

Nos. 24-1696, 24-1753

**United States Court of Appeals
for the Federal Circuit**

MOSKOWITZ FAMILY LLC,

Plaintiff-Appellant,

v.

GLOBUS MEDICAL, INC.,

Defendant-Cross-Appellant.

APPEAL FROM UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF
PENNSYLVANIA IN NO. 2:20-CV-03271-MSG, JUDGE MITCHELL S. GOLDBERG

PLAINTIFF-APPELLANT'S PRINCIPAL BRIEF

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January 30, 2025

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REPRESENTATIVE CLAIMS AT ISSUE ON APPEAL

Claim 47 of U.S. Patent No. 9,889,022 (Appx204)

47. A universal, intervertebral combination internal screw guide and fixation apparatus configured to be inserted into a disc space between a first vertebral body and a second vertebral body and to provide fusion of the first vertebral body to the second vertebral body via biological bone fusion and screw fusion, the apparatus comprising:

an intervertebral cage including:

a top wall, a bottom wall, and two sidewalls defining an open space capable of receiving bone filling for the biological bone fusion;

an internal screw guide having an internal bore with an entry opening and an exit opening, the entry opening of the internal bore formed only in a top surface of the top wall and the exit opening formed at least partially in a bottom surface of the top wall and at least partially in a side surface of the top wall, wherein the internal screw guide further includes a counterbore that is larger than and coaxial with the internal bore and has a counterbore entry opening that is formed only in the top surface of the top wall;

a second internal screw guide having a second internal bore with a second entry opening and a second exit opening, the second entry opening of the second internal bore formed only in the top surface of the top wall and the second exit opening formed at least partially in the bottom surface of the top wall and at least partially in a second side surface of the top wall; and

a circular hole extending through the top wall in a direction substantially normal to the top surface of the top wall, wherein the circular hole is positioned between the internal screw guide and the second internal screw guide at the top surface of the top wall.

Claim 1 of U.S. Patent No. 8,353,913 (Appx255-256)

1. A tool for manipulating and inserting a universal, intervertebral bone fusion spacer into a disc space between a first vertebral body and a second vertebral body for providing 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 includes an intervertebral cage having a first integral screw guide and a second integral screw guide, 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 gripper having a plurality of prongs,

wherein a distal end of each of the plurality of prongs is capable of engaging 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.

Claim 1 of U.S. Patent No. 10,478,319 (Appx308-309)

1. A system comprising:

a tool assembly which comprises:

a first tool having a first proximal end and a first distal end with a first handle and a gripper, the gripper being positioned at the first distal end, cooperating with the first handle, and having first and second engagement prongs positioned at the first distal end, wherein the first tool defines an adjusting tool passage through the first tool; and

a second adjusting tool having a second proximal end and a second distal end with a second handle positioned at the second proximal end, a screw engagement portion positioned at the second distal end, and a shaft extending from the second handle to the screw engagement portion, wherein the shaft of the second adjusting tool is sized with a smaller diameter than that of the adjusting tool passage such that the second adjusting tool can extend through the adjusting tool passage of the first tool; and

an expandable spinal implant sized and configured to be implanted in a human spine, the expandable spinal implant comprising a first expandable spinal implant structure, a second expandable spinal implant structure, and an adjusting screw having a screw head and a threaded portion, wherein the expandable spinal implant is configured to expand the first expandable spinal implant structure with respect to the second expandable spinal implant structure in response to turning of the adjusting screw, wherein the

expandable spinal implant defines first and second tool engagement indentations sized and configured for receiving the first and second engagement prongs of the first tool, wherein the adjusting screw is positioned within the expandable spinal implant in a screw location such that the second adjusting tool can extend through the adjusting tool passage of the first tool to engage the screw head of the adjusting screw while the first and second engagement prongs of the first tool are engaged with the first and second tool engagement indentations of the expandable spinal implant.

CERTIFICATE OF INTEREST

Counsel for Plaintiff-Appellant Moskowitz Family LLC (“Moskowitz”)

certifies the following:

1. Provide the full names of all entities represented by undersigned counsel in this case.

Moskowitz Family LLC

2. Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities.

N/A.

3. Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities.

None.

4. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

Clark Hill: Daniel J. McGravey.

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** no longer with firm*

5. Other than the originating case(s) for this case, are there related or prior cases that meet the criteria under Fed. Cir. R. 47.5(a)?

None.

6. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

N/A.

Dated: January 30, 2025

/s/ Lauren A. Degnan
Lauren A. Degnan

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STATEMENT OF RELATED CASES

Pursuant to Federal Circuit Rule 47.5, Moskowitz states that no appeal from the same civil action has been previously brought before this or any other appellate court, and no other cases may directly affect or be directly affected by the Court's decision in this appeal.

JURISDICTIONAL STATEMENT

The district court had jurisdiction under 28 U.S.C. §§1331 and 1338(a); entered final judgment on February 27, 2024, and as amended on March 5, 2024; and decided the last tolling post-judgment motion on August 13, 2024. This appeal, first noticed March 28, 2024, and docketed April 16, 2024, is timely. See 28 U.S.C. §2107(a); Fed. R. App. P. 4. This Court has jurisdiction under 28 U.S.C. §1295(a)(1).

STATEMENT OF THE ISSUES

1. Does the preamble term “universal” form a claim limitation of claim 47 of the '022 patent or claims 1 and 10 of the '913 patent when it provides no antecedent basis or structural support for the claim bodies and otherwise does not breathe life into the claims?

2. Does the preamble term “universal” require a single spinal implant capable of being implanted into any region of the spine using any surgical

technique where that interpretation is a physical impossibility and excludes all preferred embodiments disclosed in the specifications?

3. Does substantial evidence support the jury's noninfringement verdict for claim 1 of the '319 patent as to Globus's RISE, CALIBER, and MAGNIFY-S products where Globus failed to apply the plain meaning of the "cooperating" claim limitation?

INTRODUCTION

Moskowitz is a leading innovator in spinal surgery technology and has been on the forefront of innovating new and improved designs for spinal implants and the tools used for their insertion. This patented technology paved the way for minimally invasive spinal surgery, which has drastically reduced surgical complications and improved patient outcomes. Globus, a major medical device manufacturer, has used Moskowitz's patents for years without paying for a license. Moskowitz brought suit against Globus to rectify this harm, and Globus avoided an infringement finding only because the district court adopted Globus's erroneous claim constructions.

First, the district court improperly granted summary judgment of noninfringement of the '022 and '913 patents because it accepted Globus's argument that the term "universal" used in the preambles of the '022 and '913 patent claims is limiting. The default rule is that claim preambles are non-limiting, and the exceptions to this rule do not apply. Even if the "universal" term were limiting, the district court further erred by construing this term in a manner that excludes all medical implants, including all of the patents' preferred embodiments.

Second, the district court erred in holding that substantial evidence supports the jury's verdict of noninfringement for the '319 patent. The district court tested the verdict against a new, unreasonable interpretation of the relevant claim

language, which was provided to the jury without construction. For the products subject to this appeal, Globus argued noninfringement based on only one limitation—the positioning tool has a handle “cooperating” with the gripper at the tool’s opposite end. The undisputed trial evidence demonstrated that the handle and gripper of Globus’s positioning tools **work together** during surgery, which both parties’ experts agreed was all the plain meaning of “cooperating” requires. Yet, Globus departed from this plain meaning by arguing that its tool’s handle does not mechanically **actuate** the gripper, a position without any intrinsic record support. The district court improperly upheld the jury’s resulting noninfringement verdict based on this new claim construction.

Each of these errors requires this Court’s intervention, which Moskowitz respectfully seeks in this appeal.

STATEMENT OF THE CASE

I. Dr. Moskowitz’s Pioneering Surgical Inventions

Appellant Moskowitz is a family-owned business founded by Dr. Nathan Moskowitz and his two sons, Mosheh and Ahmnon (Andy) Moskowitz.

Dr. Moskowitz is an Assistant Professor of Neurological Surgery at The Johns Hopkins University and has practiced as a neurosurgeon at Hopkins since 1990.

Appx4672 (31:20-23). Dr. Moskowitz received his Ph.D. in Neurochemistry, and

his medical degree, from the Mount Sinai School of Medicine. Appx4669 (28:9-23).

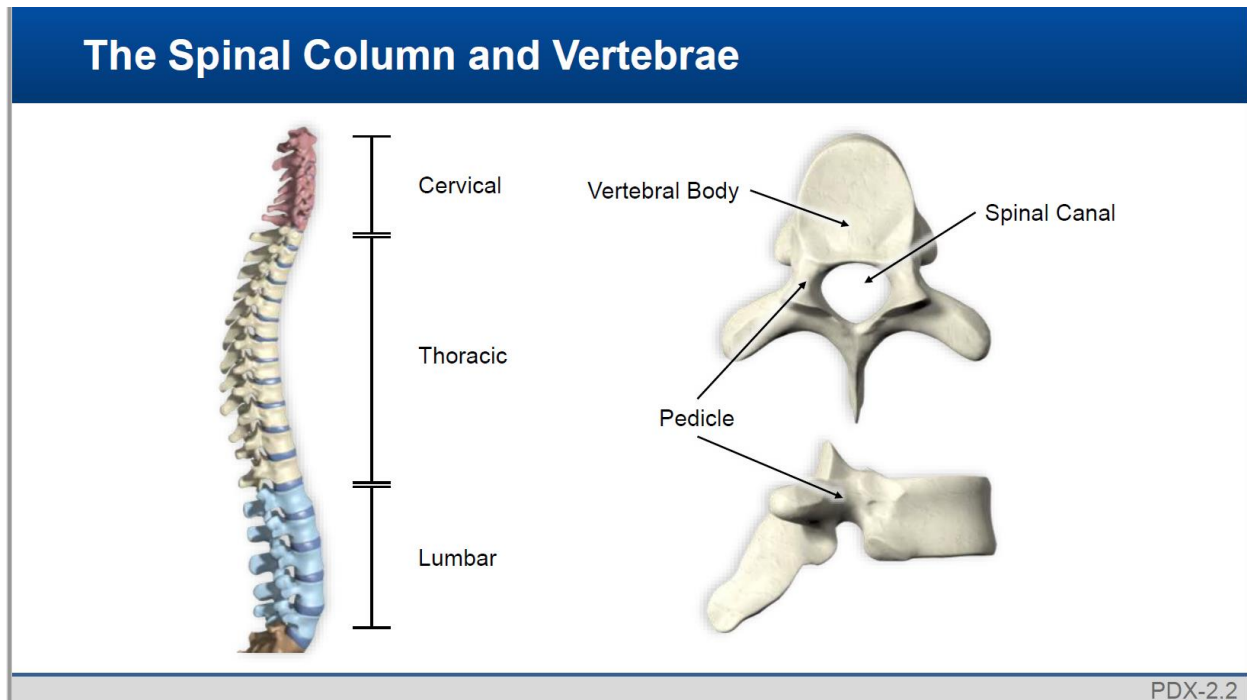
Looking to improve spinal surgery by reducing surgical risk and enhancing patient outcomes, Moskowitz began patenting key innovations in the spinal surgical space. *E.g.*, Appx4678-4685 (37:23-44:18). Moskowitz maintains a robust portfolio related to fixation systems for minimally-invasive spinal surgery. Moskowitz's patent portfolio has been recognized as within the top five in the industry, in terms of number of patents and citations by other patents, by the Spine Market publication. Appx4715-4716 (74:13-75:2).

Dr. Moskowitz and at least one or both of his sons are named inventors of U.S. Patents Nos. 9,889,022, 8,353,913, and 10,478,319, at issue in this appeal.

A. The Spine and Spinal Fusion Surgery

The spine has three major regions: (1) "cervical," located at the neck; (2) "lumbar," located at the low back; and (3) "thoracic," located between the cervical and lumbar spine. Appx4676-4677 (35:21-36:1). The spine comprises many bones stacked upon one another to form a column that reaches from the low back region of the body to the neck. These spinal bones are called vertebrae, and each vertebra includes a vertebral body formed in the anterior (or front) side of the spine, and a pedicle bone at the posterior (or rear) side of the spine. Appx4677

(36:2-9). In the center of each vertebra is a gap known as the spinal cavity or canal through which the spinal cord and spinal nerves run. Appx4677 (36:2-17).



The space between each adjacent set of vertebrae is filled in with an intervertebral disc, which acts as a “shock absorber” for the vertebrae. Appx4678 (37:1-16). Intervertebral discs can encounter a host of issues, including herniation and degeneration. Appx4678-4679 (37:7-38:14). When that happens, spinal fusion surgery may be performed to replace the problematic disc with a spinal implant (also called “spacer” or “cage”). Appx4679-4680 (38:22-39:7). In the prior art, it was often difficult to fit implants between vertebrae because of the varying anatomies of different patients. Appx4698-4699 (57:13-58:4). For instance, implants would often need to be hammered in place to fit. *Id.* The use of

such inelegant tools was dangerous because the spine contains sensitive nerves and blood vessels. *Id.*

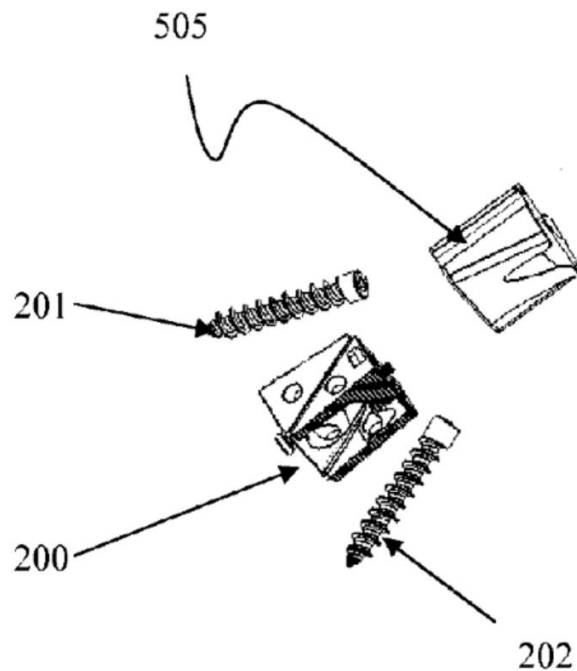
Spinal fusion surgery has traditionally also included “supplemental fixation” to hold the spinal implant in place, which involves placing screws into the vertebral body and connecting the screws using rods to achieve spinal structural stability. Appx4680 (39:15-22). A pedicle screw is a screw used in supplemental fixation that is driven through the pedicle and into the vertebral body. Appx4681 (40:1-6).

Before Moskowitz’s innovations, spinal fusion approaches in the prior art typically involved extensive use of pedicle screws to fixate spinal fusion devices. Appx196 (1:60-63). Pedicle screws, however, led to serious complications including “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.” *Id.* (1:63-2:3). Moskowitz’s innovations improved minimally invasive spinal surgery, including reducing the likelihood that supplemental pedicle screws would be needed to secure spinal implants in place. *See* Appx196 (1:47-49).

B. The Asserted '022, '913, and '319 Patents

The patents at issue originate from the same parent application and share a common specification.¹ See Appx154-205; Appx206-259; Appx260-313.

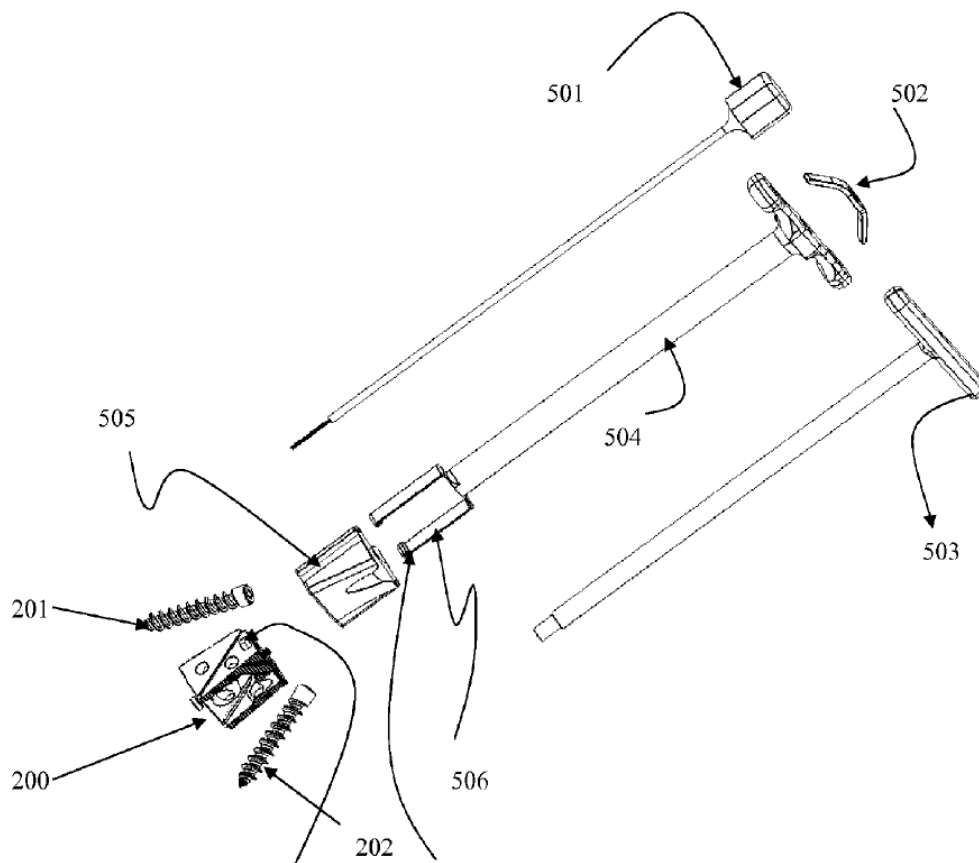
The '022 patent covers an apparatus for facilitating and encouraging bone and screw fusion. Appx204 (cl. 47). A main focus of the '022 patent is the angulation of the screws provided by the spinal implant (spacer) working in conjunction with a screw guide, which helps guide the screws into the patient's vertebrae. Appx197 (3:26-31). The screw guide 505 is shown alongside the spinal spacer 200 and screws 201 and 202 in Figure 5C:



¹ This brief cites the '022 specification when discussing multiple patents collectively.

Appx172. The screw guide may also be internal to the implant. Appx199 (8:20-33). The spacer and the specific configuration of the screw guide ensures screws are inserted at a shallow angle such that portions of the vertebral bone above and below the apparatus need not be carved away before implantation. Appx197 (3:31-39). This solution was a difficult accomplishment “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.” *Id.*

The '913 patent focuses on an implant positioning tool and its claims recite characteristics of the innovative tool that works together with the implant and the screw guide. Appx255-256 (cl. 1). The tool “provide[s] the means in any circumstance to accomplish precision screw trajectory,” and also “streamline and ease production of bi-directionally oriented transvertebral screws, and allow[] placement of longer and wider screws with greater bone penetration to provide yet a sturdier fusion construct.” Appx251 (3:32-43). Figure 5C depicts this tool as element 504:



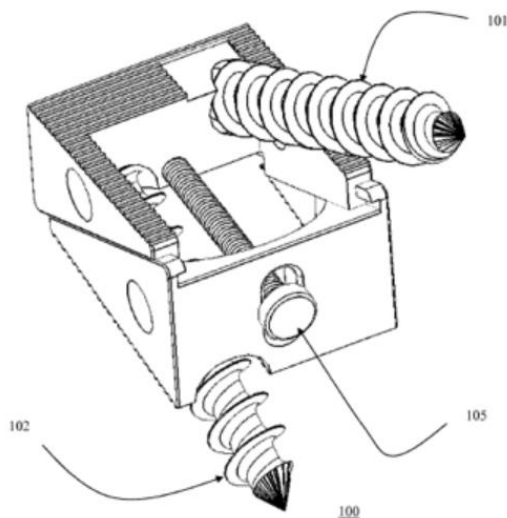
Appx225.

Unlike the prior art that used one device for maintaining disc space and another device for fixation, the '022 and '913 patents cover a system focused on deploying a single spinal implant which functions as both an intervertebral spacer and an intervertebral bone fusion screw apparatus. The specification describes “multiple device embodiments which **combine in a single construct** the **dual functions** of an [1] intervertebral spacer maintaining disc space height, and [2] transvertebral body fusion screws.” Appx196 (2:20-23); *see also* Appx199 (8:17-19) (“[T]his device **functions as both** an intervertebral bone fusion spacer and bi-

directional transvertebral screw fusion device.”).² The dual-function inventive device “provide[s] 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.” Appx197 (4:3-8).

Finally, the ’319 patent describes an expandable spinal implant designed for placement between two vertebral bodies to facilitate and encourage bone fusion and maintain anterior column height. *See, e.g.*, Appx308-309 (cl. 1), Appx303 (2:54-67). According to the ’319 patent, the expandable implant allows for a more minimally invasive surgical approach, which leads to a lower rate of complications, minimal soft tissue trauma, reduced blood loss, better patient outcomes, and allows for expansion in two simultaneous directions. Appx303 (1:42-2:10); Appx4919 (25:2-7). The expandable implant is shown in Figure 1C:

² Unless noted, all emphasis added.



Appx267.

In addition to the implant, the '319 patent's claimed system includes a surgical tool assembly (consisting of two tools) for inserting the implant into a disc space, tool 504, and then expanding it once in place, tool 501. Figure 5C, reproduced above for the '913 patent, depicts these tools. Appx279. The "positioning tool" 504 is used to insert the implant into the spine. It has a handle at one end, and a gripper portion for gripping the expandable implant at its other end. Appx308-309 (cl. 1); Appx306 (8:63-65). The gripper portion has engagement prongs that mate with, and grasp, the implant. Appx306-307 (8:67-9:4). The positioning tool also includes a passageway that allows the expander tool 501 to extend through it. Appx306-307 (8:64-9:1).

Once the implant is placed in the spine using the first positioning tool 504, the surgeon uses the second expander tool 501 tool to expand the implanted

expandable implant. When this second tool is “inserted in the insertion [passageway in the first tool] and turned, [it] turns the screw adjuster (FIG. 5C) which in turn regulates top and bottom triangular screw box base sliding,” which causes the expandable implant to expand. *Id.*

Access to the spinal disc space is limited and surrounded by critical and sensitive anatomical structures. *See* Appx4916-4918 (22:14-24:2). Because expandable implants are inserted in a contracted state, they can be much smaller during insertion than they ultimately become when implanted. *See* Appx4915-4916 (21:16-22:8). This reduced size makes it easier for the surgeon to implant the device without injury. *Id.*; Appx4919 (25:2-7). The design of the surgical tool allows for the implant to be inserted at a narrow, contracted height while also facilitating its expansion over a large range. *See* Appx4916-4918 (22:14-24:2).

II. Procedural History

A. Pre-Trial & Claim Construction

In November 2019, Moskowitz filed suit against Globus in the Western District of Texas, alleging infringement of eight patents. Appx372-428. The case was transferred to the Eastern District of Pennsylvania in July 2020. Appx337 (#50). The district court stayed the case pending the resolution of Globus’s *inter partes* review petitions, App340 (#90), and lifted the stay when the PTAB declined

to institute proceedings based on any of those petitions. Appx8011-8012; Appx340 (#94).

For the '022 and '913 patents, the parties disputed the meaning of “universal,” which appears in the body of some of the claims Moskowitz initially asserted and in only the preamble of others. During claim construction, Globus did not ask the district court to decide whether the preambles of the asserted claims of the '022 and '913 patents are limiting. In its claim construction order, the district court construed the term “universal” to mean “an intervertebral bone fusion spacer designed to be inserted between [vertebrae / vertebral bodies] in any region of the spine, *i.e.*, cervical, thoracic, or lumbar, using any approach, *e.g.*, posterior, anterior, or lateral.” Appx8-9. Moskowitz sought clarification of this construction, Appx2755-2757, and the court confirmed that its construction requires a spacer “that can be used in any region of the spine and may be inserted through any surgical approach,” Appx23.

After the district court’s clarification, Moskowitz withdrew its infringement allegations for claim 15 of the '913 patent, which recites “universal” in its claim body. Appx2864. However, Moskowitz continued to assert claim 47 of the '022 patent and claims 1 and 10 of the '913 patent, which recite “universal” in their respective preambles only, because their preambles are non-limiting, particularly with respect to the “universal” term. *Id.*; Appx2864-2865.

Globus sought summary judgment of noninfringement of the '022 and '913 patents, arguing that the preambles are limiting and thus the asserted claims require a spacer that is “universal” as construed by the district court. Appx27. Moskowitz opposed, arguing that Globus could not overcome the presumption that claim preambles are non-limiting, particularly because “universal” does not provide antecedent basis or structural support for any of the limitations recited in the bodies of the '022 and '913 patents' claims. Appx27-32. The district court held the “universal” term in the preambles limiting and entered summary judgment of noninfringement because Moskowitz agreed that it could not demonstrate infringement if the preambles were limiting under the district court’s construction of “universal.” Appx42-43.

B. Trial & Post-Trial Briefing

The case proceeded to a jury trial in December 2023. Moskowitz streamlined its infringement allegations to a single claim of the '319 patent and two other patents not being challenged on appeal. Moskowitz asserted claim 1 of the '319 patent against Globus’s CALIBER, RISE, and MAGNIFY-S products, along with several others not relevant to this appeal. Moskowitz’s expert, Dr. William Rosenberg, testified about infringement during Moskowitz’s case-in-chief. Globus argued in response that CALIBER, RISE, and MAGNIFY-S do not practice just one limitation of claim 1, requiring a positioning tool with “a gripper,

the gripper being positioned at the first distal end, **cooperating** with the first handle” Appx131-132. Although the district court had informed the parties they could use their trial time as they liked,³ the court reversed course and greatly restricted Moskowitz’s ability to offer rebuttal testimony by Dr. Rosenberg such that he ultimately did not take the stand for rebuttal. See Appx5834-5840 (165:11-171:6). The jury found that claim 1 was not infringed and not invalid. Appx114; Appx117.

Following trial, Moskowitz filed a motion for judgment as a matter of law (“JMOL”) of infringement of claim 1. Moskowitz argued that, at Globus’s prompting, the jury failed to apply the plain meaning of “cooperating” in the limitation requiring a positioning tool with “a gripper, the gripper being positioned at the first distal end, **cooperating** with the first handle” Appx6386-6387 (citing Appx308-309); Appx6391-6394. Globus’s expert, Mr. Michael Sherman, admitted that the plain meaning of “cooperating” is to work, act, or operate together. Appx5614-5615 (227:19-228:12); Appx6388-6389. Globus did not dispute that CALIBER, RISE, and MAGNIFY-S have a positioning tool with a handle that works together with a gripper to steer and insert a spinal implant. Appx6390. Globus instead argued that its products’ positioning tool’s handle does

³ See Appx4329-4330 (6:22-7:6); Appx4332 (9:2-6) (“I’m going to . . . try to give you as much leeway as I can to try your case as you deem appropriate and not micromanage.”).

not satisfy the “cooperating” limitation because the handle does not “actuate” the gripper. Appx5615 (228:13-21). Because substantial evidence does not support the jury’s verdict under the only reasonable plain meaning interpretation of “cooperating,” Moskowitz asked the district court to enter JMOL of noninfringement. Appx6391-6394.

The district court denied Moskowitz’s JMOL motion, and this appeal followed. Appx131-139.

SUMMARY OF THE ARGUMENT

For the ’022 and ’913 patents, this Court should reverse the district court’s grant of summary judgment of noninfringement for two reasons. First, the district court erred in holding that the preamble term “universal” limits claim ’47 of the ’022 patent and claims 1 and 10 of the ’913 patent. The default rule that preambles are non-limiting governs here because none of the limited exceptions to that rule apply. “Universal” does not provide antecedent basis for any term used in the respective claim bodies, does not provide structural support for the claims, and is not a fundamental characteristic of the invention. The cases the district court cited to find the preambles limiting are readily distinguishable, and instead support holding “universal” to be non-limiting.

Second, even if “universal” were limiting, the district court misconstrued the term to encompass an implant that cannot and does not exist in the real world or

the patents’ common specification. The court construed this term to require an implant for deployment into **any** region of the spine using **any** surgical technique. This construction requires an implant that is an anatomical and engineering impossibility given the widely varying shape and size of the spine from the large lumbar vertebrae in the low back to the small cervical vertebrae in the neck as well as the diverse sizes of patients’ spines more generally. Given these extreme implications, this construction unsurprisingly lacks intrinsic support. Rather, the written description uses the term “universal” to refer to the invention’s disclosure of a device having the dual functionality of an intervertebral spacer and a transvertebral bone fusion screw apparatus. The district court’s errant construction should be reversed, and the summary judgment of noninfringement vacated on this separate basis.

For the ’319 patent, this Court should reverse the district court’s denial of JMOL of infringement. Undisputed record evidence demonstrates that Globus’s RISE, CALIBER, and MAGNIFY-S products include a positioning tool with a handle at one end that works together with a gripper at the opposite end to hold and manipulate a spinal implant. Globus’s expert admitted that “work together” is the ordinary meaning of “cooperating,” but nevertheless argued the Globus products do not infringe because the “cooperating” limitation requires the handle to actuate the gripper. Rather than evaluate whether substantial evidence supports the verdict

under the ordinary meaning of “cooperating,” the district court erroneously tested the verdict by this new and more detailed interpretation of “cooperating” as requiring actuation. That interpretation is unsupported and unreasonable, and thus cannot provide substantial evidence support for the jury’s noninfringement finding. This Court should reverse the district court, enter judgment of infringement for the ’319 patent, and remand for an assessment of damages.

STANDARD OF REVIEW

Whether a preamble is limiting is an issue of claim construction. *Arctic Cat Inc. v. GEP Power Prods., Inc.*, 919 F.3d 1320, 1327 (Fed. Cir. 2019). Claim construction is a question of law we review de novo to the extent that “the issue is decided only on the intrinsic evidence.” *Id.* at 1327-28; *see also Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 331 (2015).

This Court reviews the denial of a motion for JMOL or new trial under regional circuit law. *Wisconsin Alumni Rsch. Found. v. Apple Inc.*, 905 F.3d 1341, 1346 (Fed. Cir. 2018). Under Third Circuit law, this Court “exercise[s] plenary review over a district court’s rulings on motions for JMOL, applying the same standard as the district court.” *Idenix Pharm. LLC v. Gilead Scis. Inc.*, 941 F.3d 1149, 1153 (Fed. Cir. 2019). “A grant of JMOL is appropriate where a party has been fully heard on an issue during a jury trial and the court finds that a reasonable

jury would not have had a legally sufficient evidentiary basis to find for the party on that issue.” *Id.* at 1153-54 (quotation omitted).

ARGUMENT

I. The District Court Misconstrued the ’022 and ’913 Patent Term “Universal”

The district court made two claim construction errors regarding the claim term “universal” in the ’022 and ’913 patents. First, the district court erroneously held that the term “universal” in the preambles of the relevant claims is limiting. Appx42. The term “universal,” however, does not form the antecedent basis for the structurally complete claim bodies that follow and does not otherwise breathe life into the relevant claims. Second, the district court construed “universal” to require an implant configured such that could be deployed in *any* region of the spine using *any* surgical technique. Appx8-9. This construction improperly excludes all medical implants—including all of the patents’ preferred embodiments—and lacks intrinsic evidence support. Correcting either of these errors requires vacating the district court’s noninfringement summary judgment determination for the ’022 and ’913 patents, and remanding so that these claims may proceed to trial.

A. The Preamble Term “Universal” Does Not Limit the Claims

The long- and well-established “general rule” is that claim “preamble language is not treated as limiting.” *Aspex Eyewear, Inc. v. Marchon Eyewear*,

Inc., 672 F.3d 1335, 1347 (Fed. Cir. 2012); *DeGeorge v. Bernier*, 768 F.2d 1318, 1322 n.3 (Fed. Cir. 1985) (“Generally, and in this case, the preamble does not limit the claims.”). This rule especially applies “where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention.” *Catalina Mktg. Int’l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002) (quoting *Rowe v. Dror*, 112 F.3d 473, 478 (Fed. Cir. 1997)).

Although limited exceptions to this default rule exist, none apply to the term “universal” in the preambles of ’022 patent claim 47 or ’913 patent claims 1 and 10. “Universal” does not provide necessary support for terms in the bodies of the claims at issue, nor is it “necessary to give life, meaning, and vitality” to the claims. *Catalina*, 289 F.3d at 808.

1. “Universal” Does Not Provide Necessary Support for the Claims

a. “Universal” Does Not Provide Antecedent Basis for Any Claim Limitation

One guidepost for determining whether a preamble term is a substantive claim limitation is whether the term serves as antecedent basis for a term in the body of the claims. *See Catalina*, 289 F.3d at 808. Here, “universal” describes the intended field of use for the asserted claims and does not lend antecedent basis support for any of the limitations in the bodies of the claims.

The district court did not identify a single limitation in the claim bodies that requires the preamble term “universal” to provide antecedent basis support.

Appx33-35. Indeed, for the ’022 patent, the district court did not identify **any claim limitation** that finds antecedent basis support in the preamble. Appx33-35.

For the ’913 patent, the district court identified terms in the preamble **other than** “universal”—for example, “intervertebral cage” and “integral screw guide[s]” in claim 1. That observation is irrelevant to the proper inquiry. One must analyze the limiting effect of preamble language with respect to specific terms, not the entire preamble, because claim preambles are not monolithic. *Cochlear Bone Anchored Sols. AB v. Oticon Med. AB*, 958 F.3d 1348, 1355 (Fed. Cir. 2020) (“A conclusion that some preamble language is limiting does not imply that other preamble language, or the entire preamble, is limiting.”).

For example, in *TomTom, Inc. v. Adolph*, 790 F.3d 1315 (Fed. Cir. 2015), the Court held that only a subset of the preamble language had limiting effect, whereas the contested portion of the preamble that provided no antecedent basis support did not. *Id.* at 1323. In *Cochlear Bone*, the Court recognized that, “[a]lthough the preamble term ‘a patient’ may provide antecedent basis for claim 1’s later recitation of ‘the patient,’ that is not the preamble language Cochlear argues is limiting.” *Cochlear Bone*, 958 F.3d at 1355; *see also Catalina*,

289 F.3d at 808 (explaining “dependence on a ***particular disputed preamble phrase*** for antecedent basis may limit claim scope”).

The district court notably did not address this precedent and principle in its summary judgment order, even though Moskowitz argued that it was improper to examine the preamble monolithically. *See* Appx33-35; Appx4091-4092. Citing *Bio-Rad Laboratories, Inc. v. 10X Genomics Inc.*, 967 F.3d 1353 (Fed. Cir. 2020), the district court proceeded under the presumption that it is “generally” disfavored to find a preamble partially, rather than fully, limiting. Appx37. *Bio-Rad* distinguished cases like *TomTom* where the Court found a preamble was only partially limiting. *Id.* at 1371. A distinguishing factor *Bio-Rad* recognized is that the preamble portion found non-limiting in *TomTom* simply recited “an intended use or purpose,” like here, and not a structural requirement. *Id.*; *see, e.g.*, Sec.I.A.1.b., *infra*.

Even if this Court were to consider language other than the term “universal” in the preamble of independent claim 1 of the ’913 patent, the only preamble terms that provide antecedent basis (“a slot or indentation of the intervertebral cage” and “integral screw guide[s]”) are terms related to an “intervertebral cage” with which the claimed tool must engage, not the tool itself. The claim body uses these features of the intervertebral cage to define ***functional capabilities*** of the claimed tool’s “gripper” and “screw guide.” Appx255-256 (cl. 1). Specifically, the gripper

must be “capable of engaging a respective slot or indentation of the intervertebral cage” and the screw guide must be “for controlling a direction of screws that are inserted into the first integral screw guide and the second integral screw guide[.]”

Id. These preamble terms merely provide reference points to help define the tool’s functional capabilities, and, therefore, are not limiting. *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1350 (Fed. Cir. 1998) (holding structural elements of a “tissue sampling device” in the preamble were non-limiting because they were necessary to define the functional capability of the claimed “biopsy needles”).

b. The Claims Are “Structurally Complete” Without the “Universal” Intended Use

The preamble term “universal” is also not limiting because the bodies of ’022 patent claim 47 and ’913 patent claims 1 and 10 are structurally complete standing alone. A claim body is “structurally complete” when “deletion of the preamble phrase does not affect the structure or steps of the claimed invention.” *Catalina*, 289 F.3d at 809.

As discussed above, the preamble of claim 47 does not provide antecedent basis for any term recited in its body. Claim 47’s body itself defines a structurally complete “intervertebral cage” with four walls, two internal screw guides, and a circular hole in one of the cage’s walls:

47. A universal, intervertebral combination internal screw guide and fixation apparatus configured to be inserted into a disc space between a first vertebral body and a second vertebral body and to

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

an intervertebral cage including:

a top wall, a bottom wall, and two sidewalls defining an open space capable of receiving bone filling for the biological bone fusion;

an internal screw guide having an internal bore with an entry opening and an exit opening, the entry opening of the internal bore formed only in a top surface of the top wall and the exit opening formed at least partially in a bottom surface of the top wall and at least partially in a side surface of the top wall, wherein the internal screw guide further includes a counterbore that is larger than and coaxial with the internal bore and has a counterbore entry opening that is formed only in the top surface of the top wall;

a second internal screw guide having a second internal bore with a second entry opening and a second exit opening, the second entry opening of the second internal bore formed only in the top surface of the top wall and the second exit opening formed at least partially in the bottom surface of the top wall and at least partially in a second side surface of the top wall; and

a circular hole extending through the top wall in a direction substantially normal to the top surface of the top wall, wherein the circular hole is positioned between the internal screw guide and the second internal screw guide at the top surface of the top wall.

Appx204 (cl. 47).

Each of the emphasized limitations following the term “intervertebral cage” (*e.g.*, various walls, a first and second internal screw guide, and a circular hole) define the complete structure of the intervertebral cage and nothing else. None of these limitations reference or rely on the preamble phrase “universal, intervertebral combination internal screw guide and fixation apparatus,” let alone the shorter

contested term “universal.” The limitations set forth in claim 47’s body do not suggest that “universal” has anything to do with structure of the claimed intervertebral cage. Removing “universal” or even the entire phrase “universal, intervertebral combination internal screw guide and fixation” would not affect the structure of the claimed “an intervertebral cage.” Under these circumstances, the claim body is structurally complete and the preamble is not limiting. *Catalina*, 289 F.3d at 808.

Similarly, claim 1 of the ’913 patent recites a structurally complete **tool** with two structural components, a gripper and screw guide:

1. **A tool** for manipulating and inserting a universal, intervertebral bone fusion spacer into a disc space between a first vertebral body and a second vertebral body for providing 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 includes an intervertebral cage having a first integral screw guide and a second integral screw guide, 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 gripper having a plurality of prongs,

wherein a distal end of each of the plurality of prongs is capable of engaging 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.

Appx255-256 (cl. 1).

The claimed tool has (1) a gripper with prongs and (2) a screw guide. *Id.* No other structure is required. A skilled artisan would not need to look to the preamble to understand the structure of the tool because the body’s description of these two structural elements is sufficient to understand the scope of the claim. Deleting “universal” “from the preamble . . . does not affect the structural definition” of the invention in the claim body, which confirms that “[t]he claim body defines a structurally complete invention.” *Catalina*, 289 F.3d at 810.

Instead, the statement in claim 1’s preamble that the tool is for “manipulating and inserting a universal, intervertebral bone fusion spacer” merely describes an intended use of the tool. Reciting an intended use or function is a classic instance of a non-structural—and non-limiting—preamble. *See, e.g., C.R. Bard*, 157 F.3d at 1350 (explaining when “the preamble simply states the intended use or purpose of the invention” it “usually does not limit the scope of the claim unless the preamble provides antecedents for ensuing claim terms”); *see also In re Anderson*, 662 F. App’x 958, 963 (Fed. Cir. 2016) (“The ‘for use’ language does not add a structural limitation to the claimed system or method.”).

Moreover, when Moskowitz wanted to claim both the tool and the implant, it did so in other claims of the ’913 patent. *See, e.g., Appx256-257* (cl. 15) (“15. A tool assembly comprising: a universal, intervertebral bone fusion spacer . . . and a

tool for manipulating and inserting the universal, intervertebral bone fusion spacer.”). Making a “universal spacer” (recited in only the preamble) a substantive claim requirement disregards the inventors’ choice to recite only the tool in claim 1, contrary to claim differentiation principles. *Clearstream Wastewater Sys., Inc. v. Hydro-Action, Inc.*, 206 F.3d 1440, 1446 (Fed. Cir. 2000) (holding claim differentiation “prevents the narrowing of broad claims by reading into them the limitations of narrower claims”).

Therefore, the district court erroneously concluded that the preambles define necessary structure. *See* Appx35-38.

2. “Universal” Is Not a Fundamental Characteristic of the Invention

Another exception to the default rule that preambles are non-limiting is where a preamble “discloses a fundamental characteristic of the claimed invention” as evidenced through the patent specification. *Poly-Am., L.P. v. GSE Lining Tech., Inc.*, 383 F.3d 1303, 1310 (Fed. Cir. 2004).

The intended use of a “universal” apparatus in no way reflects a fundamental novel aspect of the invention “necessary to give life, meaning, and vitality” to claim 47 of the ’022 patent or claims 1 and 10 of the ’913 patent. *Id.* at 1309-10. The word “universal” appears just **once** in the lengthy common specification of ’022 and ’913 patents. *See Arctic Cat*, 919 F.3d at 1329 (holding preamble term non-limiting when “what the specification says about it is distinctly limited”). The

specification uses this term in the section labeled “BACKGROUND OF THE INVENTION,” explaining that one aspect of an embodiment of the invention “relates” to a “universal bidirectional screw (BDS) system.” Appx250 (1:28-35). That distinguishes this case from *Proveris Scientific Corp. v. Innovasystems, Inc.*, 739 F.3d 1367, 1372-73 (Fed. Cir. 2014), on which the district court relied, Appx39, where the preamble term was used throughout the specification.

The common specification here discloses several novel inventions—including those captured by the claims at issue—without describing or defining those inventions in terms of being “universal.” For instance, the specification describes the architecture of a novel “intervertebral cage” whose attributes are fully recited by the body of claim 47 of the ’022 patent. Appx199 (8:20-33); Appx204 (17:49-18:9). The specification also describes the characteristics of a novel insertion tool that corresponds to the limitations recited in the body of claim 1 of the ’913 patent. Appx252 (5:47-52). The inventors may have contemplated use of these inventions with a “universal” system, but intended use does not counsel for giving the preamble term limiting effect.

Indeed, in *C.R. Bard*, the Court rejected the argument that the novel aspects of the biopsy gun, recited in the preamble, must be a substantive claim requirement even though the patent described the biopsy gun as one of the novel aspects of the invention. 157 F.3d at 1346, 1350. The Court’s reached this conclusion because

the biopsy gun, like the “universal” spacer here, was “the intended use or purpose of the invention.” *Id.*; see also *Neapco Drivelines LLC v. Am. Axle & Mfg., Inc.*, 847 F. App’x 856, 858 (Fed. Cir. 2021) (holding feature touted in the specification was not limiting in the preamble because it was described as “merely as part of preferred and alternative embodiments”); *cf. Arctic Cat*, 919 F.3d at 1329 (“[N]ot every preamble reference to additional structure is limiting, even when the structure . . . is underscored as important by the specification.” (quotation omitted)).

The district court also relied on the specification’s describing “the invention as possible for use in various regions of the spine and through various approaches,” and as including an “expandable embodiment” that may be suitable for “cervical, thoracic, and lumbar vertebral body replacements.” Appx40 (citing Appx251 (3:41-43); Appx197 (3:52-54)). The district court’s opinion here appears shaded by the incorrect claim construction it applied to the term “universal,” requiring a hypothetical spacer designed for insertion into “any region of the spine” or “using any approach.” See Sec. I.A.2, *infra*. As described more fully below, the ’022 and ’913 patents’ specification does not describe such a spacer, so it clearly could not form a fundamental characteristic of the invention. In any event, these portions of the specification merely show possible uses and exemplary embodiments, which are plainly not “fundamental characteristic[s]” of the invention, as they be must for

“universal” to be limiting in the preamble based on the specification. *See Poly-Am.*, 383 F.3d at 1310.

3. ***Bicon* Does Not Support the District Court’s Construction**

The district court erred in relying on *Bicon, Inc. v. Straumann Co.*, 441 F.3d 945 (Fed. Cir. 2006), to find the preambles limiting because the *Bicon* preamble and claim are vastly different and readily distinguishable from those here. Appx36-37. The patent in *Bicon* pertained to a dental implant including “a plastic cuff that is designed to preserve a space around a dental implant so that when a dental crown is placed on top of the implant, the base of the crown can fit beneath the patient’s gum line.” 441 F.3d at 946.

The preamble there had multiple parts and the parties disputed whether the term “abutment” was limiting:

An emergence cuff member for use in preserving the interdental papilla during the procedure of placing ***an abutment*** on a root member implanted in the alveolar bone of a patient in which

[a] ***the abutment has a frusto-spherical basal surface portion and***

[b] ***a conical surface portion*** having a selected height extending therefrom comprising

Id. at 948. As seen above, the preamble included a “detailed description of the abutment’s physical characteristics.” *Id.* at 950.

Importantly, the claim body defined the claimed emergence cuff “in a way that depends on those physical characteristics” from the preamble:

[e] the bore having a taper generally ***matching that of the conical surface portion of the abutment,***

...

[h] the distance between the first and second ends ***being less than the height of the [abutment's] conical surface,***

Id. at 948-49. The *Bicon* court explained that the claim body “does not recite the complete invention” because its limitations [e] and [h] “refer[] back to the features of the abutment described in the preamble.” *Id.* at 952-53. Without a limitation flowing from those specific physical features described in the preamble, “limitations [e] and [h] are rendered meaningless.” *Id.* at 951. The preamble’s highly specific physical description of the abutment thus drove the outcome in *Bicon*: the “detailed recitation of the features of the abutment is incompatible with [plaintiff]’s theory that the claim concerns only the features of the emergence cuff and that the references to the abutment merely describe the intended use of the emergence cuff.” *Id.* at 950.

The preamble in *Bicon* is nothing like “universal” in the ’022 and ’913 patent preambles. For the ’022 patent, the most the district court could say is that its preamble provides support for an “apparatus,” referring to the portion of the preamble stating “the apparatus comprising.” Appx38. For the ’913 patent, the court said the preamble provides a “precise use of which the [claimed] tool must be capable.” Appx37. Neither shows that “universal” provides physical specificity

like the detailed description of “abutment” in *Bicon*. As explained, the bodies of the relevant ’022 and ’913 patent claims are self-contained such that the claims would lose no meaning were “universal” removed from the preambles.⁴ See Sec.I.A.1.b, *supra*.

The asserted claims here instead resemble the one in *C.R. Bard*, to which the district court gave short shrift in favor of *Bicon*. Notably, *Bicon* distinguished *C.R. Bard* in a manner that reinforces that this case is more like *C.R. Bard* and *Bicon*: “the preamble merely . . . define[d] the intended function” of the claims in *C.R. Bard*, whereas the *Bicon* preamble “recites structure for the abutment that goes well beyond what is necessary to describe the intended purpose of the emergence cuff.” *Bicon*, 441 F.3d at 953. Like *C.R. Bard*, “universal” merely provides the intended function of ’022 patent claim 47 and ’913 patent claims 1 and 10, not detailed structure.

