Number:	3003/0105PUS2
Receipt Date:	04-MAY-2012
Filing Date:	11-APR-2011
Time Stamp:	10:48:44
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$180
RAM confirmation Number	8710
Deposit Account	
Authorized User	

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)	0105PUS2_PTOSB08a_IDS_20120504.pdf	612349 f197ef284ee6d22f11ab413f2e5b4925a29aefe3	no	4
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30687 6ee8f161b7e24c5329ffa22dcda32523bcefdd17	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	643036	

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.

ATTORNEY DOCKET NO.: 3003/0105PUS2

UNITED STATES PATENT AND TRADEMARK OFFICE

Application Number:	13/084,543
Filing Date:	04/11/2011
Group Art Unit:	3733
Examiner:	PHILOGENE, PEDRO
Confirmation No.:	1305
Title:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION

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

AMENDMENT UNDER 37 C.F.R. § 1.116
AND
STATEMENT OF THE SUBSTANCE OF THE INTERVIEW

Dear Sir:

This Amendment responds to the final Office Action dated April 24, 2012, and is being filed within the 2-month first reply deadline of June 24, 2012.

Please amend the application as follows:

Remarks begin on page 2 of this paper.

MOSKOWITZ-00002338

REMARKS

Claims 26-30, 33, 38-45, 48, and 53-81 were previously pending in the application. Claims 26-30, 33, 38-45, 48, and 53-81 remain unchanged. Claims 26, 41, 74, 75, 76, and 77 are independent.

Statement of the Substance of the Interview

Applicant's representative thanks Examiner Pedro Philogene for the courtesies extended during the telephonic interview conducted on May 8, 2012, with Applicants' Attorney, John J. Dresch, Reg. No. 46672.

Applicant submits this Statement to comply with the requirements of M.P.E.P. § 713.04.

In the interview, the following was discussed:

A. Identification of claim discussed:

Claims 26-30, 33, 38-45, 48, and 53-81.

B. Identification of prior art discussed:

None.

C. Identification of principal proposed amendments:

None.

D. Brief Identification of principal arguments:

Regarding the provisional nonstatutory obviousness-type double patenting rejection, Applicants representative noted that this rejection is the only rejection remaining in the present application and that the present application is the earlier filed application of the two subject applications. Therefore, under M.P.E.P. § 804(I)(B) and M.P.E.P. § 804(I)(B)(1), the provisional rejection should be withdrawn and the claims permitted to pass to allowance.

MOSKOWITZ-00002339

E. Results of the Interview:

Applicants gratefully acknowledge the Examiner's indication that the double patenting rejection should be withdrawn in view of the cited provisions of M.P.E.P. § 804.

Additionally, Applicants also noted that an Information Disclosure Statement was filed on May 4, 2012. The Examiner kindly indicated that the newly cited reference will be reviewed upon submission of the present Response.

The Provisional Double Patenting Rejection

Claims 26-30, 33, 38-45, 48, and 53-81 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 26-93 of copending Application No. 13/108,982.

In accordance with the discussions in the telephonic interview, Applicants submit that this provisional rejection should be withdrawn because (1) this rejection is the only rejection remaining in the present application and (2) the present application is the earlier filed application of the subject applications.

M.P.E.P. § 804(I)(B) states:

> The "provisional" double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in at least one of the applications.

Emphasis added Applicants.

M.P.E.P. § 804(I)(B)(1) states:

MOSKOWITZ-00002340

> If a "provisional" nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining *in the earlier filed* of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer. If the ODP rejection is the only rejection remaining in the later-filed application, while the earlier-filed application is rejectable on other grounds, a terminal disclaimer must be required in the later-filed application before the rejection can be withdrawn.
>
> Emphasis added Applicants.

The copending Application No. 13/108,982 was filed on May 16, 2011. The present application was filed on April 11, 2011. Thus, the present application is the earlier filed application.

Applicants submit that the provisional rejection should be withdrawn because (1) this rejection is the only rejection remaining in the present application and (2) the present application is the earlier filed application of the subject applications.

Applicants respectfully request withdrawal of this rejection.

CONCLUSION

In view of the above, entry of the present Amendment and allowance of Claims 26-30, 33, 38-45, 48, and 53-81 are respectfully requested. If the Examiner has any questions regarding this amendment, the Examiner is requested to contact the undersigned. If an extension of time for this paper is required, petition for extension is herewith made.

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

Respectfully Submitted,

/ John J. Dresch /

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

June 11, 2012

Dresch IP Law, PLLC
PO BOX 650903
Potomac Falls, VA 20165
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***** Customer No. 87409 ******

MOSKOWITZ-00002342

Electronic Acknowledgement Receipt

EFS ID:	12987455
Application Number:	13084543
International Application Number:	
Confirmation Number:	1305
Title of Invention:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION
First Named Inventor/Applicant Name:	Ahmnon D. MOSKOWITZ
Customer Number:	87409
Filer:	John Jeremy Dresch
Filer Authorized By:	
Attorney Docket Number:	3003/0105PUS2
Receipt Date:	11-JUN-2012
Filing Date:	11-APR-2011
Time Stamp:	23:15:32
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	Amendment After Final	30030105PUS2_Amendment_B_readyforfiling.pdf	122726 3faf0be0c0a96d7c058f1dccd5bdbc80f60e61a7	no	5

Warnings:	
Information:	

Total Files Size (in bytes):	122726

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

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New International Application Filed with the USPTO as a Receiving Office

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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
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/084,543	04/11/2011	Ahmnon D. MOSKOWITZ	3003/0105PUS2	1305

87409 7590 06/27/2012

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

EXAMINER	
PHILOGENE, PEDRO	
ART UNIT	PAPER NUMBER
3733	

NOTIFICATION DATE	DELIVERY MODE
06/27/2012	ELECTRONIC

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

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

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@dreschiplaw.com
jdresch@dreschiplaw.com
john_dresch@hotmail.com

Office Action Summary	Application No.	Applicant(s)	
	13/084,543	MOSKOWITZ ET AL.	
	Examiner	Art Unit	
	PEDRO PHILOGENE	3733	

-- 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 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 June 2012*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *26-30,33,38-45,48 and 53-81* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *26,27,30,33,38-42,45,48 and 53-81* is/are rejected.

8)☒ Claim(s) *28,29,43 and 44* is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

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) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/4/12*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claim Rejections - 35 USC § 103

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

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

Claims 26, 33,38-39, 41-45, 48, 53-54, 56-65, 68-75, 77-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Byrd, III et al (7,077,864) (submitted by applicant) in view of Bagga et al. (7,238,203).

With respect to claims 26, 41, 77, Byrd, III et al disclose a universal intervertebral combination bone fusion spacer (10) and self-drilling screw apparatus (80) into a disc space between a first vertebral body and a second vertebral body to provide fusion of the first vertebral body to the second vertebral body via biological bone fusion and screw fusion, wherein the apparatus includes an intervertebral cage guide (32) having a first predetermined angle, and a second integral screw guide (32) having a second predetermined angle, wherein the longitudinal end of the intervertebral cage includes a slot or indentation (38) formed adjacent to an edge of an upper surface of the intervertebral cage.

It is noted that Byrd, III et al did not teach of a tool comprising a handle; and a gripper cooperating with the handle and having a plurality of prongs, wherein a distal end of each of the plurality of prongs engages a respective slot or indentation of the intervertebral cage; as claimed by applicant. However, in similar art, Bagga et al provide the evidences of the use of a tool, as best seen in FIGS.23-27, comprising a handle;

and a gripper cooperating with the handle and having a plurality of prongs, wherein a distal end of each of the plurality of prongs engages a respective slot or indentation of the intervertebral cage to insert the intervertebral cage.

Therefore, given the teaching of Bagga et al, it would have been obvious to one having ordinary skill in the art, at the time the invention was made to modify the device of Byrd, III et al, as taught by Bagga et al to insert the intervertebral cage.

With respect to claims 33, 38, 39, 42-45, 48, 53, 54, 56-65, 68-73, 78-81, the above combination of references teaches all the limitations, as set forth in column 4, lines 25-68, column 5, lines 23-67, column 6, lines 1-67, and as best seen in FIGS.1-15 of Byrd et al; and as set forth in column 16, lines 1-24, and as best seen in FIGs.23-27 of Bagga et al.

With respect to the method claims 74, 75, the method steps, as set forth, would have been obviously carried out, in the operation of the device, as set forth above.

Claims 27, 30, 42, 66, are rejected under 35 U.S.C. 103(a) as being unpatentable over Byrd, III et al (7,077,864 submitted by applicant) in view of Bagga et al. (7,238,203) in view of Michelson (7,442,209).

With respect to claim 27, 30, 42, 66, it is noted that the combination above did not teach of a screw guide for controlling a direction of the self-drilling screw that is inserted into the first integral guide and the second integral screw guide, wherein the plurality of prongs engage and hold the screw guide in place and wherein the wall has four quadrants; as claimed by applicant. However, in similar art, Michelson provides the

evidences of the use of a screw guide for controlling a direction of the self-drilling screw that is inserted into the first integral guide and the second integral screw guide, wherein the plurality of prongs engage and hold the screw guide in place and wherein the wall has four quadrants to insert the screws in the vertebrae and fuse the vertebrae together and to insert each screw in a quadrant.

Therefore, given the teaching of Michelson, it would have been obvious to one having ordinary skill in the art, at the time the invention was made to modify the device of Byrd, III et al, as taught by Michelson insert the screws in the vertebrae and fuse them together and to insert each screw in a quadrant.

Claims 40, 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Byrd, III et al (7,077,864 submitted by applicant) in view of Bagga et al. (7,238,203) in view of Anderson et al. (6,655,243).

It is noted that the above combination of references did not teach of a driver assembly including a driver handle; a drive bit portion and a flexible drive shaft extending between the driver handle and the drive bit portion; as claimed by applicant. However, in similar art, Anderson et al provides the evidences of the use of a driver assembly including a driver handle; a driver bit portion; and a flexible drive shaft extending between the driver handle and the drive bit portion so that rotational movement imparting a finely controlled torque movement to the handle body and in turn to the distally disposed tool bit.

Therefore, given the teaching of Anderson et al, it would have been obvious to one having ordinary skill in the art, at the time the invention was made to modify the

device of Byrd, III et al, as taught by Anderson et al, so that rotational movement imparting a finely controlled torque movement to the handle body and in turn to the distally disposed tool bit.

Allowable Subject Matter

Claims 28, 29, 43, 44, are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Amendment

Applicant's arguments, see remarks, filed 6/11/12, with respect to the rejection(s) of claim(s) 26-76 under double Patenting have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Byrd, III et al/Michelson/Bagga et al/Anderson et al. The reference to Byrd, III et al was submitted by applicant. The examiner called applicant's representative on 6/19/12 to see if an amendment could have been made in the case. Unfortunately, applicant's representative stated that he would have to consult the applicant and the in-house attorney, which would take too long. So, the applicant's representative advised the examiner to send in another action. The examiner explained to applicant's representative that the action would be made final which is necessitated by the submission of the information disclosure statement under 37 CFR 1.97(c). Applicant's representative agreed with the examiner.

Conclusion

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 5/4/12 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PEDRO PHILOGENE whose telephone number is (571)272-4716. The examiner can normally be reached on Monday to Friday 8:00 AM to 4:30 PM.

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

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

/Pedro Philogene/
Primary Examiner, Art Unit 3733
June 20, 2012

Notice of References Cited	Application/Control No. 13/084,543	Applicant(s)/Patent Under Reexamination MOSKOWITZ ET AL.	
	Examiner PEDRO PHILOGENE	Art Unit 3733	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-7,238,203	07-2007	Bagga et al.	623/17.11
*	B	US-7,442,209	10-2008	Michelson, Gary K.	623/17.11
*	C	US-7,077,864	07-2006	Byrd et al.	623/17.11
*	D	US-6,655,243	12-2003	Anderson et al.	81/490
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13084543	MOSKOWITZ ET AL.
	Examiner	Art Unit
	PEDRO PHILOGENE	3733

SEARCHED

Class	Subclass	Date	Examiner
606	86A, 251, 246, 301, 247, 250, 252, 99, 248, 279	6/20/2012	/P.P./
623	17.11, 17.15, 17.16		

SEARCH NOTES

Search Notes	Date	Examiner
EAST search enclosed	6/20/2012	/P.P./

INTERFERENCE SEARCH

Class	Subclass	Date	Examiner

	/PEDRO PHILOGENE/ Primary Examiner.Art Unit 3733

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13084543
Filing Date	2011-04-11
First Named Inventor	Moskowitz, et al
Art Unit	3733
Examiner Name	PHILOGENE, PEDRO
Attorney Docket Number	3003/0105PUS2

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	7077864		2006-07-18	Byrd, III et al.	

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /P.P./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	First Named Inventor	Moskowitz, et al
	Art Unit	3733
	Examiner Name	PHILOGENE, PEDRO
	Attorney Docket Number	3003/0105PUS2

	1		☐

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

EXAMINER SIGNATURE

Examiner Signature	/Pedro Philogene/	Date Considered	06/16/2012

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

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

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /P.P./

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	13084543
Filing Date	2011-04-11
First Named Inventor	Moskowitz, et al
Art Unit	3733
Examiner Name	PHILOGENE, PEDRO
Attorney Docket Number	3003/0105PUS2

CERTIFICATION STATEMENT

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

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

OR

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

☐ See attached certification statement.

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

☐ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/John J. Dresch/	Date (YYYY-MM-DD)	2012-05-04
Name/Print	John J. Dresch	Registration Number	46672

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

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

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 record s.

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6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /P.P./

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	2	(("7238203") or ("7077864")).PN.	USPAT; USOCR	OR	OFF	2012/06/20 12:04
L2	3	(("7238203") or ("7077864") or ("7442209")).PN.	USPAT; USOCR	OR	OFF	2012/06/20 12:17
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L20	1	"20040093749"	US-PGPUB; USPAT	OR	OFF	2012/06/20 13:43
L21	2	driver & handle & driver near bit & flexible near drive near shaft	US-PGPUB; USPAT	OR	OFF	2012/06/20 14:11
L22	1045	driver & handle & flexible near shaft	US-PGPUB; USPAT	OR	OFF	2012/06/20 14:13
L23	15	driver & handle & flexible near shaft & drive near bit	US-PGPUB; USPAT	OR	OFF	2012/06/20 14:14