4. Moskowitz Never Admitted the Preambles Are Limiting

The district court asserted that Moskowitz’s claim construction argument regarding the meaning of “universal” demonstrates a belief by Moskowitz that the term forms a claim limitation. Appx40-42. This assertion omits a critical piece of

⁴ *Bicon* also explained that the physical description of the abutment in the preamble would have “no role in the claim” and would be “entirely superfluous” were the preamble not limiting. 441 F.3d at 950. As there are no analogous physical descriptions of structure in the preambles at issue, the superfluity concern motivating the decision in *Bicon* simply is not present here.

information: at the time of the claim construction, Moskowitz was asserting claim 15 of the '913 patent that includes the term “universal” in the claim body—not the preamble—and the Court construed “universal” in that context. *See* Appx256-257 (cl. 15); Appx7. Moskowitz withdrew its infringement allegation as to claim 15 after the district court issued its claim construction. *See* Appx2864; Appx8004-8005. Naturally, Moskowitz treated “universal” as limiting in the context of claim 15 because it formed a claim limitation. Thus, Moskowitz’s statements about the meaning of the term “universal” in the context of the invention were relevant to the term’s use in claim 15 only.

Globus notably failed to ask the district court to determine whether any preamble language is limiting during claim construction. Yet, when the parties began claim construction briefing, only Globus could know of its intention to advance a noninfringement theory based on the preambles of the '022 and '913 patent claims. Because such a position would deviate from the presumption that preambles are not limiting, Globus should have raised this claim construction issue during the claim construction process. *See, e.g., Prolitec Inc. v. ScentAir Techs., LLC*, No. CV 20-984-WCB, 2023 WL 8697973, at *5 (D. Del. Dec. 13, 2023) (Bryson, J., by designation) (explaining “it is preferable for claim construction disputes” concerning whether preamble is limiting “to be fully vetted and resolved at the time of formal claim construction proceedings”); *Donaldson Co. v. Baldwin*

Filters, Inc., No. 09-CV-1049 PJS/AJB, 2011 WL 2183179, at *9 (D. Minn. June 6, 2011) (finding waiver against party who first argued that preamble was limiting at claim construction hearing and not in briefing).

Moskowitz, therefore, properly opposed Globus’s summary judgment motion by explaining that the preambles of ’022 patent claim 47 and ’913 patent claims 1 and 10 are not substantive claim limitations:

Plaintiff dismissed any claims that contained the term within the claim body. It continued, however, to advance the argument that, to the extent the term appeared in the preamble of a claim, it was not limiting based on the general rule that preamble language is not treated as limiting. This position was neither unfounded nor objectively unreasonable, and my resolution of the parties’ dispute required extensive legal analysis.

Appx8004-8005 (citation and quotation omitted). Accordingly, Moskowitz addressed the preamble issue at its earliest opportunity and the district court erred to the extent it faulted Moskowitz for not explaining during claim construction that its discussion of “universal” pertained to claim 15 where it appears in the body of that claim. Appx40-42.

5. The Court Should Reverse the District Court’s Construction of the Preambles as Limiting

Because the preambles’ use of “universal” is non-limiting, this Court should reverse the district court’s construction and vacate its summary judgment of noninfringement.

B. The District Court Erred in Construing “Universal” To Exclude All Disclosed Embodiments and Require a Medically Impossible Spinal Implant

Even if the term “universal” found in the ’022 and ’913 patents’ preambles were limiting, the district court misconstrued this term. Under its proper construction—“stand-alone (i.e., having the dual functionality of an intervertebral spacer and a transvertebral bone fusion screw apparatus)”—the Globus products infringe.⁵ The Court should set aside the district court’s summary judgment for this additional reason.

1. The Written Description Shows That “Universal” Refers to a Dual-Function Device, Not One That Can Be Used in Any Region of the Spine and Inserted via Any Surgical Approach

The district court held that “the term ‘universal’ does not have a plain meaning” and the common specification of the ’022 and ’913 patents does not give the term a definition. Appx8. Nevertheless, the court relied heavily on portions of the written description to construe “universal” to mean “an intervertebral bone fusion spacer designed to be inserted between [vertebrae / vertebral bodies] in any region of the spine, *i.e.*, cervical, thoracic, or lumbar, using any approach, *e.g.*,

⁵ Before the district court, Moskowitz argued, in the alternative, that no construction of “universal” was necessary. Appx1806. For the purpose of this appeal, Moskowitz argues only its proposed construction.

posterior, anterior, or lateral”—largely accepting Globus’s proposal.⁶ Appx8-9. In response to Moskowitz’s request for clarification, the district court confirmed that its construction requires a single device “that can be used in any region of the spine and may be inserted through any surgical approach,” again relying on select passages from the written description. Appx23.

The parties agreed that the way the specification uses “universal” in context illustrates the proper construction of this term. Appx8; Appx1972; Appx2648 (39:14-22); Appx1807-1809; Appx2420-2423; Appx2634-2638 (25:23-29:24); *see, e.g., Eon Corp. IP Holdings v. Silver Spring Networks*, 815 F.3d 1314, 1320 (Fed. Cir. 2016) (“[A] word describing patented technology takes its definition from the context in which it was used by the inventor.”). Apart from the claims themselves, the ’022 and ’913 patents’ common specification uses the term **only once**, in reference to a “universal” system. Specifically, the written description discloses that an aspect of the invention “relates to a **universal** bidirectional screw (BDS) system . . . which can be used as a **stand-alone intervertebral device** which combines the dual functions of an intervertebral spacer . . . as well as a transvertebral bone fusion screw apparatus.” Appx196 (1:33-40). The system is “universal” in the sense that it can perform multiple functions all with a single

⁶ Globus also sought to import a vertebral adjacency requirement to the construction, which the district court correctly refused to adopt. Appx9-10.

device. The '022 and '913 patents teach that this dual-function device is an improvement over prior approaches. Appx196 (1:63-2:3); *see* Statement of the Case Sec.I.B, *supra*.

The district court disregarded these teachings that the described spacer is “universal” simply in the sense that it can perform the two functions—spacing and screw fixation—in a single device, Appx196 (1:33-4), because the written description further describes several uses for the combined device. Appx8 (citing Appx250 (1:35-43); Appx251 (3:50-53); Appx197 (3:52-54)). Relying on these possible uses, the district court misinterpreted the patent disclosure and required a hypothetical ***one-size-fits-all*** intervertebral bone fusion spacer/bi-directional transvertebral screw fusion device to be suitable for implantation in every region of the spine for every patient. This interpretation is simply nonsensical from a real-world medical and anatomical perspective, and inconsistent with the intrinsic record. *See* Appx5050 (156:10-18) (explaining “one size fits none” because patient anatomy always differs).

Although the specification teaches that the combined device is configured so it can perform the two functions (spacing and screw fixation), it by no means suggests that one single device must be designed to fit in every possible spine location and to be suitable for every possible insertion technique. Rather, the specification discloses the concept of a dual-function device and expressly teaches

“multiple device embodiments” that “combine in a single construct the dual functions of an intervertebral spacer maintaining disc space height, and transvertebral body fusion screws.” Appx196 (2:20-23). The specification then discloses embodiments of the invention (a dual-function device) tailored for different regions of the spine, which would be wholly unnecessary under a one-size-fits-all design. See Appx197 (4:30-33) (“The lumbosacral screw box embodiments”); Appx200 (10:60-65) (“The posterior lumbar spine implantation of all the screw box 100, 200, 300 embodiment”); Appx197 (3:50-51) (“The designs are also easily modifiable for anterior placement into the cervical spine.”). The physical realities of the spine, including the contour, size and spacing of the vertebrae, differ in the different regions of the spine and thus it is nonsensical to require the same spacer and fixation device to be usable in every region of the spine. This is plainly **not** what “universal” means in the context of these inventions.

Indeed, if the district court’s one-size-fits-all construction were correct, there would be no need for the disclosed embodiments tailored to different spinal regions. Appx196 (2:20-23). The specification’s differentiation of these embodiments confirms that a whole-spine applicability construction is inconsistent with the intrinsic record. Moskowitz’s construction—“stand-alone (i.e., having the dual functionality of an intervertebral spacer and a transvertebral bone fusion

screw apparatus)”—is consistent with the specification’s teaching that ***different*** implementations of the inventive device may be implanted in ***different*** regions of the spine using varying surgical approaches, but still combine the dual-functionality that the specification touts.

The district court also erroneously took the specification’s broad description about the suitability and adaptability of the innovative design as requirements for each implementation of that innovative design. Appx8. Rather than require that every implementation of the invention be suitable for implantation into all spinal regions using any surgical approach, the specification teaches that the design is “modifiable” (e.g., by changing its as-manufactured size) to be suitable for implantation into different spinal regions using various surgical techniques. Appx197 (3:50-54). For example, the specification explains the disclosed designs are “***easily modifiable*** for anterior placement into the cervical spine,” and that the “expandable embodiment of the screw box ***can also be enlarged and modified to be suitable for cervical, thoracic and lumbar vertebral body replacements.***” *Id.*

Thus, the specification shows that its inventive stand-alone, dual-function (spacer and bone fusion screw apparatus) device may be implemented in various ways that make it suitable for use in specific regions of the spine using specific surgical approaches. The district court, in contrast, erroneously forced a construction that embraced all descriptions of the invention from the specification

into a single claim. *See PPC Broadband, Inc. v. Corning Optical Commc'ns RF, LLC*, 815 F.3d 747, 755 (Fed. Cir. 2016) (rejecting proposition that “each and every claim ought to be interpreted to cover each and every embodiment”); *Baran v. Med. Device Techs., Inc.*, 616 F.3d 1309, 1316 (Fed. Cir. 2010) (“It is not necessary that each claim read on every embodiment.”).

Because the specification shows that “universal” describes the stand-alone, dual-functionality (spacer and bone fusion screw apparatus) of the claimed bidirectional screw system, the Court should adopt Moskowitz’s construction. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2005) (en banc) (noting the specification “is the single best guide to the meaning of a disputed term” (citations omitted)); *see also Schindler Elevator Corp. v. Otis Elevator Co.*, 593 F.3d 1275, 1284 (Fed. Cir. 2010) (adopting construction consistent with specification’s use “only once” in specification of claim term at issue).

2. **’913 Patent Claim 38 Shows That “Universal” Does Not Mean a Device That Can Be Used in Any Region of the Spine**

Apart from the specification’s written description, “[o]ther claims of the patent in question can also be valuable sources of enlightenment as to the meaning of a claim term.” *See Phillips*, 415 F.3d at 1314 (citations omitted). Claim 38 of the ’913 patent, a non-asserted claim that includes the term “universal” in its preamble and claim body, shows that the district court’s correction is incorrect.

Claim 38 requires “selecting the universal, intervertebral bone fusion spacer based on the measured dimension of the disc space.” Appx257-258 (cl. 38). As any skilled artisan would recognize, different parts of the spine and different patients have disc spaces of differing sizes, and spacers must be sized accordingly. *See* Appx4698-4699 (57:13-58:4); Appx5049-5050 (155:23-156:18); Appx4915-4916 (21:25-22:8); *see also* Appx1972 (“Globus recognizes that vertebrae come in different sizes.”). For example, given the anatomical realities of the spine, the vertebrae in the cervical region are smaller and more closely-spaced than the vertebrae in the lumbar region, and the size and spacing of the vertebrae will vary according to each person. *See* Appx4698-4699 (57:13-58:4); Appx5049-5050 (155:23-156:18); Appx4915-4916 (21:25-22:8).

Claim 38 addresses the medical reality that different sized implants are required for different regions of the spine and requires one to select the “universal” implant based on the targeted spinal region, for example, lumbar or cervical. Appx257-258 (cl. 38). The district court’s one-size-fits-all construction of “universal” cannot be reconciled with claim 38 because the construction requires the implant to be implantable in *every* region of the spine. Under that interpretation, claim 38’s requirement of selecting an appropriate “universal, intervertebral bone fusion spacer” is superfluous because the result of the selection would be the same every single time. Such a construction cannot be correct.

Becton, Dickinson & Co. v. Tyco Healthcare Grp., LP, 616 F.3d 1249, 1257 (Fed. Cir. 2010) (“Claims must be interpreted with an eye toward giving effect to all terms in the claim.” (citation omitted)). Moskowitz’s construction, in contrast, creates no tension with claim 38 because it recognizes that an inventive “universal, intervertebral bone fusion spacer” may be suitable for implantation in only specific spinal regions thus requiring the surgeon to select the spacer “based on the measured dimension of the disc space.”

3. The District Court’s Construction Requires a Physical Impossibility

Finally, the district court’s one-size-fits-all interpretation of “universal” places a physically and medically impossible requirement upon the ’022 and ’913 patents. Because different parts of the spine and different patients have disc spaces of differing sizes, an as-manufactured spinal implant cannot fit every region of the human spine, nor can it be appropriate for every surgical method for implantation. *See* Sec.I.B.2, *supra*; Appx5049-5050 (155:23-156:18); Appx5468 (81:13-25).

Even Globus admitted that “[i]mplants come in varying sizes to account in size differences among patients with respect to same spinal region” and that it “would be medical malpractice to simply use a ‘small’ lumbar implant in the cervical region.” Appx2814. The district court’s construction therefore violates the longstanding principle that a construction should not result in a physical impossibility. *See Becton, Dickinson*, 616 F.3d at 1255 (refusing to adopt a claim

construction that would create “a physical impossibility” and therefore “render[] the asserted claims nonsensical”).

Given the impossibility of a one-size-fits-all design, the district court unsurprisingly did not identify a single embodiment of the invention disclosing an implant that is suitable for implantation in every region of the spine using every surgical approach. This failure shows the error in the district court’s construction. *See Retractable Techs., Inc. v. Becton, Dickinson & Co.*, 653 F.3d 1296, 1305 (Fed. Cir. 2011) (instructing not to “allow the claim language to become divorced from what the specification conveys is the invention”); *Phillips*, 415 F.3d at 1316 (“The construction that stays true to the claim language and most naturally aligns with the patent’s description of the invention will be, in the end, the correct construction.”). Indeed, the district court’s construction reads out every disclosed embodiment—which are all location specific—from the scope of the ’022 and ’913 patent claims, which is further evidence that the correction is incorrect. *Kaneka Corp. v. Xiamen Kingdomway Grp. Co.*, 790 F.3d 1298, 1304 (Fed. Cir. 2015) (“A construction that excludes **all** disclosed embodiments . . . is especially disfavored.” (original emphasis)); *In re Katz Interactive Call Processing Pat. Litig.*, 639 F.3d 1303, 1324 (Fed. Cir. 2011) (“[T]here is a strong presumption against a claim construction that excludes a disclosed embodiment[.]”).

4. The Court Should Reverse the District Court’s Construction of “Universal”

This Court should vacate the district court’s construction of “universal” and adopt Moskowitz’s construction, which remains true to the intrinsic record. Under this construction, Globus’s products infringe, and the district court’s summary judgment of noninfringement should be vacated, and the case remanded for further proceedings.

II. Substantial Evidence Does Not Support the Jury’s Noninfringement Verdict for the ’319 Patent

In denying Moskowitz’s JMOL motion for the ’319 patent, the district court erred in several regards. First, the district court should have recognized that Globus’s RISE, CALIBER, and MAGNIFY-S products satisfy the “cooperating” limitation under its plain and ordinary meaning. The district court failed to appreciate the evidence as a whole and erred in suggesting the jury could have reasonably determined that Moskowitz failed to demonstrate that Globus’s products meet the “cooperating” limitation under its plain meaning.

Second, the court erroneously accepted Globus’s arguments for the “cooperating” limitation as substantial evidence support for the noninfringement verdict. Globus premised its noninfringement argument for the “cooperating” limitation on its expert’s unsupported misinterpretation of the term to require mechanical actuation of the gripper by the handle. Globus never sought a

construction of “cooperating,” and thus improperly disregard the term’s plain meaning in favor of “actuating.” Globus’s failure to seek a construction is unsurprising because nothing in the ’319 patent supports construing “cooperating” to mean “actuating.” Furthermore, its expert’s *ipse dixit* construction of “cooperating” contradicts his own admissions of the term’s ordinary meaning and his application of the term to the prior art.

Therefore, this Court should enter JMOL of infringement for the ’319 patent.

A. The Only Reasonable Conclusion from the Evidence Is That RISE, CALIBER, and MAGNIFY-S Directly Infringe the ’319 Patent Under the Plain Meaning of “Cooperating”

1. The “Cooperating” Limitation

Claim 1 of the ’319 patent recites a system including: (1) an expandable intervertebral spinal implant; and (2) a tool assembly for inserting the implant into the spine and then expanding the implant by rotating a screw within it. Appx308-309.

Moskowitz presented voluminous evidence that Globus’s RISE, CALIBER, and MAGNIFY-S products satisfy each of the limitations of claim 1. Moskowitz made this showing in its case-in-chief through the testimony of its expert, Dr. Rosenberg, much of which went unchallenged and unrebutted. *See* Appx4919-4941 (25:8-47:5). To support his infringement opinion, Dr. Rosenberg introduced into evidence a bevy of Globus’s product documentation and marketing materials,

including the technique guides that Globus distributes to surgeons to explain how Globus's implants and tools operate. See Appx4913-4914 (19:14-20:2); Appx4922 (28:12-18); Appx6767-6815; Appx6645-6689; Appx6937-7001.

Globus, through its expert, Mr. Sherman, challenged at trial the RISE, CALIBER, and MAGNIFY-S products' satisfaction of only a single limitation of claim 1. Specifically, Globus disputed that these products' positioning tool has an implant gripper "cooperating" with the handle of the positioning tool. Appx132. To be clear, Globus did not challenge that the positioning tool contains a gripper, or that the tool contains a handle. Appx5612-5613 (225:17-226:5). Rather, Globus's challenge focused on solely whether the positioning tool's gripper cooperates with the positioning tool's handle. *Id.*

The relevant portions of claim 1, emphasized to focus on the parties' dispute, recite:

a first tool having a first proximal end and a first distal end with a first handle and ***a gripper, the gripper being positioned at the first distal end, cooperating with the first handle***, and having first and second engagement prongs positioned at the first distal end, wherein the first tool defines an adjusting tool passage through the first tool . . .

. . .

an expandable spinal implant sized and configured to be implanted in a human spine . . . wherein the expandable spinal implant defines first and second tool engagement indentations sized and configured for receiving the first and second engagement prongs of the first tool.

Appx308-309 (cl. 1).

The '319 patent's written description uses the term "cooperating" only once, in a manner similar to claim 1: "a gripper cooperating with the handle and having a plurality of prongs." Appx305 (5:51-54). Without using the term "cooperating" *in haec verba*, the '319 patent expounds upon this cooperation by explaining that the "positioning tool 500a can have a rectangular handle, Embodiment I (FIG. 5H), or a circular handle, Embodiment II (FIG. 5I)," and that the "positioning tool's 500a griper [sic] handle inserts into" the implant to "maintain[] alignment" of the tool with the implant. Appx307 (9:22-29); *see also* Appx303 (2:58-60) (explaining "positioning tool" may help "further enhance trajectory precision").

Dr. Rosenberg testified that this design—i.e., a handle at one end of the position tool for the surgeon to hold and a gripper at the other end for connecting to the implant—provides for safe insertion of the implant. Appx4916 (22:14-16). He explained that, given the narrow surgical windows within which spinal surgeons must operate, it is desirable to have a positioning tool that allows the surgeon to controllably insert the implant while being able to see the insertion and positioning process. Appx4917 (23:8-19).

Thus, as claimed by claim 1, the gripper and handle work together to steer and position the implant into the disc space between adjacent vertebrae within a patient's spine. Notably, claim 1 has no requirement that the handle somehow actuate or act upon the gripper.

2. Globus’s Expert Admitted the Plain Meaning of “Cooperate” Is To “Act,” “Work,” or “Operate” Together

Because the district court did not construe “cooperate,” the plain and ordinary meaning applies. *See Hewlett-Packard Co. v. Mustek Sys., Inc.*, 340 F.3d 1314, 1321 (Fed. Cir. 2003) (explaining ordinary meaning applies when claim is not construed); *see also Aylus Networks, Inc. v. Apple Inc.*, 856 F.3d 1353, 1358 (Fed. Cir. 2017) (“There is a heavy presumption that claim terms are to be given their ordinary and customary meaning.”). Indeed, the district court correctly instructed the jury that, for claim terms which it did not construe, the jury should apply their plain and ordinary meaning. Appx6085 (19:1-5).

The experts generally agreed on the plain and ordinary meaning of “cooperate.” While being questioned about the “cooperating” limitation, Mr. Sherman, admitted that its ordinary meaning is to work together:

Q. So just to make sure we’re all clear, you’d agree that ***the ordinary meaning of cooperate is to act or work with another. Act together; right?***

A. I think I said -- well, it’s to cooperate. ***To operate together; yeah.*** If that’s what you just said, I think --

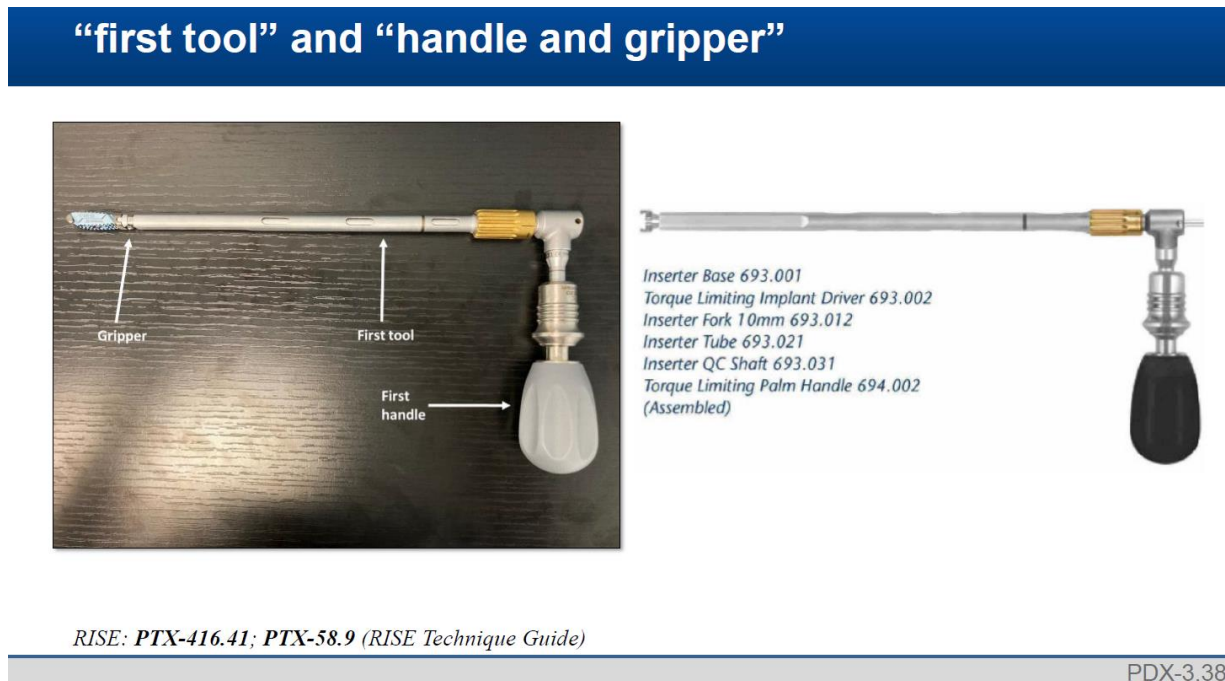
Q. ***To act together; fair?***

A. ***Sure.***

Appx5615 (228:6-12). Dr. Rosenberg similarly applied this ordinary meaning in evaluating whether the accused products satisfy the “cooperating” limitation. *See, e.g.*, Appx4923 (29:1-3).

3. The Trial Evidence Demonstrates That Globus's Products Satisfy the "Cooperating" Limitation Under Its Plain Meaning

Dr. Rosenberg's testimony and the supporting evidence upon which he relied unequivocally demonstrates that RISE, CALIBER, and MAGNIFY-S satisfy the "cooperating" claim limitation under its plain and ordinary meaning. As Dr. Rosenberg testified, the RISE positioning tool "has a handle at one end and a gripper at the other *that cooperate together.*" Appx4923 (29:1-3). Dr. Rosenberg showed the jury this configuration using annotated images of the RISE positioning tool:



Appx6498 (citing Appx7056; Appx6776); Appx4922-4924 (28:25-30:5).

Dr. Rosenberg explained that the same is true for both the CALIBER and

MAGNIFY-S products. Appx4924 (30:6-13) (citing Appx7084; Appx7123); Appx6499.

Dr. Rosenberg also described a Globus marketing video for the RISE product. He narrated for the jury what the video depicted, explaining that surgeons use the positioning tool to place the expandable implant into a patient's spine by engaging the implant with the gripper's prongs and then steering the implant into the spine while avoiding critical anatomical structures. Appx4933-4935 (39:14-41:2); *see also* Appx4933 (39:19-21).

Globus's Director of Product Development, Ms. Christy Mace, confirmed that RISE, CALIBER, and MAGNIFY-S operate exactly how Dr. Rosenberg described. Ms. Mace testified, for example, that the gripper and handle of the CALIBER product ***work together*** to guide the expandable implant into a patient's disc space:

- Q. But you agree, once the implant is -- is at the end of the tool, the handle is used to guide the tool to the surgical site; right?
- A. Are you asking me ***if the handle is attached the inserter; does it all move together?***
- Q. ***That's what I'm asking.***
- A. ***Yes; it does.***
- Q. All right. And so the surgeon uses the -- the handle in part to guide the -- the implant to the intervertebral space where it can be expanded?
- A. Yes; as it's attached, they would.

Q. All right. And ***where he guides the handle at the proximal end, the implant at the distal end will go?***

A. ***Sure.***

Appx5476-5477 (89:23-90:11).

Globus did not cross-examine Dr. Rosenberg about the “cooperating” limitation and did not dispute that the positioning tool is designed such that the gripper moves in relation to how a surgeon directs and steers the handle at the opposite end, and thus that the gripper and handle work together or cooperate. Appx135.⁷ As a result, the record supports only one evidence-backed conclusion—the tool’s gripper and handle work together to insert Globus’s expandable implants into a patient’s spine.

With “cooperating” being the only limitation Globus challenged for the ’319 patent for the RISE, CALIBER, and MAGNIFY-S products, there simply is not substantial evidence to support the jury finding of noninfringement. The district court, therefore, should have entered JMOL of infringement. *See, e.g., SunTiger, Inc. v. Sci. Rsch. Funding Grp.*, 194 F.3d 1335 (Fed. Cir. 1999) (affirming JMOL grant based on “unrebutted” testimony demonstrating accused product satisfied claim as properly interpreted).

⁷ As discussed below, Globus’s argument for noninfringement relied on a misconstruction of “cooperating.” *See* Sec.II.B.2, *infra*.

4. The District Court Erred in Upholding the Infringement Verdict Based on an Alleged Failure of Proof

Considering the uncontroverted evidence demonstrating infringement under the plain meaning of “cooperating,” the district court erred in concluding that the jury could have determined there was a failure of proof for the “cooperating” limitation. Appx138. As discussed above, Dr. Rosenberg laid the foundation for his expert opinions, describing in detail the extensive analysis he performed and the way RISE, CALIBER, and MAGNIFY-S operate. *See, e.g.*, Appx4919-4941 (25:8-47:5); Appx6767-6815; Appx6645-6689; Appx6937-7001. He unequivocally testified that these products satisfy the “cooperating” limitation. Appx4922-4924 (28:25-30:13).

The district court’s assertion (Appx138) that Dr. Rosenberg did not devote sufficient time to the “cooperating” limitation in his several hours of direct testimony ignores that he fully explained the basis for his infringement opinion for the “cooperating” limitation.⁸ In any event, under Federal Rule of Evidence 705, it

⁸ Dr. Rosenberg was poised to provide rebuttal testimony to Mr. Sherman’s noninfringement opinion regarding the operation of Globus’s tools, which is at the heart of the disputed “cooperating” limitation, but the district court forbade him from doing so. Appx5839-5840 (170:18-171:3). The court disallowed this testimony because, in its view, Dr. Rosenberg “already covered” the topic in his direct testimony. *Id.* In its JMOL order, however, the court criticized Dr. Rosenberg’s testimony on the “cooperating” dispute for being cursory. *See* Appx138. Courts in the Third Circuit have found a “manifest injustice” where rebuttal testimony has been barred in similar circumstances. *Nat’l Sur. Corp. v.*

is “proper during trial” to demonstrate infringement “simply by offering an opinion of an expert that states, in effect, that the critical claim limitation is found in the accused device,” as Dr. Rosenberg did. *See Arthur A. Collins, Inc. v. N. Telecom Ltd.*, 216 F.3d 1042, 1047 (Fed. Cir. 2000). That is for good reason: “Rule 705 functions to abbreviate trials by permitting opinion testimony without factual foundation,” with the “specific purpose” of “avoid[ing] complex and time-consuming testimony.” *Symbol Techs., Inc. v. Opticon, Inc.*, 935 F.2d 1569, 1576 (Fed. Cir. 1991) (quotations omitted). Rule 705 is particularly applicable in “[p]atent cases,” which are “so often typified by lengthy testimony on complex technical issues.” *Id.* Under this regime, “responsibility for challenging the factual underpinnings of the testimony f[alls] squarely on [defendant] during cross-examination.” *Id.* at 1575 (collecting case).

Moreover, the district court underestimated the significance of Ms. Mace’s testimony. She admitted the positioning tool’s gripper moves in relation to the way a surgeon directs and steers the handle at the opposite end—*i.e.*, the gripper and handle cooperate. Appx5476-5477 (89:23-90:11). Although Ms. Mace did not use the word “cooperating,” her testimony clearly relates to the “cooperating” limitation under its plain meaning. Globus argued in its JMOL briefing that the

Heinbokel, 154 F.2d 266, 268-269 (3d Cir. 1946) (holding that if “evidence is real rebuttal evidence, the fact that it might have been offered in chief does not preclude its admission in rebuttal”).

jury could have reached its noninfringement verdict even if no Globus witness testified, but Ms. Mace did testify, and courts “must review the record as a whole” under substantial evidence review. *See, e.g., Cordis Corp. v. Bos. Sci. Corp.*, 658 F.3d 1347, 1357 (Fed. Cir. 2011) (applying Third Circuit law).

Viewing the entire record, the jury could not have reasonably premised its noninfringement verdict on a failure of proof.

B. The District Court Should Not Have Credited Globus’s Arguments on the “Cooperating” Limitation

1. The District Court Should Not Have Deviated from the Plain and Ordinary Meaning of “Cooperating”

“[W]here the parties and the district court elect to provide the jury only with the claim language itself, and do not provide an interpretation of the language in the light of the specification and the prosecution history, . . . [t]he verdict must be tested . . . by giving the ordinary meaning of the language of the jury instruction.” *Hewlett-Packard*, 340 F.3d at 1321; *see also ePlus, Inc. v. Lawson Software, Inc.*, 700 F.3d 509, 520 (Fed. Cir. 2012) (explaining the plain and ordinary meaning applied to an unconstrued claim term). Here, the district court erroneously denied JMOL of infringement because it “adopt[ed] a new and more detailed interpretation of the claim language and test[ed] the jury verdict by that new and more detailed interpretation.” *Hewlett-Packard*, 340 F.3d at 1321.

Specifically, Globus’s argument for noninfringement required the jury to disregard the plain and ordinary meaning of “cooperating” in favor of a construction that grafted on the function of “actuating.” Appx5615 (228:6-25). To deviate from the plain meaning of “cooperating,” however, the burden was on **Globus** to seek a construction but Globus never did before trial. *E.g.*, *ePlus*, 700 F.3d at 520. In its post-trial JMOL briefing, Globus attempted to justify its construction, but claim construction arguments first advanced in post-trial motions cannot be used to support the verdict. *Hewlett-Packard*, 340 F.3d at 1321.

Globus’s extraordinary argument, credited by the district court (Appx133-134; Appx137-138), that **Moskowitz** bore the burden of seeking a construction of “cooperating” to secure an infringement verdict is backwards. Moskowitz always advocated for the plain meaning of “cooperating” to govern and applied that plain meaning in its infringement analysis. Appx4923 (29:1-3) Appx4933-4935 (39:14-41:2). There was no real dispute, furthermore, about the plain meaning of “cooperating” in the normal course. As Mr. Sherman testified, the plain meaning is to “work,” “act,” or “operate” together—the same interpretation Dr. Rosenberg’s infringement analysis adopted. Appx5615 (228:6-12) (Sherman); *see also* Appx4923 (29:1-3) (Rosenberg) (explaining the RISE positioning tool “has a

handle at one end and a gripper at the other that cooperate together”).⁹ That is the only reasonable view of “cooperating” and the district court erred by narrowing the meaning of this term to require actuation, Appx138-139. *See Avid Tech., Inc. v. Harmonic, Inc.*, 812 F.3d 1040, 1048 (Fed. Cir. 2016) (explaining party’s burden when a claim element is unconstrued).

This Court’s decision in *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306 (Fed. Cir. 2003), is instructive. In *Moba*, the district court denied a plaintiff’s infringement JMOL motion after the jury had returned a noninfringement verdict that centered on the patent’s “guiding steps” limitation. *Id.* at 1313. The district court construed “guiding steps,” but that construction “left undetermined whether the claim requires sequential performance of the steps.” *Id.* In denying the plaintiff’s JMOL motion, the district court “reasoned that the jury reasonably could have determined from the testimony presented that sequential performance is a necessary characteristic of the ‘guiding steps.’” *Id.* This Court held that the district court erred because “[i]n essence, the district court allowed the jury to add an additional limitation to the district court’s construction of ‘guiding steps.’” *Id.*

⁹ Given Mr. Sherman’s admission, Dr. Rosenberg was not required to expound further upon the plain meaning of “cooperating,” contrary to the district court’s suggestion (Appx135). *Cf. Moleculon Rsch. Corp. v. CBS, Inc.*, 793 F.2d 1261, 1270 (Fed. Cir. 1986) (“We have never **required** a party to proffer expert testimony on claim interpretation” (original emphasis)).

The same is true here. Without a construction, “cooperating” received its plain meaning, which does not encompass or require actuation.¹⁰ Just as in *Moba*, “by allowing the jury to import an additional limitation into the claims, the district court fundamentally altered the verdict.” *Id.* at 1314. The district court’s reliance on a lack of evidence that the tool “actuates” the gripper to support noninfringement impermissibly allowed the jury to import an additional limitation into the claims. *See* Appx137-138. Like in *Moba*, “the record evidence provides no basis upon which a reasonable jury could find” noninfringement under the ordinary meaning of “cooperating,” and this Court should reverse the district court’s JMOL denial. 325 F.3d at 1315, 1322; *cf. Wi-Lan, Inc. v. Apple Inc.*, 811 F.3d 455, 465-66 (Fed. Cir. 2016) (reversing vacatur of jury’s invalidity verdict because construction was narrowed post-verdict).

Moreover, *Moba* flatly rejects the suggestion that Moskowitz waived its ability to dispute Globus’s “actuation” requirement by not seeking construction of “cooperating.” The defendant in *Moba* argued that, because the plaintiff “did not object to the district court’s claim construction or instructions to the jury,” the plaintiff “waived its right to argue the interpretation of ‘guiding steps’ on appeal.” 325 F.3d at 1314. This Court rejected that argument, explaining the plaintiff “does

¹⁰ The only possible support for an actuation requirement is the *ipse dixit* testimony of Mr. Sherman, which should receive no weight. *See* Sec.II.B.2, *infra*.

not now contest the district court’s instruction to the jury on the meaning of ‘guiding steps,’” and “does not wish to alter the district court’s claim construction on appeal, but seeks enforcement of the trial court’s claim construction.” *Id.* That is precisely the position Moskowitz occupies. The only reasonable understanding of the plain meaning of “cooperating” does not require actuating. Because Moskowitz “has consistently protested the error that this court currently reviews on appeal” both “in its JMOL motions and in its argument on appeal here,” there is no waiver. *Id.*

The district court’s invocation (Appx133-134) of *Hewlett-Packard* and related cases does not support its ruling; those cases instead support Moskowitz because Globus’s “actuation” requirement narrowed the ordinary meaning of “cooperating.” The verdict premised on this non-recited actuation requirement therefore cannot stand.

2. Mr. Sherman’s Unsupported Construction of “Cooperating,” Accepted by the District Court, Is Unreasonable

Even if this Court were to entertain Globus’s untimely and waived claim construction of “cooperating” as requiring actuation, it should reject the construction because it is divorced from the intrinsic record and rests on the unreliable, speculative opinion of Mr. Sherman.

a. The Intrinsic Record Does Not Support Construing “Cooperating” To Require “Actuating”

“[C]onclusory, unsupported assertions by experts as to the definition of a claim term are not useful to a court.” *Phillips*, 415 F.3d at 1318. That is because “undue reliance on extrinsic evidence poses the risk that it will be used to change the meaning of claims in derogation of the indisputable public records consisting of the claims, the specification and the prosecution history, thereby undermining the public notice function of patents.” *Id.* at 1319 (quotation omitted). Thus, “expert testimony may not be used to diverge significantly from the intrinsic record.” *Genuine Enabling Tech. LLC v. Nintendo Co.*, 29 F.4th 1365, 1373 (Fed. Cir. 2022) (collecting cases).

Here, Mr. Sherman opined that a skilled artisan would believe that a positioning tool cannot satisfy the “cooperating” limitation unless its handle actuates the gripper. Appx5615 (228:6-25). In denying JMOL of infringement, the district court ignored the utter lack of support in the intrinsic record for Mr. Sherman’s *ipse dixit* assertion. Appx136-138.

First, Mr. Sherman acknowledged that the claim does not use the word “actuate,” Appx5615 (228:20-21), and does not recite the handle “performing action” on the gripper, Appx5615-5616 (228:22-229:4). Mr. Sherman instead admitted that the claim recites only “cooperating.” Appx5616 (229:5-10).

Critically, Mr. Sherman also admitted that he identified no example in the ’319

patent's specification where the positioning tool's handle actuates the gripper.

Appx5618-5620 (231:13-232:25, 233:10-16).

Although Mr. Sherman contended that “cooperating” had a meaning similar to “actuate” in the context of the '319 patent, he provided no basis in the patent for that conclusion. *E.g.*, Appx5618 (231:10-11).¹¹ Indeed, he could not recall if he had ever consulted the '319 patent's specification in search of support for his interpretation:

I don't recall if I went back to the specification for this term. If I felt like I understood it as a person of ordinary skill in the art, I moved on. . . . I felt like I understood it. ***I don't think cooperating is a really hard word.***

Appx5618 (231:5-12). He thus provided no intrinsic record support for his flawed interpretation of “cooperating” as requiring actuation.¹² That is unsurprising, as

¹¹ Mr. Sherman did not “identif[y] a particular meaning in the art” because he qualified his opinion as the meaning in the context of the '319 patent. Therefore, this opinion is irrelevant. *Gen. Protecht Grp., Inc. v. Int'l Trade Comm'n*, 619 F.3d 1303, 1310 (Fed. Cir. 2010); *Symantec Corp. v. Comput. Assocs. Int'l, Inc.*, 522 F.3d 1279, 1291 (Fed. Cir. 2008) (rejecting “expert testimony, which does not identify the ‘accepted meaning in the field’ to one skilled in the art” as “unhelpful” (quoting *Sinorgchem Co., Shandong v. Int'l Trade Comm'n*, 511 F.3d 1132, 1137 n.3 (Fed. Cir. 2007))).

¹² Although not relied upon by the district court, Globus's JMOL briefing identified purported support in the specification for the “actuation” requirement. This alleged support relates to an embodiment including an unclaimed screw guide 505 and spring 502. Appx306-307 (8:62-9:13). The written description for this embodiment never uses the phrase “cooperating,” and includes no discussion of the positioning tool's gripper being actuated by the handle. *Id.* Therefore, this embodiment does not support Globus's effort to rewrite “cooperating” as

there is no intrinsic support for this limitation, let alone the lexicography or disavowal required to transform the plain meaning of “cooperating.” *See Thorner v. Sony Comput. Ent. Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012).

Although this Court “seek[s] the meaning of claim terms from the perspective of the person of ordinary skill in the art,” it has emphasized that “[t]he key” “is that [one] look[s] to how that person would have understood a term ***in view of the specification.***” *Immunex Corp. v. Sanofi-Aventis U.S. LLC*, 977 F.3d 1212, 1221 (Fed. Cir. 2020) (original emphasis, citation omitted). Mr. Sherman did not do so and otherwise provided no basis showing why a skilled artisan would interpret the intrinsic record as limiting “cooperating” to actuating. Appx5618 (231:10-11).

An expert must explain “‘why’ a person of ordinary skill in the art would understand a term in a particular manner” because explaining only “how” a skilled artisan understands a term “ignores *Phillips*’s teaching that ‘conclusory, ***unsupported assertions*** by experts as to the definition of a claim term are not useful to a court.’” *Aristocrat Techs. Australia Pty Ltd. v. Int’l Game Tech.*, 709 F.3d 1348, 1361 (Fed. Cir. 2013) (original emphasis) (quoting *Phillips*, 415 F.3d at 1318). Indeed, in *Aristocrat*, the Court rejected expert testimony that failed to

“actuating.” *See Rolls-Royce, PLC v. United Techs. Corp.*, 603 F.3d 1325, 1334-35 (Fed. Cir. 2010) (rejecting use of embodiment that does not use construed term to impact construction).

explain why claim term would be understood by a skilled artisan in the manner that the expert proposed. *Id.* This Court should do the same with Mr. Sherman's opinion.

b. Mr. Sherman Did Not Require “Cooperate” To Mean “Actuate” for His Invalidity Opinions

Further illustrating the improper, results-oriented nature of his *ipse dixit* as to the alleged plain meaning of “cooperate,” Mr. Sherman took the position that the “cooperating” limitation did **not** require actuation when he analyzed the issue of invalidity. Mr. Sherman opined that the Allen prior art reference satisfies the “cooperating” limitation of claim 1, even though the handle of the Allen tool **does not actuate** its gripper. Appx5787 (118:4-13); Appx5792 (123:5-8) (agreeing “Allen does not say anything about actuating -- pressing the handle to actuate the gripper”).¹³ Mr. Sherman likewise opined that the tool of the Paes reference, which does not perform any actuation, satisfies the “cooperating” limitation. Appx5795-5796 (126:13-127:13) (“[B]efore you saw Dr. Rosenberg’s opinions on infringement, it was your position that the [Paes] reference just with the handle, prongs, **no actuation**, that satisfied the cooperating limitation; right, sir? A. Well, you just read my report. I think that’s what I said.”).

¹³ Mr. Sherman’s testimony aligned with Globus’s opening statement that Allen satisfies the “cooperating” limitation despite identifying no actuation of the gripper by the handle. Appx4518 (94:16-17) (“[Allen] has the handle **cooperating** with the gripper to hold on to the implant. You slide it in.”).

Mr. Sherman’s prior art opinions are thus contrary to the position he took for noninfringement, where he opined that the handle must actuate the gripper for there to be infringement. *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1330 (Fed. Cir. 2003) (“It is axiomatic that claims are construed the same way for both invalidity and infringement.”); *see also Data Engine Techs. LLC v. Google LLC*, 10 F.4th 1375, 1381 (Fed. Cir. 2021) (This Court has “repeatedly rejected efforts to twist claims, like a nose of wax, in one way to avoid invalidity and another to find infringement.” (citations and quotations omitted)).

Although the district court attempted to justify this disharmony as presenting an invalidity theory under a contingent, alternative claim interpretation, *see* Appx137, Mr. Sherman notably did not qualify his invalidity opinions as being based on a plain and ordinary meaning of “cooperating” different from the one he used for his noninfringement opinions—one that would apply if the jury accepted a broader plain and ordinary meaning of “cooperating.” Appx5731-5732 (62:10-25, 63:17-22) (opinion on “cooperating” limitation); *see also* Appx5696 (27:14-20) (opining that a prior art-based invalidity analysis “is the other side of a -- of an infringement analysis” because both compare the claims and the court’s construction to the prior art, for invalidity, the accused product, for infringement); Appx5783-5784 (114:20-115:2) (agreeing “a patent claim has to be interpreted the

same way for infringement and invalidity”).¹⁴

C. The Court Should Enter JMOL of Infringement

Substantial evidence does not support the finding of noninfringement when the improper “activation” requirement is stripped from the “cooperating” limitation. Therefore, the noninfringement judgment for RISE, CALIBER, and MAGNIFY-S should be set aside, and judgment of infringement entered in Moskowitz’s favor. *See, e.g., SimpleAir, Inc. v. Sony Ericsson Mobile Commc’ns AB*, 820 F.3d 419, 425 (Fed. Cir. 2016) (“Where an infringement verdict relies on an incorrect claim construction, and no reasonable jury could have found infringement under the proper claim construction, this court may reverse the district court’s determination with respect to JMOL without remand.”); *Callicrate v. Wadsworth Mfg., Inc.*, 427 F.3d 1361, 1372-73 (Fed. Cir. 2005) (reversing denial of infringement JMOL motion); *Moba*, 325 F.3d at 1315-16 (reversing denial of infringement JMOL motion”).

CONCLUSION

Moskowitz respectfully requests that the Court: (1) vacate the district court’s construction of “universal” and its associated grant of summary judgment of noninfringement for the ’022 and ’913 patents, and remand for further

¹⁴ Moreover, the district court cited inapt law regarding an alleged infringer making an alternative argument under 35 U.S.C. §112. Appx137. Globus did not, however, challenge the ’319 patent based on §112 at trial. Appx5743 (74:16-23).

proceedings; and (2) reverse the denial of JMOL of infringement for the '319 patent and remand for determination of damages.

Dated: January 30, 2025

Respectfully submitted,

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ADDENDUM

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District Court Docket Entry	Date	Description of Document	Appendix Page Numbers
143	08/25/2021	Memorandum Opinion re Disputed Claim Terms	Appx1-Appx18
144	08/25/2021	Claim Construction Order	Appx19-Appx20
229	02/03/2022	Order Denying Motion for Clarification	Appx21-Appx23
252	12/22/2022	Memorandum Opinion re Globus' Motion for Summary Judgment	Appx24-Appx58
253	12/22/2022	Order Granting In-Part and Denying In-Part Globus' Motion for Summary Judgment	Appx59-Appx59
375	03/04/2024	Amended Judgment	Appx125-Appx128
399	08/13/2024	Memorandum Opinion re Post-Trial Motions	Appx129-Appx153
1-23		U.S. Patent No. 9,889,022	Appx155-Appx205
1-26		U.S. Patent No. 8,353,913	Appx207-Appx259
JTX-008		U.S. Patent No. 10,478,319	Appx260-Appx313

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

MOSKOWITZ FAMILY LLC

Plaintiff,

v.

GLOBUS MEDICAL, INC.

Defendants.