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EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	2	(("7238203") or ("7077864")).PN.	USPAT; USOCR	OR	OFF	2012/06/20 12:04
L2	3	(("7238203") or ("7077864") or ("7442209")).PN.	USPAT; USOCR	OR	OFF	2012/06/20 12:17
L3	83	("0350420" | "2065659" | "2181746" | "2774350" | "3298372" | "3426364" | "3875595" | "3916907" | "4047524" | "4059115" | "4271832" | "4289123" | "4294753" | "4401112" | "4439152" | "4455256" | "4526909" | "4554914" | "4563489" | "4570623" | "4570624" | "4592346" | "4596574" | "4599086" | "4604995" | "4611581" | "4619989" | "4696290" | "4743256" | "4743260" | "4759769" | "4761471" | "4789732" | "4795804" | "4805602" | "4857456" | "4877020" | "4878915" | "4903882" | "4904261" | "4913144" | "4955908" | "4960420" | "5015247" | "5026373" | "5084048" | "5092893" | "5108422" | "5258031" | "5306307" | "5314427" | "5352229" | "5364399" | "5395372" | "5397364" | "5534031" | "5556431" | "5562663" | "5674296" | "5702449" | "5776199" | "6066175" | "6099531" | "6143032" | "6214005" | "6231610" | "6235059" | "6342074" | "6432106" | "6629998" | "6824564" | "6972019" | "D281814").PN. OR ("7442209").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2012/06/20 12:30
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L15	2	"20050177235"	US-PGPUB; USPAT	OR	OFF	2012/06/20 13:41
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L20	1	"20040093749"	US-PGPUB; USPAT	OR	OFF	2012/06/20 13:43

6/ 20/ 2012 1:47:27 PM

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13084543	MOSKOWITZ ET AL.
	Examiner	Art Unit
	PEDRO PHILOGENE	3733

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

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

CLAIM		DATE								
Final	Original	04/18/2012								
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	33	✓								
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CLAIM		DATE								
Final	Original	04/18/2012								
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	38	✓								
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	Examiner	Art Unit
	PEDRO PHILOGENE	3733

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

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

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	80	✓								
	81	✓								

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

Courtesy Reminder for
Application Serial No: 13/084,543

Attorney Docket No: 3003/0105PUS2
Customer Number: 87409
Date of Electronic Notification: 06/27/2012

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

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

mailroom@dreschiplaw.com
jdresch@dreschiplaw.com
john_dresch@hotmail.com

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UNITED STATES PATENT AND TRADEMARK OFFICE

Application Number:	13/084,543
Filing Date:	04/11/2011
Group Art Unit:	3733
Examiner:	PHILOGENE, PEDRO
Confirmation No.:	1305
Title:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION

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

AMENDMENT UNDER 37 C.F.R. § 1.116
AND
STATEMENT OF THE SUBSTANCE OF THE INTERVIEW

Dear Sir:

This Amendment responds to the final Office Action dated June 27, 2012, having a response deadline of September 27, 2012.

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

Please amend the application as follows:

Amendments to the Claims, as reflected in the listing of claims, begin on page 2 of this paper; and

Remarks begin on page 20 of this paper.

MOSKOWITZ-00002367

IN THE CLAIMS:

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

1-25. (Canceled)

26. (Currently amended) A tool for manipulating and inserting a universal, intervertebral ~~combination~~ bone fusion spacer ~~and self-drilling screw apparatus~~ into a disc space between a first vertebral body and a second vertebral body for providing ~~to provide~~ fusion of the first vertebral body to the second vertebral body via biological bone fusion and screw fusion, wherein the universal, intervertebral bone fusion spacer ~~apparatus~~ includes an intervertebral cage having a first integral screw guide ~~having a first predetermined angle,~~ and a second integral screw guide ~~having a second predetermined angle~~, wherein each longitudinal end of the intervertebral cage includes a slot or indentation formed adjacent to an edge of an upper surface of the intervertebral cage,

the tool comprising:

~~a handle; and~~

a gripper ~~cooperating with the handle and~~ having a plurality of prongs,

wherein a distal end of each of the plurality of prongs is capable of engaging ~~engages~~ a respective slot or indentation of the intervertebral cage; and

a screw guide for controlling a direction of screws that are inserted into the first integral screw guide and the second integral screw guide,

wherein the screw guide is positioned between the plurality of prongs.

27. (Currently amended) The tool of claim 26, further comprising:

~~a screw guide for controlling a direction of self-drilling screws that are inserted into the first integral screw guide and the second integral screw guide,~~

wherein the plurality of prongs engage and hold the screw guide in place.

MOSKOWITZ-00002368

28. (Currently amended) The tool of claim 26 [[27]], wherein the screw guide includes a slot or indentation for receiving one of the plurality of prongs.

29. (Currently amended) The tool of claim 26 [[27]], wherein the screw guide includes slots or indentations on opposing sides for receiving the plurality of prongs.

30. (Currently amended) The tool of claim 26 [[27]], wherein the screw guide includes an integral trajectory guide that is capable of receiving and guiding ~~receives and guides~~ one of the ~~self-drilling~~ screws of the universal, intervertebral ~~combination~~ bone fusion spacer ~~and self-drilling screw apparatus~~.

31-32. (Canceled)

33. (Currently amended) The tool of claim 26, further comprising a handle wherein the gripper includes a tubular portion that is capable of receiving and guiding ~~receives and guides~~ a portion of the handle therein.

34-37. (Canceled)

38. (Currently amended) The tool of claim 26, further comprising a handle [[32]], wherein an end of the handle includes a rectangular handle portion.

39. (Currently amended) The tool of claim 26, further comprising a handle [[32]], wherein an end of the handle includes a circular handle portion.

40. (Currently amended) The tool of claim 26, further comprising:

a driver assembly, the driver assembly including:

a driver handle;

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a drive bit portion; and

a flexible drive shaft extending between the driver handle and the drive bit portion for manipulating one of the ~~self-drilling~~ screws of the universal, intervertebral ~~combination~~ bone fusion spacer ~~and self-drilling screw apparatus~~.

41. (Currently amended) A tool assembly comprising:

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

an intervertebral cage including [[:]] a first integral screw guide ~~having a first predetermined angle;~~ and a second integral screw guide ~~having a second predetermined angle~~; and

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

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

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

a tool for manipulating and inserting the universal, intervertebral ~~combination~~ bone fusion spacer ~~and self-drilling screw apparatus~~ into the disc space between the first vertebral body and the second vertebral body to provide fusion of the first vertebral body to the second vertebral body via biological bone fusion and screw fusion, the tool comprising:

~~a handle; and~~

a gripper ~~cooperating with the handle and~~ having a plurality of prongs,

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wherein a distal end of each of the plurality of prongs engages a respective slot or indentation of the intervertebral cage; and

a screw guide for controlling a direction of the first screw and the second screw that are inserted into the first integral screw guide and the second integral screw guide,

wherein the screw guide is positioned between the plurality of prongs.

42. (Currently amended) The tool assembly of claim 41, ~~further comprising:~~

~~a screw guide for controlling a direction of the first screw member and the second screw member that are inserted into the first integral screw guide and the second integral screw guide,~~

wherein the plurality of prongs engage and hold the screw guide in place.

43. (Currently amended) The tool assembly of claim 41 [[42]], wherein the screw guide includes a slot or indentation for receiving one of the plurality of prongs.

44. (Currently amended) The tool assembly of claim 41 [[42]], wherein the screw guide includes slots or indentations on opposing sides for receiving the plurality of prongs.

45. (Currently amended) The tool assembly of claim 41 [[42]], wherein the screw guide includes an integral trajectory guide that is capable of receiving and guiding ~~receives and guides~~ one of the first screw ~~member~~ and the second screw ~~member~~ of the universal, intervertebral ~~combination~~ bone fusion spacer ~~and self-drilling screw apparatus~~.

46-47. (Canceled)

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48. (Currently amended) The tool assembly of claim 41, further comprising a handle, wherein the gripper includes a tubular portion that is capable of receiving and guiding ~~receives and guides~~ a portion of the handle therein.

49-52. (Canceled)

53. (Currently amended) The tool assembly of claim 41, further comprising a handle [[47]], wherein an end of the handle includes a rectangular handle portion.

54. (Currently amended) The tool assembly of claim 41, further comprising a handle [[47]], wherein an end of the handle includes a circular handle portion.

55. (Currently amended) The tool assembly of claim 41, further comprising:

a driver assembly, the driver assembly including:

a driver handle;

a drive bit portion; and

a flexible drive shaft extending between the driver handle and the drive bit portion and manipulating one of the first screw ~~member~~ and the second screw ~~member~~ of the universal, intervertebral ~~combination~~ bone fusion spacer ~~and self-drilling screw apparatus~~.

56. (Currently amended) The tool assembly of claim 41, wherein each of the first internal screw guide and the second internal screw guide is angled to orient the first screw ~~member~~ and the second screw bi-directionally in opposite directions.

57. (Currently amended) The tool assembly of claim 41, wherein the first screw ~~member~~ is a self-tapping and self-drilling screw ~~member~~ having a tapered end and a threaded body, and

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

58. (Previously presented) The tool assembly of claim 41, further comprising:

a bone graft cavity for receiving bone packing material for bone fusion between the first vertebral body and the second vertebral body.

59. (Previously presented) The tool assembly of claim 41, wherein the intervertebral cage includes a side having a plurality of ridges.

60. (Previously presented) The tool assembly of claim 41, wherein the first integral screw guide and the second integral screw guide are adjacent to each other and at an angulation with respect to a wall having the first integral screw guide and the second integral screw guide.

61. (Previously presented) The tool assembly of claim 60, wherein a first angulation of the first integral screw guide is opposed to a second angulation of the second integral screw guide.

62. (Previously presented) The tool assembly of claim 41, wherein the first integral screw guide and the second integral screw guide are adjacent to each other along a longitudinal extent of a wall having the first integral screw guide and the second integral screw guide, and

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

63. (Previously presented) The tool assembly of claim 62, wherein a part of the first integral screw guide overlaps a part of the second integral screw guide along the

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longitudinal extent of the wall having the first integral screw guide and the second integral screw guide.

64. (Previously presented) The tool assembly of claim 62, wherein the first integral screw guide and the second integral screw guide are at an angulation with respect to the wall having the first integral screw guide and the second integral screw guide.

65. (Previously presented) The tool assembly of claim 64, wherein a first angulation of the first integral screw guide extends in a first direction from the wall having the first integral screw guide and the second integral screw guide toward a first side of the intervertebral cage,

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

wherein the first side is opposed to the second side.

66. (Previously presented) The tool of claim 26, wherein the intervertebral cage includes a wall having an entry opening of the first integral screw guide and an entry opening of the second integral screw guide,

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

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

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

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

wherein one of:

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

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

67. (Previously presented) The tool of claim 26, wherein the intervertebral cage includes a wall having an entry opening of the first integral screw guide and an entry opening of the second integral screw guide,

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

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

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

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

wherein one of:

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

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

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

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

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

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

70. (Previously presented) The tool of claim 26, wherein the intervertebral cage includes an arcuate wall.

71. (Previously presented) The tool assembly of claim 41, wherein the first integral screw guide and the second integral screw guide are at an angulation with respect to a wall having the first integral screw guide and the second integral screw guide.

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72. (Previously presented) The tool assembly of claim 41, wherein the first integral screw guide and the second integral screw guide diverge from each other.

73. (Previously presented) The tool assembly of claim 41, wherein the first integral screw guide and the second integral screw guide diverge from each other and at an angulation with respect to a wall having the first integral screw guide and the second integral screw guide.

74. (Currently amended) A method of inserting a universal, intervertebral ~~combination~~ bone fusion spacer ~~and self-drilling screw apparatus~~ into a disc space between a first vertebral body and a second vertebral body using a tool for manipulating and inserting the universal, intervertebral ~~combination~~ bone fusion spacer ~~and self-drilling screw apparatus~~ into the disc space between the first vertebral body and the second vertebral body,

wherein the universal, intervertebral ~~combination~~ bone fusion spacer ~~and self-drilling screw apparatus~~ includes:

an intervertebral cage having a first integral screw guide and a second integral screw guide, wherein a surface of each longitudinal end of the intervertebral cage includes a slot or indentation formed adjacent to an edge of an upper surface of the intervertebral cage for receiving a distal end of a prong of tool; and

wherein the tool includes:

~~a handle; and~~

a gripper ~~cooperating with the handle and~~ having a plurality of prongs,

wherein a distal end of each of the plurality of prongs is capable of engaging ~~engages~~ a respective slot or indentation of the intervertebral cage, and

a screw guide for controlling a direction of a first screw and a second screw that are inserted into the first integral screw guide and the second integral screw guide, wherein the screw guide is positioned between the plurality of prongs, and

the method comprising:

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

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

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

selecting the screw guide based on the selected universal, intervertebral bone fusion spacer and positioning the screw guide between the plurality of prongs;

positioning the intervertebral cage between the plurality of prongs such that ~~engaging~~ each slot or indentation of the intervertebral cage corresponds with the distal end of each of the plurality of prongs;

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

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

75. (Currently amended) A method of inserting a universal, intervertebral ~~combination~~ bone fusion spacer ~~and self-drilling screw apparatus~~ into a disc space between a first vertebral body and a second vertebral body and fusing the first vertebral body to the second vertebral body via biological bone fusion and screw fusion using a

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tool for manipulating and inserting the universal, intervertebral ~~combination~~ bone fusion spacer ~~and self-drilling screw apparatus~~ into the disc space between the first vertebral body and the second vertebral body,

wherein the universal, intervertebral ~~combination~~ bone fusion spacer ~~and self-drilling screw apparatus~~ includes:

an intervertebral cage including:

a first integral screw guide ~~having a first predetermined angle~~;

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

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

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

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

wherein the tool includes:

~~a handle; and~~

a gripper ~~cooperating with the handle and~~ having a plurality of prongs,

wherein a distal end of each of the plurality of prongs is capable of engaging ~~engages~~ a respective slot or indentation of the intervertebral cage, and

a screw guide for controlling a direction of the first screw and the second screw that are inserted into the first integral screw guide and the second integral screw guide, wherein the screw guide is positioned between the plurality of prongs, and

the method comprising:

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

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

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

engaging each slot or indentation of the intervertebral cage with the distal end of each of the plurality of prongs;

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

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

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

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

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

76. (Currently amended) A tool assembly comprising:

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

an intervertebral cage including:

a first integral screw guide ~~having a first predetermined angle~~;

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

a bone graft cavity for receiving bone packing material for bone fusion between the first vertebral body and the second vertebral body;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

wherein one of:

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

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

a tool for manipulating and inserting the universal, intervertebral ~~combination~~ bone fusion spacer ~~and self-drilling screw apparatus~~ into the disc space between the first vertebral body and the second vertebral body to provide fusion of the first vertebral body to the second vertebral body via biological bone fusion and screw fusion, the tool comprising:

~~a handle; and~~

a gripper ~~cooperating with the handle and~~ having a plurality of prongs,

wherein a distal end of each of the plurality of prongs engages a respective slot or indentation of the intervertebral cage; and

a screw guide for controlling a direction of the first screw and the second screw that are inserted into the first integral screw guide and the second integral screw guide,

wherein the screw guide is positioned between the plurality of prongs, and

wherein the screw guide includes slots or indentations on opposing sides for receiving the plurality of prongs.