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CIVIL ACTION

No. 20-3271

Goldberg, J.

August 25, 2021

MEMORANDUM OPINION

Before me is a patent infringement case wherein Plaintiff Moskowitz Family LLC (“Plaintiff”) alleges that Defendant Globus Medical, Inc. (“Defendant”) has infringed eight of Plaintiff’s patents. The parties currently seek construction of ten disputed terms in seven of the patents pursuant to Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995), aff’d, 517 U.S. 370 (1996) (“Markman”). The disputed claim terms are construed as indicated in this Memorandum and accompanying Order.

I. FACTUAL BACKGROUND

A. Spinal Fusion Procedures and the Parties

The patents in question pertain to spinal implants. By way of background, the human spine is composed of vertically arranged bones—vertebrae—separated by cartilaginous intervertebral discs. The vertebrae are divided into three portions: (1) the uppermost seven vertebrae called the cervical spine; (2) twelve middle vertebrae called the thoracic spine; and (3) the five bottom vertebrae called the lumbar spine. Two pedicle bones dorsally extend from each vertebra and form an arch that protects the spinal cord.

In some individuals, the cartilaginous disc between vertebrae may wear, causing pain and pressure on the spinal cord. For those individuals, spinal fusion surgery may offer relief. The procedure permanently connects two or more spinal vertebrae to improve spinal stability, correct deformations, and reduce pain. The procedure, however, can result in adverse patient outcomes such as high-impaction, neural or vascular injury, esophageal injuries, excessive blood loss, prolonged surgical duration, prolonged recovery, and incomplete return to work results. These adverse events result from static and non-expandable implants, misplaced implants, and implant pull-out after the operation.

Plaintiff patents minimally invasive spinal implants that are designed to reduce adverse outcomes in spinal fusion patients. Plaintiff's inventions include minimal impaction, steerable, and custom-fit intervertebral implants that reduce musculoskeletal disruption and nerve root retraction during and after the procedure. Defendant also is a spinal fusion company that sells intervertebral spinal implants.

B. Plaintiff's Patents

From January 15, 2013 through November 19, 2019, the United States Patent and Trademark Office ("PTO") issued the eight patents at issue here, which Plaintiff owns by assignment. (First Am. Compl. ¶¶ 17-24.) These patents are directed to intervertebral spinal implant screws, staples, and expandable implant systems. U.S. Patent Nos. 8,353,913 (the "913 patent"), 10,307,268 (the "268 patent"), and 10,478,319 (the "319 patent") are for tools used for manipulating and inserting spacers into a disc space between two vertebral bodies to facilitate bone and screw fusion. U.S. Patent No. 9,889,022 (the "022 patent") is for an intervertebral screw guide and fixation apparatus for insertion into a disc space between two vertebrae to encourage bone and screw fusion. U.S. Patent No. 10,028,740 (the "740 patent") claims a "curvilinear nail screw," a holding structure that is implanted into a vertebra and around the pedicle bones to avoid

penetrating them, which allegedly reduces risks associated from prior inventions that inserted into pedicle bones. U.S. Patent No. 10,251,643 (the “‘643 patent”) relates to an intervertebral mechanism that expands between vertebral bodies and engages vertebral endplates to keep the mechanism in place. U.S. Patent No. 10,076,367 (the “‘367 patent”) is for a bidirectional system inserted between vertebrae to facilitate their linking and fusion. Finally, U.S. Patent No. 10,376,386 (the “‘386 patent”) claims a spinal staple with a curved base and ridged spikes that hinder the staple’s removal.

C. Procedural Background

According to the Complaint, on June 3, 2015, Plaintiff’s counsel sent a letter to Defendant’s General Counsel that identified the ‘913 patent and the patent application for the ‘022 patent, which at the time was pending at the PTO. (First Am. Compl. ¶ 26.) In the letter, Plaintiff identified additional pending patent applications, of which the remaining patents at issue are continuations. (*Id.*) The parties failed to reach an agreement, and thereafter the PTO issued the seven pending patent applications. (*Id.* ¶¶ 17-24, 27-29.) Plaintiff alleges that Defendant has infringed the eight patents listed above and contained in the June 3, 2015 letter through selling various Globus products. (*Id.* ¶¶ 30.)

Plaintiff initiated this action on November 20, 2019, the day after the eighth patent—the ‘319 patent—issued.¹ On April 14, 2021, it filed its First Amended Complaint, setting forth allegations of direct infringement, inducement of infringement, contributory infringement, and willful infringement.

¹ Plaintiff initially filed the action in the United States District Court for the Western District of Texas, but on July 2, 2020, the case was transferred to the Eastern District of Pennsylvania. (Doc. No. 50.)

On May 13, 2021, the parties submitted opening claim construction briefs setting forth their positions on ten disputed claim terms in seven of the eight patents at issue.² I held a Markman hearing regarding these terms on July 27, 2021. Having fully reviewed the parties' briefing and evidentiary submissions, I now set forth the legal construction of the disputed claim terms.

II. STANDARD OF REVIEW

The first step in a patent infringement analysis is to define the meaning and scope of the claims of the patent. Markman, 52 F.3d at 976. Claim construction, which serves this purpose, is a matter of law exclusively for the court. Id. at 979. “[T]here is no magic formula or catechism for conducting claim construction.’ Instead, the court is free to attach the appropriate weight to appropriate sources ‘in light of the statutes and policies that inform patent law.’” SoftView LLC v. Apple Inc., No. 10-389, 2013 WL 4758195, at *1 (D. Del. Sept. 4, 2013) (quoting Phillips v. AWH Corp., 415 F.3d 1303, 1324 (Fed. Cir. 2005)).

“It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude.” Phillips, 415 F.3d at 1312 (internal quotation marks omitted). The focus of a court’s analysis must therefore begin and remain on the language of the claims, “for it is that language that the patentee chose to use to ‘particularly point[] out and distinctly claim[] the subject matter which the patentee regards as his invention.’” Interactive Gift Express, Inc. v. Compuserve, Inc., 256 F.3d 1323, 1331 (Fed. Cir. 2001) (quoting 35 U.S.C. ‘112, & 2). The terms used in the claims bear a “heavy presumption” that they mean what they say and have their ordinary and customary meaning. Texas Digital Sys., Inc. v. Telegeniz, Inc., 308 F.3d 1193, 1202 (Fed. Cir. 2002). That ordinary meaning “is the meaning that the term would have to

² The ‘319 patent does not contain any of the disputed claim terms.

a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.” Phillips, 415 F.3d at 1313.

“Generally, a person of ordinary skill in the art would not understand the ordinary and customary meaning of a claim term in isolation.” Shire ViroPharma Inc. v. CSL Behring LLC, No. 17-414, 2019 WL 266327, at *3 (D. Del. Jan. 18, 2019). As such, the ordinary meaning may be derived from a variety of sources including intrinsic evidence, such as the claim language, the written description, drawings, and the prosecution history; as well as extrinsic evidence, such as dictionaries, treatises, or expert testimony. Dow Chem. Co. v. Sumitomo Chem. Co. Ltd., 257 F.3d 1364, 1373 (Fed. Cir. 2001).

The “most significant source” of authority is the “intrinsic evidence of record, i.e., the patent itself, including the claims, the patent specification³ and, if in evidence, the prosecution history.” Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996); see also Phillips, 415 F.3d at 1313 (holding that a person of ordinary skill in the art is deemed to read the claim terms in the context of the entire patent, including the specification). The specification “is the single best guide to the meaning of a disputed term” and is usually dispositive as to the meaning of words. Vitronics, 90 F.3d at 1582. Although it is improper to import limitations from the specification into the claims, “one may look to the written description to define a term already in a claim limitation, for a claim must be read in view of the specification of which it is a part.” Renishaw PLC v. Marposs Societa’ per Azioni, 158 F.3d 1243, 1248 (Fed. Cir. 1998). On occasion, “the specification may reveal a special definition given to a claim term . . . that differs from the meaning it would otherwise possess. In such cases, the inventor’s lexicography governs.”

³ The specification is “that part of a patent application which precedes the claim and in which the inventor specifies, describes, and discloses the invention in detail.” McCarthy’s Desk Encyclopedia of Intellectual Property 408 (2d ed. 1995).

Phillips, 415 F.3d at 1316. The specification may also “reveal an intentional disclaimer, or disavowal, of claim scope by the inventor . . . [, which] is regarded as dispositive.” Id. “The construction that stays true to the claim language and most naturally aligns with the patent’s description of the invention will be, in the end, the correct construction.” Renishaw, 158 F.3d at 1250.

The court “should also consider the patent’s prosecution history, if it is in evidence.” Markman, 52 F.3d at 980. This consists of “the complete record of proceedings before the Patent Office and includes the prior art cited during examination.” Phillips, 415 F.3d at 1317. “Like the specification, the prosecution history provides evidence of how the [Patent and Trademark Office] and the inventor understood the patent.” Id. at 1317. Nonetheless, it is the least probative form of intrinsic evidence because it “represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation.” Id.

If ambiguity still exists after considering all the intrinsic evidence, the court may rely on extrinsic evidence, which is “all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.” Markman, 52 F.3d at 980. “[D]ictionaries, and especially technical dictionaries, . . . have been properly recognized as among the many tools that can assist the court in determining the meaning of particular terminology.” Phillips, 415 F.3d at 1318. Additionally, expert testimony can provide background on the technology at issue, explain how it works, speak to what a person of ordinary skill in the art would understand, and establish that a particular term has a particular meaning in the pertinent field. Id. Notably, however, extrinsic evidence is “less significant than the intrinsic record in determining ‘the legally operative meaning of claim language.’” C.R. Bard, Inc. v. U.S. Surgical Corp., 388

F.3d 858, 862 (Fed. Cir. 2004) (quoting Vanderlande Indus. Nederland BV v. Int’l Trade Comm’n, 366 F.3d 1311, 1318 (Fed. Cir. 2004)).

Ultimately, during claim construction, “[t]he sequence of steps used by the judge in consulting various sources is not important; what matters is for the court to attach the appropriate weight to be assigned to those sources in light of the statutes and policies that inform patent law.” Phillips, 415 F.3d at 303.

III. DISCUSSION

Ten claim terms in seven of Plaintiff’s patents are in dispute. Specifically, the parties disagree on the correct construction of: (1) the term “universal” in the ‘913 and ‘022 patents; (2) the term “intervertebral / disc space / intervertebral space” in the ‘913, ‘022, ‘367, and ‘643 patents; (3) the phrase “third and fourth opposing side surfaces positioned on opposite sides of the second vertebral body engagement surface” in the ‘268 patent; (4) the phrase “gripper having a plurality of prongs” in the ‘913 patent; (5) the term “counterbore” in the ‘022 patent; (6) the phrase “curvilinear nail screw / curvilinear nail-screw” in the ‘740 patent; (7) the phrase “first [and second] means for engaging a cancellous core” in the ‘740 patent; (8) the term “shell” in the ‘643 patent; (9) the phrase “bone-piercing screw extendable from the at least one implant body” in the ‘367 patent; (10) and the phrase “means to facilitate irreversible extraction” in the ‘386 patent. I address each claim term below.

A. “Universal”

<i>Claim Term</i>	<i>Plaintiff’s Proposal</i>	<i>Defendant’s Proposal</i>
“universal” (‘913 patent claims 1, 15; ‘022 patent claim 47)	Plain and ordinary meaning <i>or</i> to the extent the Court believes this term requires construction: “stand-alone (<i>i.e.</i>, having the dual functionality of an intervertebral spacer and a transvertebral bone fusion screw apparatus)”	“an intervertebral bone fusion spacer designed to be inserted between two adjacent [vertebrae / vertebral bodies] in any region of the spine, <i>i.e.</i>, cervical, thoracic, or lumbar, using any approach, <i>e.g.</i>, posterior, anterior, or lateral”

The first disputed claim term is “universal,” which appears in claims 1 and 15 of the ‘913 patent and claim 47 of the ‘022 patent. (‘913 patent, col. 12, line 53, col. 14, line 46; ‘022 patent, col. 17, line 43.) Plaintiff contends that the ‘913 and ‘022 patent specifications make clear that “universal” refers to the inventions’ “dual functions of an intervertebral spacer . . . [and] a transvertebral bone fusion screw apparatus.” (‘913 patent, col. 1, lines 32-35; see ‘022 patent, col. 2, lines 21-23.) Defendant, however, highlights the sentence in the ‘913 patent immediately following Plaintiff’s quoted language, which enumerates invention uses in multiple spinal regions. (‘913 patent, col. 1, lines 35-43.) Defendant also emphasizes other specification language in both patents discussing the inventions’ ability to be modified to fit various spinal regions. (‘913 patent, col. 3, lines 39-41; ‘022 patent, col. 3, lines 52-54.)

I agree with Defendant’s proposed construction. The term “universal” does not have a plain meaning nor was it given a definition in either patent. Accordingly, this term must be construed. To that end, both patents’ specifications provide a multitude of invention uses in all three spinal regions. (See, e.g., ‘913 patent, col. 1, lines 35-43, col. 3, lines 50-53; ‘022 patent, col. 3, lines 52-54.) Indeed, both specifications note that the invention “can also be enlarged and modified to be suitable for cervical, thoracic and lumbar vertebral” placement. (‘022 patent, col. 3, lines 52-54; see ‘913 patent, col. 3, lines 39-41.) Moreover, both specifications reference complications found in prior art, and discuss how the inventions address those complications by “propos[ing] the use of novel . . . screws which can be strategically inserted via anterior or posterior surgical spinal approaches into the anterior and middle columns of the intervertebral [sic] disc space.” (‘913 patent, col. 2, lines 33-37; ‘022 patent, col. 2, lines 39-43.) These portions of the specifications reflect the inventor’s intent that a universal invention is one that can be modified for use in any spinal region and via multiple surgical approaches. Therefore, the term “universal” is

construed as “**an intervertebral bone fusion spacer designed to be inserted between [vertebrae / vertebral bodies] in any region of the spine, i.e., cervical, thoracic, or lumbar, using any approach, e.g., posterior, anterior, or lateral.**”⁴

B. “Intervertebral / Disc Space / Intervertebral Space”

<i>Claim Term</i>	<i>Plaintiff’s Proposal</i>	<i>Defendant’s Proposal</i>
“intervertebral / disc space / intervertebral space” (‘913 patent claims 1, 15; ‘022 patent claim 47; ‘367 patent claim 1; ‘643 patent claim 1)	“ a disc space between two vertebral bodies ”	“ a bone fusion spacer designed to be inserted between two adjacent [vertebral bodies / vertebrae]” or “the disc space between two adjacent [vertebral bodies / vertebrae]”

The next contested claim term is the phrase “intervertebral / disc space / intervertebral space,” which appears in claims 1 and 15 of the ‘913 patent, claim 47 of the ‘022 patent, claim 1 of the ‘367 patent, and claim 1 of the ‘643 patent. (‘913 patent, col. 12, lines 54, 58, 61-62, 67, col. 14, lines 46-47, 50, 52, 55-56, 65; ‘022 patent, col. 17, lines 43, 45, 49; ‘367 patent, col. 9, lines 22, 25-27, 52, 54, 58, 63; ‘643 patent, col. 10, lines 56, 58, col. 11, line 8.) Defendant contends that an intervertebral space is only between two adjacent vertebral bodies because the inventor did not contemplate the invention spanning more than two vertebral bodies. (Doc. No. 116 at 8.) Plaintiff, however, submits that the “adjacent” limiting language should not be read into the claims. (Doc. No. 117 at 13-14.)

I agree with Plaintiff’s proposed construction. Defendant improperly seeks to add limiting language from the specification into the claims. Although there are examples in the specification of the inventions’ uses between two adjacent vertebral bodies, there is nothing to suggest the inventor only conceived of adjacent insertions or intended to exclude non-adjacent insertions. For

⁴ For reasons discussed when construing the claim term “intervertebral / disc space / intervertebral space” in Section III.B *infra*, the adjective phrase “two adjacent” in Defendant’s proposed construction is removed from my construction.

example, dependent claims 6 and 55 of the ‘022 patent require fusion of adjacent bodies, giving relevancy to the omission of “adjacent” elsewhere in the patent. (‘022 patent, col. 13, line 57, col. 18, line 46.)

Finally, it is noted that omission of “adjacent” is consistent with numerous extrinsic dictionary definitions defining “intervertebral” only as a space between two vertebrae, not necessarily two adjacent vertebrae. See, e.g., Intervertebral, Merriam-Webster.com Dictionary, [webster.com/dictionary/intervertebral](https://www.merriam-webster.com/dictionary/intervertebral). (Aug. 9, 2021) (defining “intervertebral” as “situated or occurring between vertebrae of the spinal column”). Thus, the phrase “intervertebral / disc space / intervertebral space” is construed as **“a disc space between two vertebral bodies.”**

C. “Third and Fourth Opposing Side Surfaces Positioned on Opposite Sides of the Second Vertebral Body Engagement Surface”

<i>Claim Term</i>	<i>Plaintiff’s Proposal</i>	<i>Defendant’s Proposal</i>
“third and fourth opposing side surfaces positioned on opposite sides of the second vertebral body engagement surface” (‘268 patent claims 1, 7, 22, 25)	“two surfaces located on opposite sides of the second vertebral engagement surface”	“two surfaces, each integral with the second vertebral body engagement surface and located on opposite sides of the second vertebral body engagement surface”

The third challenged claim term is the phrase “third and fourth opposing side surfaces positioned on opposite sides of the second vertebral body engagement surface,” which appears in claims 1, 7, 22, and 25 of the ‘268 patent. (‘268 patent, col. 13, lines 59-62, col. 14, lines 52-57, col. 19, lines 2, 4-5, 12, col. 19, line 24.) Defendant argues that the third and fourth sides of the invention must contain a vertebral body engagement surface because the first and second sides are so limited. (Doc. No. 116 at 26-27.) Conversely, Plaintiff avers it is improper to read the omitted limitation into the claims. (Doc. No. 117 at 14-16.)

I agree with Plaintiff's proposed construction. Claim 1 of the '268 patent describes "a first implant structure defining the first vertebral body engagement surface and a first angled wedge portion" ('268 patent, col. 13, lines 11-12.) However, when defining the second implant structure, which contains the third and fourth opposing side surfaces, the inventor only claimed "a second implant structure defining a second angled wedge portion," omitting a vertebral body engagement surface limitation. (*Id.*, lines 36-37.) This distinction was purposeful and would render superfluous the first vertebral body engagement surface limitation. It thus is improper to read a limitation from the first implant structure into the second implant structure. Therefore, the phrase "third and fourth opposing side surfaces positioned on opposite sides of the second vertebral body engagement surface" is construed as **"two surfaces located on opposite sides of the second vertebral engagement surface."**

D. "Gripper Having a Plurality of Prongs"

<i>Claim Term</i>	<i>Plaintiff's Proposal</i>	<i>Defendant's Proposal</i>
"gripper having a plurality of prongs" ('913 patent claims 1, 15)	"a part of a tool assembly with two or more prongs"	"a tool having two or more prongs to grasp the slot or indentation of the spacer and the grooves of the screw guide"

The next disputed claim term is the phrase "gripper having a plurality of prongs," which appears in claims 1 and 15 of the '913 patent. ('913 patent, col. 12, line 64, col. 15, line 3.) In support of its proposed construction, Defendant emphasizes claim and specification language describing a gripper that includes a screw guide, and argues the language requires the gripper have means to grasp the screw guide. (Doc. No. 116 at 15-16.) Plaintiff again argues Defendant's construction improperly reads limitations from the specification into the claim. (Doc. No. 117 at 16-18.)

I agree with Plaintiff's proposed construction. Plaintiff's construction mirrors the language in claims 1 and 15, which claim only a gripper having a plurality of prongs. ('913 patent, col. 12, line 64, col. 15, line 3.) The gripper language is limited in later dependent claims that require, for example, that "the plurality of prongs engage and hold the screw guide" ('913 patent, col. 15, lines 14-15.) Initially omitting the limitation was a deliberate choice of the patentee, and it is improper to read the later limitation into the broad definition of a gripper. Thus, the phrase "gripper having a plurality of prongs" is construed as **"a part of a tool assembly with two or more prongs."**

E. "Counterbore"

<i>Claim Term</i>	<i>Plaintiff's Proposal</i>	<i>Defendant's Proposal</i>
"counterbore" (‘022 patent claim 47)	"an enlargement of the mouth of a cylindrical bore for accommodating a screw head"	"a flat-bottomed enlargement of the mouth of a cylindrical bore"

The fifth contested claim term is "counterbore," which appears in claim 47 of the ‘022 patent. ('022 patent, col. 17, lines 60-61.) Defendant argues that a "counterbore" necessarily has a flat-bottom and supports its position with extrinsic dictionary evidence defining a bore as a "deep vertical hole" (Doc. No. 116 at 17-18.) Plaintiff disagrees, highlighting two figures in the ‘022 patent specification that utilize angled-bottomed counterbores. (Doc. No. 117 at 18-20; ‘022 patent, Figs. 1C, 4C.)

I agree with Plaintiff's proposed construction. First, two figures in the ‘022 patent show angled-bottomed counterbores. (*Ids.*) The intrinsic use of angled counterbore bottoms in these figures refutes the extrinsic evidence Defendant relies upon. Second, the dictionary definitions Defendant proffers define a counterbore as a "deep vertical hole" but are silent about the orientation of a counterbore's bottom. (Doc. No. 116 at 17-18.) For these reasons, Plaintiff's

construction is persuasive and the term “counterbore” is construed as “**an enlargement of the mouth of a cylindrical bore for accommodating a screw head.**”

F. “Curvilinear Nail Screw / Curvilinear Nail-Screw”

<i>Claim Term</i>	<i>Plaintiff’s Proposal</i>	<i>Defendant’s Proposal</i>
“curvilinear nail screw / curvilinear nail-screw” (‘740 patent claims 1, 16)	“ a body having a curvilinear shape with the attributes of both a nail and a screw ”	“ a curved, threaded body for penetration into an intervertebral body along a horizontal trajectory ” <i>or</i> indefinite

Next, the parties dispute the meaning of the claim term “curvilinear nail screw / curvilinear nail-screw,” which appears in claims 1 and 16 of the ‘740 patent. (‘740 patent, col. 13, lines 27, 30, 34, 37, 40, 43, 48, 51, 55-62, col. 14, lines 65-67, col. 15, lines 1, 3.) Defendant argues that the ‘740 patent inventor only contemplated inserting the curvilinear nail screw—the invention—in a horizontal, and not a vertical, trajectory to avoid piercing the spinal pedicle bones. (Doc. No. 116 at 20-21.) Defendant posits that threads are the distinguishing feature of a screw and must be included as part of the claimed nail screw. (*Id.* at 21-22.) Conversely, Plaintiff asserts that references to an insertion trajectory or restricting the screw to only have threads—as opposed to fishhooks, ridges, or equivalent structures—unduly limits the claim term. (Doc. No. 117 at 21-22.)

I agree with Defendant’s basic description of the curvilinear nail screw because it is more faithful to the ‘740 patent specification and “most naturally aligns with the patent’s description of the invention” Renishaw, 158 F.3d at 1250. However, Plaintiff’s arguments are convincing. First, reference to the curvilinear nail screw’s insertion angle unduly limits the claim term by reading in limitations from the specification. A reference to the curvilinear nail screw’s insertion angle is unhelpful because one would not know whether a product infringed the curvilinear nail screw until its insertion, as opposed to its production. Second, as will be discussed in more detail

in Section III.G *infra*, the ‘740 patent discloses a nail screw containing not only threads but also similar structures, such as fishhooks, and it is improper to limit the claim to only include threads. (See, e.g., ‘740 patent, col. 14, line 19; Figs 1E, 1F.) For these reasons, the term “curvilinear nail screw / curvilinear nail-screw” is construed as “**a curved body for penetration into an intervertebral body.**”

G. “First [and Second] Means for Engaging a Cancellous Core”

<i>Claim Term</i>	<i>Plaintiff’s Proposal</i>	<i>Defendant’s Proposal</i>
“first [and second] means for engaging a cancellous core” (‘740 patent claim 1)	<p>Construe pursuant to 35 U.S.C. § 112(6):</p> <p><u>Function:</u> engaging a first/second cancellous core of the first/second vertebral body</p> <p><u>Structure:</u> a series of fish-hooks, threads, ridges, or equivalent structure known to a POSITA, extending along a linear direction of the curvilinear nail-screw</p>	<p>Construe pursuant to 35 U.S.C. § 112(6):</p> <p><u>Function:</u> engage a cancellous core</p> <p><u>Structure:</u> threads or fishhooks</p>

The seventh disputed claim term is the means-plus-function phrase “first [and second] means for engaging a cancellous core,” which appears in claim 1 of the ‘740 patent. (‘740 patent, col. 13, lines 34-35, 48-49.) The parties agree that their function constructions are similar. (Doc. No. 117 at 23.) However, as discussed in Section III.F *supra*, they dispute the structures of a curvilinear nail screw to engage a cancellous core. Defendant contends that the ‘740 patent only discloses threads and fishhooks as engagement structures. (Doc. No. 116 at 22-24.) Contrarily, Plaintiff submits that the fishhooks and threads examples in the ‘740 patent specification are only exemplary embodiments and should not limit the claim. (Doc. No. 117 at 23.)

I agree with Plaintiff's construction. Regarding the parties' function construction, although the parties' constructions are similar, Plaintiff's construction is preferred because it reflects the claim language. ('740 patent, col. 13, lines 34-35, 48-49.) Concerning the structure construction, the claim should not be limited to only threads or fishhooks. The '740 patent discloses numerous embodiments utilizing threads and fishhooks, but also notes that "[o]ther variations and embodiments . . . can include any other type of mechanism that allows insertion and immobility . . . into and within the vertebral body" (*Id.*, col. 5, lines 12-15.) In fact, Claim 5 of the '740 patent claims ridges as one of these other mechanisms. (*Id.*, col. 14, line 19.) Accordingly, the inventor contemplated and disclosed mechanisms other than threads or fishhooks, and it is improper to limit the claim to only the exemplary embodiments in the specification. Therefore, the phrase "first [and second] means for engaging a cancellous core" is construed pursuant to 35 U.S.C. § 112(6), with a function of "**engaging a first/second cancellous core of the first/second vertebral body,**" and a structure of "**a series of fish-hooks, threads, ridges, or equivalent structure known to a POSITA, extending along a linear direction of the curvilinear nail-screw.**"

H. "Shell"

<i>Claim Term</i>	<i>Plaintiff's Proposal</i>	<i>Defendant's Proposal</i>
"shell" ('643 patent claims 1, 2)	Plain and ordinary meaning <i>or</i> "an exterior structure of the artificial expansile spinal implant"	"the ends of an implantable intervertebral device, which ends are capable of moving in at least two directions defined by at least two axes"

The next disputed claim term is "shell," which appears in claims 1 and 2 of the '643 patent. ('643 patent, col. 10, lines 47-48, 53-54, 57, 62, 64, col. 11, lines 1, 11-12.) Defendant contends that in the '643 patent specification the patentee defined "shell" as "fully described in [a] . . . previous PCT Patent Application PCT/US2005/016493" ('643 patent, col. 7, lines 36-38; see

also Doc. No. 116 at 28-29.) It argues the PCT Patent Application defined an outer shell as capable of “mov[ing] in multiple directions . . .” and “expand[ing] geometrically in all three x, y, and z planes, horizontally, vertically and width wise.” (Doc. No. 116 at 28.) Plaintiff submits that “shell” has a plain and ordinary meaning, and in the alternative, argues that neither the ‘643 patent nor the referenced PCT Patent Application defined “shell” and the claim should not be limited as Defendant proposes. (Doc. No. 117 at 25-27.)

I agree with Plaintiff’s proposed construction. The ‘643 patent discloses a shell as “fully described in [a] . . . previous PCT Patent Application PCT/US2005/016493;” however, that language shows an intent to incorporate the Application’s prior disclosures and not to define “shell.” (‘643 patent, col. 7, lines 36-38.) Further, Defendant’s proposed construction improperly seeks to read movement limitations from the ‘643 patent specification into the claim. For these reasons, I construe the term “shell” as **“an exterior structure of the artificial expansile spinal implant.”**

I. “Bone-Piercing Screw Extendable from the at Least One Implant Body”

<i>Claim Term</i>	<i>Plaintiff’s Proposal</i>	<i>Defendant’s Proposal</i>
“bone-piercing screw extendable from the at least one implant body” (‘367 patent claim 1)	“screw extendable from the implant body capable of piercing into the vertebral body”	“bone-piercing screw positioned entirely within the implant body and capable of extending from the implant body”

The next disputed claim term is the phrase “bone-piercing screw extendable from the at least one implant body,” which appears in claim 1 of the ‘367 patent. (‘367 patent, col. 9, lines 55-56, 59-60.) Defendant argues that the claim should be limited as it proposes because the ‘367 patentee only discloses inventions with screws positioned entirely within an implant body and that can extend from the body. (Doc. No. 116 at 24-26.) Plaintiff, however, alleges its construction

recites the claim language and it is improper, as Defendant proposes, to limit the claim with language from the specification. (Doc. No. 117 at 27-28.)

I find that the claim language “bone-piercing screw extendable from the at least one implant body” is unambiguous and construed as written. Defendant’s proposed construction improperly reads limitations from the specification into the claim language. Moreover, although Plaintiff states its proposed construction merely follows the claim language, it is unnecessary to alter the “bone-piercing screw” language in the claim to a screw “capable of piercing into the vertebral body.” The language as written in the patent has a facially plain and ordinary meaning. Thus, I conclude the phrase “bone-piercing screw extendable from the at least one implant body” needs no construction and has its plain and ordinary meaning of **“bone-piercing screw extendable from the at least one implant body.”**⁵

J. “Means to Facilitate Irreversible Extraction”

<i>Claim Term</i>	<i>Plaintiff’s Proposal</i>	<i>Defendant’s Proposal</i>
“means to facilitate irreversible extraction” (‘386 patent claim 1)	Construe pursuant to 35 U.S.C. § 112(6): <u>Function:</u> facilitate irreversible extraction <u>Structure:</u> ridges, fishhooks, or equivalent structures known to a POSITA	Indefinite

Finally, the last disputed claim term is the phrase “means to facilitate irreversible extraction,” which appears in claim 1 of the ‘386 patent. (‘386 patent, col. 13, lines 11-12, 21.)

⁵ The Federal Circuit Court of Appeals has held that the duty to resolve “fundamental dispute[s] regarding the scope of a claim . . . resides with the court because, of course, the ultimate question of construction” is a question of law. Eon Corp. IP Holdings v. Silver Spring Networks, 815 F.3d 1314, 1318 (Fed. Cir. 2016) (quotation marks and citations omitted). Accordingly, a court has the power to determine a claim “needs no construction.” Id.; see also O2 Micro Int’l Ltd. v. Beyond Innovation Tech. Co., Ltd., 521 F.3d 1351, 1361 (Fed. Cir. 2008).

Defendant contends that the phrase is indefinite and cannot be construed because it is contradictory that the means used to insert the invention into bone also would serve to keep the invention permanently extracted from bone. (Doc. No. 116 at 29-30.) In contrast, Plaintiff contends that the ‘386 patent specification describes means such as fishhooks and ridges that anchor the invention into a bone and, upon the invention’s removal from the bone, render the invention unsuitable for reinsertion. (Doc. No. 117 at 28-29.)

I agree with Plaintiff’s proposed construction. Regarding the phrase’s structure, the ‘386 patent discloses ridges and fishhooks as means to anchor the invention into a bone, and during the patent’s prosecution, the patentee noted equivalent features can be used for anchoring. (‘386 patent, col. 9, lines 40-42; Doc. No. 117 Ex. 25.) Moreover, regarding function, “irreversible extraction” has a plain and ordinary meaning of an inability to be reinserted after removal.⁶ (Doc. No. 135 at 14.) Accordingly, Defendant’s contention that the phrase is indefinite, contradictory, and incapable of construction is rejected. Therefore, the phrase “means to facilitate irreversible extraction” is construed pursuant to 35 U.S.C. § 112(6), with a function of “**facilitate irreversible extraction,**” and a structure of “**ridges, fishhooks, or equivalent structures known to a POSITA.**”

IV. CONCLUSION

The claims shall be construed as set forth above and in the Claim Construction Order that follows.

⁶ Plaintiff provides a useful analogy to a desk staple, wherein the removal process deforms the staple such that it is incapable of being reused. (Doc. No. 123 at 30.)

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

MOSKOWITZ FAMILY LLC

Plaintiff,

v.

GLOBUS MEDICAL, INC.

Defendants.

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CIVIL ACTION

No. 20-3271

ORDER

AND NOW, this 25th day of August, 2021, upon consideration of the parties' Opening Claim Construction Briefs (Doc. Nos. 116, 117), their corresponding responses and replies to the Briefs (Doc. Nos. 122, 123, 134, 135), and the arguments of counsel for the parties at the July 27, 2021 hearing, and in accordance with the Opinion of the Court issued on this day, it is hereby **ORDERED** that the following terms are construed as follows:

1. The term "universal" is construed as "**an intervertebral bone fusion spacer designed to be inserted between [vertebrae / vertebral bodies] in any region of the spine, i.e., cervical, thoracic, or lumbar, using any approach, e.g., posterior, anterior, or lateral.**"
2. The term "intervertebral / disc space / intervertebral space" is construed as "**a disc space between two vertebral bodies.**"
3. The phrase "third and fourth opposing side surfaces positioned on opposite sides of the second vertebral body engagement surface" is construed as "**two surfaces located on opposite sides of the second vertebral engagement surface.**"
4. The phrase "gripper having a plurality of prongs" is construed as "**a part of a tool assembly with two or more prongs.**"

5. The term “counterbore” is construed as **“an enlargement of the mouth of a cylindrical bore for accommodating a screw head.”**
6. The term “curvilinear nail screw / curvilinear nail-screw” is construed as **“a curved body for penetration into an intervertebral body.”**
7. The phrase “first [and second] means for engaging a cancellous core” is construed pursuant to 35 U.S.C. § 112(6), with a function of **“engaging a first/second cancellous core of the first/second vertebral body,”** and a structure of **“a series of fish-hooks, threads, ridges, or equivalent structure known to a POSITA, extending along a linear direction of the curvilinear nail-screw.”**
8. The term “shell” is construed as **“an exterior structure of the artificial expansile spinal implant.”**
9. The phrase “bone-piercing screw extendable from the at least one implant body” is construed as **“bone-piercing screw extendable from the at least one implant body.”**
10. The phrase “means to facilitate irreversible extraction” is construed pursuant to 35 U.S.C. § 112(6), with a function of **“facilitate irreversible extraction,”** and a structure of **“ridges, fishhooks, or equivalent structures known to a POSITA.”**

BY THE COURT:

/s/ Mitchell S. Goldberg
MITCHELL S. GOLDBERG, J.

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

MOSKOWITZ FAMILY LLC

Plaintiff,

v.

GLOBUS MEDICAL, INC.

Defendants.

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CIVIL ACTION

No. 20-3271

ORDER

AND NOW, this 3rd day of February, 2022, upon consideration of Plaintiff Moskowitz Family LLC’s Motion for Clarification Regarding the Construction of “Universal” (Doc. No. 162), Defendant Globus Medical, Inc.’s Response (Doc. No. 182), and Plaintiff’s Reply (Doc. No. 190), I find as follows:

1. Following the claim construction hearing held on July 27, 2021, I considered the meaning of the term “universal,” as used in two of the patents-in-suit, and defined it as **“an intervertebral bone fusion spacer designed to be inserted between [vertebrae/vertebral bodies] in any region of the spine, i.e., cervical, thoracic, or lumbar, using any approach, e.g., posterior, anterior, or lateral.”** Moskowitz Family LLC v. Globus Med., Inc., No. 20-cv-3271, 2021 WL 3784243, at *4 (E.D. Pa. Aug. 25, 2021). In doing so, I reasoned that:

[B]oth patents’ specifications provide a multitude of invention uses in all three spinal regions. (See, e.g., ’913 patent, col. 1, lines 35–43, col 3, lines 50–53; ’022 patent, col. 3, lines 52–54.) Indeed, both specifications note that the invention “can also be enlarged and modified to be suitable for cervical, thoracic and lumber vertebral” placement. (’022 patent, col. 3, lines 52–54; see ’913 patent, col. 3, lines 39–41.) Moreover, both specifications reference complications found in prior art, and discuss how the inventions address those complications by “propos[ing] the use of novel . . . screws which can be strategically inserted via anterior or posterior surgical spinal approaches into the anterior and middle columns of the intervertebral [sic] disc space.” (’ 913 patent, col. 2, lines 33–37; ’022 patent, col.

2, lines 39–43.) These portions of the specifications reflect the inventor’s intent that a universal invention is one that can be modified for use in any spinal region and via multiple surgical approaches.

Id.

2. Revisiting this issue, Plaintiff now contends that the only plausible interpretation of “universal” that stays true to “the plain language of the construction,” the “teachings” of the patents, and “the anatomical realities of the human spine” is that the word “any” does not mean “all,” and the conjunction “or” does not mean “and.” Plaintiff posits that the word “any” means “one or more,” “at least one,” or “any one of multiple.” Plaintiff reasons that the inventive implants defined in the patents cannot, as Defendant contends, require a single, as-manufactured, device suitable for implantation in all regions of the spine using all surgical approaches without any modifications. According to Plaintiff, such an interpretation “represents a physical impossibility, as no manufactured spinal implant fits in all regions of the spine given the anatomical realities of the size and spacing of vertebrae.” Rather, Plaintiff asserts that the specifications of the patents-in-suit simply “teach embodiments of the invention that may be modified and tailored for implantation into different regions of the spine.” (Pl.’s Mem. Supp. Mot. for Clarification 10, 13.)
3. I disagree with Plaintiff and find that my construction clearly sets forth the proper scope of this claim. The term “universal,” as used here, modifies the term “intervertebral bone fusion spacer.” As such, the claimed invention is not simply an “intervertebral bone fusion spacer,” but rather a “universal” one. “It is the usual (though not invariable) rule that, in patent claims as elsewhere, the construction of a clause as a whole requires construction of the parts, with meaning to be given to each part so as to avoid rendering any part superfluous.” Frans Nooren Afidchtingssystemen B.V. v. Stopaq Amcorr Inc., 744 F.3d 715, 722 (Fed. Cir. 2014).

4. Contrary to Plaintiff’s argument that my construction results in a physical impossibility because “no manufactured spinal implant fits in all regions of the spine given the anatomical realities of the size and spacing of vertebrae in different regions of the spine,” (Pl.’s Mem. Supp. Mot. for Clarification 12), the claimed invention—*i.e.*, its novel aspects—do not describe a product manufactured to a specific size. Rather, the claimed invention combines in “a single construct the dual functions of an interverbal spacer maintaining disc space height, and transvertebral body fusion screws,” without regard to size, where it is placed in the spine, or how it is inserted. (See ’913 patent, col. 2, lines 14–17.) As such, under the construction I adopted, the novel aspects of the invention can exist in a spacer—without regard to size—that can be used in any region of the spine and may be inserted through any surgical approach.

WHEREFORE, it is hereby **ORDERED** that the Motion for Clarification is **DENIED**.

BY THE COURT:

/s/ Mitchell S. Goldberg
MITCHELL S. GOLDBERG, J.

**PIN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

MOSKOWITZ FAMILY LLC

Plaintiff,

v.

GLOBUS MEDICAL, INC.

Defendants.

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CIVIL ACTION

No. 20-3271

MEMORANDUM OPINION

Goldberg, J.

December 22, 2022

Plaintiff Moskowitz Family LLC (“Plaintiff”) holds several patents pertaining to spinal implants designed to reduce adverse outcomes in spinal fusion patients. Plaintiff’s inventions include minimal impaction, steerable, and custom-fit intervertebral implants that minimize musculoskeletal disruption and nerve root retraction during and after the procedure. Defendant Globus Medical, Inc. (“Defendant”) is another spinal fusion company that sells intervertebral spinal implants. Plaintiff accuses Defendant’s products of directly and indirectly infringing on Plaintiff’s patents.

Defendant moves for partial summary judgment on Plaintiff’s direct infringement and indirect infringement claims. For the following reasons, I will grant Defendant’s Motion and enter judgment on its behalf regarding the direct infringement claims but will deny Defendant’s Motion on induced infringement.

I. GENERAL FACTUAL BACKGROUND

As explained during the claim construction hearing, the human spine is composed of vertically arranged bones called vertebrae, which are separated by cartilaginous intervertebral

discs. The vertebrae are divided into three portions: (1) the uppermost seven are called the cervical spine; (2) the middle twelve are called the thoracic spine; and (3) the bottom five are called the lumbar spine. Two pedicle bones dorsally extend from each vertebra and form an arch that protects the spinal cord.

In some individuals, the cartilaginous disc between vertebrae may wear, causing pain and pressure on the spinal cord. For such individuals, spinal fusion surgery may offer relief. This procedure permanently connects two or more spinal vertebrae to improve spinal stability, correct deformations, and reduce pain. This procedure can also result in some adverse patient outcomes such as high-impaction, neural or vascular injury, esophageal injuries, excessive blood loss, prolonged surgical duration, prolonged recovery, and incomplete return to work results. These adverse events may be the result of static and non-expandable implants, misplaced implants, and implant pull-out after surgery.

Plaintiff sought to invent minimally invasive spinal implants designed to reduce these adverse outcomes. From January 15, 2013 through November 19, 2019, the United States Patent and Trademark Office (“PTO”) issued to Plaintiff the eight patents at issue. These patents are directed to intervertebral spine implant screws, staples, and expandable implant systems. U.S. Patent Nos. 8,353,913 (the “’913 patent”), 110,307,268 (“’268 patent”), and 10,478,319 (the “’319 patent”) are for tools used to manipulate and insert spacers into a disc space between two vertebral bodies to facilitate bone and screw fusion. U.S. Patent No. 9,889,022 (the “’022 patent”) is for an intervertebral screw guide and fixation apparatus for insertion into a disc space between two vertebrae to encourage bone and screw fusion. U.S. Patent No. 10,028,740 (the “’740 patent”) claims a “curvilinear nail screw,” a holding structure implanted into a vertebra and around the pedicle bones to avoid penetrating them. U.S. Patent No. 10,251,643 (the “’643 patent”) relates

to an intervertebral mechanism that expands between vertebral bodies and engages vertebral endplates to keep the mechanism in place. U.S. Patent No. 10,076,367 (the “’367 patent”) is for a bidirectional system inserted between vertebrae to facilitate their linking and fusion. Finally, U.S. Patent No. 10,376,386 (the “’386 patent”) claims a spinal staple with a curved based and ridged spikes that hinder the staple’s removal.

On November 20, 2019, Plaintiff sued Defendant alleging both direct and indirect infringement of these various patents.

II. STANDARD OF REVIEW

Federal Rule of Civil Procedure 56 states, in pertinent part:

A party may move for summary judgment, identifying each claim or defense—or the part of each claim or defense—on which summary judgment is sought. The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law. The court should state on the record the reasons for granting or denying the motion.

Fed. R. Civ. P. 56(a). “Through summary adjudication, the court may dispose of those claims that do not present a ‘genuine dispute as to any material fact’ and for which a jury trial would be an empty and unnecessary formality.” Capitol Presort Servs., LLC v. XL Health Corp., 175 F. Supp. 3d 430, 433 (M.D. Pa. 2016). A factual dispute is “material” if it might affect the outcome of the suit under the applicable law. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). An issue is “genuine” only if there is a sufficient evidentiary basis that would allow a reasonable factfinder to return a verdict for the non-moving party. Id.

The initial burden is on the moving party to adduce evidence illustrating a lack of genuine, triable issues. Hugh v. Butler Cnty. Family YMCA, 418 F.3d 265, 267 (3d Cir. 2005). Once the moving party satisfies its burden, the non-moving party must, in rebuttal, present sufficient evidence of a genuine issue, in rebuttal. Santini v. Fuentes, 795 F.3d 410, 416 (3d Cir. 2015). The

court must then resolve all doubts as to the existence of a genuine issue of material fact in favor of the non-moving party. Saldana v. Kmart Corp, 260 F.3d 228, 232 (3d Cir. 2001). Summary judgment is appropriate if the non-moving party provides merely colorable, conclusory or speculative evidence. Anderson, 477 U.S. at 249. There must be more than a scintilla of evidence supporting the non-moving party and more than some metaphysical doubt as to the material facts. Id. at 252. Unsubstantiated arguments made in briefs are not considered evidence of asserted facts. Versarge v. Twp. of Clinton, 984 F.2d 1359, 1370 (3d Cir. 1993). Moreover, “a party resisting a [Rule 56] motion cannot expect to rely merely upon bare assertions, conclusory allegations or suspicions.” Gans v. Mundy, 762 F.2d 338, 241 (3d Cir. 1985) (citing Ness v. Marshall, 660 F.2d 517, 519 (3d Cir. 1981)).

III. MOTION FOR SUMMARY JUDGMENT ON DIRECT INFRINGEMENT

A. Facts Relating to Direct Infringement

The following facts are derived from the evidence submitted by the parties in support and opposition to summary judgment. Where there is conflicting evidence about a particular fact, Federal Rule of Civil Procedure 56 requires that I view all facts and evidence in the light most favorable to Plaintiffs.¹

Plaintiff accuses Defendant’s products of direct infringement. Defendant seeks summary judgment on the direct infringement claims relating to the ’913 patent and the ’022 patent.

Claim 1 of the ’913 patent recites:

¹ References to the parties’ pleadings will be made as follows: Defendant’s Statement of Undisputed Facts (“DSUF”); Plaintiff’s Response (“PR”), Plaintiff’s Additional Statement of Facts (“PASF”), and Defendant’s Response (“DR”). To the extent a statement is undisputed by the parties, I will cite only to the parties’ submissions. If a statement is disputed and the dispute can be easily resolved by reference to the exhibits, I will cite the supporting exhibits. If a statement is disputed, but the dispute cannot be resolved by reference to the exhibits, I will note the disputed fact. I will not rely on any statement of fact that is unsupported by reference to a specific exhibit.

A tool for manipulating and inserting a universal, intervertebral bone fusion spacer into a disc space between a first vertebral body and a second vertebral body for providing 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 includes an intervertebral cage having a first integral screw guide and a second integral screw guide, 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 gripper having a plurality of prongs,

wherein a distal end of each of the plurality of prongs is capable of engaging 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.

(DSUF ¶ 1; PR ¶ 1.)²

Asserted claim 47 of the '022 Patent states:

A universal, intervertebral combination internal screw guide and fixation apparatus configured to be inserted into a disc space between a first vertebral body and a second vertebral body and to provide fusion of the first vertebral body to the second vertebral body via biological bone fusion and screw fusion, the apparatus comprising:

an intervertebral cage including;

a top wall, a bottom wall, and two sidewalls defining an open space capable of receiving bone filling for the biological bone fusion;

an internal screw guide having an internal bore with an entry opening and an exit opening, the entry opening of the internal bore formed only in a top surface of the top wall and the exit opening formed at least partially in a bottom surface of the top wall and at

² Asserted claim 10 of the '913 Patent depends from claim 1 and shares its preamble. (DSUF ¶ 2; PR ¶ 2.)

least partially in a side surface of the top wall, wherein the internal screw guide further includes a counterbore that is larger than and coaxial with internal bore and has a counterbore entry opening that is formed only in the top surface of the top wall;

a second integral screw guide having a second internal bore with a second entry opening and a second exit opening, the second entry opening of the second internal bore formed only in the top surface of the top wall and the second exit opening formed at least partially in the bottom surface of the top wall and at least partially in a second side surface of the top wall; and

a circular hole extending through the top wall in a direction substantially normal to the top surface of the top wall, wherein the circular hole is positioned between the internal screw guide and the second internal screw guide at the top surface of the top wall.

(DSUF ¶ 3; PR ¶ 3.)³

In my August 25, 2021 claim construction order, I construed the term “universal”—as used in both Patents—to mean “an intervertebral bone fusion spacer designed to be inserted between [vertebrae/vertebral bodies] in any region of the spine, *i.e.*, cervical, thoracic, or lumbar, using any approach, *e.g.*, posterior, anterior, or lateral.” (ECF No. 144, p.1). Based on that claim construction, Plaintiff concedes that none of the products accused of infringing the ‘022 and ‘913 Patents are “universal.” (DSUF ¶ 7; PR ¶ 7.)

Plaintiff’s expert neurosurgeon, William Rosenberg, has opined that certain of Defendant’s products—specifically the COALITION, COALITION AGX, HEDRON IC, and INDEPENDENCE products—infringe claims 1 and 10 of the ’913 Patent. (Pl.’s Ex. 1, Decl. of William Rosenberg (“Rosenberg Decl.”) ¶ 6.) Dr. Rosenberg has also opined that certain of Defendant’s products infringe the ’022 Patent. (Rosenberg Decl., Ex. B (“Rosenberg Dep.”) ¶ 63; Def.’s Ex. 2, Expert Report of Michael C. Sherman (“Sherman Rep.”) ¶ 4.) Plaintiff agrees that

³ Claim 58 of the ’022 Patent depends from claim 47 and shares its preamble. (DSUF ¶ 4; PR ¶ 4.)

the accused products are not “universal” under the Court’s construction but nonetheless presses that because the term “universal” appears only in the preambles of claims 1 and 10 of the ’913 Patent and claim 47 of the ’022 Patent, it is not limiting on those patents.

B. Analysis of Direct Infringement

“Generally, . . . the preamble does not limit the claims.” Am. Med. Sys. Inc. v. Biolitec, Inc., 618 F.3d 1354, 1358 (Fed. Cir. 2010) (quotations omitted). Nonetheless, “it is not unusual . . . to treat preamble language as limiting.” Bicon v. Strauman Co., 441 F.3d 945, 952 (Fed. Cir. 2006). Whether to treat a preamble as a limitation is a determination “resolved only on review of the entire[] . . . patent to gain an understanding of what the inventors actually invented and intended to encompass by the claim.” Corning Glass Works v. Sumitomo Elec. U.S.A., Inc., 868 F.2d 1251, 1257 (Fed. Cir. 1989).

“In general, a preamble limits the invention if it recites essential structure or steps, or if it is ‘necessary to give life, meaning and vitality’ to the claim.” Catalina Mktg. Int’l, Inc. v. Coolsavings.com, Inc., 289 F.3d 801, 808 (Fed. Cir. 2002) (quoting Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305 (Fed. Cir. 1999)). Thus, where preamble terms “give meaning to the claim and properly define the invention,” the preamble is considered limiting. Bausch & Lomb Inc. v. Moria S.A., 222 F. Supp. 2d 616, 648 (E.D. Pa. 2002); see also Pitney Bowes, 182 F.3d at 1306 (where “term can only be understood in context of preamble statement,” preamble is limiting). Conversely, a preamble is not regarded as limiting “when the claim body describes a structurally complete invention such that deletion of the preamble phrase does not affect the structure or steps of the claimed invention,” or where a patentee uses the preamble only to state a purpose or intended use of the invention. Catalina Mktg., 289 F.3d at 809; Bicon, Inc., 441 F.3d at 952.

“No litmus test defines when a preamble limits claim scope,” but the Federal Circuit has identified several “guideposts” to assist in the determination. Catalina Mktg., 289 F.3d at 808. Primarily, “dependence on a particular disputed preamble phrase for antecedent basis” or the need for the preamble “to understand limitations or terms in the claim body” may indicate that the preamble limits claim scope because it demonstrates a “reliance on both the preamble and the claim body to define the claimed invention.” Id.; see Gen. Elec. Co. v. Nintendo Co., Ltd., 179 F.3d 1350, 1361 (Fed. Cir. 1999) (preamble reading a “system for displaying a pattern on a raster scanned display device by mapping bits from a display location in a member associated with a computer onto the raster” was incorporated by reference because of language in claim and was held to be limiting for breathing life and meaning into claim).

In addition, “when reciting additional structure or steps underscored as important by the specification, the preamble may operate as a claim limitation.” Catalina Mktg., 289 F.3d at 808; see also Corning Glass Works v. Sumitomo Elec. U.S.A., Inc., 868 F.2d 1251, 1257 (Fed. Cir. 1989) (finding preamble limiting where the patent’s specification clarified that inventors were working on a particular problem in optical communications and, without preamble language, claim would “indiscriminately cover all types of optical fibers,” which would be “divorced from reality”).

“[C]lear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art transforms the preamble into a claim limitation because such reliance indicates use of the preamble to define, in part, the claimed invention.” Catalina Mktg., 289 F.3d at 808. Absent such reliance, the preamble is generally not limiting, so long as the claim body describes a structurally complete invention, such that deletion of the preamble phrase does not affect the structure or steps of the claimed invention. Id. at 809.

Finally, preambles that merely describe the use of an invention or give an intended purpose “generally do not limit the claims because the patentability of apparatus or composition depends on the claimed structure, not on the use or purpose of that structure.” *Id.* This is because the “inventor of a machine is entitled to the benefit of all the uses to which it can be put, no matter whether he had conceived the idea of the use or not.” *Id.* (quoting Roberts v. Ryers, 91 U.S. 150, 157 (1875)).

In particular, when dealing with apparatus claims—such as the claims at issue here—construction is “governed by the well-established principle that ‘[a]pparatus claims cover what a device *is*, not what a device *does*.’” Eli Lilly & Co v. Teva Pharms Int’l GmbH, 8 F.4th 1331, 1340 (Fed. Cir. 2021) (quoting Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1468 (Fed. Cir. 1990)). For claims directed to apparatuses or compositions, the Federal Circuit has “often relied on the proposition that ‘[p]reamble language that merely states the purpose or intended use of an invention is generally not treated as limiting the scope of the claim.’” *Id.* (quoting Bicon, 441 F.3d at 952); *see, e.g., Cochlear Bone Anchored Solutions AB v. Oticon Med. AB*, 958 F.3d 1348, 1355 (Fed. Cir. 2020) (holding that a statement of intended purpose in the preamble—“for rehabilitation of unilateral hearing loss”—was not limiting because the claimed apparatus (a hearing aid) was fully structurally claimed in the body of the claim, and its structure would allow it to function identically whether or not used for its stated intended purpose); TomTom, Inc. v. Adolph, 790 F.3d 1315, 1324 (Fed. Cir. 2015) (noting language stating a purpose or intended use tends to employ the standard pattern of such language: “a method for a purpose or intended use comprising” followed by the body of the claim.).⁴ “Even with respect to

⁴ See, e.g., STX, LLC v. Brine, Inc., 211 F.3d 588, 591 (Fed. Cir. 2000) (preamble phrase “which provides improved playing and handling characteristics” followed by claim that was “self-contained description that could stand alone, with or without the preamble” held to be non-limiting preamble.”); Bristol-Myers Squibb Co. v. Ben Venue Lab., Inc., 246 F.3d 1368, 1375–76 (Fed.

apparatus or composition claims, however, [the Federal Circuit has], when warranted by the facts, found statements of intended purpose to be limiting.” Eli Lilly, 8 F.4th at 1341.

Applying these “guideposts” here, I find that the preambles at issue are limiting for several reasons.

First, as noted above, where terms in the preamble provide an antecedent basis for the same terms in the body of the claim, there is a “strong indication that the preamble acts ‘as a necessary component of the claimed invention.’” Bio-Rad Labs., Inc. v. 10X Genomics Inc., 967 F.3d 1353, 1371 (Fed. Cir. 2020) (quotation omitted); see also In re Fought, 941 F.3d 1175, 1178. “In patent law, it is widely understood that the recitation of the term ‘the’ or ‘said’ before a feature [in the body of the claim] indicates to a reader that the feature following these terms has been introduced prior in the claim language.” In re Ciprodex, No. 15-cv-5756, 2017 WL 2784410, at *8 (D.N.J. June 27, 2017). “[A]s such, recitation of ‘the’ or ‘said’ feature simply indicates that a new feature is not being introduced in the claim” and that reference to an earlier cited feature is necessary. Id.

For both of the patents-in-suit, the claim language depends on the preamble phrase for an antecedent basis and uses the term “the” before a feature in the body of the claim, such that the preamble is essential to understanding the limitations or terms in the claim body. The claim body of Claim 1 of the ’913 Patent, *without* the preamble, recites:

Cir. 2001) (preamble reading a “method for treating a cancer patient to effect regression of a taxol-sensitive tumor, said method being associated with reduced hematologic toxicity” held to be a statement of purpose that failed to result in a “manipulative difference in the steps of the claim”).

the tool comprising:

a gripper having a plurality of prongs,

wherein a distal end of each of the plurality of prongs is capable of engaging 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.

(’913 patent, claim 1 (emphasis added).) Read in isolation from the preamble, the claim references a gripper tool with (a) a plurality of prongs that can be used to engage some type of slot on “the” intervertebral cage and (b) a screw guide for controlling the direction of screws “the” integral screw guides. The claim language does not, however, answer any questions about the nature, location, and design of “the intervertebral” cage, the slot or indentation on such cage, or “the integral screw guides” with which the claimed “tool” is designed to work. Without reference to the preamble, the claimed tool is structurally incomplete in that it is unclear what type of slot or indentation the prongs on the gripper must be designed to engage, where the screw guides need to be placed, or how they are to be designed so that the tool can control the screws’ direction.

The preamble resolves those questions by describing an intervertebral cage that is part of the “universal, intervertebral bone fusion spacer.” That cage has a “slot or indentation” on each longitudinal end, which is “formed adjacent to an edge of an upper surface of the intervertebral cage.” In addition, the preamble clarifies that the tool must be capable of controlling screws that go into “the” first integral screw guide and “the” second integral screw guide, which are included in “the” intervertebral cage and allow for the insertion of the universal bone fusion disc spacer.

By referencing “the intervertebral cage” and “the integral screw guide,” the claim effectively incorporates by reference the description of those terms within the preamble.

Second, I disagree with Plaintiff’s position that the *entirety* of the preamble—particularly the part containing the term “universal”—is not limiting because none of the terms in the body reference the phrase “universal, intervertebral combination internal screw guide fixation apparatus.” Plaintiff points out that the claim’s body language describes only “[a] tool” that can manipulate and insert the universal, intervertebral bone fusion spacer to provide fusion of the first vertebral body to the second vertebral body via biological bone fusion and screw fusion. Thus, according to Plaintiff, the portion of the preamble using the term “universal” constitutes language stating a purpose or intended use and thus cannot be construed as limiting.

In support of this position, Plaintiff relies on C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340 (Fed. Cir. 1998), wherein the patent claimed:

A biopsy needle for use with a tissue sampling device having a housing with a forward end, a first slide mounted for longitudinal motion within said housing, and a second slide mounted for longitudinal motion within said housing, said biopsy needle comprising:

a hollow first needle having proximal and distal ends;

a second needle extending through said hollow first needle and freely slidable therewithin, said second needle having proximal and distal ends;

a first head mounted to said proximal end of said hollow first needle, said first head including first flange means associated therewith for coupling said hollow first needle to said first slide for longitudinal motion both toward and away from said forward end of said housing; and

a second head mounted to said proximal end of said second needle, said second head including second flange means associated therewith for coupling said second needle to said second slide for

longitudinal motion both toward and away from said forward end of said housing.

Id. at 1348–49. The Federal Circuit found that the preamble’s recitation of the portion and structure of the gun housing into which the claimed needles fit was not limiting because the claimed patent only referred to the needles not the gun. Id. at 1350. The Court determined that the description of the housing defined the intended function of the needles that were the subject of the claim. Id.

In contrast to Bard, the Federal Circuit in Bicon, Inc. v. Straumann Co., 441 F.3d 945 (Fed. Cir. 2006) found a preamble to be limiting for a patent which claimed an apparatus used with dental implants. The patent in suit described a plastic cuff designed to preserve a space around a dental implant so that when a crown was placed on top of the implant, the base of the crown fit beneath the patient’s gum line. Id. at 946. The preamble of the claim recited elements pertaining to the structure of the “abutment” used with the claimed emergence cuff. Id. at 952. Distinguishing Bard, the Court noted that the preamble language in Bard merely described what the claimed needle was for (coupling to the structure in the preamble), but the plain language of the claim did not require an actual coupling to this structure. Id. at 953. With respect to the patent before it, however, the preamble language was limiting because “[d]espite the fact that the claim beg[an] with a reference to the emergence cuff alone, the full text of the claim, read in context of the entire patent, indicated that the claimed invention is the combination of the emergence cuff and the abutment, operating together in the fashion recited in the claim and described in the specification.” Id. at 952; see also Eaton Corp. v. Rockwell Int’l Corp., 323 F.3d 1332, 1340–42 (Fed. Cir. 2003) (distinguishing Bard and finding that preamble was limiting where the manipulation and operation of the structure described by the preamble gave meaning and purpose to the manipulative steps of the claim).

Cognizant that the Federal Court has generally been “disinclined to sanction finding a preamble ‘partially’ limiting by splicing it,” Bio-Rad Labs., 967 F.3d at 1371, I find that the claim at issue is more akin to Bicon than Bard. The tool identified in claim 1 of the ’913 Patent only has “life, meaning, and vitality” when read in conjunction with all of the preamble language. The claim language does not just refer to any gripper with prongs and a screw guide, but rather one that is capable of manipulating and inserting “a universal, intervertebral bone fusion spacer” into a disc space by engaging a certain slot or indentation of the intervertebral cage and controlling the direction of screws into the screw guides contained on that intervertebral cage. In other words, the claimed tool, the bone fusion spacer, and the intervertebral cage are interlocking items operating together in the fashion recited in the claim. The tool’s use with the spacer and cage is not a preferred or intended use; rather it is the precise use of which the tool must be capable. Like in Bicon, the detailed description in the preamble is necessary to define the structure of the claimed device.

This rationale applies equally, if not more so, to asserted claim 47 of the ’022 Patent, which describes the “intervertebral cage.” As noted above, claim 47 states:

A universal, intervertebral combination internal screw guide and fixation apparatus configured to be inserted into a disc space between a first vertebral body and a second vertebral body and to provide fusion of the first vertebral body to the second vertebral body via biological bone fusion and screw fusion, the apparatus comprising:

an intervertebral cage including;

a top wall, a bottom wall, and two sidewalls defining an open space capable of receiving bone filling for the biological bone fusion;

an internal screw guide having an internal bore with an entry opening and an exit opening, the entry opening of the internal bore formed only in a top surface of the top wall and the exit opening formed at least partially in a bottom surface of the top wall and at

least partially in a side surface of the top wall, wherein the internal screw guide further includes a counterbore that is larger than and coaxial with internal bore and has a counterbore entry opening that is formed only in the top surface of the top wall;

a second integral screw guide having a second internal bore with a second entry opening and a second exit opening, the second entry opening of the second internal bore formed only in the top surface of the top wall and the second exit opening formed at least partially in the bottom surface of the top wall and at least partially in a second side surface of the top wall; and

a circular hole extending through the top wall in a direction substantially normal to the top surface of the top wall, wherein the circular hole is positioned between the internal screw guide and the second internal screw guide at the top surface of the top wall.

Although Plaintiff contends that the body of claim 47 of the '022 patent defines a structurally complete “intervertebral cage,” closer scrutiny reveals that the claim language actually discloses an “apparatus comprising” an intervertebral cage with (a) a top wall, bottom wall, and two sidewalls; (b) an internal screw guide; (c) a second internal screw guide; and (d) a circular hole extending through the top wall. By referring to “the apparatus,” the claim necessarily seeks an antecedent basis in the preamble language, which discloses “[a] universal, intervertebral combination internal screw guide and fixation apparatus configured to be inserted into a disc space between a first vertebral body and a second vertebral body and to provide fusion of the first vertebral body to the second vertebral body via biological bone fusion and screw fusion.” In other words, the invention is not merely any intervertebral cage with the indicated specifications and without any requirement as to the cage’s function. Rather, the invention includes the entire “universal, intervertebral combination internal screw guide and fixation apparatus,” which has the capabilities defined by the preamble. And like claim 1 of the '913 patent, the preamble language is not merely an intended use; rather it defines the claimed invention itself.

Third, guidance in the specifications of the patents also supports the conclusion that the preambles limit the claims. “[A] preamble may be construed as limiting when it recites particular structure or steps that are highlighted as important by the specification.” Proveris Sci. Corp. v. Innovasystems, Inc., 739 F.3d 1367, 1372 (Fed. Cir. 2014). For example, in Proveris, the claim at issue read:

An apparatus for producing image data representative of at least one sequential set of images of a spray plume, each of the images being representative of a density characteristic of the spray plume (i) along a geometric plane that intersects the spray plume, and (ii) at a predetermined instant in time, comprising:

an illuminator for providing an illumination of the spray plume along at least one geometric plane that intersects the spray plume; and,

an imaging device for generating the image data representative of an interaction between the illumination and the spray plume along the at least one geometric plane.

Id. at 1372. In determining whether the preamble was limiting, the Federal Circuit noted that he specification identified the invention as producing a “sequential set of images” and focused on the ability of the invention to capture “the time evolution of the spray.” Id. at 1373. The Court determined that the preamble was the only reference in the claim language to the inventive concept of capturing a sequence of images in order to characterize the time evolution of the spray plume. Id. The Court held that “[t]his fact alone is likely sufficient to support a conclusion that the preamble is limiting.” Id. (citing Deere & Co. v. Bush Hog, LLC, 703 F.3d 1349, 1358 (Fed. Cir. 2012) (finding that preamble phrase “rotary cutter deck” was a limitation where the specification referred to “the present invention” as a “rotary cutter deck”); Poly-Am., LP v. GSE Lining Tech., Inc., 383 F.3d 1303, 1310 (Fed. Cir. 2004) (construing preamble as limiting where it disclosed a “fundamental characteristic of the claimed invention”)).

Here, the “Background of the Invention” section of both the ’913 patent and the ’022 patent indicates that the 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 function of an intervertebral spacer which can be filled with bone fusion material(s), as well as a transvertebral bone fusion screw apparatus.” (’913 patent, col. 1, lines 28–35; ’022 patent, col. 1 lines 32–40.) Throughout both specifications, the inventors describe the invention as possible for use in the various regions of the spine and through various approaches, and they specifically discuss an “expandable embodiment of the screw box [that] can also be enlarged and modified to be suitable for cervical, thoracic and lumb[a]r vertebral body replacements.” (See, e.g., ’913 patent col. 3, lines 41–43; ’022 patent, col. 3, lines 52–54.)

Yet, when reaching the claim language itself, the body of claim 1 of the ’913 patent references only a gripper tool with both a plurality of prongs that can engage a slot on an intervertebral cage and a screw guide for controlling a direction of screws. The body of claim 47 of the ’022 patent references an apparatus with an intervertebral cage that has four walls capable of receiving bone filling, two integral screw guides, and a circular hole through the top wall. The preamble of both patents contains the only claim language capturing the “unique universal bidirectional screw (BDS) system” and its application to the spine. Absent the limitations provided by the preamble, the body of the claims fails to capture a fundamental characteristic of the claimed invention.

Finally, I address the parties’ arguments during the claim construction process. The effect of preamble language is a claim construction issue. Cochlear Bone Anchored Solutions AB v. Oticon Med. AB, 958 F.3d 1348, 1354 (Fed. Cir. 2020). District courts may engage in

“rolling claim construction, in which the court revisits and alters its interpretation of the claim terms as its understanding of the technology evolves.” Guttman, Inc. v. Kopykake Enters., Inc., 302 F.3d 1352, 1361 (Fed. Cir. 2002). Moreover, a party is not judicially estopped from asserting a different claim construction position so long as the positions are not “irreconcilably inconsistent” and the change was not done in bad faith. Merck Sharp & Dohme Corp. v. Xellia Pharms. ApS, No. 14-cv-199, 2015 WL 82386 (D. Del. Jan. 6, 2015).

Plaintiff’s arguments during claim construction, however, are instructive as to its own understanding as to the importance and function of the preamble. Specifically, throughout claim construction briefing, arguments made during the Markman hearing, and in a motion for clarification, Plaintiff—albeit urging a different construction of the term “universal”—clearly emphasized that “universal” was a limiting term, asserting:

- “[T]he ’022 and ’913 patents teach that the invention is ‘universal’ in the sense that it ‘can be used as a stand-alone intervertebral device which combines the dual functions of an intervertebral spacer . . . as well as a transverterbral bone fusion screw apparatus.’” (Pl.’s Opening Cl. Constr. Br., ECF No. 117, p. 7)
- “The patent specification makes abundantly clear that ‘universal’ in this context refers to the stand-alone, dual-use (spacer and bone fusion screw apparatus) functionality of the claimed bidirectional screw system.” (Id. at p. 9.)
- “The intrinsic evidence shows that ‘universal’ in the context of the [’913 and ’022 patents] means the invention supports the dual functions of an intervertebral spacer and intervertebral bone fusion screw apparatus . . . In this way, the stand-alone device is more versatile than a device that must be compatible with other specific devices.” (Pl.’s Resp. Cl. Constr. Br., ECF No. 123, p. 2.)
- “The idea of Moskowitz’s invention was to – was to try to preclude that by having a – that’s the sense of the term universal, as used here. We have one device that has dual functionality.” (Tr. Cl. Constr. Hrg. 28:10–13.)
- “The parties genuinely dispute the proper interpretation of the Court’s construction of ‘universal’ as it relates to the ’913 and ’022 patents. Resolution of this dispute affects the infringement and validity issues for the ’913 and ’022 patents.” (Pl.’s Mot. for Clarification, ECF No. 162, p. 9.)

- “Not only will resolution of this dispute [over the meaning of the term ‘universal’] save considerable judicial and party resources, it is legally required.” (Pl.’s Reply, ECF No. 190, p. 1.)
- “[Defendant’s] opposition also fails to rebut the critical fact that its interpretation [of ‘universal’] would exclude each and every embodiment disclosed in the ’913 and ’022 patents from the scope of the claims.” (*Id.* at 1–2.)

These repeated statements made by Plaintiff, in various contexts, that the ’913 and ’022 patents claim a “universal” invention reinforces my finding that the preamble of both patents is indeed limiting.⁵

Having determined that the preambles of both claim 1 of the ’913 patent and claim 47 of the ’022 patent are limiting, I now consider whether Defendant is entitled to summary judgment of noninfringement. “When an accused infringer moves for summary judgment of noninfringement, such relief may be granted only if at least one limitation of the claim in question does not read on an element of the accused product, either literally or under the doctrine of equivalents.” *M2M Solutions LLC v. Enfora, Inc.*, 167 F. Supp. 3d 665, 672 (D. Del. 2016) (citing *Chimie v. PPG Indus., Inc.*, 402 F.3d 1371, 1376 (Fed. Cir. 2005); *TechSearch, L.L.C. v. Intel Corp.*, 286 F.3d 1360, 1369 (Fed. Cir. 2002) (“Summary judgment of noninfringement is . . . appropriate where the patent owner’s proof is deficient in meeting an essential part of the legal standard for infringement, because such failure will render all other facts immaterial.”)). “Thus, summary judgment of non-infringement can only be granted if, after viewing the alleged facts in the light most favorable to the non-movant, there is no genuine issue as to whether’ the accused

⁵ Defendant also argues that, during IPR proceedings for the ’913 and ’022 Patents, Plaintiff repeatedly relied on the preamble to distinguish the claimed invention over the prior art. While statements made by a patent owner during an IPR proceeding can be considered during claim construction and relied upon to support a finding of prosecution disclaimer, the statements used to invoke the doctrine of prosecution disclaimer must “be both clear and unmistakable.” *Aylus Networks, Inc. v. Apple, Inc.*, 856 F.3d 1353, 1359 (Fed. Cir. 2017). Having reviewed the IPR proceedings in this case, I decline to determine whether Plaintiff made any “clear and unmistakable” statements that the term “universal is limiting.

product is covered by the claims as construed by the court.” *Id.* (quoting *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1304 (Fed. Cir. 1999)).

Under this standard, I find, as a matter of law, that Defendant is entitled to summary judgment on Plaintiff’s claims of direct infringement of the ’022 and ’913 patents. “Universal” is a limiting term for both the ’022 and ’913 patents. Plaintiff has expressly stated that it “does not dispute that none of the products accused of infringing the ’022 and ’913 patents is ‘universal’ as construed by the Court.” (PR ¶ 7.) Given this concession and its clear impact on the infringement issue, Defendant cannot, as a matter of law, be liable for infringement.

III. MOTION FOR SUMMARY JUDGMENT ON INDIRECT INFRINGEMENT UNDER 35 U.S.C. § 271(b)

A. Facts Relating to Indirect Infringement

Plaintiff contends that Defendant induced infringement of the ’022 patent, the ’268 patent, the ’319 patent, the ’913 patent, the ’740 patent, and the ’643 patent by providing materials to surgeons—including Surgical Technique Guides, Product Overviews, and through internal sales force presentations—all of which teach surgeons specifically how to use their accused products. Plaintiff posits that for the accused products that do not necessarily infringe on one of Plaintiff’s patents, Defendant’s written materials and Defendant’s sales force presentations teach surgeons to use the products in an infringing manner.

Each of the accused products has a Surgical Technique Guide, which is a document that provides step-by-step guidance for surgeons with respect to how to surgically insert the spinal implant. (Pl.’s Ex. 3, Rule 30(b)(6) Dep. of Archana Bhat (“Bhat Dep.”) 54:9–21.) The Surgical Technique Guides for the alleged infringing products list the instruments that are available in the instrument set. (DSUF ¶ 8; PR ¶ 8.)

One of the instruments included in the accused products' instrument set is a "drill guide" ("DTS") which is used with Defendant's INDEPENDENCE implants and COALITION implants that works with the drill tap and screw instruments. (Def.'s Ex. 20, Rule 30(b)(6) Dep. of Colm McLaughlin ("McLaughlin 30(b)(6) Dep.") 223:6–9.) According to Defendant, the drill guide tool is not *always* used with the INDEPENDENCE and COALITION implants, and there are other options. (Id. at 223:10–24.) Defendant's representative testified that the drill guide tool could, in theory, be removed from the INDEPENDENCE and COALITION sets. (Id. at 224:1–4; see also Def.'s Ex. 14 at Globus-Mosk–00122 (noting that for COALITION instrumentation, "[s]elf-centering instruments ensure proper trajectory without the use of DTS guides.")). Indeed, in 2012, Defendant removed the DTS from certain consigned instrument sets because it was rarely used by surgeons. (Def.'s Ex. 14, Report of Michael Sherman ("Sherman Rep.") ¶ 171 (DTS Guide has "an estimated use in the field of less than 10% of the cases."); Def.'s Ex. 21, Def.'s Rule 30(b)(6) Dep. of Christy Mace ("Mace 30(b)(6) Dep."), 222:11–18.)

According to Plaintiff, however, the insertion tool for each of the accused products is designed to work with the corresponding implant and vice versa. (Rosenberg Rep. ¶¶ 106, 112, 114, 120.) Although the Surgical Technique Guides for at least the COALITION, INDEPENDENCE, and MAGNIFY-S products describe different insertion instruments that a surgeon can choose to use during surgery (Def.'s Exs. 14, 18, 19), Dr. Rosenberg opined that for several of the accused products, surgeons do not have the ability to choose between more than one insertion tool. (Rosenberg Rep. ¶¶ 106, 112, 114, 120.)

Defendant also contends that it does not sell the accused product tools to hospitals. Rather, its sales representatives and distributors "generally maintain custody of the tools, and typically provide the tools to the customer as needed when there is a procedure." (Def.'s Ex. 22, Resp. to

Interrog. No. 2, at 6.) Defendant notes that there are a few instances in which hospitals store or consign the tools. (Id.) Defendant does acknowledge that there “may be instances” in which Defendant sells a set to the hospital directly. (Bhat Dep. 316:8–19.)

The parties agree that the Surgical Technique Guides for at least some of the accused products describe different anchor and screw configurations and different endplate configurations that a surgeon can use during surgery, some of which may be infringing. (DSUF ¶¶ 13–14; PR ¶¶ 13–14.) The Surgical Technique Guides may be provided either prior to the sale of the product or after the sale has been made to assist the surgeon with actual surgery. (Bhat Dep. 55:5–13.) Defendant’s sales representative could either send a copy of the Surgical Technique Guides remotely or physically hand a hard copy to the surgeon. (Id. at 55:15–24.) In addition, Defendant’s sales representatives are commonly at the hospitals and interacting in person with the surgeons and may be present at the surgery to answer any questions depending on the experience level of the surgeon. (Id. at 56: 1–57:4.) The Surgical Technique Guides are typically reviewed with the surgeon prior to the surgery, but in some cases, if the surgeon is familiar with the device or the procedure, he or she may not need the review. (Id. at 57:15–24.)

Each Surgical Technique Guide is imprinted with a disclaimer that states:

The Surgical Technique shown is for illustrative purposes only. The technique(s) actually employed in each case always depend on the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Additionally, as instruments may occasionally be updated, the instruments depicted in this Surgical Technique may not be exactly the same as the instruments currently available. Please consult with your sales representative or contact Globus directly for more information.

(Def.’s Ex. 14; DSUF ¶ 16; PR ¶ 16.)

Defendant also publishes a “Product Overview” for each product that is available to Defendant’s sales representatives before the product launches. Each Product Overview is imprinted with a disclaimer that states: “Confidential and proprietary. Do not distribute. This material is for informational purposes only and is intended only for Globus Medical employees and representatives.” Defendant does not distribute Product Overview documents directly to hospitals or surgeons. (Def.’s Ex. 24; DSUF ¶ 17; PR ¶ 17.)

B. Analysis of Indirect Infringement Claims

Under 35 U.S.C. § 271(b), “[w]hoever actively induces infringement of a patent shall be liable as an infringer.” To demonstrate inducement of infringement, the patentee must establish, first, that there has been direct infringement, and second, that the alleged infringer had “knowledge that the induced acts constitute patent infringement.” Global-Tech Appliances, Inc. v. SEB S.A., 563 U.S. 754, 766 (2011). “Inducement requires evidence of culpable conduct, directed to encouraging another’s infringement, not merely that the inducer had knowledge of the direct infringer’s activities.” DSU Medical Corp. v. JMS Co., Ltd., 471 F.3d 1293, 1306 (Fed. Cir. 2006).

Defendant seeks summary judgment on Plaintiff’s induced infringement claim, arguing that Plaintiff has pointed to insufficient evidence to prove either direct infringement by a third party or intent to induce infringement.

1. Evidence of Direct Infringement by Defendant’s Customers

a. The ’740, ’643, and ’913 patents

Under the first element of an induced infringement claim, a plaintiff must show that a third party directly infringed the asserted claims. Lucent Techs., Inc. v. Gateway, Inc., 580 F.3d 1301, 1322 (Fed. Cir. 2009). A showing of direct infringement by a third party requires *either* a finding

that the accused products necessarily infringe—*i.e.*, that there are no substantial non-infringing uses of a product—or a finding of specific instances of direct infringement by third parties. ACCO Brands, Inc. v. ABA Locks Mfrs. Co., 501 F.3d 1307, 1313 (Fed. Cir. 2007). “On multiple occasions, the Federal Circuit has held that circumstantial evidence is sufficient to support a jury verdict of indirect infringement, both with respect to the element of inducement and the element of direct infringement by the induced party.” IOENGINE, LLC v. PayPal Holdings, Inc., Nos. 18-cv-452, 18-cv-826, 2022 WL 2800861, at *19 (D. Del. June 15, 2022) (collecting Federal Circuit cases). Circumstantial evidence, however, “must show that at least one person directly infringed an asserted claim during the relevant time period.” Toshiba Corp. v. Imation Corp., 681 F.3d 1358, 1364 (Fed. Cir. 2012) (citing Lucent Techs., 580 F.3d at 1317).

The Federal Circuit illustrated the operation of this principle in ACCO Brands, Inc. v. ABA Locks Mfrs. Co., Ltd., 501 F.3d 1307 (Fed. Cir. 2007). There, the plaintiff brought an action against its competitor defendant alleging direct and induced infringement of a patent directed toward locking systems that inhibited theft of equipment such as personal computers. Id. at 1310. In support of its induced infringement claim, the plaintiff argued that a set of instructions in defendant’s product described the infringing method, and it pointed to expert testimony that the infringing use was the “natural and intuitive way to employ the device.” Id. at 1312. Plaintiff asserted that the jury was entitled to accept the expert’s testimony and find that, at least some of the time, all users of defendant’s product would use it in an infringing manner. Id. at 1312. The Federal Circuit rejected this argument noting that the accused device could be operated in both an infringing and in a non-infringing manner, meaning that “the accused device does not necessarily infringe” the patent in suit. Id. at 1313. The Court noted that the plaintiff had not pointed to specific instances of direct infringement, the sole testimony on using the lock in an infringing

manner was plaintiff's expert, and "the record contain[ed] no evidence of actual users having operated the lock in an infringing manner." Id. Based on its determination that the record lacked substantial evidence to support a finding of direct infringement, the Federal Circuit reversed the jury verdict of inducement. Id. at 1314; see also SRI Int'l Inc.v. Internet Sec. Sys., Inc., 647 F. Supp. 2d 323, 338 (D. Del. 2009) (finding no indirect infringement where accused products did not "necessarily infringe" the patents and, at trial, the plaintiff did not present any witness testimony of any of defendant's employees or its actual customers demonstrating that direct infringement occurred).

Here, it is undisputed that the '740, '643, and '913 patents do not "necessarily infringe" because Defendant does not sell pre-assembled systems that necessarily infringe the asserted claims. Rather, Defendant makes implant and instrument sets available to surgeons prior to surgery, and the surgeon chooses, based on his/her experience and skill, which instruments to use with which implant. The Surgical Technique Guides provided by Defendant for the instrument sets products describe different configurations of implants and instruments that a surgeon can use during surgery. Some of the configurations are alleged to infringe the asserted claims, while others are not.

Because there is no dispute that the accused products have non-infringing uses, the accused products do not "necessarily infringe" and Plaintiff must point to specific instances of direct infringement. According to Defendant, Plaintiff has not produced testimony from a single surgeon showing that he/she used Defendant's products in an infringing manner. Defendant contends that the absence of such evidence is crucial because if Plaintiff's documents actually encouraged its customers to infringe, infringement would not be an isolated incident and Plaintiff would be able to adduce evidence of at least one example of actual infringement. See Lucent Techs., Inc., 543

F.3d at 723 (finding no error in court’s analysis that if using the infringing combination of software was “so common and routine, then certainly [plaintiff] could have produced evidence of at least one instance” where infringement occurred.”). Defendant notes that Dr. Rosenberg, Plaintiff’s expert, himself testified that he did not refer to Surgical Technique Guides during surgery and did not rely on sales representatives to teach him how to perform the procedure. (Def.’s Ex. 1, Rosenberg Dep., 32:18–33:10.) Defendant also presses that, Plaintiff did not perform any user surveys or studies to show that all surgeons necessarily used the accused products in an infringing manner. (Id. at 29:10–14.)

Defendant’s argument, however, disregards the principle that a plaintiff need not specifically identify third-party infringers. Rather, it is well established that a party may present “circumstantial evidence that some party committed direct infringement of the asserted method claims by using the accused product.” O2 Micro Int’l Ltd. v. Beyond innovation Tech. Co. Ltd., 449 F. App’x 923, 928 (Fed Cir. 2011); see, e.g., i4i Ltd. Partnership v. Microsoft Corp., 598 F.3d 831, 852 (Fed. Cir. 2010) (“Evidence that consumers were using Word in an infringing manner included Microsoft data on usage of Word, as well as a Microsoft marketing document listing ‘real’ examples of custom XML’s use in Word.”); Arthrocare Corp. v. Smith & Nephew, Inc., 406 F.3d 1365, 1377 (Fed. Cir. 2005) (finding sufficient circumstantial evidence of direct infringement showing that accused products were used in an infringing manner including admissions by the defendant’s expert, videotapes of electrosurgeries during which accused product was used, and an admission by project managers for two of the accused products that the products were used in an infringing manner); Malibu Boats, LLC v. Skier’s Choice, Inc., 534 F. Supp. 3d 888, 904 (E.D. Tenn. 2021) (finding that defendant’s materials and published videos showing boats with surf

systems practicing the patented methods sufficient to create a jury question of whether there was direct infringement by third parties).

While Plaintiff concedes that it has not identified any particular surgeon who used the accused products in an infringing manner, Plaintiff points to several pieces of evidence that it claims shows specific instances of direct infringement for each of the three patents:

- **'740 Patent:** For the accused product to infringe the '740 patent, at least two anchors must be used during surgery. Plaintiff identifies a Defendant-produced spreadsheet for some of the accused products identifying the “anchor unit usage per surgery,” showing over \$32 million in revenue associated with surgeries where surgeons used more than two anchors. (Pl.’s Ex. 8.) Such revenue information reflects usage because Defendant invoices the surgeon’s hospital based on an order form created after surgery, and sales reps then then fill out “usage reports.” (Pl.’s Ex. 9, Rule 30(b)(6) Dep. of Robert Miller (“Miller Dep.”), 158:9–159:21; Pl’s Ex. 3, Bhat Dep. 144:6–145:12.)
- **'643 Patent:** For the accused product to infringe the '643 patent, the accused product must have endplates with spikes or screws to infringe. Plaintiff identifies a Defendant-produced spreadsheet showing usage data for “spike constructs,” which indicates approximately \$8 million in revenue where surgeons used the infringing “spike construct[]” configuration. (Pl.’s Ex. 12, Supp. Resp. to Interrog. No. 17.) Again, the revenue information equates with actual usage. (Miller Dep. 158:9–159:21; Bhat Dep. 144:6–145:12.)
- **'913 Patent:** The '913 patent is directed to an insertion tool. Plaintiff concedes that surgeons have the option to insert implants using the accused implant/drill guide insertion tool or the non-accused laterally holder, but notes that Defendant’s corporate witness and Defendant’s expert both stated that there is at least some minimal (approximately ten percent) usage of the accused tool for inserting implants. (Pl.’s Ex. 13, Rule 30(b)(6) Dep. of Christy Mace (“Mace Dep.”) 219:3–11; Pl’s Ex. 14, Expert Rep. of Michael Sherman (“Sherman Rep.”) ¶ 171.)

Defendant challenges the sufficiency of this evidence, arguing that (a) Plaintiff has failed to connect Defendant’s conduct/marketing materials to these various usages and (b) the evidence shows that non-infringing sales account for at least half of the usage, and a showing that a tool is used in an infringing manner less than 10% of the time is insufficient to support an induced infringement claim.

While Defendant's responses may be highly persuasive to a factfinder, I conclude they are insufficient to justify granting summary judgment. First, Defendant cites to no authority for the proposition that, to prove direct infringement, a plaintiff must connect the reasons for the infringing use with the defendant's conduct. Indeed, the Federal Circuit has emphasized that "where an alleged infringer designs a product for use in an infringing way and instructs users to use the product in an infringing way, there is sufficient evidence for a jury to find direct infringement." Toshiba, 681 F.3d at 1365. The Federal Circuit has "affirmed induced infringement verdicts based on circumstantial evidence of inducement (*e.g.*, advertisements, user manuals) directed to a class of direct infringers (*e.g.*, customers, end users) without requiring hard proof that any individual third-party direct infringer was actually persuaded to infringe by that material." Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc., 843 F.3d 1315, 1335 (Fed. Cir. 2016).

As to Defendant's second argument, it is well established that "a finding of infringement can rest on as little as one instance of the claimed method being performed during the pertinent time period." Lucent Techs., Inc. v. Gateway, Inc., 580 F.3d 1301, 1317 (Fed. Cir. 2009); see also Toshiba Corp., 681 F.3d at 1364. As such, the mere fact that the infringing use of the accused product is less common than the non-infringing uses is of no moment.⁶

⁶ Defendant's cited cases are inapposite. See Exergen Corp. v. Wal-Mart Stores, Inc., 575 F.3d 1312, 1323 (Fed. Cir. 2009) (reversing jury finding of active inducement where accused device did not necessarily infringe and no reasonable jury could find that a purchaser of the accused device who followed the accompanying instructions would have used the device in an infringing manner); MBO Labs., Inc. v. Becton, Dickinson & Co., No. 03-cv-10038, 2011 WL 1740711, at *3-4 (D. Mass. May 6, 2011) (cursorily noting that the plaintiff failed to provide any admissible evidence that any acts of direct infringement occurred); Minsurg Int'l Inc. v. Fronter Devices, No. 10-cv-1589, 2011 WL 486120, at *3-4 (M.D. Fl. Feb. 7, 2011) (noting that because the plaintiff failed to provide any "substantial evidence" that surgeons have used any of the defendant's products in an infringing manner, induced infringement claim could not survive).

In short, Plaintiff’s evidence—while not identifying by name particular surgeons who used the products in an infringing fashion—does create an issue of fact as to whether the accused products were actually being used in an infringing manner. This evidence, taken as true, may be sufficient to support a jury’s finding that at least one surgeon or other end user used the accused products in an infringing way. In turn, a jury could reasonably find direct infringement by a third party.

b. The ’022, ’268, and ’319 patents

In its opening brief in support of its Motion for Partial Summary Judgment, Defendant argued that it was seeking summary judgment on the induced infringement claims as to all of the asserted patents. In doing so, it discussed these patents as a group without parsing out individual proof for each patent and without demonstrating substantial non-infringing uses for any specific accused product.

In response, Plaintiff contends that for the remaining three patents—the ’022, ’268, and ’319 patents—there are no non-infringing configurations of the accused products and, thus, they necessarily infringe. Plaintiff details evidence of how the claims of each of these three patents have no non-infringing uses, such that every use of the accused products constitutes an act of direct infringement. (Pl.’s Opp’n Summ. J. 15–18.) Plaintiff also references the report of its expert, William Rosenberg, who opines that there are no non-infringing uses of the accused products for any of these three patents. (Pl.’s Ex. 1, Decl. of William Rosenberg (“Rosenberg Decl.”), Ex. B (“Rosenberg Rep.”) ¶¶ 106, 114, 130.) Only in its reply brief does Defendant cite to excerpts from the report of its own expert, Michael Sherman, who reaches the opposite conclusion that the accused products have substantial non-infringing uses. (See Def.’s Reply Br. 8 (citing Def. Ex. 2, Sherman Rep. at pp. 66, 104, 115.)

Despite bearing the burden of proving its entitlement to summary judgment, Defendant offers little briefing on this issue and presents only its expert report, which conflicts with Plaintiff's expert report. Based on the limited information before me, I cannot determine whether the accused products for the '022, '268, and '319 patents have substantial non-infringing configurations such that Plaintiff would have to produce evidence of direct infringement. Accordingly, I find that, for purposes of Plaintiff's induced infringement claim regarding these three patents, a genuine issue of material fact remains as to direct infringement.

2. Specific Intent to Induce Infringement

As noted above, to establish liability under § 271(b), a patent holder must also prove that “once the defendants knew of the patent, they ‘actively and *knowingly* aid[ed] and abet[ed] another’s direct infringement.’” DSU Med. Corp. v. JMS Col., Ltd., 471 F.3d 1293, 1305 (Fed. Cir. 2006) (quoting Water Techs. Corp. v. Calco, Ltd., 850 F.2d 660, 668 (Fed. Cir. 1998) (emphasis in original)). The mere knowledge of possible infringement by others is not enough; rather specific intent and action to induce infringement must be proven. Id. (quotations omitted). As clarified by the Federal Circuit:

It must be established that the defendant possessed specific intent to encourage another’s infringement and not merely that the defendant had knowledge of the acts alleged to constitute inducement. The plaintiff has the burden of showing that the alleged infringer’s actions induced infringing acts *and* that he knew or should have known his actions would induce actual infringements.

Manville, 917 F.2d at 553. In short, inducement requires a showing that the alleged inducer knew of the patent, knowingly induced the infringing acts, and possessed a specific intent to encourage another’s infringement of the patent. DSU Med. Corp. v. JMS Co., 471 F.3d 1293, 1304 (Fed. Cir. 2006) (en banc in relevant part). Intent can be shown by circumstantial evidence, but the mere knowledge of possible infringement will not suffice. Id. at 1305–06.

Here, Defendant contends that it is entitled to summary judgment on the inducement of infringement claims because Plaintiff has not shown that Defendant had a specific intent to induce infringement. Specifically, it argues that: (1) liability cannot be predicted on acts that occurred before Defendant had notice of the patent, and (2) there is no evidence that Defendant encouraged, recommended, or promoted use of its implants and instruments in an infringing manner.

a. Pre-notice Activity

Defendant first contends that it cannot be liable because it created the Surgical Technique Guides, Product Overviews, and internal sales force training materials for each of the accused products *before* the issue date of five of the six asserted patents. According to Defendant, the FDA requires Defendant to develop the Surgical Technique Guides before it launches a product on the market. Therefore, Defendant contends that, as a matter of law, these materials are not valid evidence of a specific intent to induce infringement for five of the six patents in this case, given that they were not developed at a time that Defendant had knowledge of the asserted patents.

“Evidence of active steps taken to encourage direct infringement such as advertising an infringing use or instructing how to engage in an infringing use, show an affirmative intent that the product be used to infringe, and a showing that that infringement was encouraged overcomes the law’s reluctance to find liability when a defendant merely sells a commercial product suitable for some lawful use.” Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd., 545 U.S. 913, 936 (2005) (internal quotations omitted). Although advertising and technical support for infringing products can constitute evidence of intent to induce infringement, such marketing activities are not sufficient unless such activities are coupled with actual knowledge of the patents-in-suit and awareness that the accused products infringe the patents-in-suit. ReefEdge Networks, LLC v. Juniper Networks, Inc., 29 F. Supp. 3d 455, 459 (D. Del. 2014). As such, the Federal Circuit has

emphasized that, as a matter of law, affirmative acts taken before a patent issues cannot violate § 271(b). GlaxoSmithKline LLC v. Teva Pharms USA, Inc., 7 F.4th 1320, 1337 (Fed. Cir. 2021).

When, however, a defendant begins an action before a patent issues and then continues to take that action after the patent issues, with intent to cause third parties to directly infringe, a jury can find that the requisite intent exists. Id. at 1337–38 (holding that a jury could infer from defendant’s placement of information on its website—information that was taken from pre-patent press releases—that defendant intended its website to be a source of information for prescribing doctors and that its website promoted the infringing use throughout the period of infringement); Barry v. Medtronic, Inc., 914 F.3d 1310, 1336 (Fed. Cir. 2019) (evidence that, after plaintiff’s patents issued, defendant’s sales force provided training materials to doctors and was constantly teaching surgeons the nuances of and techniques for using the accused devices was sufficient for jury to find induced infringement, even though the accused products were on the market for years before the patents-in-suit issued).