77. (Currently amended) A tool assembly comprising:

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

an intervertebral cage including:

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a plurality of internalized screw guides, wherein each of the plurality of internalized screw guides includes a proximal screw head recess that is entirely encased within an upper surface of the intervertebral cage, wherein each of the plurality of internalized screw guides includes a tunnel-guide that projects into the intervertebral cage from the proximal screw head recess, the tunnel-guide including a proximal tunnel-guide portion that is entirely encased by walls of the intervertebral cage and a distal tunnel-guide portion that is partially encased by the walls of the intervertebral cage, the distal tunnel-guide portion being contiguous with and exiting into a bone cavity of superior and inferior walls of the intervertebral cage, and wherein a surface of each longitudinal wall of the intervertebral cage includes a slot or indentation formed adjacent to an edge of the upper surface of the intervertebral cage; and

a screw ~~member~~ disposed in each of the plurality of internalized screw guides ~~at a predetermined angle~~ and at least partially within the intervertebral cage; and

a tool for manipulating and inserting the universal, intervertebral ~~combination~~ bone fusion spacer ~~and self-drilling screw apparatus~~ into the disc space between the first vertebral body and the second vertebral body for providing ~~to provide~~ fusion of the first vertebral body to the second vertebral body via biological bone fusion and screw fusion, the tool comprising:

~~a handle; and~~

a gripper ~~cooperating with the handle and~~ having a plurality of prongs each having a distal end,

wherein the distal end of each of the plurality of prongs respectively is capable of engaging ~~engages~~ the slot or indentation of the intervertebral cage on the surface of each longitudinal wall of the intervertebral cage; and

a screw guide for controlling a direction of the first screw and the second screw that are inserted into the first integral screw guide and the second integral screw guide.

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wherein the screw guide is positioned between the plurality of prongs, and

wherein the screw guide includes slots or indentations on opposing sides for receiving the plurality of prongs.

78. (Previously presented) The tool assembly of claim 77, wherein the distal tunnel-guide portion that is partially encased by the walls of the intervertebral cage is parabola shaped.

79. (Currently amended) The ~~the~~ tool assembly of claim 78, wherein the screw ~~member~~ extends through one of the plurality of internalized screw guides via the proximal screw head recess that is entirely encased within a top plane of the intervertebral cage, into the proximal tunnel-guide portion that is entirely encased by the walls of the intervertebral cage, into the parabola shaped distal tunnel-guide portion that is partially encased by the walls of the intervertebral cage, and then exits from the bone cavity of the superior and inferior walls.

80. (Currently amended) The tool assembly of claim 58, wherein the bone graft cavity is accessible through an opening formed in a lateral wall of the intervertebral cage, a perimeter of the opening including an indentation through which one of the first screw ~~member~~ and the second screw ~~member~~ passes from the bone graft cavity to an exterior of the intervertebral cage.

81. (Currently amended) The tool assembly of claim 77, wherein the bone cavity is accessible through an opening formed in a lateral wall of the intervertebral cage, a perimeter of the opening including an indentation through which the screw ~~member~~ passes from the bone cavity to an exterior of the intervertebral cage.

REMARKS

Claims 26-30, 33, 38-45, 48, and 53-81 were previously pending in the application. This Amendment amends claims 26-30, 33, 38-45, 48, 53-57, 74-77, and 79-81. Claims 26, 41, and 74-77 are independent.

Entry of this Amendment is proper because it does not raise any new issues requiring further search by the Examiner, narrows the issues on appeal, and is believed to place the present application in condition for immediate allowance.

Allowable Subject Matter

Applicants gratefully acknowledge the indication by the Office Action that claims **28, 29, 43, and 44** would be **allowable** if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Statement of the Substance of the Interview

Applicant's representative thanks Primary Examiner Pedro Philogene for the courtesies extended during the telephonic interview conducted on August 28, 2012, with Applicants' Attorney, John J. Dresch, Reg. No. 46,672.

Applicant submits this Statement to comply with the requirements of M.P.E.P. § 713.04.

In the interview, the following was discussed:

A. Identification of claims discussed:

Claims 26, 27, 28, 41, 42, 43, and 74-76

B. Identification of prior art discussed:

Byrd, III et al (U.S. Patent No. 7,077,864)

Bagga et al. (U.S. Patent No. 7,238,203)

Michelson (U.S. Patent No. 7,442,209)

Anderson (U.S. Patent No. 6,655,243)

C. Identification of principal proposed amendments:

Applicants discussed possible clarifying amendments to claims 26 and 41 and other claims. Applicants proposed incorporating features of the screw guide from claim 27 into independent claim 26, and features of the screw guide from claim 42 into independent claim 41, and similar amendments to the other independent claims.

D. Brief Identification of principal arguments:

Applicants argued that the Michelson reference (which is relied upon for the teaching of a screw guide) does not disclose a screw guide, as claimed. Instead, the Michelson reference teaches inserting a locking tool 184 through an opening 182 in order to reach a locking mechanism 144. See, e.g., FIGS. 9 and 10; see also col. 9, lines 45-54. Therefore, the Michelson reference does not disclose a screw guide, as recited in claims 27 and 42.

Applicants also discussed proposed editorial and clarifying amendments to the claims (as set forth in this Amendment) in view of the indication of allowable subject matter and incorporation of the features of the screw guide into the independent claims.

E. Results of the Interview:

No formal agreement on allowability was reached in the interview. The Examiner stated that the search will be updated prior to making a formal indication of allowability.

Applicants gratefully acknowledge the Examiner's indication that the features of the screw guide in claims 27 and 42 are not disclosed by the Michelson reference, and therefore, incorporating the features of the screw guide of claims 27 and 42 into the independent claims will overcome the present rejections.

The Examiner also kindly agreed to consider Applicants' proposed editorial and clarifying amendments to the claims.

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The Rejections under 35 U.S.C. § 103

Claims 26, 33,38-39, 41-45, 48, 53-54, 56-65, 68-75, and 77-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Byrd, Ill et al reference (U.S. Patent No. 7,077,864) in view of the Bagga et al. reference (U.S. Patent No. 7,238,203). Claims 27, 30, 42, and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Byrd, Ill et al reference, the Bagga et al. reference, in view of the Michelson reference (7,442,209). Claims 40 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Byrd, Ill et al reference, the Bagga et al. reference, in view of the Anderson et al. reference (U.S. Patent No. 6,655,243).

Applicants respectfully traverse these rejections.

This Amendment amends the independent claims to incorporate features of the screw guide of claims 27 and 42 in accordance with the discussions in the telephonic interview.

Applicants submit that the Michelson reference (which is relied upon for the teaching of a screw guide) does not disclose a screw guide, as claimed. Instead, the Michelson reference teaches, at col. 9, lines 45-51, a drive instrumentation 172 having an opening 182 that is coaxially aligned with a locking mechanism 144 of the implant 100. A locking tool 184 is inserted through the opening 182 in order to reach the locking mechanism 144. See, e.g., FIGS. 9 and 10; see also col. 9, lines 52-54. FIG. 9 shows a broken line extending from the tool 184 through the opening 182 and to the locking mechanism 144, thereby illustrating the insertion of the tool 184 into the opening 182. The opening 182 does not guide the screw 128 of the implant, as shown by FIGS. 9 and 10.

For at least these reasons, the Michelson reference does not disclose a screw guide, as recited in independent claims 26, 41, 74, 75, 76, and 77, and therefore, does not make up for the acknowledged deficiencies of the other references.

Applicants gratefully acknowledge the Examiner's indication in the telephonic interview that the features of the screw guide are not disclosed by the Michelson

reference, and therefore, incorporating the features of the screw guide of claims 27 and 42 into the independent claims overcomes the present rejections.

Accordingly, independent claims 26, 41, 74, 75, 76, and 77 are patentable over the applied references. Claims 27-30, 33, 38-40, 42-45, 48, 53-73, and 78-81 are patentable over the applied references by virtue of their dependency from independent claims 26, 41, and 77, respectively, as well as for the additional features recited therein.

Applicants respectfully request withdrawal of these rejections.

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CONCLUSION

In view of the above, entry of the present Amendment and allowance of Claims 26-30, 33, 38-45, 48, and 53-81 are respectfully requested. If the Examiner has any questions regarding this amendment, the Examiner is requested to contact the undersigned. If an extension of time for this paper is required, petition for extension is herewith made.

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

Respectfully Submitted,

/ John J. Dresch /
John J. Dresch
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Reg. No. 46,672

August 31, 2012

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***** Customer No. 87409 ******

MOSKOWITZ-00002390

Electronic Acknowledgement Receipt

EFS ID:	13644018
Application Number:	13084543
International Application Number:	
Confirmation Number:	1305
Title of Invention:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION
First Named Inventor/Applicant Name:	Ahmnon D. MOSKOWITZ
Customer Number:	87409
Filer:	John Jeremy Dresch
Filer Authorized By:	
Attorney Docket Number:	3003/0105PUS2
Receipt Date:	31-AUG-2012
Filing Date:	11-APR-2011
Time Stamp:	22:06:14
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Amendment After Final	30030105PUS2_Amend_C_and_SSEI_readyforfiling.pdf	145885 6c031423428da90b3360869cae89126da8a31544	no	24

Warnings:	
Information:	

Total Files Size (in bytes):	145885

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 (07-06)
Approved for use through 1/31/2007. 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	Filing Date	☐ To be Mailed
13/084,543	04/11/2011	

APPLICATION AS FILED – PART I

	(Column 1)	(Column 2)	SMALL ENTITY ☒		OR	OTHER THAN SMALL ENTITY	
FOR	NUMBER FILED	NUMBER EXTRA	RATE ($)	FEE ($)		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 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			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT 08/31/2012	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 44	Minus	** 51	= 0	X $30 =	0	OR	X $ =	
Independent (37 CFR 1.16(h))	* 6	Minus	***6	= 0	X $125 =	0	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	0	OR	TOTAL ADD'L FEE	

AMENDMENT	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)		RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =		OR	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =		OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ 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 number found in the appropriate box in column 1.

Legal Instrument Examiner:
/TONI HAKIM/

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

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

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UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/084,543	04/11/2011	Ahmnon D. MOSKOWITZ	3003/0105PUS2	1305

87409 7590 09/05/2012

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

EXAMINER	
PHILOGENE, PEDRO	
ART UNIT	PAPER NUMBER
3733	

NOTIFICATION DATE	DELIVERY MODE
09/05/2012	ELECTRONIC

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

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

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@dreschiplaw.com
jdresch@dreschiplaw.com
john_dresch@hotmail.com

Applicant-Initiated Interview Summary	Application No.	Applicant(s)	
	13/084,543	MOSKOWITZ ET AL.	
	Examiner	Art Unit	
	PEDRO PHILOGENE	3733	

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

(1) *PEDRO PHILOGENE*. (3)_____.

(2) *John J. Dresch*. (4)_____.

Date of Interview: *28 August 2012*.

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: *26-28*.

Identification of prior art discussed: *Bagga et al. (7,238,203); Michelson (7,442,209)*.

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...)

Applicant argument's over Bagga et al did not overcome the rejection in the last office action. Applicant stated that Bagga et al did not teach of flexible plurality of prongs. However, applicant also did not teach of flexible plurality of prongs. Therefore, no agreement was reached with respect to Bagga et al. Furthermore, applicant stated that he would include the language of claim 27 in the independent claims since Michelson did not teach of a screw guide for controlling a direction of slef-drilling screws that are inserted into the first integral screw guide. Applicant also stated that the passage "wherein the plurality of prongs engage and hold the screw guide in place" will be deleted and replaced with --wherein the screw guide positioned betweeen the plurality of prongs--. the examiner agrees with the changes and the applicant will send in the amended claims for further consideration and the examiner will conduct an update search..

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

/Pedro Philogene/ Primary Examiner, Art Unit 3733	

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.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

87409 7590 09/13/2012

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

EXAMINER
PHILOGENE, PEDRO

ART UNIT	PAPER NUMBER
3733	

DATE MAILED: 09/13/2012

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/084,543	04/11/2011	Ahmnon D. MOSKOWITZ	3003/0105PUS2	1305

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

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$870	$300	$0	$1170	12/13/2012

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

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: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

87409 7590 09/13/2012

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

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)

(Signature)

(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/084,543	04/11/2011	Ahmnon D. MOSKOWITZ	3003/0105PUS2	1305

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

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nonprovisional	YES	$870	$300	$0	$1170	12/13/2012

EXAMINER	ART UNIT	CLASS-SUBCLASS
PHILOGENE, PEDRO	3733	606-251000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,

(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 has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

☐ Issue Fee

☐ Publication Fee (No small entity discount permitted)

☐ Advance Order - # of Copies _____

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

☐ A check is enclosed.

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

☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

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

☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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MOSKOWITZ-00002398

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UNITED STATES DEPARTMENT OF COMMERCE
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Dresch IP Law, PLLC
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Potomac Falls, VA 20165

EXAMINER	
PHILOGENE, PEDRO	

ART UNIT	PAPER NUMBER
3733	

DATE MAILED: 09/13/2012

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

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 Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

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.	Applicant(s)	
	13/084,543	MOSKOWITZ ET AL.	
	Examiner	Art Unit	
	PEDRO PHILOGENE	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *applicant's amendment filed 8/31/12*.

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 *26-30, 33, 38-45, 48, 53-81*.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ 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).

7. ☐ 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. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☐ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

/Pedro Philogene/
Primary Examiner, Art Unit 3733

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13084543	MOSKOWITZ ET AL.
	Examiner	Art Unit
	PEDRO PHILOGENE	3733

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

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

CLAIM		DATE								
Final	Original	09/05/2012								
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	2	-								
	3	-								
	4	-								
	5	-								
	6	-								
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	32	-								
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	34	-								
	35	-								
	36	-								

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13084543	MOSKOWITZ ET AL.
	Examiner	Art Unit
	PEDRO PHILOGENE	3733

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

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

CLAIM		DATE								
Final	Original	09/05/2012								
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7	38	=								
8	39	=								
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14	70	=								
34	71	=								
35	72	=								

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13084543	MOSKOWITZ ET AL.
	Examiner	Art Unit
	PEDRO PHILOGENE	3733

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

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

CLAIM		DATE								
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44	81	=								

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13084543	MOSKOWITZ ET AL.
	Examiner	Art Unit
	PEDRO PHILOGENE	3733

SEARCHED

Class	Subclass	Date	Examiner
606	86A, 251, 246, 301, 247, 250, 252, 99, 248, 279	9/5/2012	/P.P./
623	17.11, 17.15, 17.16		

SEARCH NOTES

Search Notes	Date	Examiner
EAST search enclosed	9/5/2012	/P.P./

INTERFERENCE SEARCH

Class	Subclass	Date	Examiner
606	86A	9/5/2012	/P.P./
Interference Search History Printout		9/5/2012	/P.P./