Plaintiff emphasizes that it is not relying solely on Defendant’s one-time creation of the referenced materials, such as Surgical Technique Guides, for evidence of inducement. Rather, Plaintiff relies on Defendant’s post-issuance conduct, including its “continuous and systematic marketing campaign in which its sales force team distributes technique guides to surgeons and performs product demos to encourage surgeons to use the accused products.” (Def.’s Opp’n Summ. J. 21.) In particular, Plaintiff cites the following evidence:

- Defendant’s Rule 30(b)(6) witness Dr. Bhat, testified that the purpose of the surgical technique guides is to instruct the surgeons on how to use the implant, and the guides “are typically reviewed with the surgeon prior to the surgery.” (Bhat Dep. 57:15–24, 205:13–25.) Plaintiff has produced evidence that surgeons used the accused products after the patents issued. (Miller Dep. 158:9–159:21.)

- Defendant’s sales force representatives conduct product demos for surgeons, and other of Defendant personnel provide cadaver labs showing surgeons how to insert the products. (Bhat Dep. 136:22–137:9; 147:14–148:1, 273:15–274:17.)
- Defendant’s Product Overview documents teach sales force representatives how to provide a “successful demo” for surgeons and direct representatives to “[u]se samples to highlight ease of anchor insertion, anchor removal, and accompanying Anchor Removal Tool.” (Pl.’s Ex. 17, at GLOBUS-MOSK_00028911.)
- Plaintiff’s expert Dr. Rosenberg notes that Defendant disseminates brochures and other marketing materials and also maintains a website called MERC academy, which provides events such as symposiums, educational courses, and cadaver labs instructing surgeons how to use the accused products according to the surgical techniques described in the technique guides and training and product demonstration videos. (Rosenberg Rep. ¶ 141.)

Such evidence, if believed by a jury, could support a finding that that Defendant intended to induce infringement subsequent to learning about Plaintiff’s patents.

b. Evidence that Defendant “Encouraged” Surgeons to Infringe

Alternatively, Defendant contends that the record “fails to show that [Defendant] encouraged, recommended, or promoted use of its implants and instruments in an infringing matter.” (Pl.’s Mot. Summ. J. 24.) Defendant asserts that the Surgical Technique Guides merely describe various combinations of implants and instruments that a surgeon could use to perform spinal fusion surgery, and that some of the combinations allegedly infringe while others do not. According to Defendant, Plaintiff fails to show that Defendant’s instructions to surgeons evince the requisite *mens rea* and *scienter*.

“[P]roof of actual intent to cause the acts which constitute the infringement is a necessary prerequisite to finding active inducement.” Hewlett-Packard Co. v. Bausch & Lomb, Inc., 909 F.2d 1464, 1469 (Fed. Cir. 1990); see also DSU Med. Corp. v. JMS Co., Ltd., 471 F.3d 1293, 1306 (Fed. Cir. 2006). As noted above, “[e]vidence of active steps taken to encourage direct infringement such as advertising an infringing use or instructing how to engage in an infringing use, show an affirmative intent that the product be used to infringe, and a showing that that

infringement was encouraged overcomes the law’s reluctance to find liability when a defendant merely sells a commercial product suitable for some lawful use.” Metro-Goldwyn-Mayer, 545 U.S. at 936. Notably, a patentee may prove intent to induce infringement by circumstantial evidence and “[t]he drawing of inferences, particularly in respect of an intent-implicating question . . . is peculiarly within the provision of the fact finder that observed the witnesses.” Broadcom Corp. v. Qualcomm Inc., 543 F.3d 683, 700 (Fed. Cir. 2008) (quoting Rolls-Royce Ltd. v. GTE Valeron Corp., 800 F.2d 1101, 1110 (Fed. Cir. 1986)).

Defendant contends that Plaintiff cites to no evidence that surgeons regularly received and reviewed the Surgical Technique Guides or any other of Defendant’s materials before or during surgery. Defendant further notes that Plaintiff’s own expert, who was a practicing surgeon for more than two techniques, testified that he did not review Surgical Technique Guides either during or in advance of surgery to select which products to use. In addition, Defendant claims that Plaintiff has adduced no evidence of what Defendant’s sales force representatives orally communicate and physically demonstrate to surgeons, such that a jury could infer intent to induce infringement.

Plaintiff responds, that for the accused products of at least three of the patents—the ’022, ’268, and ’319 patents—there is only one possible configuration a surgeon must use, and those configurations necessarily infringe. Plaintiff reasons that Defendant has a “sales force” team to disseminate the Sales Technique Guides and promotional materials and to conduct demos to convince surgeons to use its products. (Bhat Dep. 25:23–27:7.) As such, it presses that there is sufficient evidence of encouragement.

As to the remaining patents—the ’740, ’643, and ’913 patents—Plaintiff again concedes that the accused products have both infringing and non-infringing configurations. Nonetheless,

Plaintiff points to evidence that Defendant instructs its sales representatives to teach use of the accused products in an infringing manner, and advertises that the “two-anchor” configuration of one of the products is “less invasive” in contrast to the non-infringing configuration. (Pl.’s Ex. 17 at GLOBUS-MOS_00028913; Ex. 18 at GLOBUS-MOSK_00000237; Ex. 19 at GLOBUS-MOSK_000290072.) As this evidence suggests that accused products were “capable of infringing” and Defendant’s representatives actively taught some of these infringing configurations to surgeons, a jury could find that Defendant designed the products to be used in an infringing way and purposefully instructed users to use them in the infringing way through its sales force presentations. At minimum, such evidence is sufficient to create a genuine issue of fact and preclude summary judgment.⁷

IV. CONCLUSION

In light of the foregoing, I will grant summary judgment in favor of Defendant with respect to Plaintiff’s direct infringement claims relating to the ’913 patent and the ’022 patent. As to Plaintiff’s claims of induced infringement, I find that a genuine issue of material fact remains regarding whether there was direct infringement by third parties and whether Defendant possessed the requisite intent to induce infringement. An appropriate Order follows.

⁷ Defendant’s cited cases are inapposite. In Vita-Mix Corp. v. Basic Holding, Inc., 581 F.3d 1317, 1329 & n.2 (Fed. Cir. 2009), the Federal Circuit found that the original product instructions did not evidence a specific intent to encourage infringement since they taught a “stirring action” which the defendant could have reasonably believed was non-infringing. In addition, the amended product instructions taught an undisputedly non-infringing use and the product design naturally encouraged a non-infringing use, evidencing intent to *discourage* infringement. *Id.* at 1329. By contrast here, Plaintiff presents evidence that the Surgical Technique Guides taught infringing uses and that Defendant’s sales representatives were directed to teach surgeons to use the accused products in an infringing manner, evidencing an intent to *encourage* infringement.

In ACCO Brands, Inc. v. ABA Locks Mfrs. Co., Ltd., 501 F.3d 1307 (Fed. Cir. 2007), the Federal Circuit determined that there was no evidence of direct infringement and, therefore, never reached the issue of whether there was evidence of intent to induce infringement. *Id.* at 1314.

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

MOSKOWITZ FAMILY LLC

Plaintiff,

v.

GLOBUS MEDICAL, INC.

Defendants.

CIVIL ACTION

No. 20-3271

ORDER

AND NOW, this 22nd day of December, 2022, upon consideration of Defendant Globus Medical, Inc.'s Motion for Summary Judgment (Doc. No. 237), Plaintiff Moskowitz Family LLC's Response (Doc. No. 240), Defendant's Reply (Doc. No. 247), and Plaintiff's Sur-reply (Doc. No. 250), it is hereby **ORDERED** that the Motion is **GRANTED IN PART** and **DENIED IN PART** as follows:

1. Summary judgment is **GRANTED** in favor of Defendant and against Plaintiff on Plaintiff's claims of direct infringement of the '913 patent and the '022 patent.
2. Defendant's Motion is **DENIED** with respect to Plaintiff's claims of induced infringement under 35 U.S.C. § 271(b).

It is **FURTHER ORDERED** that a trial scheduling conference is set for **Tuesday, January 24, 2023 at 2:30 p.m.** Counsel are directed to dial in as follows: (1) Call: 888-684-8852; (2) Enter access code: 2187450#; (3) Press # to enter as a participant.

BY THE COURT:

/s/ Mitchell S. Goldberg
MITCHELL S. GOLDBERG, J.

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

MOSKOWITZ FAMILY LLC

Plaintiff,

v.

GLOBUS MEDICAL, INC.

Defendant.

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CIVIL ACTION

No. 20-3271

AMENDED JUDGMENT

AND NOW, this 4th day of March, 2024, after a jury trial held in the above case, pursuant to Federal Rule of Civil Procedure 58, and in accordance with the jury’s verdict, all prior proceedings herein, and the entirety of the record available to the Court, I find the following:

1. On December 13, 2023, the jury returned a verdict finding that Plaintiff had not met its burden of proving, by a preponderance of the evidence, infringement by certain of Defendant’s accused products of specified claims on three of the patents-in-suit. The jury also found that Defendant had not met its burden of proving, by clear and convincing evidence, that the specified claims of three of the patents-in-suit were invalid. This verdict did not address all claims and counterclaims raised in the parties’ respective pleadings.
2. The parties dispute whether the jury’s verdict disposed of all of Plaintiff’s infringement claims on all patents asserted in the Second Amended Complaint (“SAC”) or whether that verdict only pertains to those claims that were not withdrawn by Plaintiff during the course of litigation. Having reviewed the parties’ submissions on this issue (Doc. Nos. 371 and 372), I find that the jury’s verdict only addressed the specific claims before it and that all other claims should be dismissed, but without prejudice to Plaintiff’s right to file a new lawsuit on these claims.
3. The Federal Circuit has declined to hold that “a formal motion or stipulation is required to remove claims from a case On the contrary, . . . a patentee’s announcement that it was no longer

pursuing particular claims, coupled with its ceasing to litigate them, [is] sufficient to remove those claims even without such formalities.” Alcon Research Ltd. v. Barr Labs., Inc., 745 F.3d 1180, 1193 (Fed. Cir. 2014). “A court should not render judgment with respect to claims ‘reference[d] in the complaint’ but not raised in the pretrial statement or litigated at trial; ‘a reference in the complaint is not sufficient to support a judgment.’” Id. (quotation omitted). Rather, a notification by a plaintiff that it is no longer pursuing certain claims is “akin to either a Federal Rule of Civil Procedure 15 amendment to the complaint . . . or a Rule 41(a) voluntary dismissal of claims without prejudice.” SanDisk Corp. v. Kingston Tech. Co., 695 F.3d 1348, 1353 (Fed. Cir. 2012). “The scope of any judgment should conform to the issues *that were actually litigated*.” Alcon, 745 F.3d at 1193 (emphasis added).

4. In assessing Defendant’s position that the jury verdict of noninfringement mandates dismissal of all of Plaintiff’s remaining claims with prejudice, I have considered the Federal Circuit’s decision in Nuance Communications, Inc. v. ABBYY USA Software House, Inc., 813 F.3d 1368 (Fed. Cir. 2016) but find it distinguishable. There, the plaintiff voluntarily narrowed the case to its best patents, and the extensive course of dealings between the parties revealed that Plaintiff “only intended to have a single trial on a subset of patents that would be representative of all patents.” Id. at 1374. The Federal Circuit reviewed the factual record to find that “as the district court winnowed the case, [the plaintiff] made no motion, objection, or assertion otherwise that an limits on the number of claims or patents it could assert deprived it of any due process rights to adjudication on each unique legal issue its operative complaint presented.” Id. at 1376.
5. Here, by contrast, Defendant has pointed to no similar factual record that would overcome the principles set forth in Alcon. Based on my scheduling orders, Plaintiff was *required* to narrow its asserted patent claims, and Defendant was required to narrow its asserted primary prior art references. (See ECF No. 98.) Each of Plaintiff’s narrowing of claims was accompanied by a reservation of rights in which Plaintiff “reserve[d] the right to assert any of the non-selected claims

in a different proceeding.” By the time of trial, the claims were substantially narrowed, and neither party raised any arguments or evidence on the merits of infringement or validity of those claims that were not placed before the jury.

6. Defendant contends that it raised non-infringement counterclaims as to all the patents and claims asserted in the Second Amended Complaint, thus preserving its right to judgment on those claims. But Defendant’s pretrial memorandum narrowed its counterclaims to only those patents pursued by Plaintiff, and, at trial, Defendant presented invalidity arguments on only those narrowed patent claims, thus implicitly withdrawing its counterclaims on such other patents. Courts typically encourage and require parties to narrow their case for trial and should “not penalize such attempts to narrow issues by entering judgment on issues not presented at trial.” VirnetX Inc. v. Apple Inc., 925 F. Supp. 2d 816, 849 (E.D. Tex. 2013), aff’d in part, vacated in part, rev’d in part on other grounds, 767 F.3d 1308 (Fed. Cir. 2014).

WHEREFORE, it is hereby **ORDERED** that **JUDGMENT IS ENTERED** as follows:

- a. Judgment is entered in favor of Defendant and against Plaintiff on Plaintiff’s claims of infringement of claim 1 of Plaintiff’s U.S. Patent No. 10,307,268 (the “’268 Patent”) by Defendant’s RISE and RISE-L products.
- b. Judgment is entered in favor of Plaintiff and against Defendant as to Defendant’s claims of invalidity of claim 1 of the ’268 Patent.
- c. Judgment is entered in favor of Defendant and against Plaintiff on Plaintiff’s claims of infringement of claim 1 of Plaintiff’s U.S. Patent No. 10, 478,319 (the “’319 Patent”) by Defendant’s RISE, RISE-L, SABLE, MAGNIFY-S, ELSA, and CALIBER products.
- d. Judgment is entered in favor of Plaintiff and against Defendant as to Defendant’s claim of invalidity of claim 1 of the ’319 Patent.
- e. Judgment is entered in favor of Defendant and against Plaintiff on Plaintiff’s claim of infringement of claim 1 of Moskowitz’s U.S. Patent No. 10,028,740 (the “’740 Patent”) by

Defendant's COALITION MIS, HEDRON IA, CORBEL, and INDEPENDENCE MIS products.

- f. Judgment is entered in favor of Plaintiff and against Defendant as to Defendant's claim of invalidity of claim 1 of the '740 Patent.¹

It is **FURTHER ORDERED** that:

- a. Any motion for costs and attorneys' fees (including under 35 U.S.C. § 285) shall be filed within **fourteen (14) days** after the entry of this judgment.
- b. All claims not presented to the jury are dismissed without prejudice.
- c. This Amended Judgment disposes of all claims and all parties remaining in this action and is final and appealable.

BY THE COURT:

/s/ Mitchell S. Goldberg
MITCHELL S. GOLDBERG, J.

¹ Pursuant to my December 22, 2022 Summary Judgment Order, judgment was already entered in favor of Defendant and against Plaintiff on Plaintiff's claims of direct infringement on all claims of the '913 Patent and the '022 Patent.

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

MOSKOWITZ FAMILY LLC

Plaintiff,

v.

GLOBUS MEDICAL, INC.

Defendants.

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CIVIL ACTION

No. 20-3271

MEMORANDUM OPINION

Goldberg, J.

August 13, 2024

This case involves patent infringement and invalidity claims centered around spinal implants. Plaintiff Moskowitz Family LLC holds several patents spinal implant-related patents designed to avoid the adverse outcomes that sometimes occur with spinal fusion surgery. Plaintiff's inventions include minimal impaction, steerable, and custom-fit intervertebral implants that minimize musculoskeletal disruption and nerve root retraction during and after the procedure. Defendant Globus Medical, Inc. is a spinal fusion company that sells intervertebral spinal implants.

On November 20, 2019, Plaintiff sued Defendant alleging both direct and indirect infringement of these various patents. Defendant counterclaimed on invalidity grounds. Following a trial held from December 4, 2023 to December 13, 2023, a jury returned a verdict finding that Plaintiff had not met its burden of proving, by a preponderance of the evidence, infringement by certain of Defendant's accused products of specified claims on three of the patents-in-suit (the '269 patent, the '319 patent, and the '740 patent). The jury also found that Defendant had not met its burden of proving, by a preponderance of the evidence, that the specified claims of three of the patents-in-suit were invalid.

Currently before me is Plaintiff's Motion for Judgment as a Matter of Law under Federal Rule of Civil Procedure 50(a) and/or for a New Trial Under Federal Rule of Civil Procedure 59. For the following reasons, I will deny the Motion in its entirety.

I. MOTION FOR JUDGMENT AS A MATTER OF LAW

A. Standard of Review

To prevail on a renewed motion for judgment as a matter of law following a jury trial and verdict, the moving party "must show that the jury's findings, presumed or express, are not supported by substantial evidence or, if they were, that the legal conclusion(s) implied [by] the jury's verdict cannot in law be supported by those findings." Pannu v. Iolab Corp., 155 F.3d 1344, 1348 (Fed. Cir. 1998) (internal quotations omitted). "Substantial evidence" is defined as "such relevant evidence from the record taken as a whole as might be accepted by a reasonable mind as adequate to support the finding under review." Perkin-Elmer Corp. v. Computervision Corp., 732 F.2d 888, 893 (Fed. Cir. 1984).

The court should only grant the motion "if, viewing the evidence in the light most favorable to the nonmovant and giving it the advantage of every fair and reasonable inference, there is insufficient evidence from which a jury reasonably could find liability" or no liability. Lightning Lube, Inc. v. Witco Corp., 4 F.3d 1153, 1166 (3d Cir. 1993) (citing Witekamp v. Gulf Western Inc., 991 F.2d 1137, 1141 (3d Cir. 1993)). "In determining whether the evidence is sufficient to sustain [the verdict], the court may not weigh the evidence, determine the credibility of witnesses, or substitute its version of the facts for the jury's version." Lightning Lube, 4 F.3d at 1166 (citing Fineman v. Armstrong World Indus., Inc., 980 F.2d 171, 190 (3d Cir. 1992)). Rather, the court must resolve all conflicts of evidence in favor of the non-movant. Williamson v. Consol. Rail Corp., 926 F.2d 1344, 1348 (3d Cir. 1991); Perkin-Elmer Corp., 732 F.2d at 893. "Entry of judgment as a matter of law is a 'sparingly' invoked remedy, granted only, if viewing the evidence in the light most favorable to the nonmovant and giving it the advantage of every fair and reasonable inference, there is insufficient evidence from which a jury could reasonably [have reached its verdict]." Marra v. Phila. Hous. Auth., 497 F.3d 286, 300 (3d Cir. 2007).

Where the movant bears the burden of proof, the court must “appl[y] a stricter standard.” AVM Techs., LLC v. Intel Corp., 334 F. Supp. 3d 623, 626 (D. Del. 2018) (citing Fireman’s Fund Ins. Co. v. Videofreeze Corp., 540 F.2d 1171, 1177 (3d Cir. 1976)). To grant judgment as a matter of law in favor of a party that bears the burden of proof on an issue, the Court “must be able to say not only that there is sufficient evidence to support the [movant’s proposed] finding, even though other evidence could support as well a contrary finding, but additionally that there is insufficient evidence for permitting any different finding.” Id.; see also Mentor H/S, Inc. v. Medical Device Alliance, Inc., 244 F.3d 1365, 1375 (Fed. Cir. 2001) (“Courts grant JMOL for the party bearing the burden of proof only in extreme cases, when the party bearing the burden of proof has established its case by evidence that the jury would not be at liberty to disbelieve and the only reasonable conclusion is in its favor.”). “A district court may overturn a jury’s verdict only if upon the record before the jury, reasonable jurors could not have reached that verdict.” LNP Eng’g Plastics, Inc. v. Miller Waste Mills, Inc., 275 F.3d 1347, 1353 (Fed. Cir. 2001).

B. Whether Globus Directly Infringes the ’319 Patent as a Matter of Law

Among the patents-in-suit is the ’319 patent, which is comprised of: (1) an expandable intervertebral spinal implant, and (2) a tool assembly for inserting the implant into the spine and then expanding the implant by rotating a screw within it. The claim language (with emphasis on the disputed limitation) states:

1. A system comprising:

a tool assembly which comprises:

a first tool having a first proximal end and first distal end with a first handle and ***a gripper, the gripper being positioned at the first distal end, cooperating with the first handle***, and having first and second engagement prongs positioned at the first distal end, wherein the first tool defines an adjusting tool passage through the first tool; and

a second adjusting tool having a second proximal end and second distal end with a second handle positioned at the second proximal end, a screw engagement portion positioned at the second distal end, and a shaft extending from the second handle to the screw engagement portion, wherein the shaft of the second adjusting tool is sized with a smaller

diameter than that of the adjusting tool passage such that the second adjusting tool can extend through the adjusting tool passage of the first tool; and

an expandable spinal implant sized and configured to be implanted in a human spine, the expandable spinal implant comprising a first expandable spinal implant structure, a second expandable spinal implant structure, and an adjusting screw having a new screw head and a threaded portion, wherein the expandable spinal implant is configured to expand the first expandable spinal implant structure in response to turning of the adjusting screw, wherein the expandable spinal implant defines first and second tool engagement indentations sized and configured for receiving the first and second engagement prongs of the first tool, wherein the adjusting screw is positioned within the expandable spinal implant in a screw location such that the second adjusting tool can extend through the adjusting tool passage of the first tool to engage the screw head of the adjusting screw while the first and second engagement prongs of the first tool are engaged with the first and second tool engagement indentations of the expandable spinal implant.

(’319 patent, cl. 1 (emphasis added).)

The jury found no infringement of this patent by any of Defendant’s accused products. At trial, Defendant only disputed infringement as to a single limitation—whether the accused products’ inserter tool had an implant gripper “cooperating” with the handle of the inserter tool. According to Defendant, the claim language “cooperating” required that the handle actuate the gripper at the first distal end so that it grasps or grip the implant using its prongs. As the accused products’ handles did not have any role in actuating the gripping functionality of the mechanism that attaches to the implant, Defendant contended that the accused products did not satisfy the “cooperating” limitation.

Plaintiff now contends that it presented voluminous evidence that Defendant’s RISE, CALIBER, and MAGNIFY-S products satisfy each of the limitations of the ’319 patent. With respect to the “cooperating” limitation, Plaintiff argues that the ordinary meaning of the term “cooperating” requires only that two components work together. Because Defendant’s Director of Product Development admitted that the gripper and handle of the accused inserter tool work together, it asserts that the limitation is satisfied.

The crux of the Plaintiff’s Motion turns on the unresolved meaning of the term “cooperating” as used in the ’319 patent. It is well established that, absent a specific definition, “[c]laim terms are generally given their plain and ordinary meaning, which is the meaning one of ordinary skill in the art would ascribe to a term when read in the context of the claim, specification, and prosecution history.” Kyocera Senco Indust. Tools Inc. v. Int’l Trade Comm’n, 22 F.4th 1369, 1378 (Fed. Cir. 2022). “[P]arties cannot reserve issues of claim construction for the stage of post-trial motions.” Hewlett-Packard Co. v. Mustek Systems, Inc., 340 F.3d 1314, 1320 (Fed. Cir. 2003). “When issues of claim construction have not been properly raised in connection with the jury instructions, it is improper for the district court to adopt a new or more detailed claim construction in connection with the JMOL [judgment as a matter of law] motion.” Id. Rather, the issue is “limited to the question of whether substantial evidence supported the verdict under the agreed instruction.” Id. “In other words, where the parties and the district court elect to provide the jury only with the claim language itself, and do not provide an interpretation of the language in light of the specification and the prosecution history, it is too late at the JMOL stage to argue for or adopt a new and more detailed interpretation of the language and test the jury verdict by that new and more detailed interpretation.” Id. at 1320–21; see also Packet Intelligence LLC v. NetScout Syst., Inc., 965 F.3d 1299, 1312 (Fed. Cir. 2020) (holding that where parties and court elect to provide the jury with only the claim language itself, analysis on JMOL “is confined to whether substantial evidence supports the jury’s verdict under the undisputed claim construction at trial”).

The Federal Circuit has refused to remand a case for further construction of a claim term when the purported dispute over claim construction was raised for the first time after the jury verdict. Verizon Servs. Corp. v. Cox Fibernet Virginia, Inc., 602 F.3d 1325, 1333–34 (Fed. Cir. 2010); see also Lighting Ballast Control LLC v. Philips Elecs. N. Am. Corp., 790 F.3d 1329, 1341 (Fed. Cir. 2015) (holding that a party waived its right to seek a new claim construction because it did not seek that construction until after trial). When there is conflicting evidence as to the plain and ordinary meaning of a term, a jury is entitled to credit certain evidence, and that determination should not be disturbed on a JMOL motion.

See Finesse Wireless LLC v. AT&T Mobility LLC, 689 F. Supp. 3d 332, 352 (E.D. Tex. 2023). “[T]he verdict must be tested by the charge actually given and by giving the ordinary meaning of the language of the jury instruction.” Hewlett-Packard, 340 F.3d at 1321.

Here, during claim construction proceedings in July 2021, neither party indicated that the term “cooperating” required construction beyond its plain and ordinary meaning. The parties then proceeded through expert discovery, at which time Defendant’s expert Michael Sherman—in a report submitted on April 4, 2022—opined that any alleged gripper of an accused Globus product “does not cooperate with the first handle” because “*the plain meaning of the term given the context is that there must [be] some actuation of the gripper by or using the handle.*” (Sherman Report ¶ 119 (emphasis added).) As such, Plaintiff was on notice of Defendant’s position that the plain and ordinary meaning of the word “cooperate” as used in the ’319 patent to one of ordinary skill in the art was that it meant to “actuate.”

Just prior to trial, the parties brought to light an additional claim construction dispute regarding the term “connecting support structure.” In an effort to avoid additional construction issues being raised at trial, I directed the parties to brief any remaining terms requiring claim construction. (See Nov. 21, 2023 Order, ECF No. 319.) Neither party raised the term “cooperating.”

Thereafter, at trial, Plaintiff’s expert, Dr. William Rosenberg provided limited testimony regarding whether Defendant’s RISE, CALIBER, and MAGNIFY-S products satisfied the “cooperating” claim limitation. Dr. Rosenberg testified that the RISE inserter tool “has a handle at one end and a gripper at the other that cooperate together.” (N.T. 12/6/23 at 29:1–3.) This configuration was shown in Exhibit PTX-416.41. Dr. Rosenberg went on to explain that the “cooperating” claim limitation was present in both the CALIBER and MAGNIFY-S products. (Id. at 28:25–30:13.) Dr. Rosenberg’s entire testimony on this subject was:

Q. What does this claim limitation [“cooperating” in the ’319 patent] require?

A. So this is talking about the first tool. And that has a handle at one end and a gripper at the other that cooperate together. And it has

engagement prongs at the end, as well as a passageway for that expansion tool.

Q. Does the RISE product have an inserter tool at the gripper.

A. It does. We can see here from the technique guide—on the left is a photograph, PTX—which is a photograph, PTX-416, page 41. ON the right is an illustration from the technique guide, PTX-58, page 9. And there—there’s the first tool with its handle and gripper.

(*Id.* 28:25–29:11.) Dr. Rosenberg played a video, created by Defendant, to show the placement of the RISE and its expansion. (*Id.* at 39:14–25.) He opined that the video showed “the tool coming in and mating with [the implant], with the prongs.” (*Id.* at 40:2–3.) Dr. Rosenberg did not provide any testimony showing “cooperation” in connection with that video. (*Id.* at 39:14–46:19.) Moreover, Dr. Rosenberg was never asked to explain what the claim term “cooperating” meant, never suggested that it meant only that the handle and gripper “act or work with” one another, and never explained how he applied it to the facts of the case.¹ The jury was at liberty to find his testimony not credible.

Subsequently, Defendant’s expert, Michael Sherman, provided the following testimony regarding the plain and ordinary meaning of the “cooperation” limitation in the ’319 patent:

Q. What is it—what—what does cooperation between the gripper and the handle involve?

A. I think it involves an actuation. Right? It’s—it’s—it’s a co-operation. You need to do something—so—well, you need to do something to the handle—for it—and it does something to the gripper. They operate together. They co-operate. There needs to be some action and reaction,

¹ Plaintiff contends that Defendant did not ask Dr. Rosenberg about the “cooperating” term on cross-examination, and, thus, he was unable to respond to Defendant’s arguments. As Defendant correctly notes, however, Plaintiff had the burden to show infringement during direct, knew what Defendant’s position was, and failed to elicit the proper testimony during direct. Defendant had no obligation to raise the issue on cross-examination.

Plaintiff also argues that, after Defendant’s expert testified, it requested that Dr. Rosenberg be permitted to provide rebuttal testimony, but I initially declined to allow it. When I asked Plaintiff’s counsel to explain what exactly Mr. Rosenberg would clarify, counsel identified four specific areas where rebuttal was required: (a) testimony about the second implant structure of the ’268 patent; (b) testimony about serrations on the bone anchor; (c) testimony about a single continuous arc; and (d) “that the tools operate exactly how he believes they operate, but there’s infringement nonetheless.” (N.T. 12/12/23, 166:3–170:22.) I allowed rebuttal testimony on only the first two subject areas. (*Id.*) Plaintiff now contends that Dr. Rosenberg’s rebuttal testimony regarding the “cooperation” limitation would have been included in the fourth subject area. But Plaintiff did not make that argument, let alone explain how it could not have anticipated Mr. Sherman’s definition of “cooperation” based on his expert report. Moreover, even had Dr. Rosenberg given an alternative definition, the jury would have remained free to credit Mr. Sherman’s definition.

Q. Does the handle in the accused products cause any gripping functionality in the accused products?

A. No, it doesn't.

(N.T. 12/11/23 at 181:3–12.) Defense counsel then walked Mr. Sherman through each of the accused products in detail to demonstrate that none of the handles of those products performed any “cooperation” with the gripper. (*Id.* at 181:13–194:4.)

On cross-examination, Plaintiff's counsel pressed Mr. Sherman on the meaning of “cooperating”

Q. So just to make sure we're all clear, you'd agree that the ordinary meaning of cooperate is to act or work with another. Act together; right?

A. I think I said — well, it's to cooperate. To operate together; yeah. If that's what you just said, I think—

Q. To act together; fair?

A. Sure.

Q. Okay. But your opinion is that, for the gripper to cooperate with the handle, there must be some actuation of the gripper by the handle; right?

A. Yes, because it's—it's got to cooperate on the gripping function. So that's how I read the claim. It's got to actuate. There has to be an action, reaction. There has to be something that the handle does so that the gripper grips.

Q. The claim does not use the word actuate; right?

A. No; it doesn't use that.

Q. And when you say actuate, you meant the handle has to actually perform an action on the gripper. Is that what I just heard you say, sir?

A. Yes, I think that's right.

Q. But the claim doesn't say perform action either; right?

A. The claim says cooperate. Cooperating, actually.

Q. Okay. And it doesn't say perform action; right?

A. It doesn't say the words perform action; that's correct.

Q. Okay. And the ordinary meaning of actuate is to put into mechanical action or motion?

A. That's a—I think that's a reasonable meaning.

Q. And that's obviously a different word than cooperate; right?

A. It is.

Q. With a different meaning?

A. I don't—I don't think it's a terribly different meaning. I'm not sure it is, in a context of this claim.

(N.T. 12/11/23 at 228:6–229:13.) Mr. Sherman further stated that his definition of the word “cooperate”—as used in the patent—was based on “a plain and ordinary meaning as would have been known to a person of ordinary skill in the art. So a person like me, an engineer developing an implant

at the time of the invention.”² (*Id.* at 227:25–228:5.); see also *Eon Corp. IP Holdings v. SilverSpring Networks*, 815 F.3d 1314, 1320 (Fed. Cir. 2016) (“The ordinary meaning of a claim term is not the meaning of the term in the abstract. Instead, the ordinary meaning of a claim term is its meaning to the ordinary artisan after reading the entire patent. . . . The claims . . . do not have meaning removed from the context from which they arose.” (internal quotation marks omitted)).

At no point did Plaintiff advance an argument that the “cooperating” claim limitation meant any of the things Plaintiff now says it means: acting together with, moving with, directing, or guiding. Plaintiff points to no other testimony regarding the plain and ordinary meaning of the term “cooperating” to a person of ordinary skill in the art and concedes that Dr. Rosenberg did not otherwise explain the plain meaning of “cooperating.” (Pl.’s Reply Br. 4.)

Plaintiff also raised no issue regarding the proper construction of the term “cooperating” during jury instructions but rather agreed to the jury instructions that provided: “when you look at the claim for words . . . which have not provided a definition, you should apply the ordinary meaning of those terms, as understood by [a] person of ordinary skill in the field of the technology at issue of the patents in suit at the time of their invention.” (N.T. 12/13/23 at 19:1–5.) This instruction, framed without a clarifying construction, placed on Plaintiff the “difficult task of showing, based simply on the words, that the only reasonable view” is that “cooperating” meant acting together with, guiding, or directing, and it failed to meet that burden. *Avid Tech., Inc. v. Harmonic, Inc.*, 812 F.3d 1040, 1049 (Fed. Cir. 2016); see also

² Plaintiff contends that, when analyzing the issue of invalidity and comparing the patents-in-suit to the prior art, Mr. Sherman took the opposite position that the “cooperating” limitation did not require actuation. (N.T. 12/12/23 at 118:4–127:13.) Plaintiff contends that, “[i]t is axiomatic that claims are construed the same way for both invalidity and infringement.” *Amgen Inc. v. Hoechst Marion Roussel*, 314 F.3d 1313, 1330 (Fed. Cir. 2003).

The Federal Circuit, however, has recognized that because the features of the accused product are often undisputed, this axiom results in a common approach by accused infringers: the principal argument challenges a broad claim construction while a contingent argument challenges validity of the asserted patents under 35 U.S.C. § 112 in light of that broad construction. *Id.* Thus, the fact that Mr. Sherman took opposing positions was a legitimate litigation strategy. Here, the jury’s rejection of Defendant’s invalidity argument was consistent with its finding that the plain meaning of the term “cooperating” required actuation and was the same as for infringement.

Enovsys LLC v. Nextel Commc'ns, Inc., 614 F.3d 1333, 1344 (Fed. Cir. 2010) (denying JMOL where “at no time before or during trial did [defendant] object to the district court’s claim construction, request clarification, or offer the construction it now advances on appeal.”). The jury thus properly credited Mr. Sherman’s explanation of the plain and ordinary meaning of the term “cooperating” as being “actuating.” See ePlus, Inc. v. Lawson Software, Inc., 700 F.3d 509, 520 (Fed. Cir. 2012) (“In the absence of such a construction, however, the jury was free to rely on the plain and ordinary meaning of the term . . .”); Comcast IP Holdings I LLC v. Sprint Commc'ns Co., L.P., 850 F.3d 1302, 1312 (Fed. Cir. 2017) (finding that jury reasonably relied upon expert testimony regarding the plain and ordinary meaning of the term); (see also N.T. 12/5/23 at 139:1–6 (Plaintiff’s counsel conceding that what a claim term should mean to a person of ordinary skill in the art is “classic expert testimony”).).

With the term “cooperating” given its plain and ordinary meaning to a person of ordinary skill in the art, there was sufficient evidence from which a jury reasonably could find noninfringement. First, Dr. Rosenberg provided scant testimony on the “cooperating” limitation, never explaining to the jury how the handle and the gripper in the accused products perform any kind of infringing “cooperating” or even how the handles worked with the gripper. Although Dr. Rosenberg relied on Globus technique guides to explain how implants and tools operate, Plaintiff did not identify where those technique guides say anything about the handle “cooperating” with the gripper.

Second, Mr. Sherman opined, in detail, how the accused products failed to meet the “cooperating” limitation, using a definition of “cooperating” that required some actuating or operation between the handle and the gripper. Although he agreed that the “ordinary meaning” of “cooperate” was to act or work with another, he clarified that, in the context of the patent and to one of ordinary skill in the art, the term “cooperate” meant “actuate.” (N.T. 12/11/23 at 228:6–229:13.)

Third, Defendant called its Director of Product Development, Christy Mace, to describe the functioning of the accused products. Ms. Mace testified as follows:

- Q. What role does the handle which you've now removed play in operating the mechanism that grips the CALIBER implant onto the tool?
- A. None at all.
- Q. No role?
- A. No role.

(N.T. 12/11/23 at 63:22–64:2.) She testified similarly with respect to the other accused products. (*Id.* at 64:3–69:10.) On cross-examination, Ms. Mace testified that the gripper and the handle of the accused products “move together” to guide the expandable implant into a patient’s disc space:

- Q. But you agree, once the implant is—is at the end of the tool, the handle is used to guide the tool to the surgical site; right?
- A. Are you asking me if the handle is attached to the inserter; does it all move together?
- Q. That’s what I’m asking.
- A. Yes; it does.
- Q. All right. And so the surgeon uses the—the handle in part to guide the—the implant to the intervertebral space where it can be expanded?
- A. Yes; as it’s attached they would.
- Q. All right. And where he guides the handle at the proximal end, the implant at the distal end will go?
- A. Sure.

(N.T. 12/11/23 at 89:23–90:11.) But Plaintiff does not point to any evidence from any expert that using the handle to “guide” or “direct” a tool is equivalent to the handle “cooperating” with the gripper. Accordingly, this testimony fails to substantiate Plaintiff’s argument.

In short, there was ample evidence that the handles of the accused products did not “cooperate” with the grippers of those products. While Dr. Rosenberg testified differently, the jury was free to assign less weight to his opinion. Ultimately, Plaintiff has not met its burden of showing that, viewing the evidence in the light most favorable to Defendant and giving it the advantage of every fair and reasonable inference, there is insufficient evidence from which a jury could reasonably find noninfringement.

C. Whether Globus Directly Infringes the '740 Patent as a Matter of Law

Plaintiff also claimed that Defendant’s accused products infringed the '740 patent, which relates to an anchor—referred to as a “curvilinear nail-screw”—designed to be implanted in the vertebrae of

the spine while avoiding penetrating the pedicle bones in the vertebral body. Plaintiff's asserted claim one of the '740 patent states (with highlights to show disputed limitations):

A spinal fusion implant comprising:

a first curvilinear nail-screw for penetration and implantation into a first vertebral body along a first curved trajectory that avoids penetrating pedicles, wherein the first curvilinear nail screw extends from a first proximal end to a first distal end along the first curved trajectory with a first head at the first proximal end and a first bone penetrating pointed tip at the first distal end, wherein the first curvilinear nail-screw comprises first ***means for engaging a first cancellous core*** of the first vertebral body positioned along a first distal portion of the first curvilinear nail-screw proximate the first distal end, wherein the first curved trajectory is along a ***first single continuous arc***;

a second curvilinear nail-screw for penetration and implantation into a second vertebral body along a second curved trajectory that avoids penetrating pedicles, wherein the second curvilinear nail screw from a second proximal end to a second distal end along the second curved trajectory with a second head at the second proximal end and a second bone penetrating pointed tip at the second distal end, wherein the second curvilinear nail-screw comprises second ***means for engaging a second cancellous core*** of the second vertebral body positioned along a second distal portion of the second curvilinear nail-screw proximate the second distal end, wherein the second curved trajectory is along a ***second single continuous arc***; and

a connecting support structure defining a first hole sized and configured for receiving the first curvilinear nail screw and a second hole sized and configured for receiving the second curvilinear nail screw such that the first curvilinear nail-screw is held with respect to the second curvilinear nail-screw with the first curvilinear nail-screw extending into the first vertebral body without penetrating pedicles and the second curvilinear nail-screw extending into the second vertebral body without penetrating pedicles.

('740 patent, JTX-3 at cl. 1.)

Figure 1 A of the patent specification illustrates this curvilinear nail screw as follows:

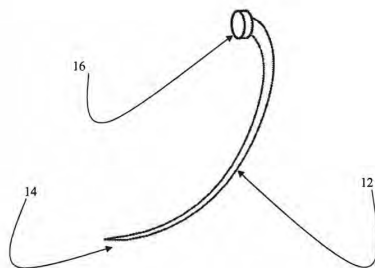
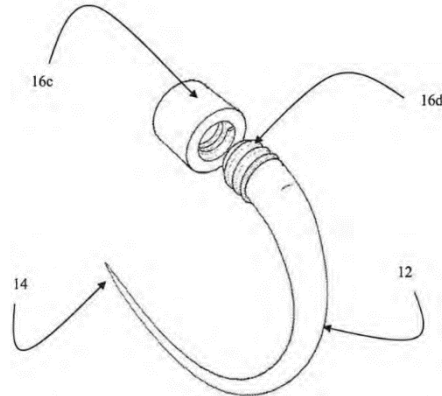


Figure 1 D presents a different view:



At trial, Plaintiff sought to prove that Defendant’s COALITION MIS, INDEPENDENCE MIS HEDRON, and CORBEL products—which are also spinal implant devices—infringe the ’740 patent. Defendant’s noninfringement argument was that: (a) the accused products do not have a “single continuous arc,” and (b) the accused products do not have a “means for engaging a cancellous core.” Plaintiff now contends that, based on the evidence presented at trial, no reasonable jury could have concluded that the bone anchors of the accused products do not meet these claim elements.

1. “Single Continuous Arc”

The first limitation at issue involves the ’740 patent’s requirement that there be a first and second “curvilinear nail-screw” for penetration and implantation wherein the “curved trajectory is along a . . . single continuous arc.” Plaintiff argues that the relevant curved trajectory is the trajectory along which the curvilinear nail-screw is actually implanted into the vertebral body (the bone). According to Plaintiff, only the implanted portion must be curved in a “continuous arc,” while the remainder of the screw, including the head, need not be. Plaintiff contends that both parties’ experts agreed, and Defendant’s own documents show, that the portion of the accused bone anchors that penetrates and is implanted into the bone is continuously curved. (See N.T. 12/6/23 at 91:1–15, 190:1–190:9 (Dr. Rosenberg opining that even though the continuous arc does not extend through the entirety of the head, that is irrelevant to infringement because the head does not penetrate into the bone); N.T. 12/11/23 at 250:20–251:24 (Mr.

Sherman opining that the curvature of the accused anchors runs from the midpoint of the head to the end, and that the anchor head stays in the implant and does not penetrate the bone); PDX-3.144; PTX-38; PDX-3.245 (Defendant’s documents showing that the accused products have a single continuous arc beginning midway through the anchor head).)

Defendant does not dispute Plaintiff’s description of the accused bone anchors, *i.e.*, that the portion that penetrates and is implanted into the bone is continuously curved. Rather, it argues that the claim language of the ’740 patent requires that the entire length of the curvilinear nail screw extend along a “single continuous arc” from end to end, including the head and the tip. Defendant posits that this construction is supported not only by the plain language of the claim but also with the position that Plaintiff took during prosecution of the ’740 patent. Defendant urges that, because the head of the accused products is not curved along the single continuous arc, the accused products do not infringe.

Plaintiff’s motion again constitutes a belated “claim construction argument regarding the meaning of the term [‘single continuous arc’] . . . in the guise of a challenge to the sufficiency of the evidence of [non-]infringement.” ePlus, Inc., 700 F.3d at 520. “On JMOL, the issue here should [be] limited to the question of whether substantial evidence supported the verdict under the agreed instruction.” Hewlett-Packard, 340 F.3d at 1320. “[L]itigants waive their right to present new claim construction disputes if they are raised for the first time after trial.” Conoco, Inc. v. Energy & Env’tl. Int’l, L.C., 460 F.3d 1349, 1359 (Fed. Cir. 2006) (internal citations omitted).

Plaintiff never pressed its version of this claim language during claim construction proceedings, during the supplemental briefing period for claim construction issues prior to trial, or during the jury charge conference.³ Indeed, both parties agreed that the jury should be instructed that the term should be given its plain and ordinary meaning. ePlus, Inc., 700 F.3d at 520 (holding that absent a more detailed interpretation of the claim language presented prior to trial, “[t]he jury was free to rely on the plain and

³ During claim construction, the parties disputed the meaning of the term “curvilinear nail screw” but only as to whether the nail screw must have threads, or whether it could have fishhooks, ridges, or equivalent structures. Neither party raised the issue of what “single continuous arc” meant.

ordinary meaning of the term”). As explained above, a jury can rely on expert testimony as to the plain and ordinary meaning of the term. Id.; see also TRUSTID, Inc. v. Next Caller, Inc., No. 18-cv-172, 2022 WL 318299, at *4–5 (D. Del. Jan. 5, 2022). Plaintiff—as the unsuccessful party—has the burden to show that it has the only reasonable view of the claim limitation, and that the jury’s verdict was not supported by substantial evidence. Comcast IP Holdings I, 850 F.3d at 1312.

Thus, the inquiry here is whether there was substantial evidence on which the jury could find that the language of the ‘740 patent meant that the “single continuous arc” included the head (Defendant’s position), or whether the plain and ordinary meaning of the term was that the head is separate from the portion that defines the “single continuous arc” because the head is not implanted into the vertebral body (Plaintiff’s position). Viewing the trial evidence in the light most favorable to Defendant, I conclude that Plaintiff has not proven entitlement to the “sparingly invoked remedy” of judgment as a matter of law.

As a primary matter, the jury’s interpretation finds support in the plain language of the claim. The claim refers to a “first curvilinear nail-screw” that “extends from a first proximal end to a first distal end along the first curved trajectory,” thus suggesting that “first curved trajectory” goes from end to end. The claim further defines the curvilinear nail screw as having a “first head” at the proximal end and a “first bone penetrating tip” at the distal end. It then states that the “first curved trajectory” must be along a “first single continuous arc.” A reasonable plain reading of this language suggests that “continuous arc” describes the entirety of the nail screw, including the head and the bone penetrating tip. Nothing in the plain language of the claim suggests that only the portion of the nail screw that is implanted into the bone must be curved.