	/PEDRO PHILOGENE/ Primary Examiner.Art Unit 3733

Issue Classification

Application/Control No.	Applicant(s)/Patent Under Reexamination
13084543	MOSKOWITZ ET AL.
Examiner	**Art Unit**
PEDRO PHILOGENE	3733

ORIGINAL		INTERNATIONAL CLASSIFICATION										
CLASS	SUBCLASS	CLAIMED					NON-CLAIMED					
606	86A	A	6	1	B	17 / 56 (2006.0)						

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

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

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
	1		17	6	33		49	33	65	44	81				
	2		18		34		50	10	66						
	3		19		35		51	11	67						
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	5		21		37	21	53	13	69						
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	15		31		47	31	63	43	79						
	16		32	20	48	32	64	37	80						

NONE (Assistant Examiner) (Date)	**Total Claims Allowed:** 44	
/PEDRO PHILOGENE/ Primary Examiner.Art Unit 3733 9/5/12 (Primary Examiner) (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 5A

ATTORNEY DOCKET NO.: 3003/0105PUS2

UNITED STATES PATENT AND TRADEMARK OFFICE

Application Number:	13/084,543
Filing Date:	04/11/2011
Group Art Unit:	3733
Examiner:	PHILOGENE, PEDRO
Confirmation No.:	1305
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

OK TO ENTER: /P.P./

AMENDMENT UNDER 37 C.F.R. § 1.116
AND
STATEMENT OF THE SUBSTANCE OF THE INTERVIEW

Dear Sir:

This Amendment responds to the final Office Action dated June 27, 2012, having a response deadline of September 27, 2012.

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

Please amend the application as follows:

Amendments to the Claims, as reflected in the listing of claims, begin on page 2 of this paper; and

Remarks begin on page 20 of this paper.

MOSKOWITZ-00002407

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	16	moskowitz near ahmnon.in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/09/05 15:59
L2	804	606/86A	US-PGPUB; USPAT	OR	OFF	2012/09/05 16:01
L7	263	("1920821" | "20010009971" | "20010021851" | "20010037112" | "20010047172" | "20020022843" | "20020022847" | "20020045897" | "20020045898" | "20020049444" | "20020055741" | "20020058939" | "20020058940" | "20020082606" | "20020143336" | "20020147450" | "20020151899" | "20020156474" | "20020183754" | "20020183757" | "20020188296" | "20020198533" | "20030023242" | "20030040749" | "20030045880" | "20030060828" | "20030065251" | "20030083658" | "20030135213" | "20030181912" | "20030187436" | "20030187440" | "20030187442" | "20030187454" | "20030208204" | "20030229348" | "20030233098" | "20040015169" | "20040015174" | "20040019353" | "20040034352" | "20040034354" | "20040087951" | "20040092947" | "20040097935" | "20040133205" | "20040204716" | "20050021040" | "2466023" | "2486303" | "2494229" | "2695688" | "2756742" | "3244170" | "3463148" | "3552389" | "3596656" | "3626471" | "3659595" | "3695259" | "3716050" | "3779240" | "3824995" | "3900025" | "4119092" | "4187841" | "4219015" | "4224699" | "4257411" | "4388921" | "4408601" | "4454876" | "4493317" | "4502475" | "4503848" | "4513744" | "4524765" | "4541424" | "4651724" | "4686972" | "4733657" | "4744353" | "4773402" | "4800874" | "4838252" | "4848327" | "4887596" | "4936844" | "4957495" | "5002544" | "5006120" | "5041113" | "5041114" | "5041133" | "5052373" | "5053036" | "5059194" | "5067477" | "5088472" | "5129899" | "5129903" | "5147361" | "5151103" | "5180381" | "5234290"	US-PGPUB; USPAT; USOCR	OR	OFF	2012/09/05 16:10

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L11	3	bone near fusion near spacer & disc near	US-PGPUB;	OR	ON	2012/09/05

		space & screw & intervertebral near cage & screw near guide & (slot or indentation) & (gripper or handle) & prongs	USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB			17:11
L14	1506	A61B017/56.ipc.	FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/09/05 17:13

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
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L13	0	(606/86A).CCLS.	UPAD	OR	OFF	2012/09/05 17:12

9/ 5/ 2012 5:17:12 PM

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P.O.BOX 1450
ALEXANDRIA VA 22313-1451

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NNNNN

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

Courtesy Reminder for
Application Serial No: 13/084,543

Attorney Docket No: 3003/0105PUS2
Customer Number: 87409
Date of Electronic Notification: 09/13/2012

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

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

mailroom@dreschiplaw.com
jdresch@dreschiplaw.com
john_dresch@hotmail.com

Please verify that these email addresses are correct.

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

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
13/084,543	04/11/2011	3733	1723	3003/0105PUS2	51	5

CONFIRMATION NO. 1305

CORRECTED FILING RECEIPT

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

OC000000057176835

Date Mailed: 10/19/2012

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Inventor(s)

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

Applicant(s)

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

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

Domestic Priority data as claimed by applicant

This application is a CON of 11/842,855 08/21/2007 PAT 7942903
which is a CIP of 11/536,815 09/29/2006 PAT 7846188
which is a CIP of 11/208,644 08/23/2005 PAT 7704279
which claims benefit of 60/670,231 04/12/2005

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

If Required, Foreign Filing License Granted: 04/20/2011
The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 13/084,543**
Projected Publication Date: Not Applicable

Non-Publication Request: No

Early Publication Request: No
** **SMALL ENTITY** **
Title

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

Preliminary Class

606

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

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

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

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

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

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

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

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

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

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign 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 USA offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to encourage, facilitate, and accelerate business investment. To learn more about why the USA is the best country in the world to develop technology, manufacture products, and grow your business, visit SelectUSA.gov.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

87409 7590 09/13/2012

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

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)

(Signature)

(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/084,543	04/11/2011	Ahmnon D. MOSKOWITZ	3003/0105PUS2	1305

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

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	~~$870~~ $885	$300	$0	~~$1170~~ $1185	12/13/2012

EXAMINER	ART UNIT	CLASS-SUBCLASS
PHILOGENE, PEDRO	3733	606-251000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☒ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,

(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 DRESCH IP LAW, PLLC
2 JOHN J. DRESCH
3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

☒ Issue Fee

☒ Publication Fee (No small entity discount permitted)

☐ Advance Order - # of Copies _____

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

☐ A check is enclosed.

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

☒ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number 505364 (enclose an extra copy of this form).

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

☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature /John J. Dresch/ Date December 13, 2012

Typed or printed name John J. Dresch Registration No. 46,672

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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

Electronic Patent Application Fee Transmittal

Application Number:	13084543
Filing Date:	11-Apr-2011
Title of Invention:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION
First Named Inventor/Applicant Name:	Ahmnon D. MOSKOWITZ
Filer:	John Jeremy Dresch
Attorney Docket Number:	3003/0105PUS2

Filed as Small Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Utility Appl issue fee	2501	1	885	885
Publ. Fee- early, voluntary, or normal	1504	1	300	300

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**1185**

Electronic Acknowledgement Receipt

EFS ID:	14455058
Application Number:	13084543
International Application Number:	
Confirmation Number:	1305
Title of Invention:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION
First Named Inventor/Applicant Name:	Ahmnon D. MOSKOWITZ
Customer Number:	87409
Filer:	John Jeremy Dresch
Filer Authorized By:	
Attorney Docket Number:	3003/0105PUS2
Receipt Date:	13-DEC-2012
Filing Date:	11-APR-2011
Time Stamp:	01:40:43
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$1185
RAM confirmation Number	9724
Deposit Account	
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)