Moreover, both experts testified in manner such that the jury could find that the “single continuous arc” described in the claim language went from end to end of the nail screw, *i.e.*, included the head. Dr. Rosenberg testified:

- “Q. And what is the curved structure that you just referred to called in the patent? A. It’s a nail screw. So it has some features that are like a nail and some features that are like a screw, and there’s a curve to it.” (N.T. 12/6/23 at 80:12–16.)
- Q. Does the ’740 patent teach a benefit of strength compared to straight screws? A. It does. In one of the—the benefits it teaches is the ability to have the same strength as a conventional screw with a curved trajectory. And the curved trajectory allows you to avoid certain structures, if you want to, by changing what is obligated for a screw to be a straight trajectory, we can now curve that. (*Id.* at 81:22–82:4.)
- Q. Let’s talk about insertion of the curvilinear nail screw. How does the ’740 patent describe insertion? A. Well, it talks about using—there’s a pointy tip to it so it can penetrate the bone. And since it’s curved, it can—it can go in any one of a number of different directions. You can decide what direction for it to go. And—and it *includes* a—a head that you can tamp. (*Id.* at 82:7–14 (emphasis added).)
- Q. Would you explain, Dr. Rosenberg, what the next element that we’re going to discuss about the curvilinear nail screw element requires? A. So it requires that this curved trajectory be from the proximal end, which is the one closest to the surgeon, to the distal end, which is the one furthest away from the surgeon. And it has a head at the end closest to the surgeon, the proximal end.” (*Id.* at 95:10–17.)
- Q. Let’s drill down on the claim element that requires a curved trajectory being a single continuous arc. What—what do you understand that claim limitation to require, Dr. Rosenberg? A. Well, as a single continuous arc, meaning that it’s *curved at all spots, it doesn’t come to a point or a straight spot or anything like that* . . . (*Id.* at 96:9–15 (emphasis added).)
- Q. And a single continuous arc is another way of saying a continuous curve. Right? A. Yes. Q. Can’t have any kind of corner or vertex or angle, sharp edge. Right? It’s got to be a continuous curve. Right? A. Correct. (*Id.* at 183:5–10.)
- [Describing the accused product] Q. You are excluding the head from your determination of the single continuous arc. Right? A. *No, I think it starts at the head. Q. Well, it starts at the head but it doesn’t include the head? It includes a portion of the head. Is . . . that fair? A. That’s fair. . . . Q. Okay. If you extended your curve—excuse me. If you included the remainder of the head, that would no longer be a single continuous arc. Correct? A. Yes.* (*Id.* at 184:15–186:10 (emphasis added).)
- Q. [B]ecause if you included my straight line [on the accused products], which goes to the end of the anchor, there’s no infringement. Correct. A. There would be—well, there’s no curve. Correct. (*Id.* at 187:6–8.)

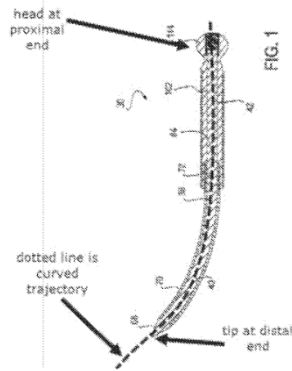
- Q. But you're not including the rest of the head in—on the other end of the line. Right? A. The head doesn't penetrate. (*Id.* at 190:7–9.)

Mr. Sherman then testified:

- Q. Why don't the Globus accused products have a single continuous arc? A. . . . So you need to have a curved—single continuous arc from a first proximal end to a first distal end, from end to end. And I don't believe the Globus anchors have that. I—my analysis shows me that there's a linear section on the Globus anchors. Q. So let me ask you this, *using the plain language*, do the Globus anchors have a single continuous arc from the proximal end to the distal end? A. No, I don't believe they do. (N.T. 12/11/23 at 144:11–145:5 (emphasis added).)
- Q. You were in the courtroom when Dr. Rosenberg started his curve, right, at that crosshair in the middle of the anchor? Do you recall that? A. . . . Yes, I recall that. Q. There's—there's a curve starting at that crosshair going all the way to the pointy end. Does that satisfy this claim limitation? A. No, I don't believe so. Q. Why not? A. *Well, again, I think the claim says from the first proximal end to the first distal end. It doesn't say near the first proximal. It says from the end to end.* (N.T. 12/11/23, 148:3–15 (emphasis added).)
- Q. Do you agree with Dr. Rosenberg's interpretation of this graphic [of the accused product]? A. Well, I think he's showing the curve terminating under the head. And I agree that the curve terminates, you know, short of the distal—proximal end, but I don't believe this anchor meets the claim construction or the claim limitation, which says—and I've highlighted or underlined it anyway, the first proximal end to a first distal end, a single continuous arc. . . . Q. Is the absence of a single continuous arc from the accused anchors enough for the jury to find noninfringement? A. It is. . . ." (*Id.* at 149:5–20.)

Thus, there was ample evidence from which a jury could find that the accused product did not infringe.

Further, the jury considered evidence and testimony regarding the '740 patent's prosecution history. According to the patent prosecution documents for the '740 patent, the patent examiner told Plaintiff that one of the prior art references, Matityahu, disclosed a spinal implant with a curvilinear nail screw, that looked as follows:



(JTX0911.0117–18.) Plaintiff’s validity expert agreed that “the curved trajectory that the patent examiner identified went all the way from the head at the proximal end though the tip.” (N.T. 12/12/23 at 313:4–14.) To overcome this prior art, Plaintiff explained that its nail-screw was different from Matityahu as the “nail-screw was ‘continuously’ curved from proximal to distal end while the screw of Matityahu had a straight portion.” (JTX0911.0168.) Thereafter, in an effort to overcome a different prior art reference—Lieberman—Plaintiff stated that the curved trajectory of its invention extends from the first proximal “which contains the head,” while in Lieberman, “the trajectory ends at the head.” (*Id.*)

At trial, Plaintiff did not address this prosecution history and the inferences to be drawn from therefrom. Plaintiff’s counsel now contends that the prosecution history does not impose Defendant’s “end to end” requirement where the head of the nail-screw must be fully curved. But such attorney argument does not factor into whether the evidence at trial was sufficient to sustain the verdict. Ultimately, the jury had substantial evidence on which to base its finding that the plain and ordinary meaning of “single continuous arc” described in the ’740 patent required that the nail screw be curved end to end, all the way through the head. Upon reaching that conclusion, the jury reasonably found that accused products did not have such a single continuous arc and, thus, did not infringe.

2. “Means for Engaging a Cancellous Core”

The second limitation in dispute for the ’740 patent is the requirement that the product has a “means for engaging a cancellous core.” I construed this claim as a means-plus-function limitation “with

a function of ‘engaging a first/second cancellous core of the first/second vertebral body,’ and a structure of ‘a series of fish-hooks, threads, ridges, or equivalent structures known to a POSITA, extending along a linear direction of the curvilinear nail-screw.’” (D.I. 144 ¶ 7.) Plaintiff now contends that the evidence was insufficient for jury to find that the accused products did not meet this limitation.

In support of its position, Plaintiff cites to the following evidence:

- Dr. Rosenberg identified two structures in the accused products that engage the bone. First, Dr. Rosenberg explained that the accused products have T-shaped ridges. Second, he remarked that the accused products have serrations at the distal tip. He explained that both of these structures are used to “engage the cancellous core,” *i.e.*, grab onto the bone, because they maximize surface area for resistance to expulsion. (N.T. 12/6/23 at 100:22–104:24.)
- Dr. Rosenberg reviewed the CAD drawings for the accused products showing mechanical testing and noted that “there are diagrams or drawings of these anchors with the serrations and T—T-beam, which is used to grab on to the bone.” (N.T. 12/6/23 at 103:17–104:19.) Dr. Rosenberg testified that the Defendant produced mechanical testing document, referred to “robust anchor fixation” appears to by referring to the serrations and T-shaped beam, which are features that engage with the cancellous core. (*Id.* at 28:12–29:16; PTX 272.2.)
- Defendant’s expert, Mr. Sherman, agreed that a structure that has biased or ratcheted faces that extend outwardly from the body of the curvilinear nail screw to engage the surrounding bone would meet the construction. (N.T. 12/11/23 at 246:2–7.) He further conceded that Defendant stated, in its technique guide, that anchor design provides purchase, *i.e.* the ability of one component to grip another without slipping. (N.T. 12/11/23 at 246:14–247:9.) In addition, he agreed that “purchasing,” “opposing withdrawal of the device,” or “grabbing onto” would satisfy the “means for engaging” limitation. (N.T. 12/11/23 at 152:10–20, 244:7–14.)

Defendant responds that the jury had a sufficient basis to warrant a noninfringement finding.

- Mr. Sherman testified that Defendant’s anchors lack the required structure because they do not have fishhooks or threads, and do not have “ridges or equivalent structure.” (N.T. 12/11/23 at 151:2–19.)
- Mr. Sherman then testified that the ridges or ribs on the accused anchors do provide any additional purchase (*Id.* 152:14–153:6.) Moreover, the T-shaped elements do not provide any engaging functionality. (*Id.* 155:23–157:24.)
- Dr. Rosenberg admitted that he did not perform any testing to confirm his opinion that the T-shaped elements and the serrations would provide additional purchase. (N.T. 12/6/23 at 151:5–164:3.)

- Although Defendant’s mechanical testing documents refer to “resistance to expulsion,” the full text of the documents refers to a “[d]ove-tailed anchor design [that] maximizes surface area for resistance to expulsion.” This document does not mention T-shaped elements or serrations. (PTX 272.7.)
- Mr. Sherman explained that the structure on the accused devices that prevented backout was the rotatable cut-out screw heads on the body of the *implant*. According to Mr. Sherman, nothing on the accused *anchors* prevented backout, *i.e.*, engaging a cancellous core. (N.T. 12/11/23 at 154:20–157:24.)
- Mr. Sherman stated that the T-shaped elements and serrations were used to stiffen and strengthen the anchors, not to provide any additional purchase in Defendant’s anchors. (N.T. *Id.* at 152:1–153:6.)
- Dr. Rosenberg relied on an anchor drawing that had a note, “all flags & burrs to be removed, all edges to be left sharp,” as evidence that serrations provide additional purchase in the bone. (N.T. 12/8/23, 34:4–22.) Mr. Sherman explained that a sharper edge is not designed to engage the bone, and there is nothing on it to “grab purchase”—no ridge and no feature to purchase the bone. (N.T. 12/11/23, 157:1–13.)

Whether “means for engaging a cancellous core” is satisfied by the T-shaped elements or serrations on the accused products thus becomes a pure factual issue. Dr. Rosenberg identified several features on the bone anchors—including T-shaped ridges with serrations—that engage the bone. By contrast, Mr. Sherman explained that the anchors did not have any ridges or equivalent structures that provide any engaging functionality or purchase, and the T-shaped elements and serrations were included for bending strength. The jury was free to reject Dr. Rosenberg’s testimony based on any number of reasons: its general distrust of his qualifications, his failure to test the accused products, or perhaps what it perceived to be a mischaracterization of Defendant’s documents. The jury also had ample testimony from Mr. Sherman to substantiate a finding that the accused products lacked a key claim limitation and that the documents on which Plaintiff relied referred to the mechanical strength of the implant and not its ability to engage with the bone. See generally *Packet Intelligence LLC v. NetScot Sys., Inc.*, 965 F.3d 1299, 1311 (Fed. Cir. 2020) (“While NetScot asks us to accept its interpretation of the record, the jury was permitted to weigh Dr. Almeroth’s testimony over that of Mr. Waldbusser.”)

Ultimately, Plaintiff has not met the “high standard needed to disregard the jury’s fact-finding function on this issue.” *Versata Software, Inc. v. SAP Am., Inc.*, 717 F.3d 1255, 1262 (Fed. Cir. 2013).

Even if I were to weigh the evidence differently, I could not substitute my credibility determinations in place of the jury's. Rather, I must view the evidence in the light most favorable to Defendant and give it the benefit of every reasonable inference. Doing so, I find that the jury had sufficient evidence on which it could have found no infringement.

For all of the foregoing reasons, I will deny Plaintiff's Motion for Judgment as a Matter of Law.

II. RULE 59 MOTION FOR NEW TRIAL

In an alternative to its Motion for Judgment as a Matter of Law, Plaintiff moves for a new trial. Motions for new trials are governed by Federal Rule of Civil Procedure 59(a), which provides in pertinent part: "[t]he court may, on motion, grant a new trial on some or all of the issues . . . for any reason for which a new trial has heretofore been granted in an action at law in federal court[.]" Fed. R. Civ. P. 59(a)(1)(A). The Third Circuit has instructed that a new trial should only be granted when "the great weight of the evidence cuts against the verdict and . . . [] a miscarriage of justice would result if the verdict were to stand." Leonard v. Stemtech Int'l Inc., 834 F.3d 376, 386 (3d Cir. 2016) (citing Springer v. Henry, 435 F.3d 268, 274 (3d Cir. 2006)); see also Grazier ex rel. White v. City of Philadelphia, 328 F.3d 120, 128 (3d Cir. 2003) ("[N]ew trials because the verdict is against the weight of the evidence are proper only when the record shows that the jury's verdict resulted in a miscarriage of justice or where the verdict, on the record, cries out to be overturned or shocks our conscience.") (quoting Williamson v. Consol. Rail Corp., 926 F.2d 1344, 1352–53 (3d Cir. 1991).) The decision on whether or not to grant a new trial is committed to the sound discretion of the district court. Wagner by Wagner v. Fair Acres Geriatric Ctr., 49 F.3d 1002, 1017 (3d Cir. 1995).

Plaintiff's Motion for a New Trial rests on several grounds. First, as to the '319 patent, Plaintiff argues that the clear weight of the evidence demonstrates that the "cooperating" limitation was met, *i.e.*, the inserter tool's gripper moves in response to the surgeon moving the handle to guide the implant into place. As set forth above, however, the jury had ample grounds to find that the plain and ordinary

meaning of the term “cooperating” to a person of ordinary skill in the art requires some type of actuation, which was not present in the accused products.

Second, as to the ’740 patent, Plaintiff argues that the clear weight of the evidence shows that Defendant’s accused ’740 products infringe because (a) the bone anchors of the accused products proceed along a single continuous arc, and (b) the bone anchors engage a patient’s cancellous core. Again, however, the jury had sufficient evidence to find that these limitations were not satisfied. As such, Plaintiff is hard pressed to argue that the great weight of the evidence cuts against the jury’s verdict.

Finally, Plaintiff contends that “juror confusion regarding infringement very likely occurred in this case.” (Pl.’s Mot. New Trial 24.) Specifically, Plaintiff notes that, during closing arguments, Defendant argued that the jury should analyze the claims of the priority applications for the asserted patents and note that they differed from the claims of the asserted patents. (N.T. 12/13/23 at 88:7–89:9 (“[T]his is the 2009 application. This is the sum total of the claims in 2009. This is the invention in 2009. Do those claims look anything like the claims of the ’740? Doesn’t say anything about a connecting support structure. Doesn’t say anything about a single continuous arc. It is a different invention.”).) During jury instructions, I told the jury that “[a] provisional application is a temporary placeholder for a more substantive nonprovisional application to follow” and that “[t]he provisional application serves the purpose of setting a priority date for the claimed invention provided it contains 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 make and use the claimed invention.” (N.T. 12/13/23 at 37:3–11.)

Thereafter, during deliberations, the jurors requested the asserted patents’ priority applications and a timeline showing various dates, including the issue date of the priority applications and asserted patents. (N.T. 12/13/23 at 129:15–134:7.). Plaintiff now contends that, “[g]iven the dearth of evidence supporting the jury’s noninfringement verdicts for the ’319 and ’740 patents, there is a strong possibility the jury improperly: i) concluded there is no infringement because the filing dates of the asserted patents

are after the release of the accused products; or ii) compared the accused products to the claims of the priority applications rather than to the asserted patents.”⁴

Plaintiff’s speculation that this was a “strong possibility” of jury confusion does not warrant a new trial. This is especially the case where the priority applications were mentioned throughout the trial, including references made by Plaintiff.

During opening statements, Plaintiff’s counsel was the first to reference the timelines of the asserted patents and their priority applications:

You’re going to see time lines from us. I’m pretty sure you’re going to see time lines from Globus’ lawyers as well. There’s one time line now that I want to show you that just harkens back to something that I said earlier. And that’s the invention time line. ***From our perspective, it will be important***, and the evidence will show, that you have in mind, that while the actual direct patent applications that were filed that led to the 268 and the 319, and the 740 patents were filed in 2018 and 2019, the applications to which they claim priority, which have the same specification and the same figures, and the same disclosure, were filed at the patent office in 2007 and 2009. The 2007 application is the application to which the 268 and 319 claim priority. The 2009 priority date is the one to which the 740 patent claims priority. ***And the reason that’s important*** is because those two applications had already been filed at the patent office before any of the accused products that I just showed you were ever launched in the marketplace.

And so what I expect that you will hear in this case, from Globus is, well wait a minute. Dr. Moskowitz didn’t file the patent applications until long after these products were on the market. That’s not quite right. It’s not quite right in the sense that the applications themselves were filed in 2018 and 2019, and we can’t dispute that. But the disclosure, the inventive ideas, you will hear, they were included in those applications from 2007 and 2009.

(N.T. 12/4/23 at 61:19–62:19 (emphasis added).)

Defendant’s opening responded to these arguments in kind:

⁴ Plaintiff also argues that, during the cross-examination of Plaintiff’s validity expert Dr. Kenneth Gall, Defendant’s counsel asked about the fact that the claims in the priority applications are different from the asserted claims. (N.T. 12/12/23 at 307:11–311:6.) Plaintiff contends that this “sowed confusion” for the jury, and Plaintiff was unable to establish the irrelevance of this fact because I precluded redirect examination of Mr. Gall.

This testimony was not improper, and Defendant properly referenced it in its subsequent examination of Mr. Gall regarding whether these patents were invalid under the prior art.

So remember when I said before—spinal fusion implants have been around for many, many decades. And you heard a lot about—from the plaintiff's lawyer that you're going to see similarities between what the Moskowitz patents claim and things in certain of Globus's accused products.

That there are similarities should come as no surprise because there are a lot of designs for different implants out there that pre-date the Moskowitz's patent claims. They predate the boundaries that Moskowitz wrote to define its property.

Some of those product designs, by the way, are Globus's own product designs. I mentioned the timeline before that I disagreed with. Here's the timeline that shows what really matters. Most of the Globus products in this case came out before Moskowitz applied for those patents.

Remember, when the claims were written, the language describing how you infringe and what you have to have in your product to infringe, Globus's products were out there.

(N.T. 12/4/23 at 81:22–82:14.)

Thereafter, during Mr. Sherman's invalidity testimony, he was asked, on cross-examination, about the fact that each of the asserted patents had a priority date that was much earlier than the 2018 and 2019 filing dates. (N.T. 12/12/23 at 107:13–21.) Mr. Sherman conceded that there was no dispute as to the priority dates for each of the asserted patents. (*Id.* at 111:11–23, 176:25–177:2.) When Mr. Sherman was questioned about differences between the priority applications and the applications for the patents-in-suit and Mr. Sherman indicated that he had not seen the prior applications, Plaintiff's counsel then suggested that it was going to put those priority applications before the witness and the jury but did not do so. (*Id.* at 150:12–25.)

Given these repeated references to the priority applications and the filing timelines, the jury's subsequent request for these documents was neither surprising nor an indication that the jury misunderstood the law. Indeed, Plaintiff concedes that the jury was properly instructed on the infringement analysis and priority dates, and there is a presumption that jurors follow the instructions given to them. Robinson v. First State Community Action Agency, 920 F.3d 182, 191 (3d Cir. 2019). Plaintiff's speculation that the jury's request for the priority application demonstrates a misapplication

of the law fails to meet its burden of showing an “overwhelming probability” that the jury was unable to follow the instructions and a likelihood that the evidence wrongfully admitted was “devastating” to the other party. Id.

Accordingly, I will deny Plaintiff’s Motion for a New Trial. An appropriate Order follows.

(12) **United States Patent**
Moskowitz et al.

(10) **Patent No.:** **US 9,889,022 B2**

(45) **Date of Patent:** ***Feb. 13, 2018**

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

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MD (US); **Mosheh T. Moskowitz**,
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MA (US)

(73) Assignee: **Nathan C. Moskowitz**, Rockville, MD
(US)

(*) Notice: Subject to any disclaimer, the term of this
patent is extended or adjusted under 35
U.S.C. 154(b) by 278 days.

This patent is subject to a terminal dis-
claimer.

(21) Appl. No.: **13/210,157**

(22) Filed: **Aug. 15, 2011**

(65) **Prior Publication Data**
US 2013/0018468 A1 Jan. 17, 2013

Related U.S. Application Data

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Apr. 11, 2011, now Pat. No. 8,353,913, and a
(Continued)

(51) **Int. Cl.**
A61F 2/44 (2006.01)
A61F 2/46 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC **A61F 2/4611** (2013.01); **A61B 17/0642**
(2013.01); **A61B 17/7064** (2013.01);
(Continued)

(58) **Field of Classification Search**

CPC A61B 17/0642; A61B 17/809; A61B
17/8894; A61B 17/7064; A61B 17/86;
(Continued)

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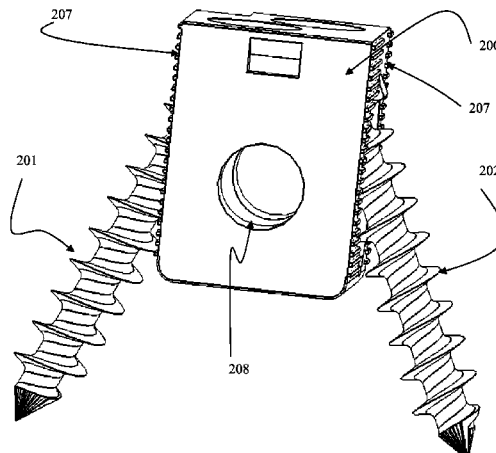
Primary Examiner — Pedro Philogene

(74) *Attorney, Agent, or Firm* — Fish & Richardson P.C.

(57) **ABSTRACT**

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.

70 Claims, 38 Drawing Sheets



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	USPC 623/17.11–17.16; 606/300–305, 249, 99, 606/144, 151, 251, 266; 227/181.1			
	See application file for complete search history.			

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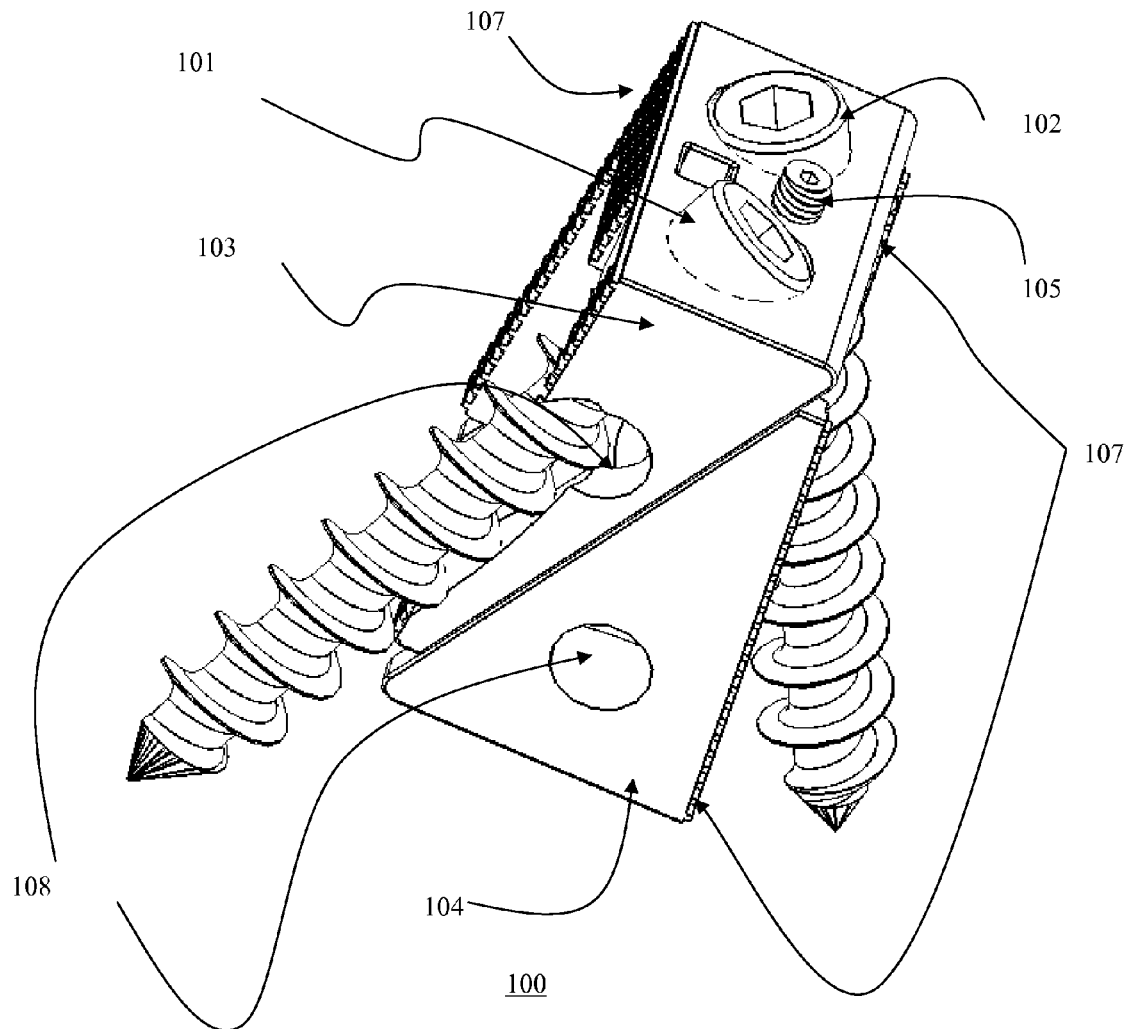
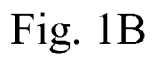