1	Post Allowance Communication - Incoming	30030105PUS2_sb0047_fee_address.pdf	203861 c6f624444a8e22610d0f06c62dcf69aba8d2d339	no	2
Warnings:					
Information:					
2	Issue Fee Payment (PTO-85B)	30030105PUS2_IF_transmittal20121213_A.pdf	1301508 3912baeb80bf6897778529ae632e4dc6667676a1	no	1
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	32058 c669945c1109f91c62906209bea34c6014abe87b	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	1537427		

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/47 (03-09)
Approved for use through 05/31/2015. OMB 0651-0016
U.S. Patent and Trademark Office; U. S. DEPARTMENT OF COMMERCE
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"FEE ADDRESS" INDICATION FORM

Address to:
Mail Stop M Correspondence
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

- OR -

Fax to:
571-273-6500

INSTRUCTIONS: The issue fee must have been paid for application(s) listed on this form. In addition, only an address represented by a Customer Number can be established as the fee address for maintenance fee purposes (hereafter, fee address). A fee address should be established when correspondence related to maintenance fees should be mailed to a different address than the correspondence address for the application. **When to check the first box below**: If you have a Customer Number to represent the fee address. **When to check the second box below**: If you have no Customer Number representing the desired fee address, in which case a completed Request for Customer Number (PTO/SB/125) must be attached to this form. For more information on Customer Numbers, see the Manual of Patent Examining Procedure (MPEP) § 403.

For the following listed application(s), please recognize as the "Fee Address" under the provisions of 37 CFR 1.363 the address associated with:

☑ Customer Number: 87409

OR

☐ The attached Request for Customer Number (PTO/SB/125) form.

PATENT NUMBER (if known)	APPLICATION NUMBER
	13/084,543

Completed by (check one):

☐ Applicant/Inventor — /John J. Dresch/ (Signature)

☑ Attorney or Agent of record 46672 (Reg. No.) — John J. Dresch (Typed or printed name)

☐ Assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96) — 571-333-0930 (Requester's telephone number)

☐ Assignee recorded at Reel _____ Frame _____ — December 13, 2012 (Date)

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

☑ * Total of 1 forms are submitted.

This collection of information is required by 37 CFR 1.363. 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 5 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 COMPLETED FORMS TO THIS ADDRESS.
SEND TO: Mail Stop M Correspondence, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.
If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Privacy Act Statement

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

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

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/084,543	01/15/2013	8353913	3003/0105PUS2	1305

87409 7590 12/22/2012

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

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

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 USA offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to encourage and facilitate business investment. To learn more about why the USA is the best country in the world to develop technology, manufacture products, and grow your business, visit SelectUSA.gov.

STATEMENT UNDER 37 CFR 3.73(b)

Applicant/Patent Owner: Moskowitz et al.

Application No./Patent No.: 13/084,543 Filed/Issue Date: 4/11/2011

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

, Nathan C. Moskowitz
(Name of Assignee)

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

states that it is:

1. ☒ the assignee of the entire right, title, and interest; or
2. ☐ an assignee of less than the entire right, title and interest.
   The extent (by, percentage) of its ownership interest is _____%
3. ☐ the assignee of an undivided interest in the entirety of (a complete assignment from one of the joint inventors was made)

in the patent application/patent identified above by virtue of either:

A. ☒ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel (035557, 039331 and 039331), Frame (0312, 0648 and 0867), or for which a copy thereof is attached.

OR

B. ☐ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as shown below:

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

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

☒ As required by 37 CFR 3.73(b)(1)(i), the documentary evidence of the chain of title from the original owner to the assignee was, or concurrently is being, submitted for recordation pursuant to 37 CFR 3.11.
[NOTE: A separate copy (*i.e.*, a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, if the assignment is to be recorded in the records of the USPTO. See MPEP 302.8]

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

/Michael T. Hawkins/	July 20, 2017
Signature	Date
Michael T. Hawkins , 57,867	(612) 335-5070
Printed or Typed Name	Telephone Number
Attorney for Assignee	
Title	

PTO/SB/80 (11-08)
Approved for use through 11/30/2011. OMB 0651-0035
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.

POWER OF ATTORNEY TO PROSECUTE APPLICATIONS BEFORE THE USPTO

I hereby revoke all previous powers of attorney given in the application identified in the attached statement under 37 CFR 3.73(b).

I hereby appoint:

☒ Practitioners associated with the Customer Number: 26191

OR

☐ Practitioner(s) named below (if more than ten patent practitioners are to be named, then a customer number must be used):

Name	Registration Number	Name	Registration Number

as attorney(s) or agent(s) to represent the undersigned before the United States Patent and Trademark Office (USPTO) in connection with any and all patent applications assigned only to the undersigned according to the USPTO assignment records or assignment documents attached to this form in accordance with 37 CFR 3.73(b).

Please change the correspondence address for the application identified in the attached statement under 37 CFR 3.73(b) to:

☒ The address associated with Customer Number: 26191

OR

☐ Firm or Individual Name	Fish & Richardson P.C.		
Address	P.O. Box 1022		
City	Minneapolis	State MN	Zip 55440-1022
Country	United States		
Telephone		Email	

Assignee Name and Address:
Nathan C. Moskowitz
212 N Adams St
Rockville, MD 20850

A copy of this form, together with a statement under 37 CFR 3.73(b) (Form PTO/SB/96 or equivalent) is required to be filed in each application in which this form is used. The statement under 37 CFR 3.73(b) may be completed by one of the practitioners appointed in this form if the appointed practitioner is authorized to act on behalf of the assignee, and must identify the application in which this Power of Attorney is to be filed.

SIGNATURE of Assignee of Record

The individual whose signature and title is supplied below is authorized to act on behalf of the assignee

Signature	Nathan C. Moskowitz	Date	4/20/17
Name	Nathan C. Moskowitz	Telephone	
Title			

This collection of information is required by 37 CFR 1.31, 1.32 and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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

Electronic Acknowledgement Receipt

EFS ID:	29845381
Application Number:	13084543
International Application Number:	
Confirmation Number:	1305
Title of Invention:	BI-DIRECTIONAL FIXATING TRANSVERTEBRAL BODY SCREWS AND POSTERIOR CERVICAL AND LUMBAR INTERARTICULATING JOINT CALIBRATED STAPLING DEVICES FOR SPINAL FUSION
First Named Inventor/Applicant Name:	Ahmnon D. MOSKOWITZ
Customer Number:	87409
Filer:	Michael T. Hawkins/Abby Remer
Filer Authorized By:	Michael T. Hawkins
Attorney Docket Number:	3003/0105PUS2
Receipt Date:	20-JUL-2017
Filing Date:	11-APR-2011
Time Stamp:	16:09:46
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Power of Attorney	POA.pdf	420991 d462ad30b867994b3ed4e27a830f3d31ae878b1e	no	2

Warnings:

Information:	
Total Files Size (in bytes):	420991

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.

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
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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
13/084,543	04/11/2011	Ahmnon D. MOSKOWITZ	3003/0105PUS2

CONFIRMATION NO. 1305

POWER OF ATTORNEY NOTICE

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Potomac Falls, VA 20165

OC000000093141418

Date Mailed: 08/01/2017

NOTICE REGARDING CHANGE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 07/20/2017.

- The Power of Attorney to you in this application has been revoked by the assignee who has intervened as provided by 37 CFR 3.71. Future correspondence will be mailed to the new address of record(37 CFR 1.33).

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

/qtran/

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POA ACCEPTANCE LETTER

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

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Date Mailed: 08/01/2017

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 07/20/2017.

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

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

/qtran/