Fig. 1A



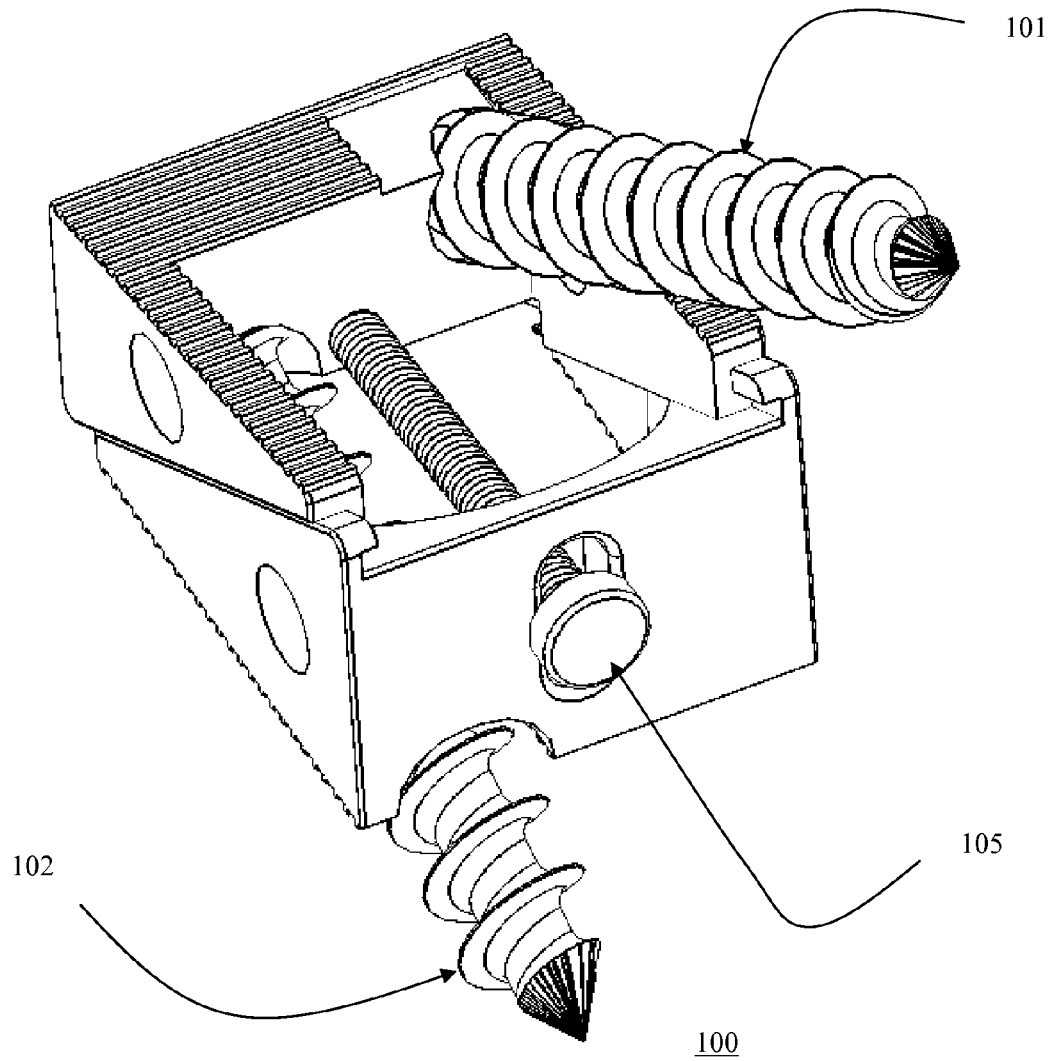


Fig. 1C

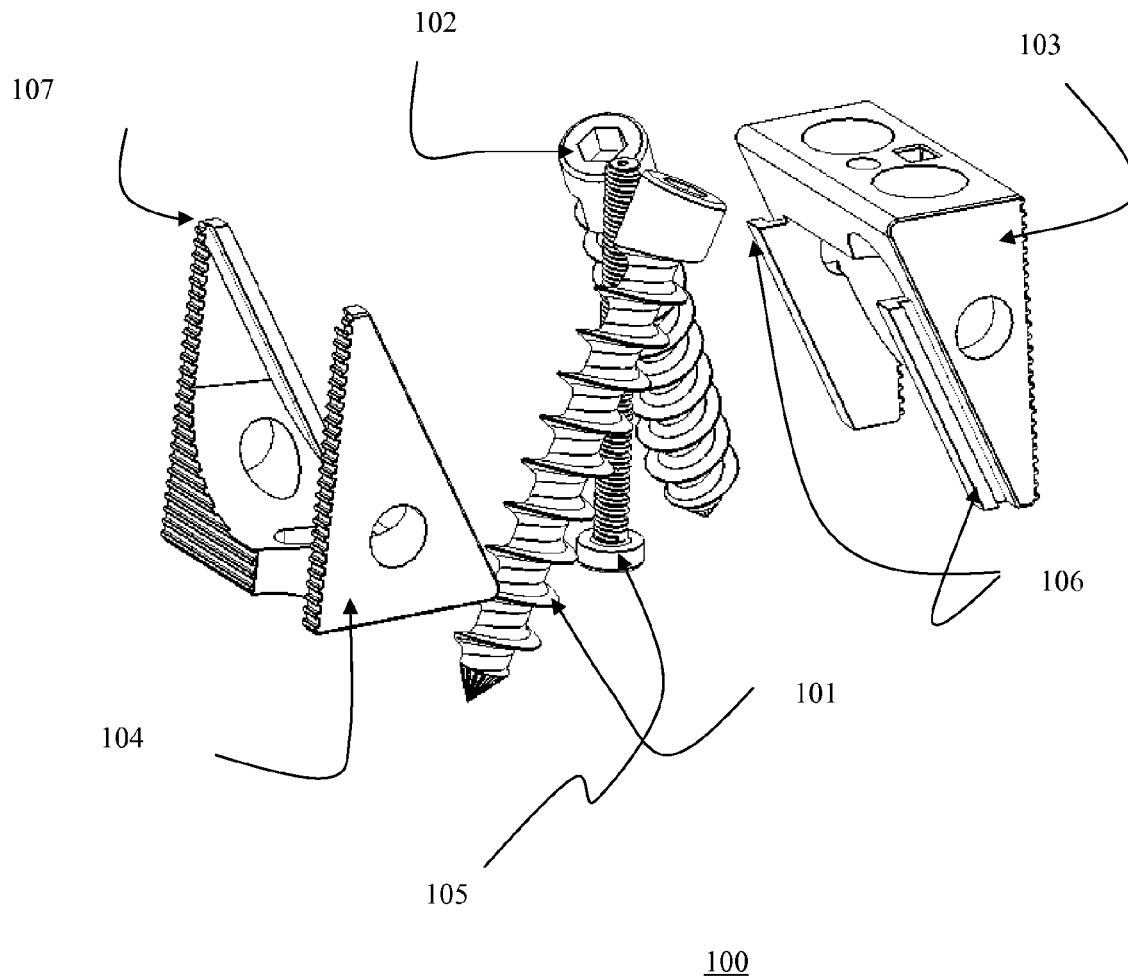


Fig. 1D

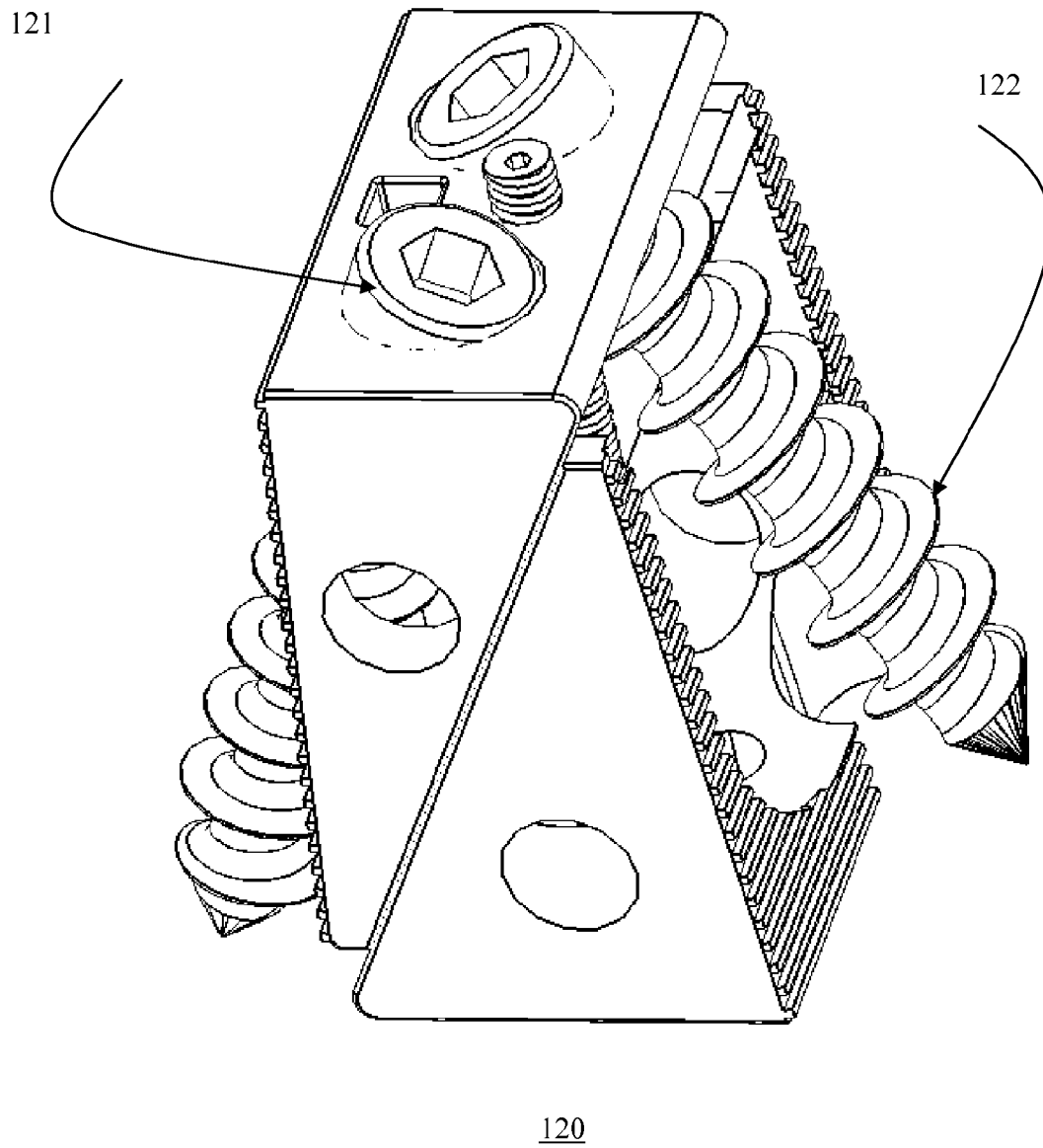


Fig. 1E

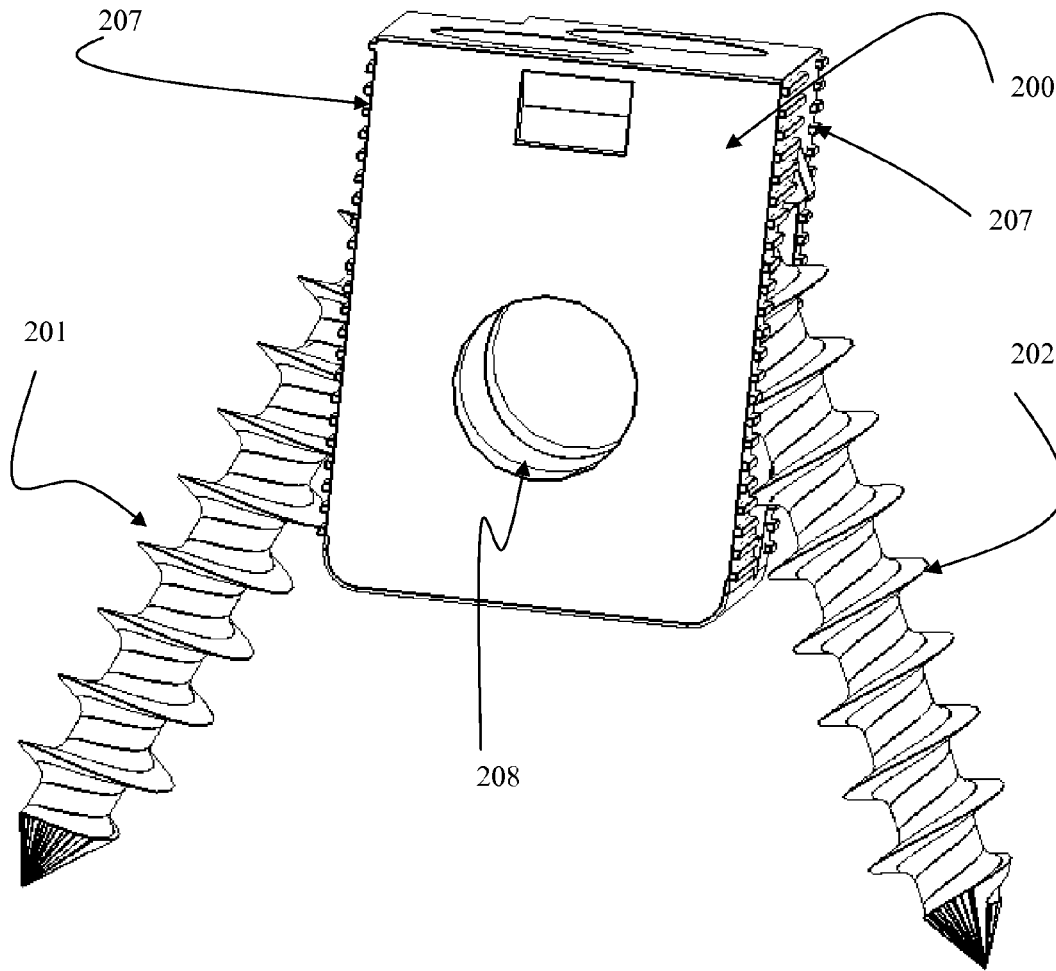


Fig. 2A

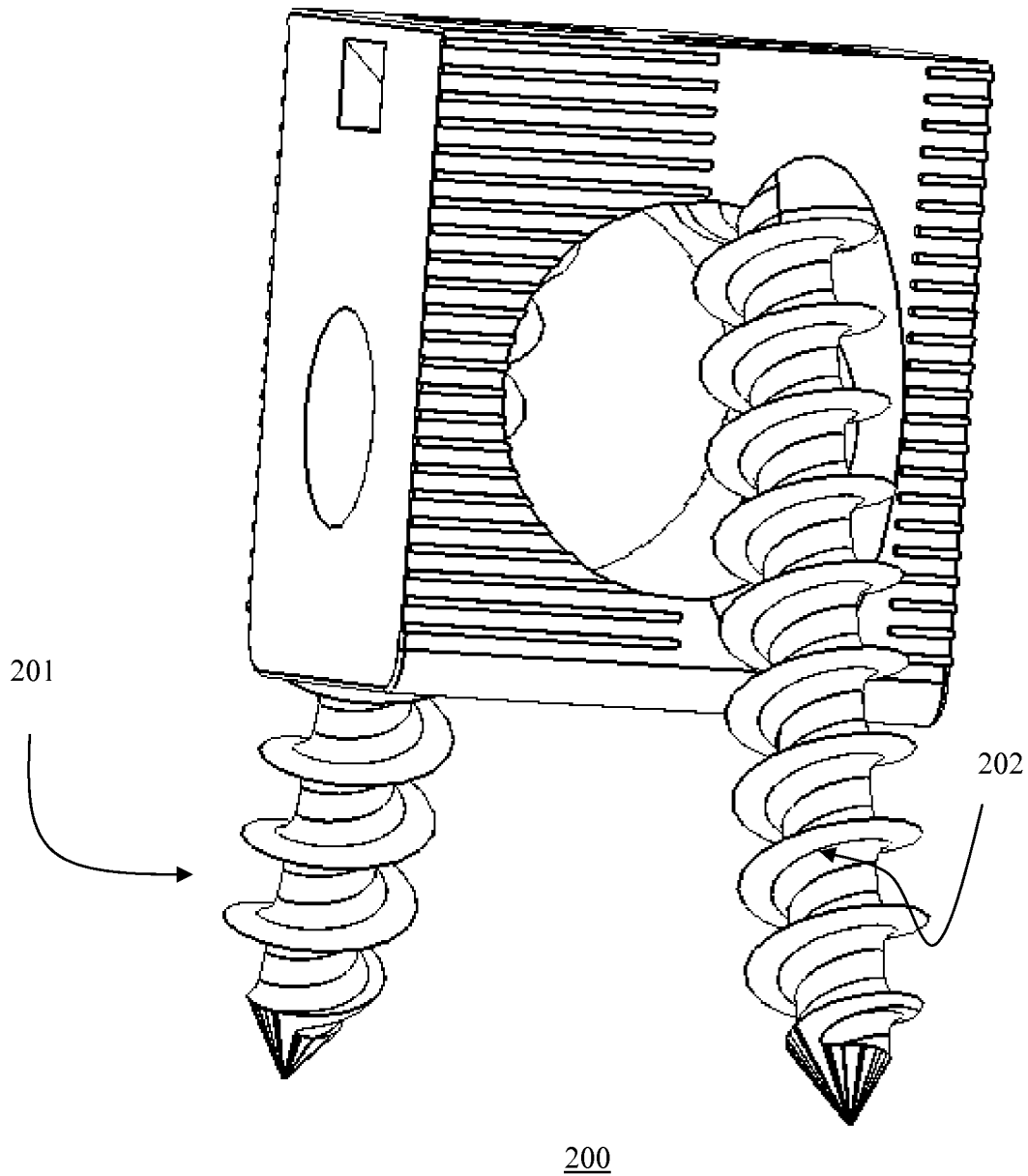


Fig. 2B

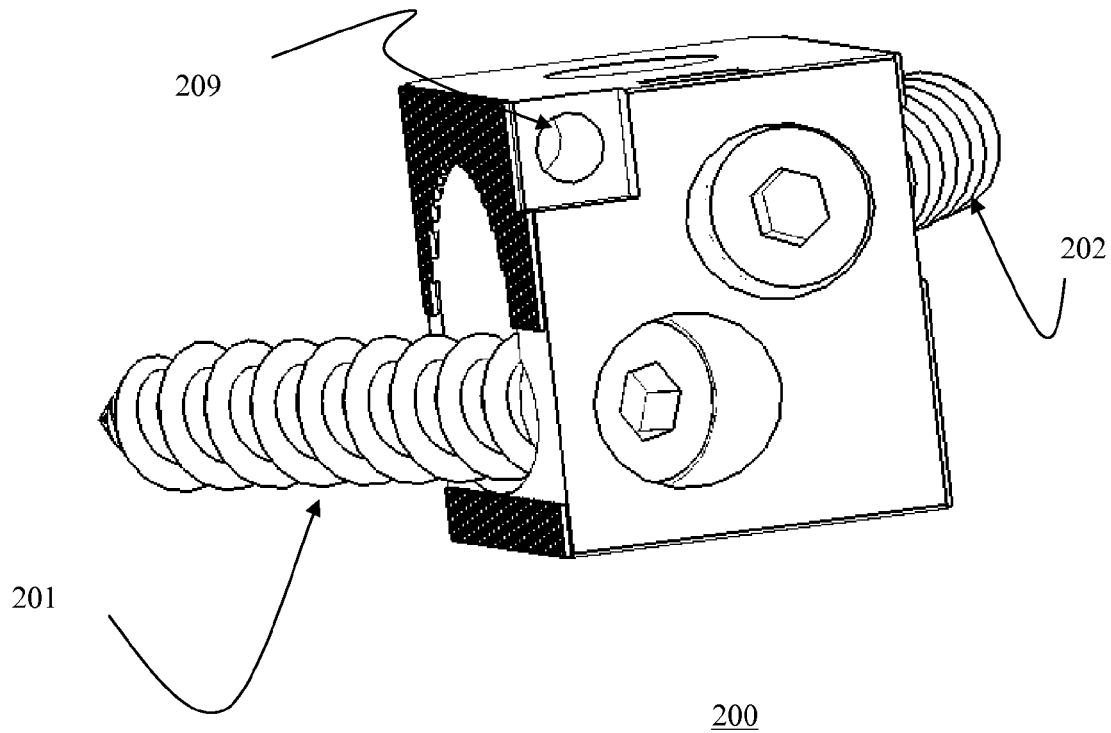


Fig. 2C

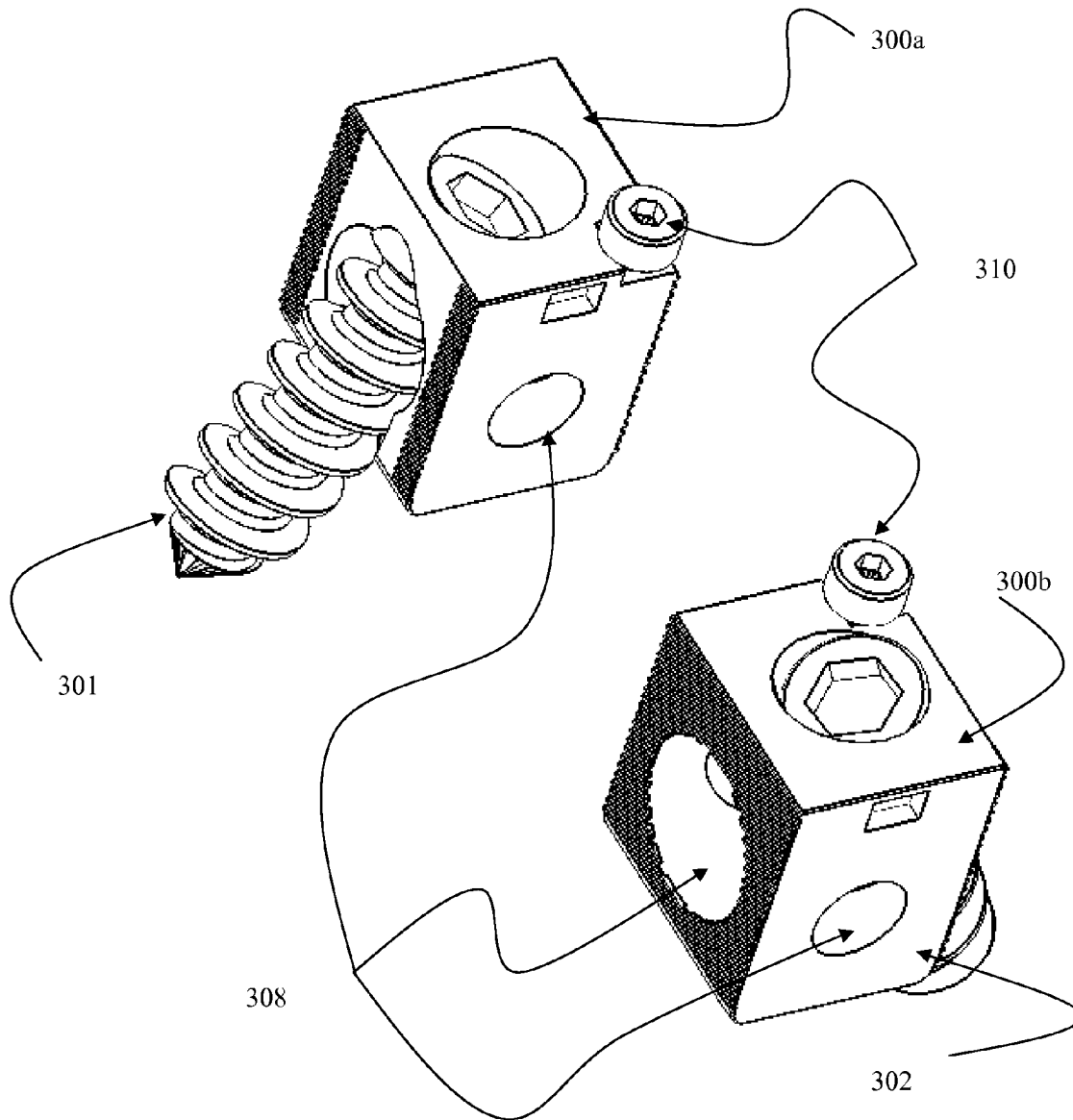


Fig. 3

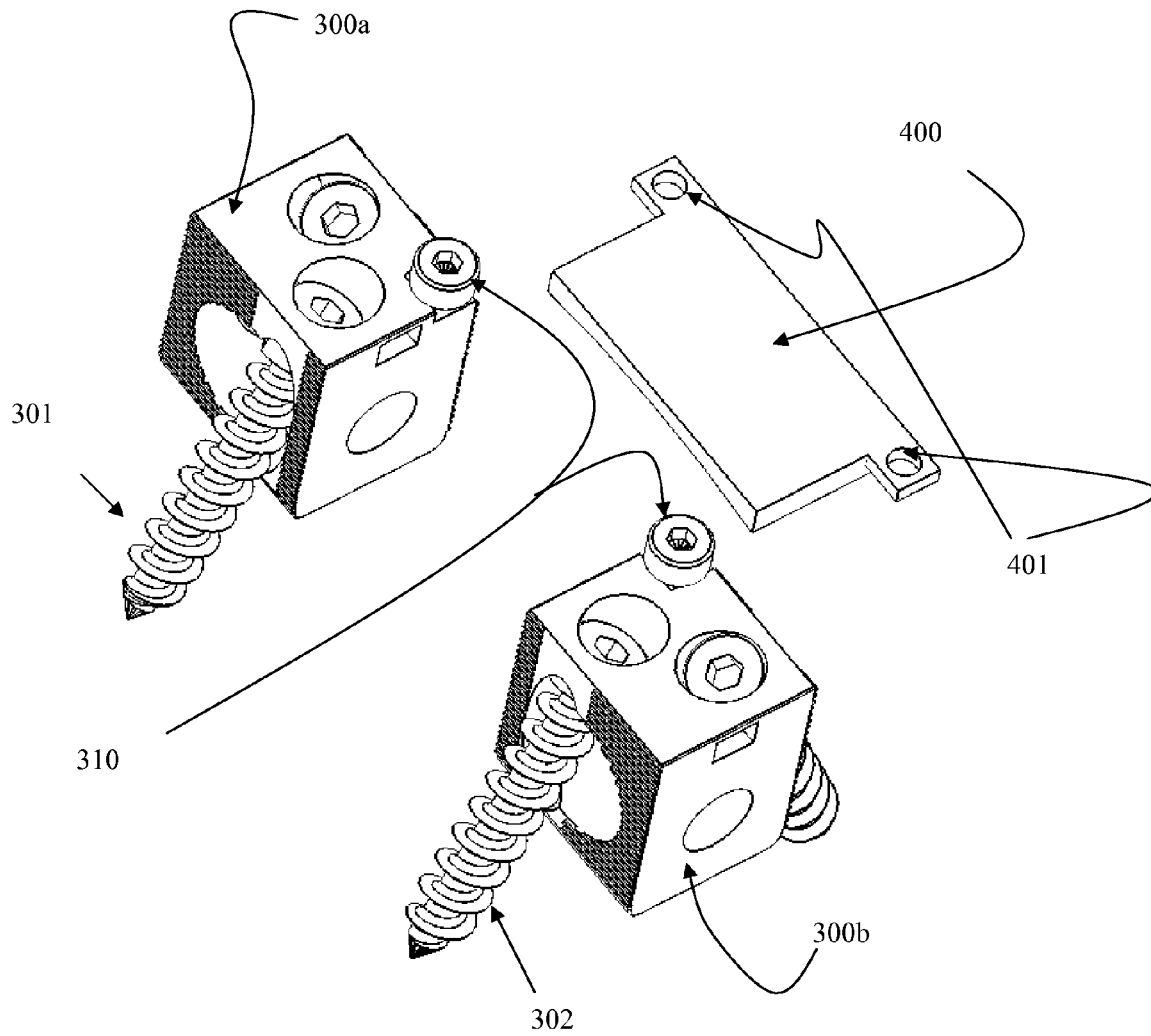


Fig. 4A

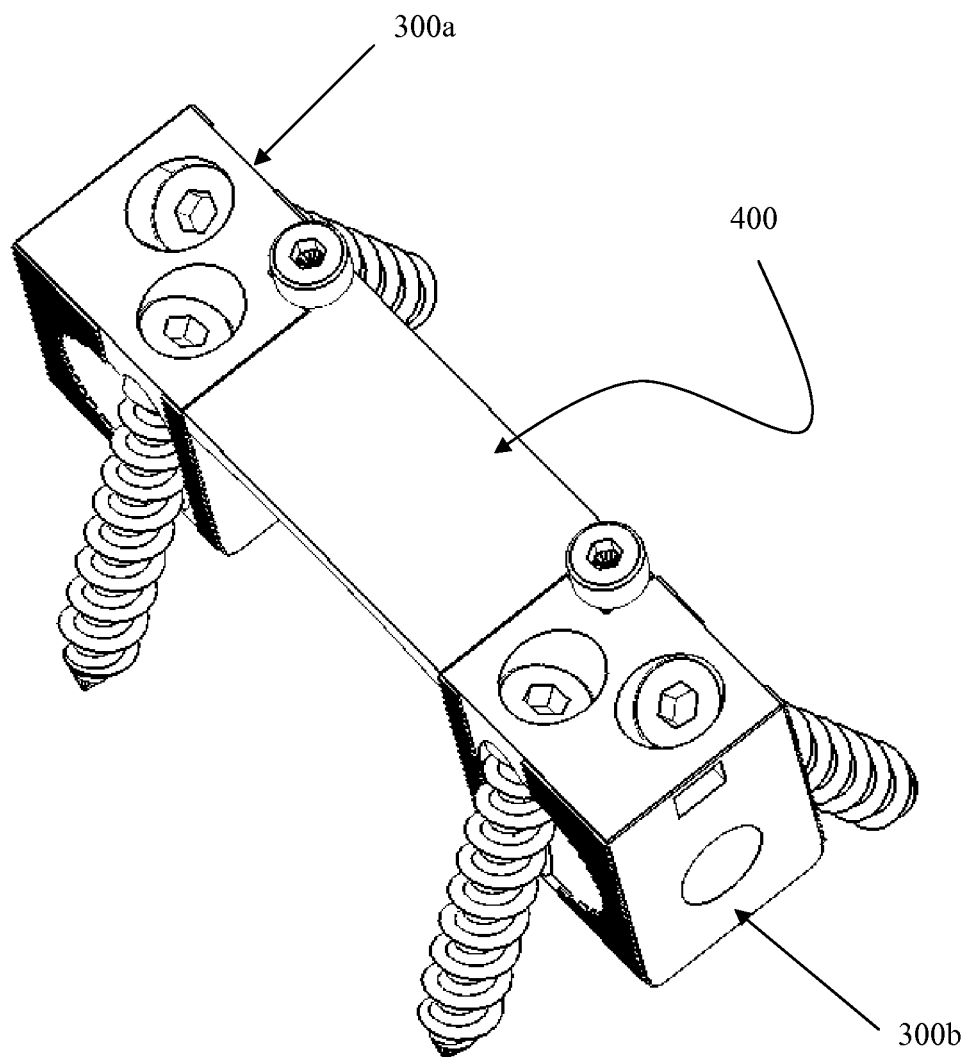


Fig. 4B

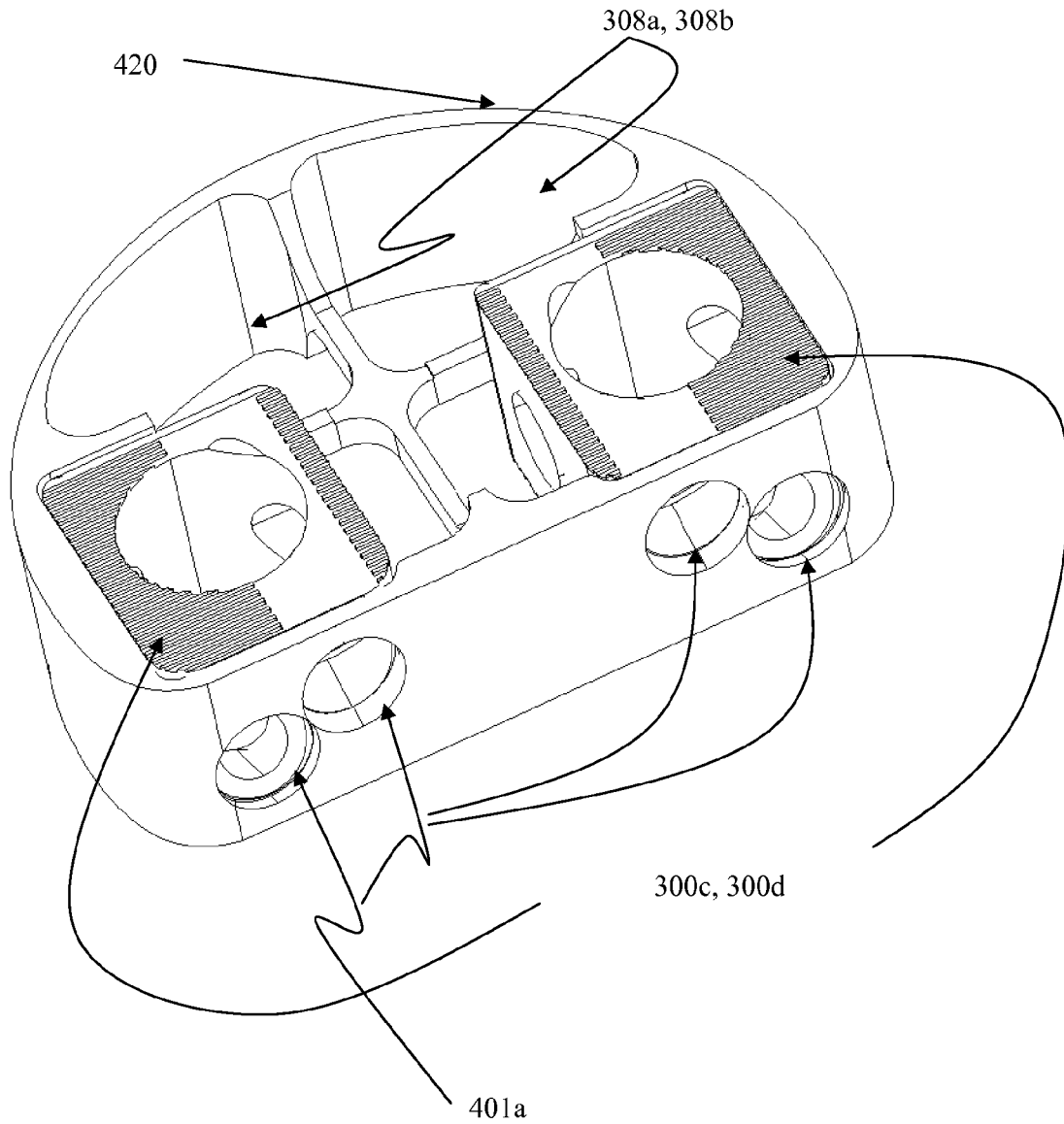


FIG. 4C

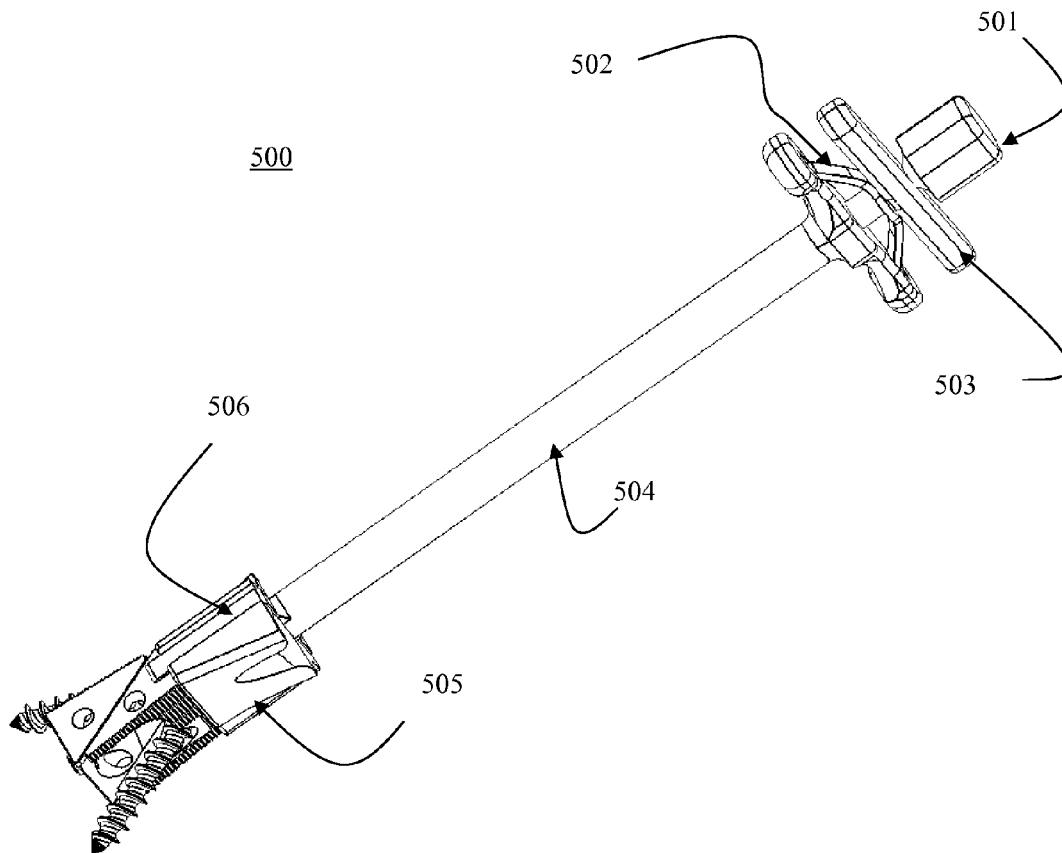


Fig. 5A

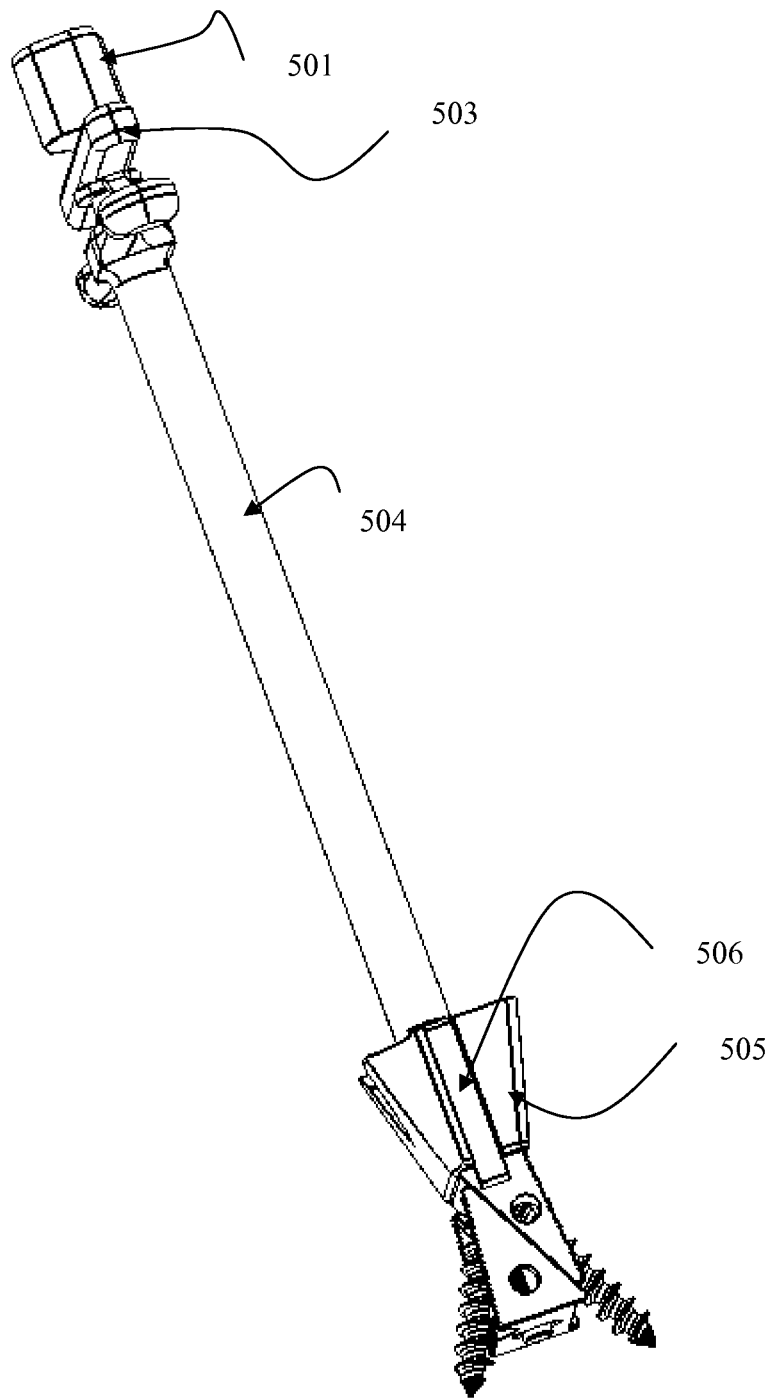


Fig. 5B

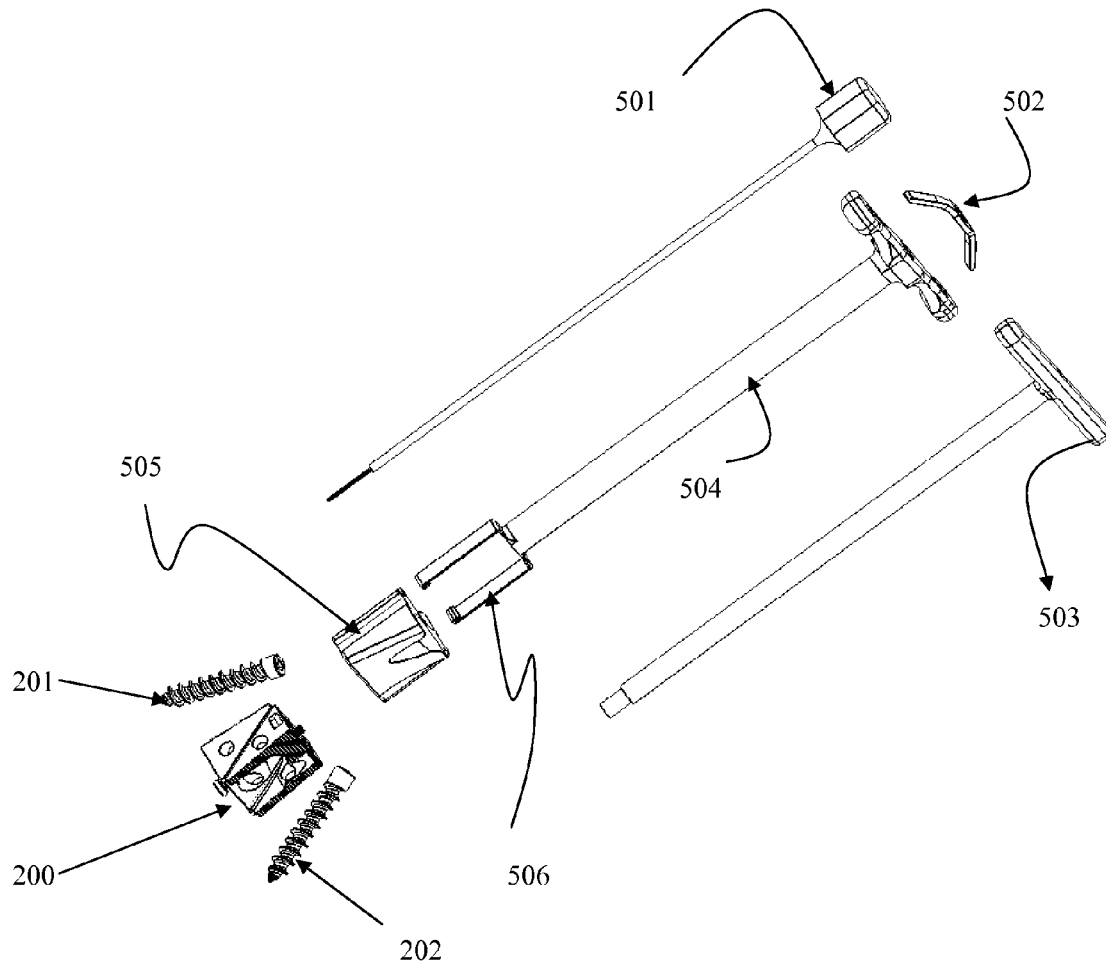


Fig. 5C

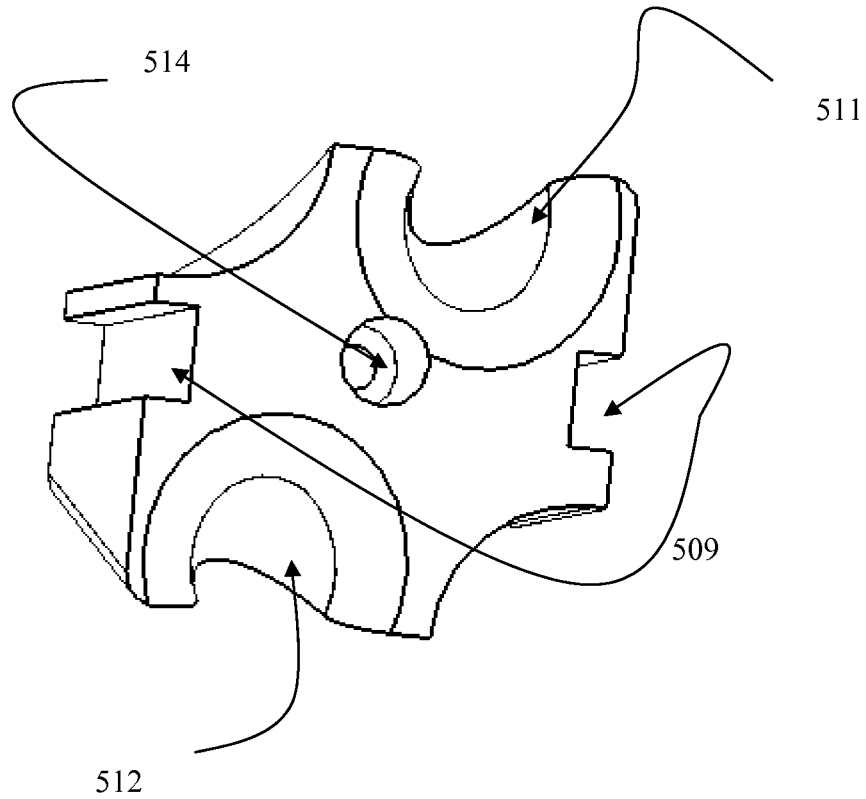


Fig. 5D

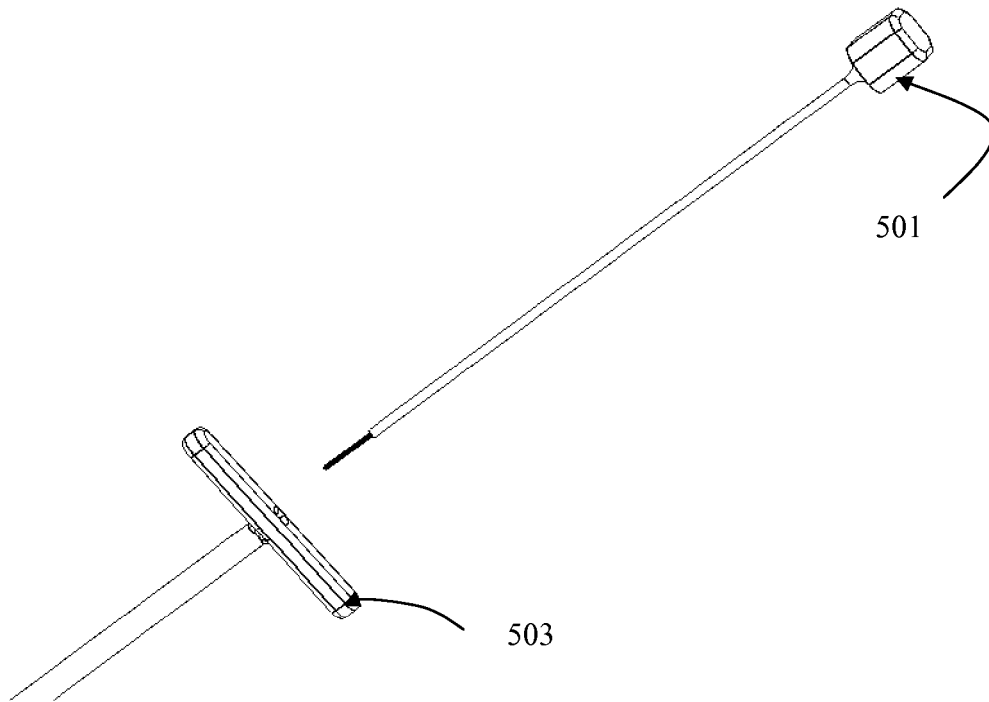


Fig. 5E

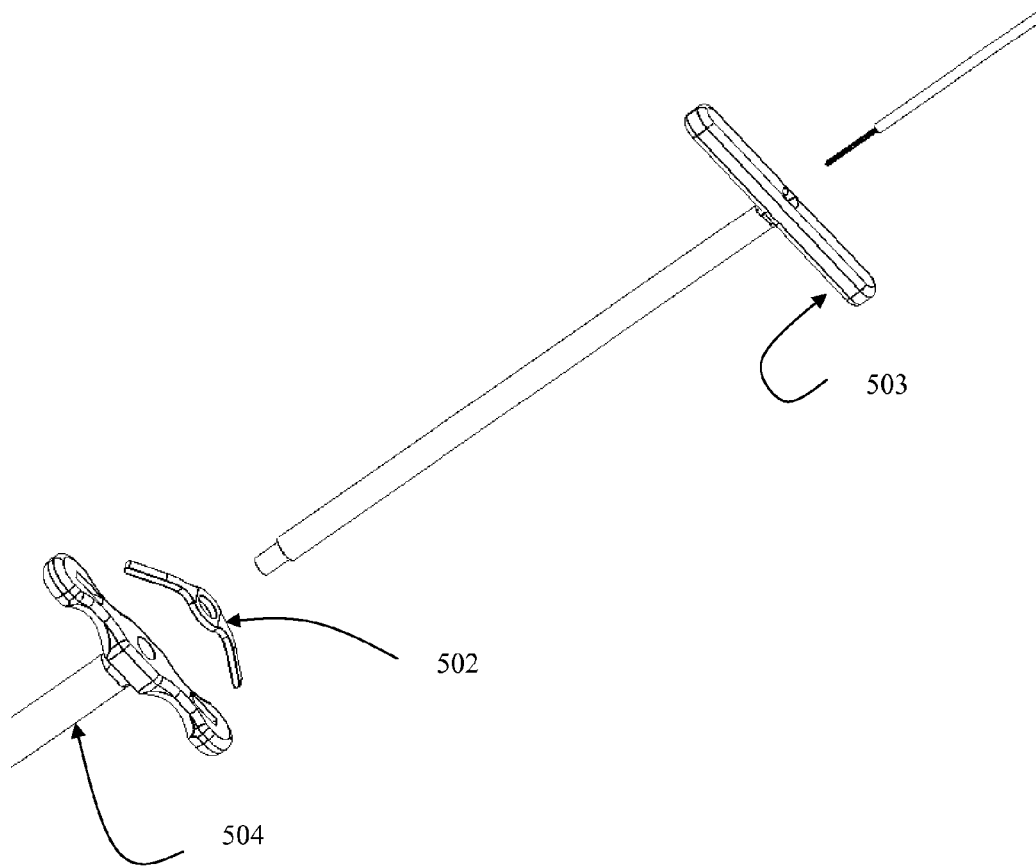


Fig. 5F

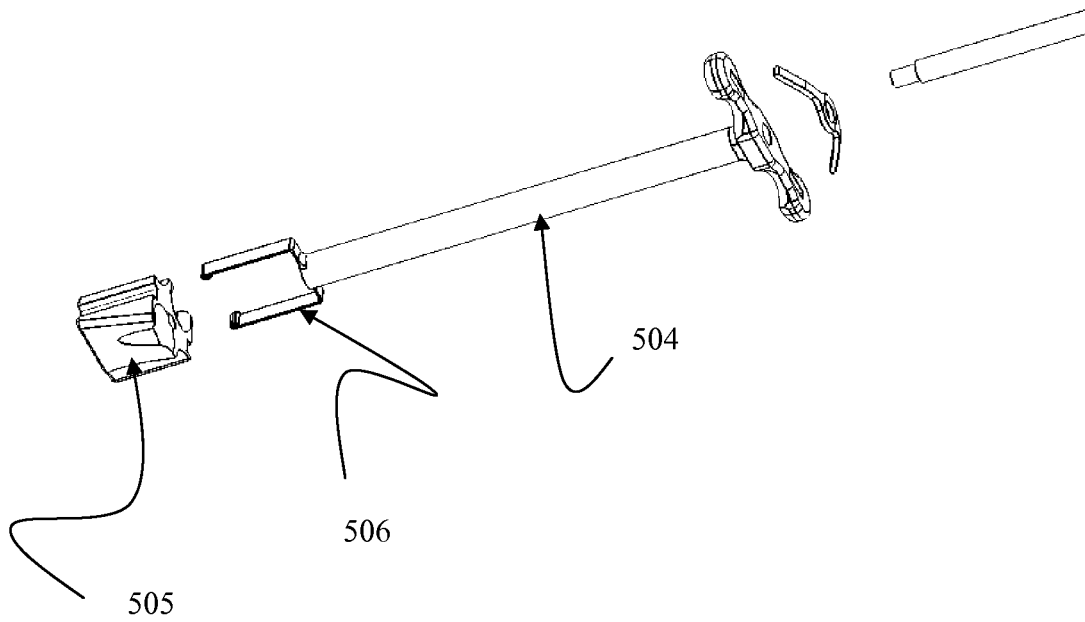


Fig. 5G

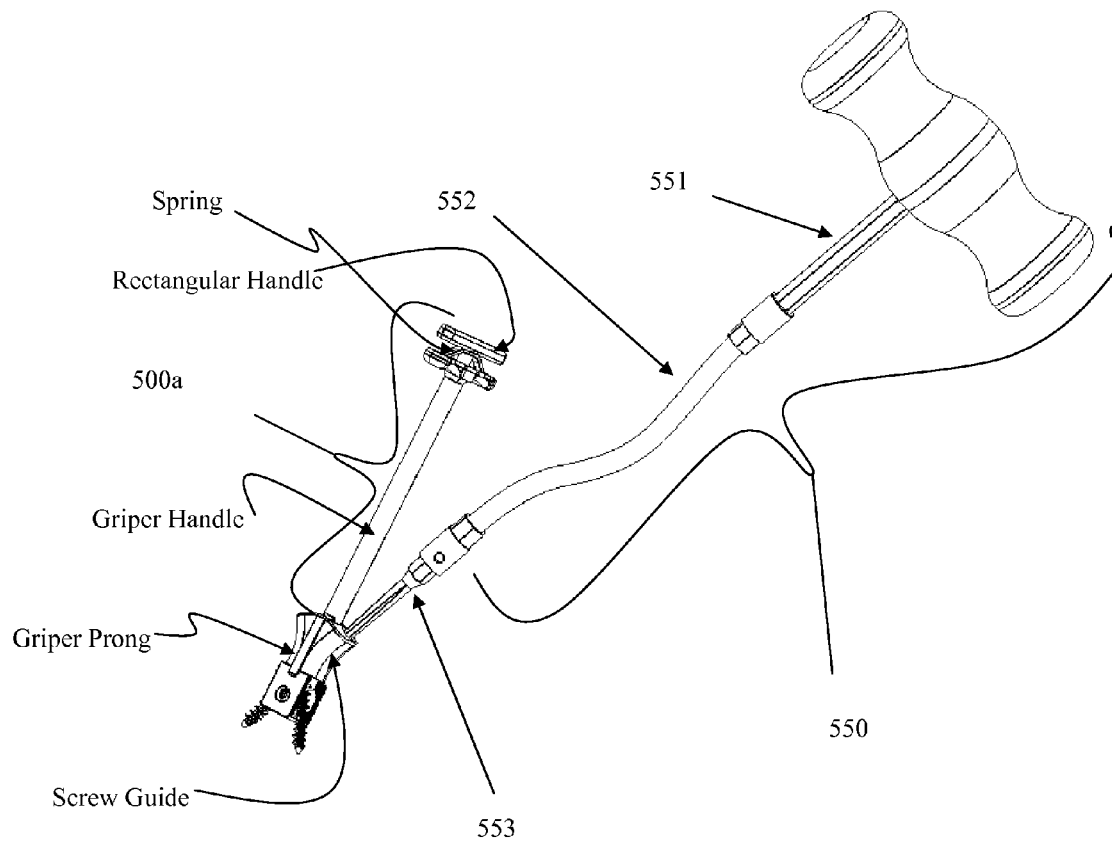


FIG. 5H

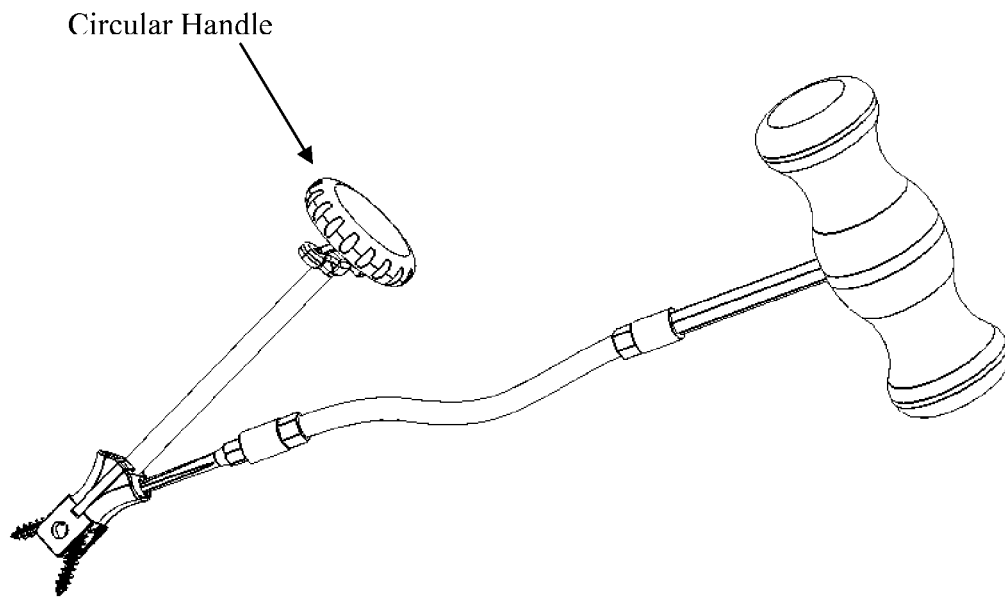


FIG. 5I

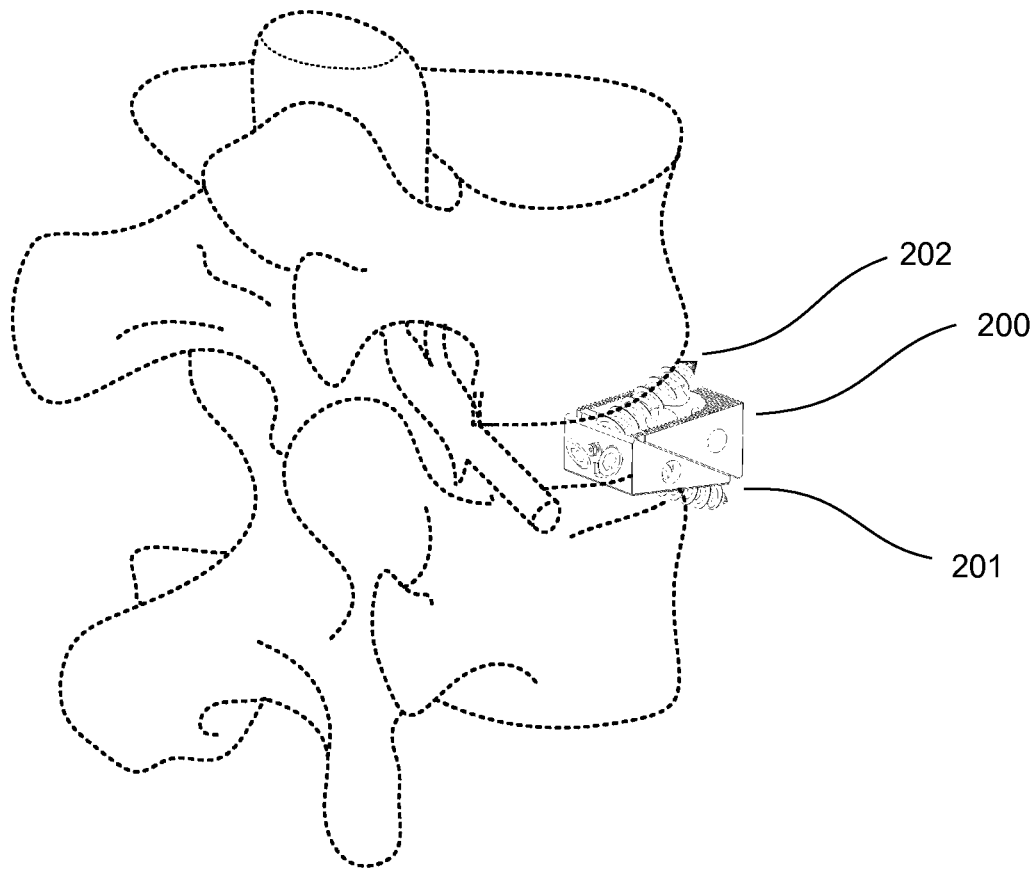


Fig. 6A

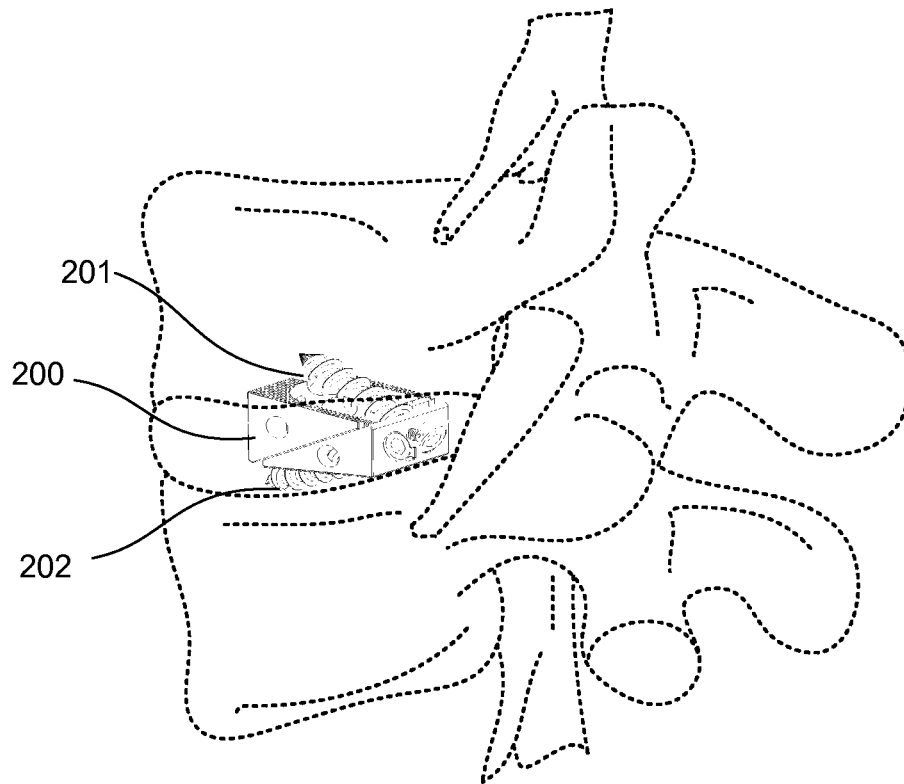


Fig. 6B

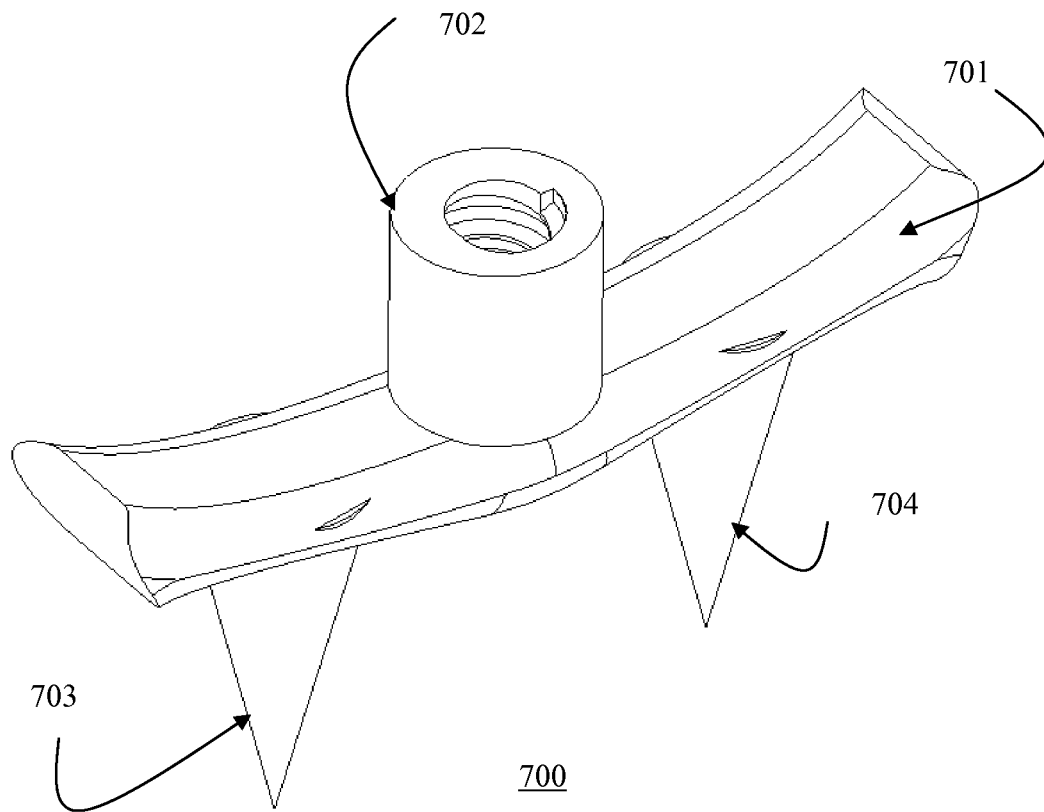


Fig. 7A

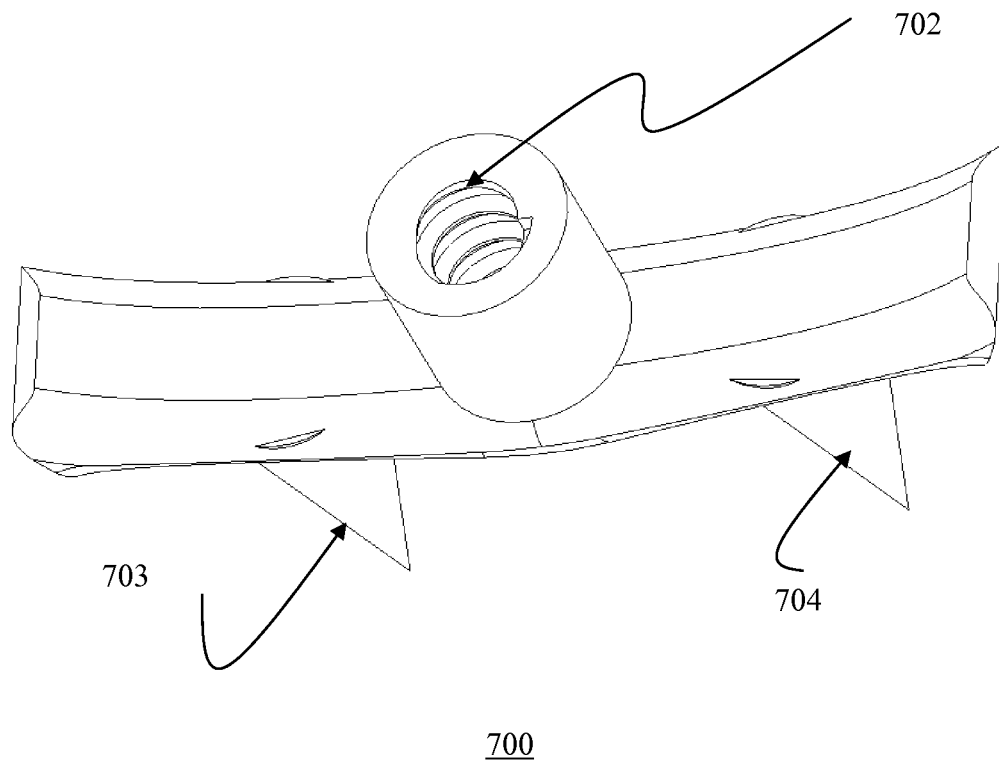


Fig. 7B

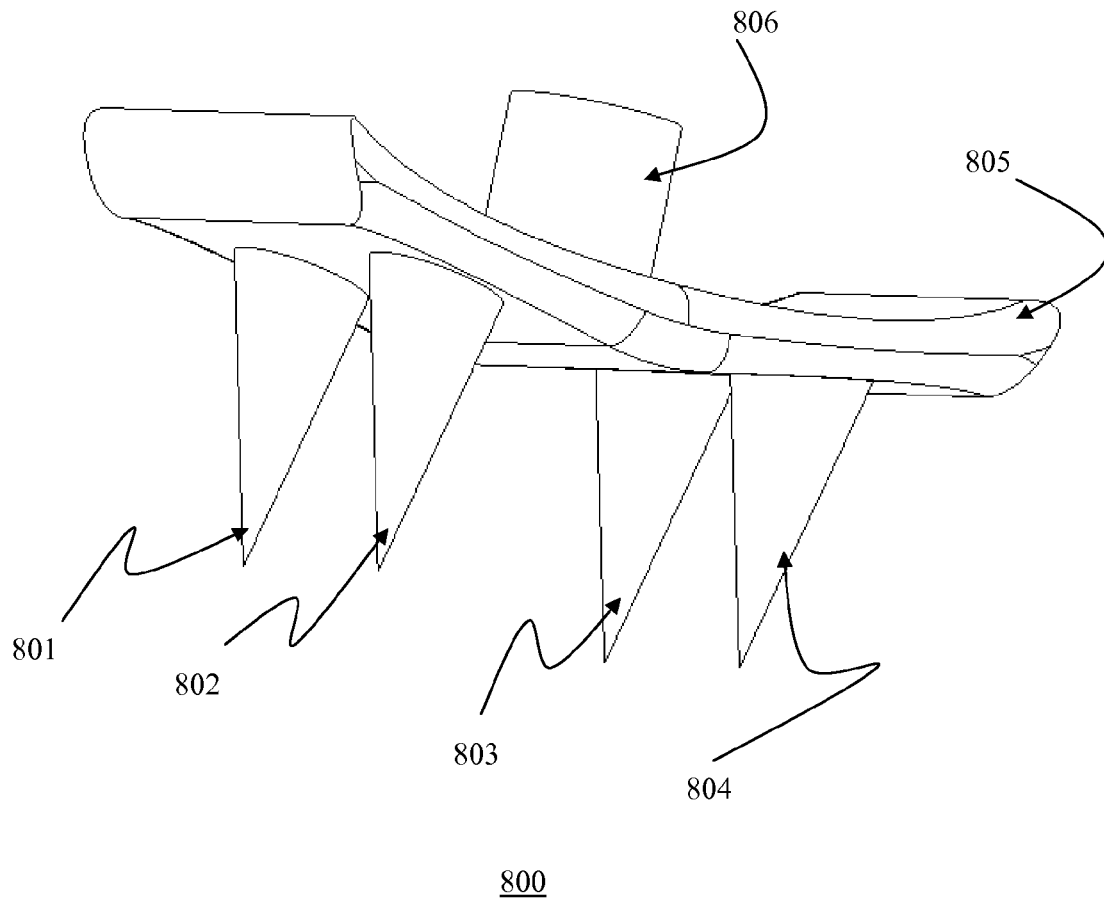


Fig. 8A

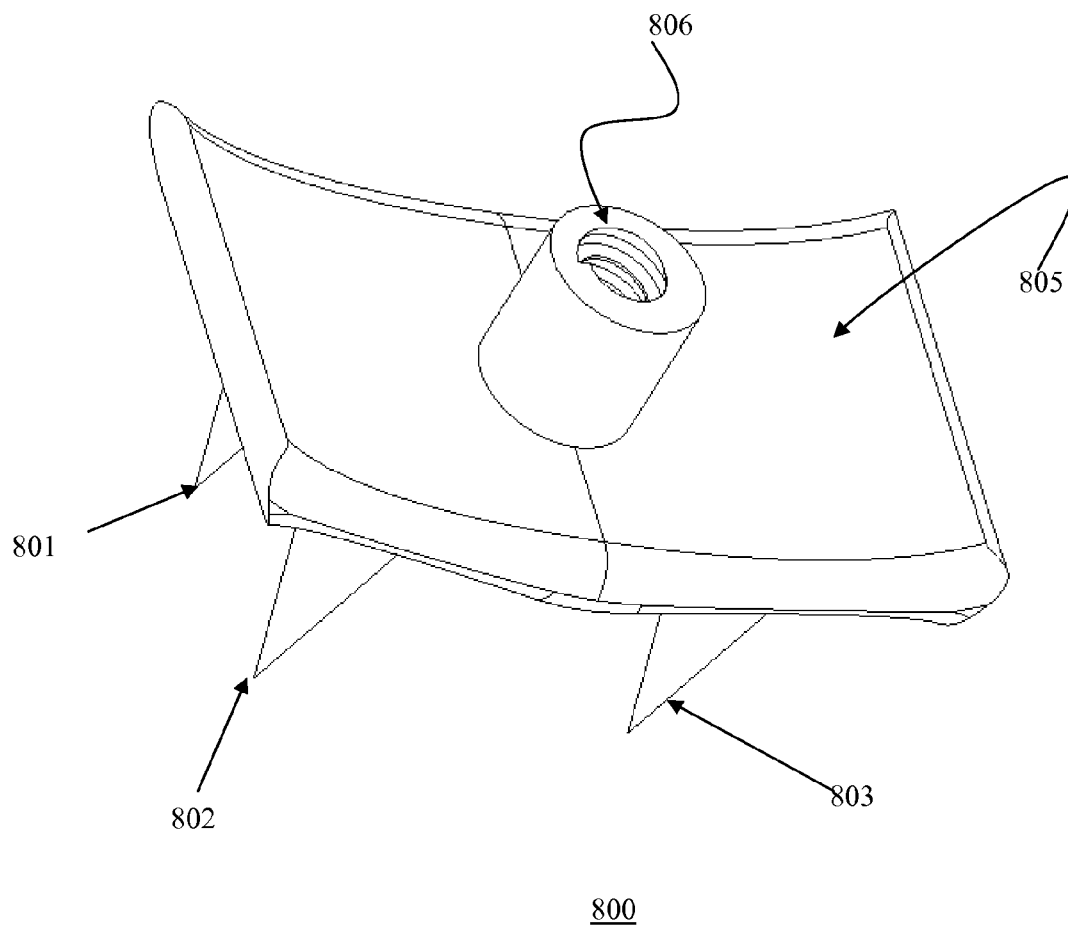


Fig. 8B

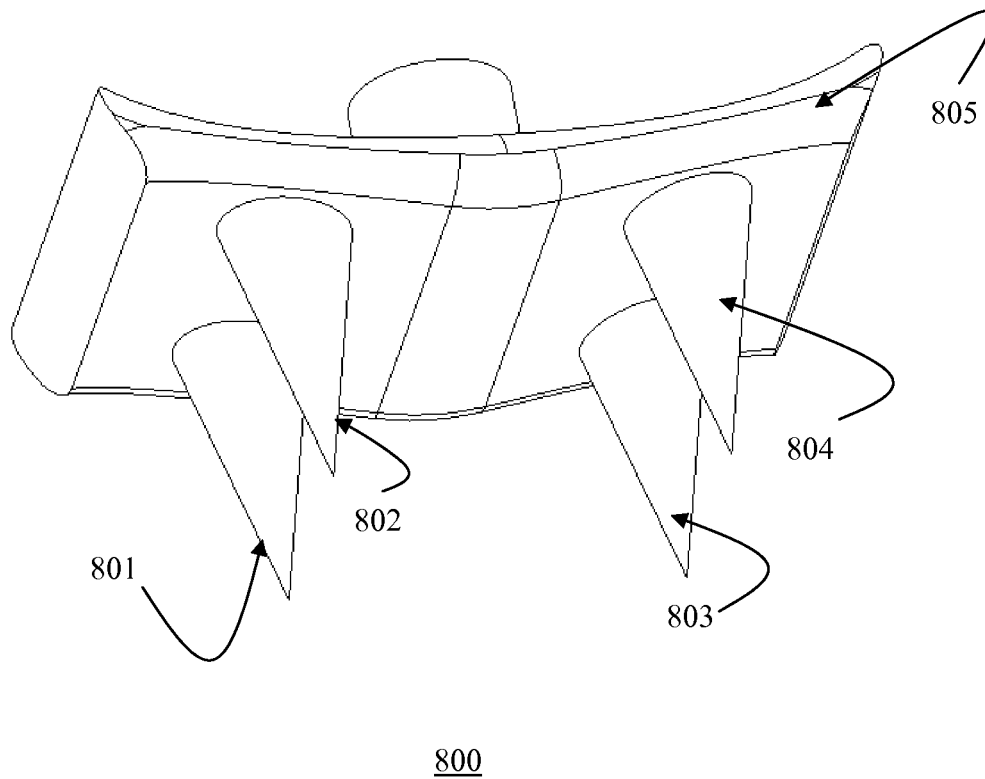


Fig. 8C

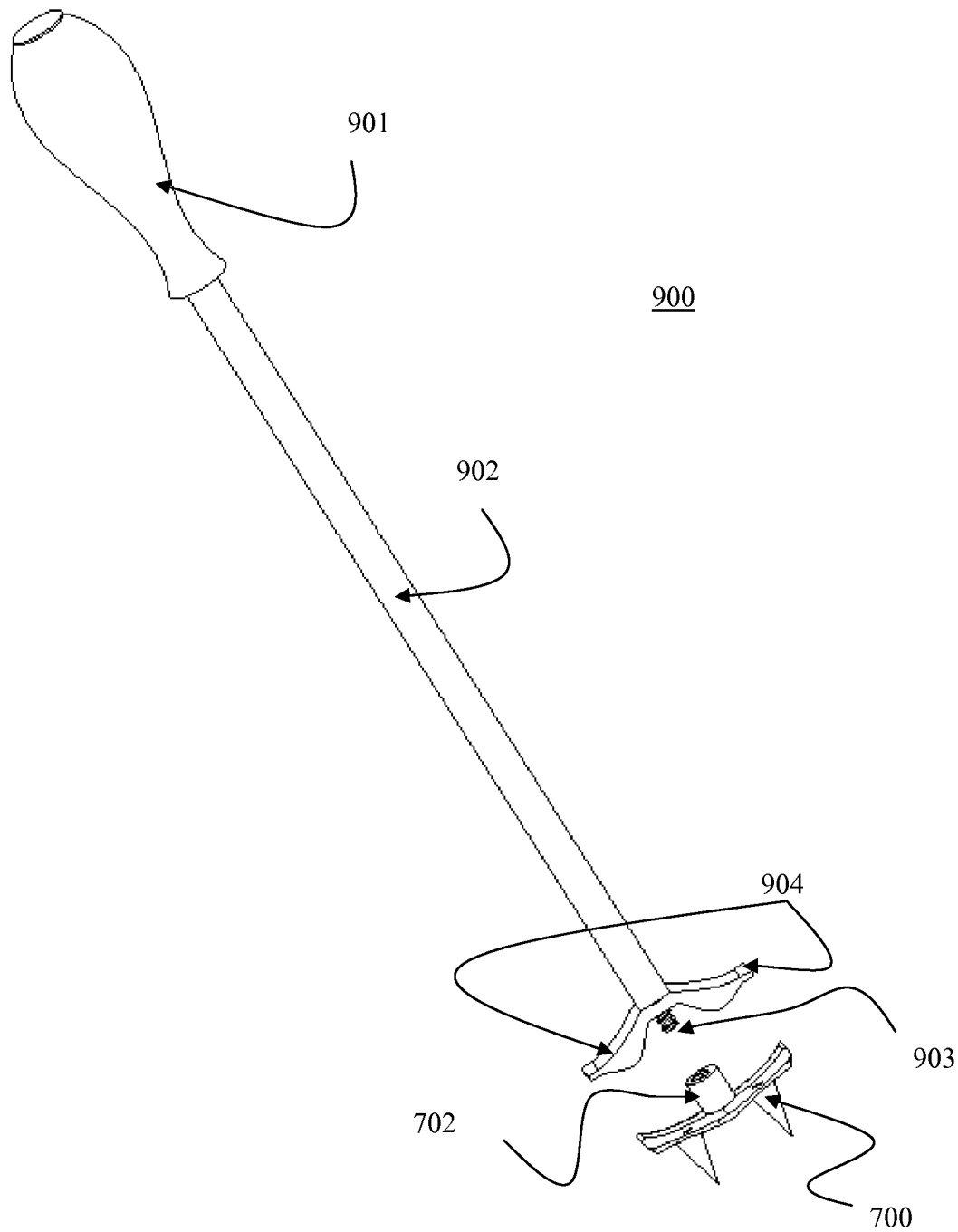


Fig. 9A

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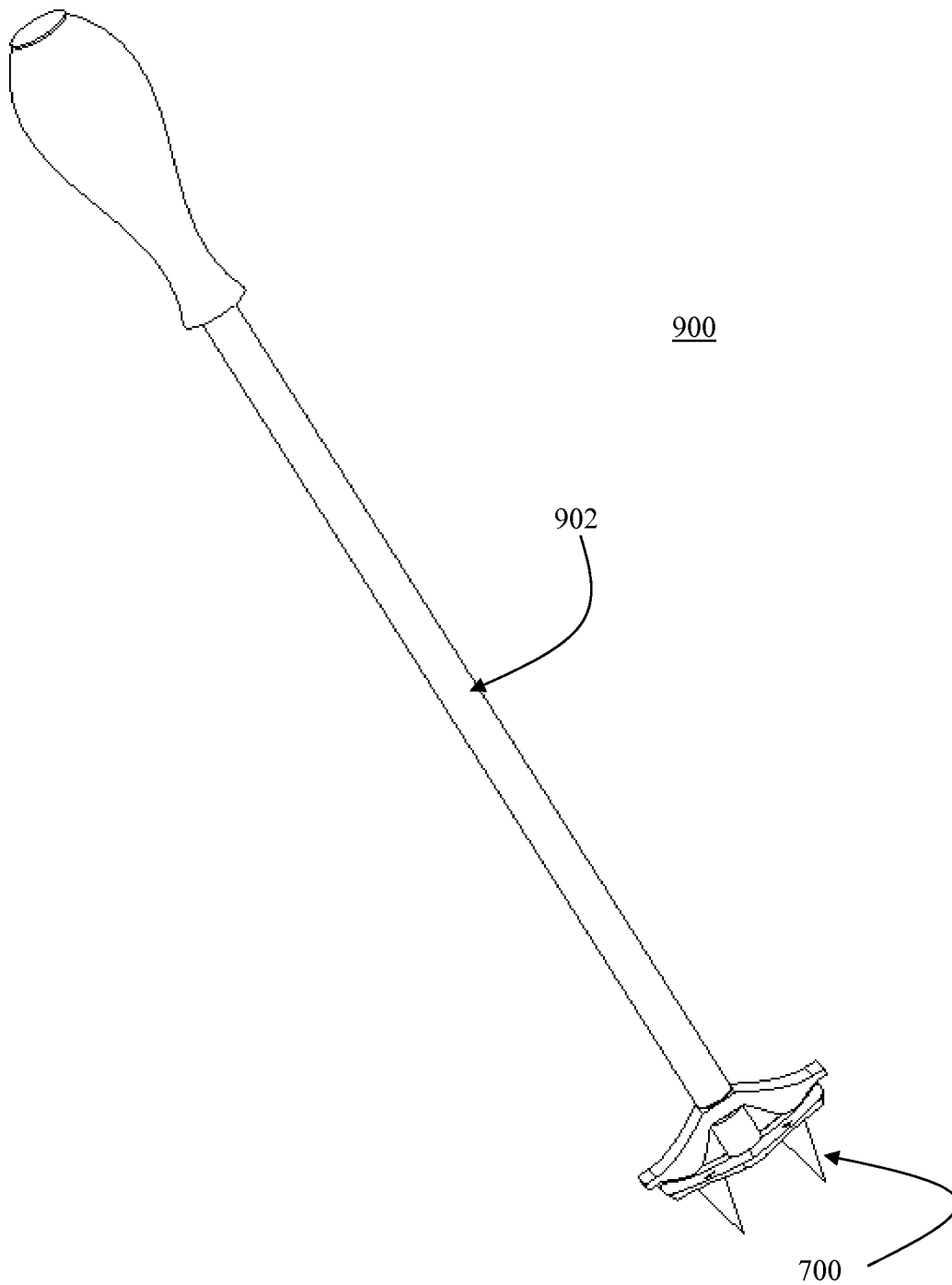


Fig. 9B

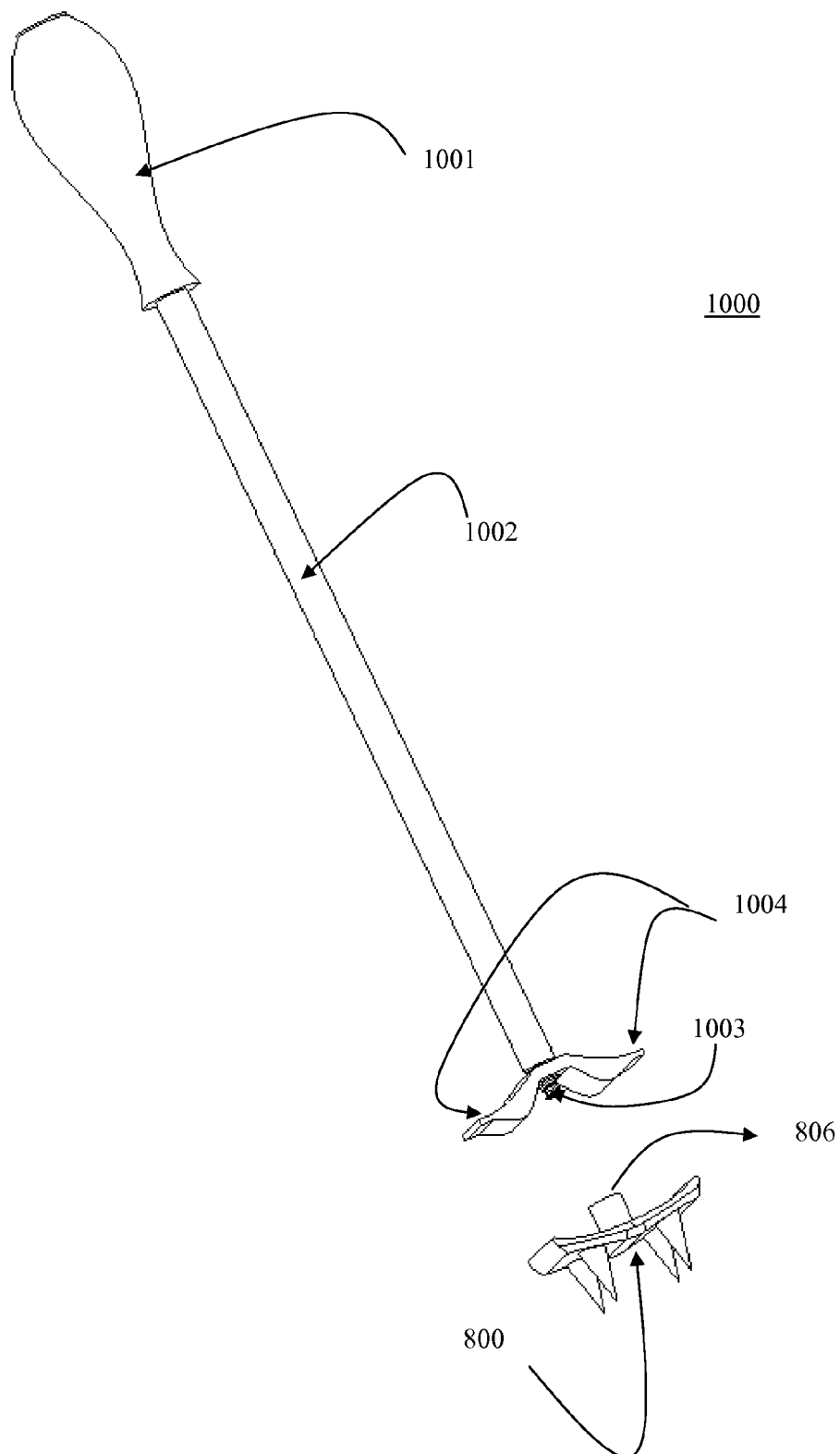


Fig. 10A

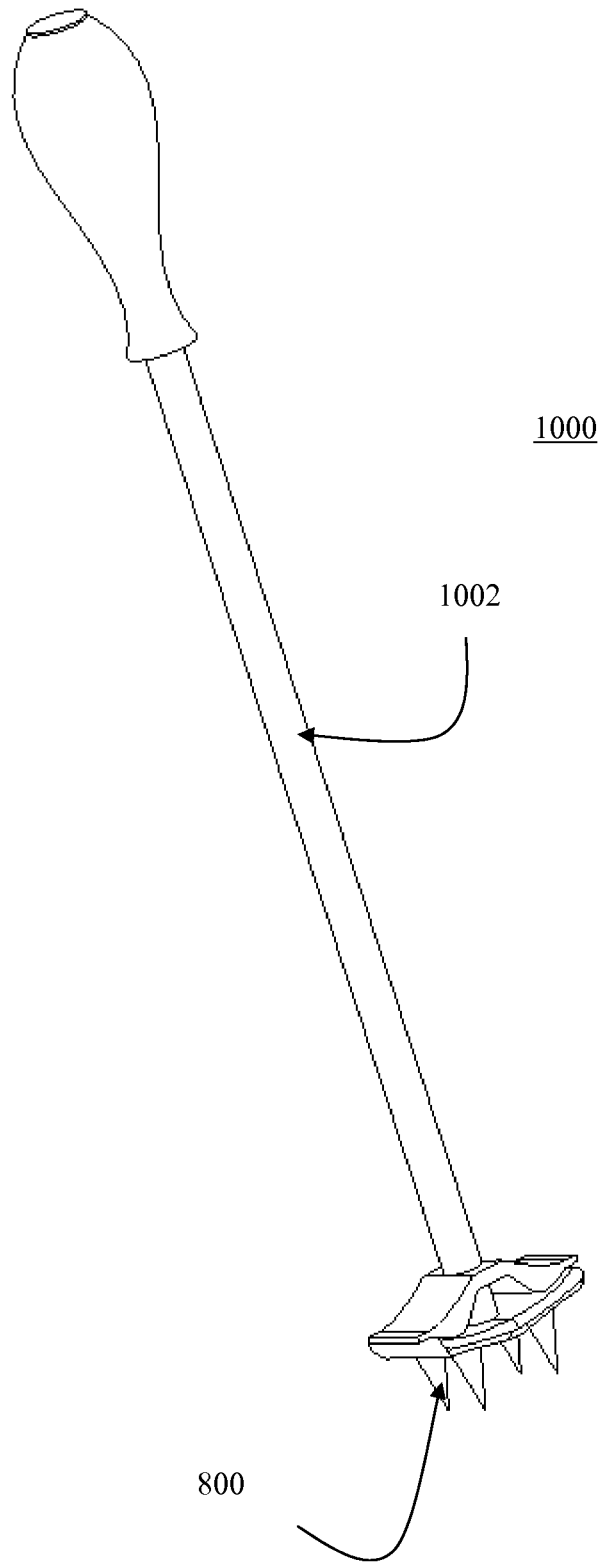


Fig. 10B

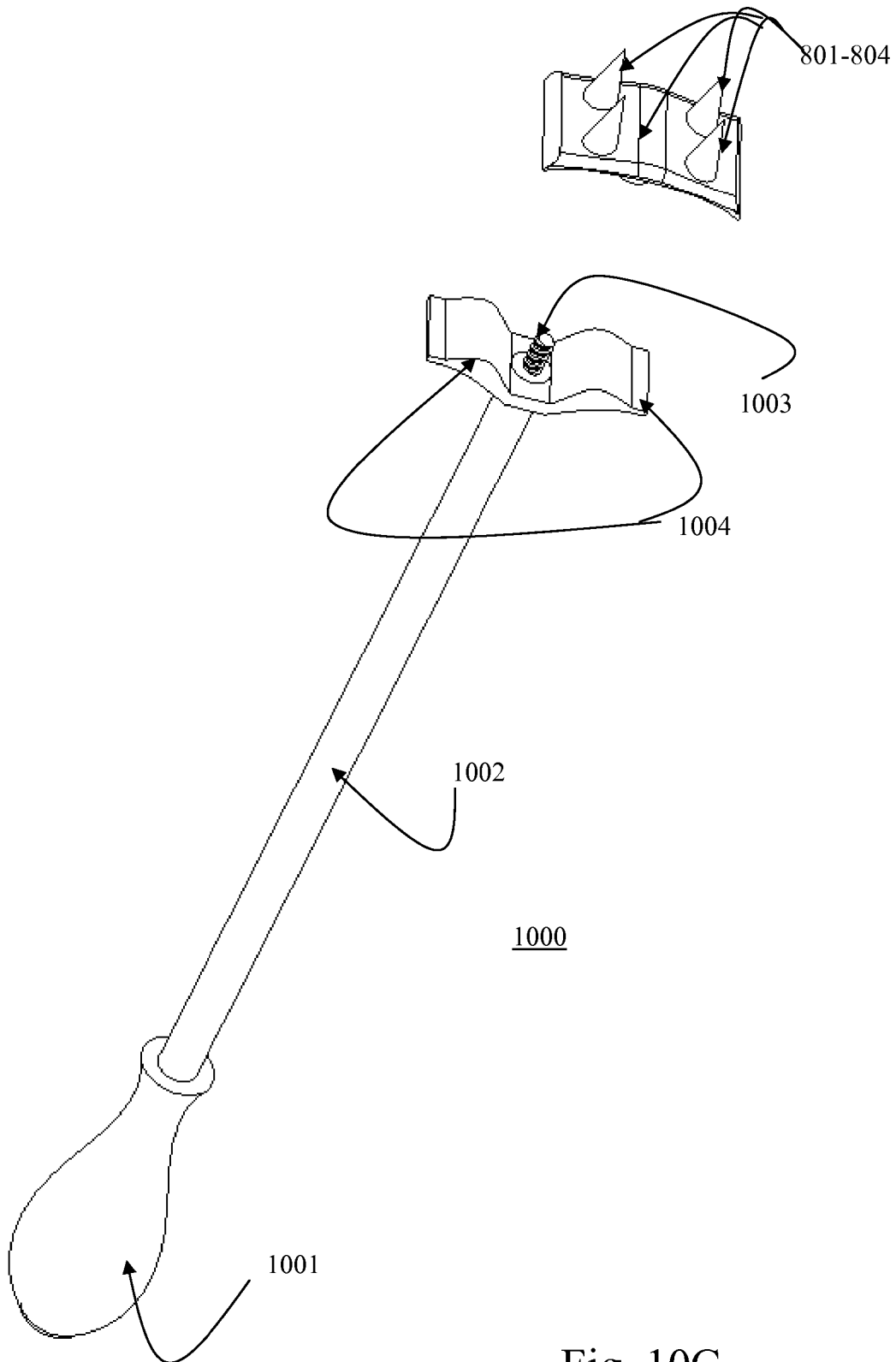


Fig. 10C

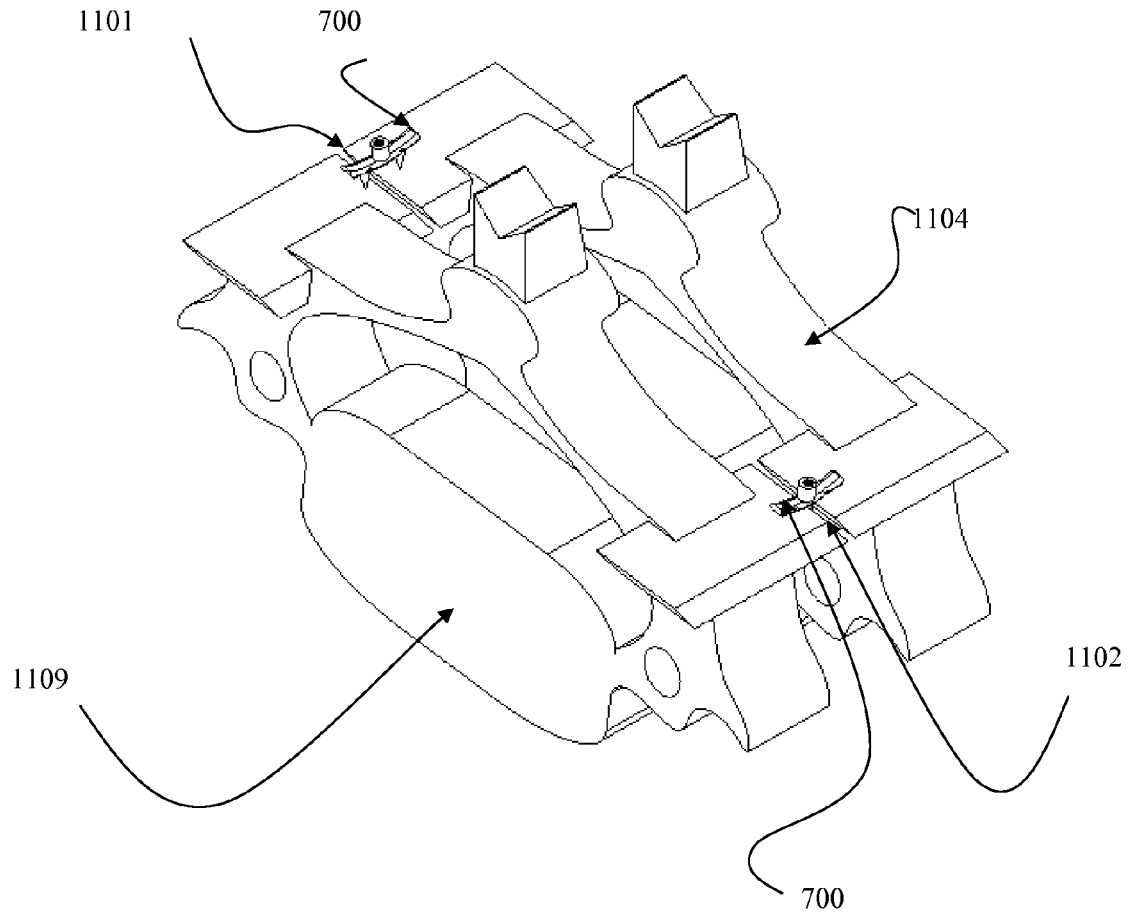


Fig. 11A

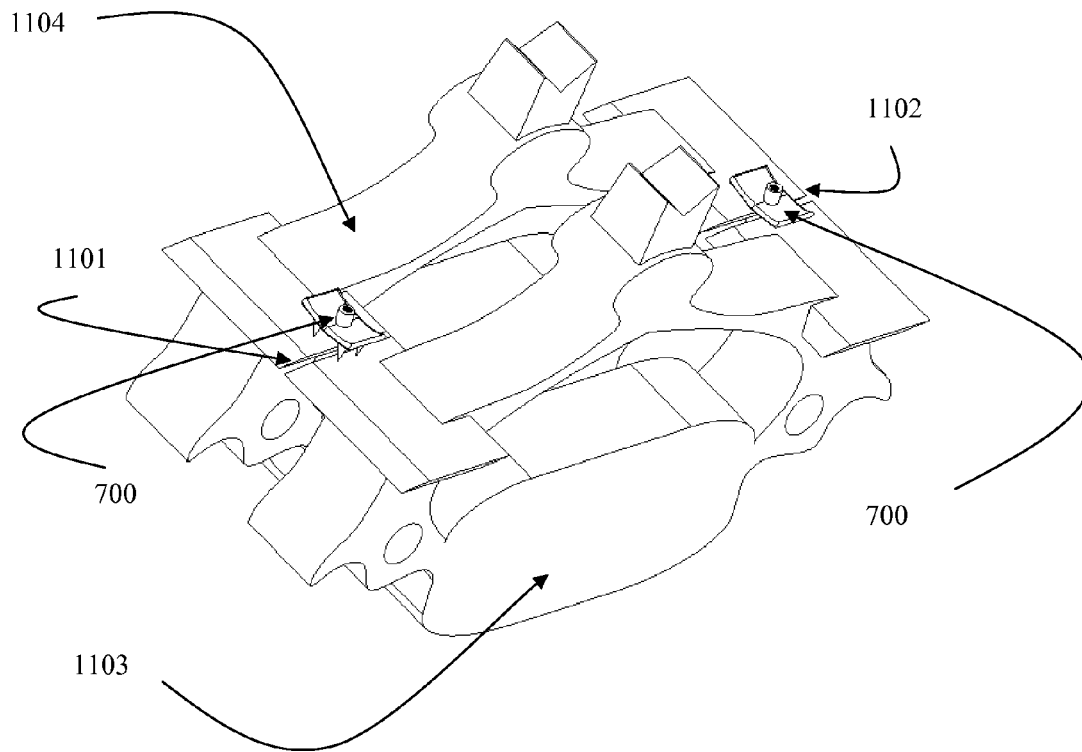


Fig. 11B

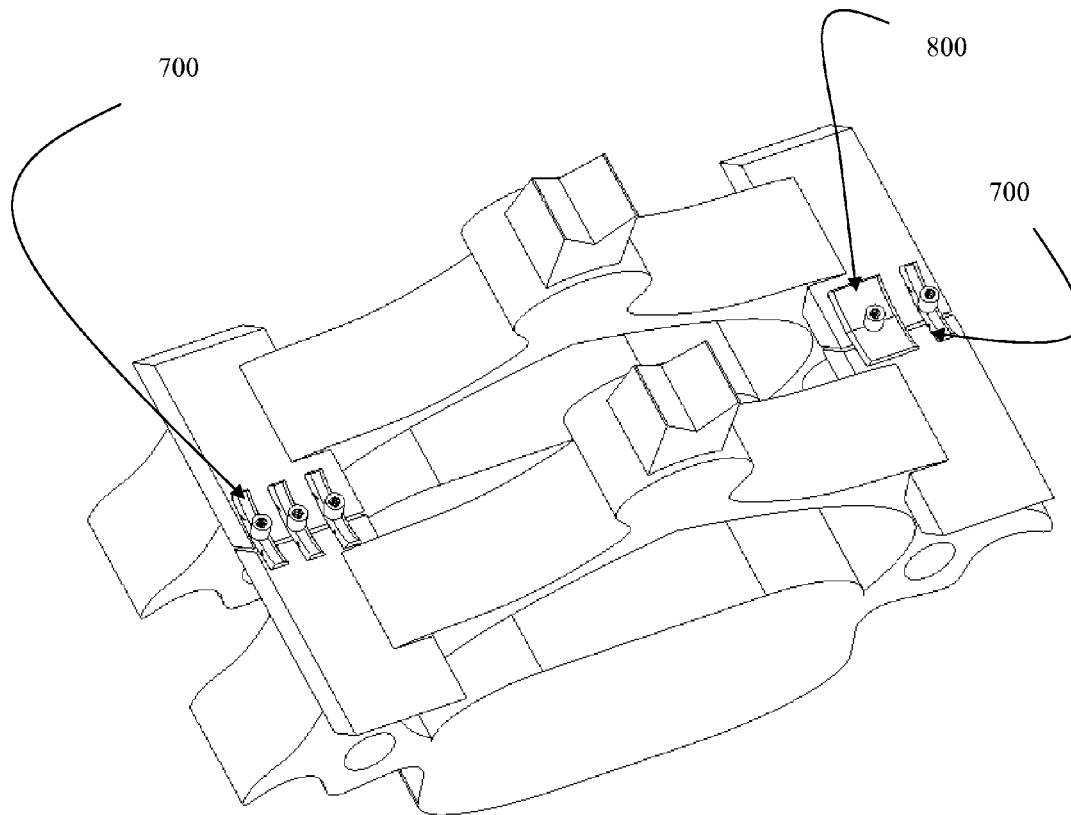


Fig. 11C

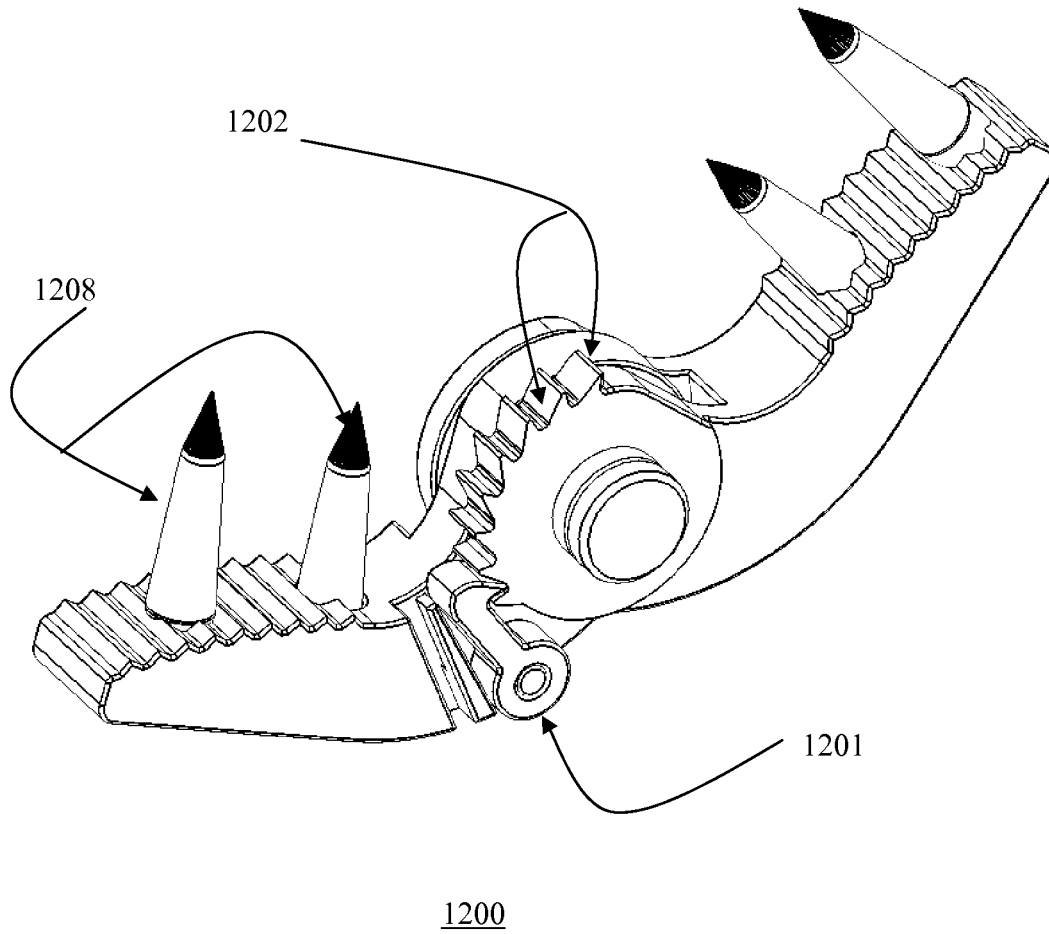


Fig. 12A

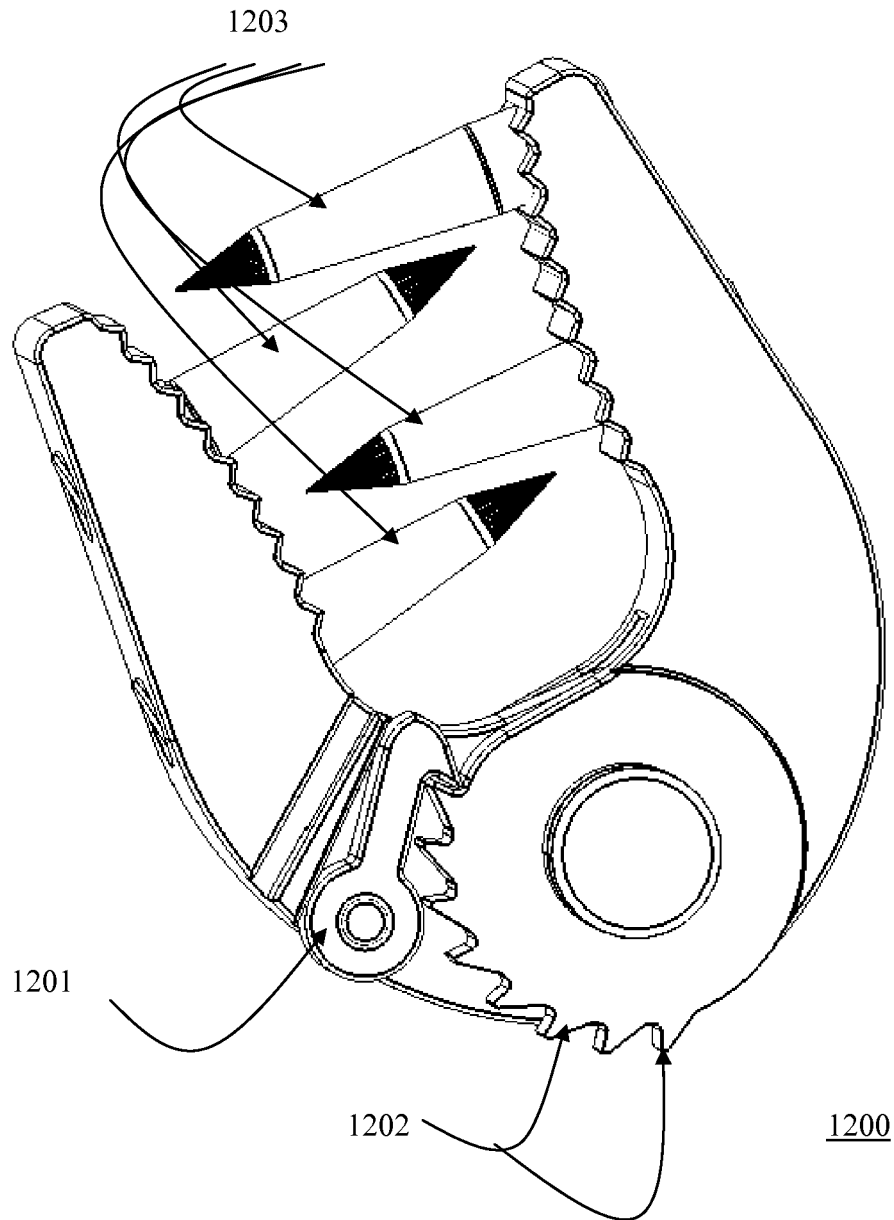


Fig. 12B

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

CROSS-REFERENCE TO RELATED
APPLICATIONS

This application is a Continuation Application of application Ser. No. 13,084,543, filed on Apr. 11, 2011, which is a Divisional Application of application Ser. No. 11/842,855, filed on Aug. 21, 2007, now U.S. Pat. No. 7,942,903 issued on May 17, 2011, and a Continuation Application of application Ser. No. 13,108,982, filed on May 16, 2011, which also is a Continuation Application of application Ser. No. 11/842,855, filed on Aug. 21, 2007, now U.S. Pat. No. 7,942,903 issued on May 17, 2011, which is a Continuation-In-Part Application of application Ser. No. 11/536,815, filed on Sep. 29, 2006, now U.S. Pat. No. 7,846,188 issued on Dec. 7, 2010, which is a Continuation-In-Part Application of application Ser. No. 11/208,644, filed on Aug. 23, 2005, now U.S. Pat. No. 7,704,279 issued on Apr. 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 Apr. 12, 2005; the entire contents of all the above identified patent applications are hereby incorporated by reference.

BACKGROUND OF THE INVENTION

Field of Invention

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.

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

The history and evolution of instrumented spinal fusion in the entire human spine has been reviewed in our two prior copending application 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

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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.

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

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.

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.

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.

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

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.

In yet another embodiment, in addition to these features we designed an expanding screw box with sliding triangular

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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.

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.

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

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

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can be combined with a circumferential cage (also 2 in 1) to be placed anteriorly into the lumbar spine.

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

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.

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.

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.

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.

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.

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.

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.

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.

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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.

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.

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.

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.

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.

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.

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.

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.

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

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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.

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.

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.

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.

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.

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

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

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

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.

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

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.

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.

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

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

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FIGS. 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).

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).

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.

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

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

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

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

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

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

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

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

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

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.

FIGS. 12A-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

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.

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).

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

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the screw box **100** allowing individualized custom fitting of the screw box **100** conforming to the dimensions of the disc space.

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.

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.

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.

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).

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).

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).

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

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.

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**.

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**.

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.

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

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.

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.

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.

FIGS. **9A-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

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facilitating staple impaction. The handle **901** of the impactor **900** is broad in order to allow impaction by a mallet.

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**.

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.

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.

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.

FIGS. **12A-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.

2. The Surgical Method

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

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.

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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.

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.

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.

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.

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.

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.

The anterior thoracic and lumbar spine implantation of one, two or three screw box constructs **100**, **200**, **300** and BDFT screws can be performed in a similar manner to the posterior application. Likewise, a horizontal mini-plate **400** can be used to cap two or three screw box constructs **100**, **200**, **300** (one placed midline deeply, one placed left and one placed right, forming a triangulation). Alternatively two screw box constructs may be placed into a circumferential ring for anterior placement. Anterior placement of these devices can be performed into the L4/5 and L5/S1 spaces on the supine anesthetized patient via previously described open microscopic or endoscopic techniques. Once the disc space is exposed and discectomy and space preparation are performed, placement of one, two or three screw box embodiments **100**, **200**, **300** (I-III) or a 2 in 1 construct can be placed. The screw placement is facilitated by the internal screw guides, and different positioning tools ((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.

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

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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.

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

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.

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.

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.

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.

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

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profile anterior or posterior horizontal spinal plates which traverse the diameter of the disc space has not been previously described.

We claim:

1. A universal, intervertebral combination internal screw guide and fixation apparatus configured to be inserted into a disc space between a first vertebral body and a second vertebral body and to provide fusion of the first vertebral body to the second vertebral body via biological bone fusion and screw fusion, the apparatus comprising:

an intervertebral cage including:

a top wall, a bottom wall, and two sidewalls defining an open space capable of receiving bone filling for the biological bone fusion; and

an internal screw guide having an internal bore with an entry opening and an exit opening, the entry opening of the internal bore formed only in a top surface of the top wall and the exit opening formed at least partially in a bottom surface of the top wall and at least partially in a side surface of the top wall, wherein the side surface of the top wall is patterned with a plurality of surface features to create a rough side surface, wherein at least some of the plurality of surface features are positioned on the side surface closer to the top surface of the top wall than the exit opening,

wherein a threaded hole extends through the top wall in a direction substantially normal to the top surface of the top wall with a diameter of the threaded hole being smaller than a diameter of the internal screw guide, and

wherein a rectangular indentation extends into at least part of the top wall and is oriented with at least one side of the rectangular indentation being substantially parallel to the side surface of the top wall.

2. The apparatus of claim 1, wherein an internal surface of the internal screw guide extends continuously from the entry opening to the exit opening.

3. The apparatus of claim 1, wherein the internal screw guide extends through an entire depth of the top wall from the top surface to the bottom surface and exiting at least partially into the open space.

4. The apparatus of claim 1, wherein the internal screw guide permits only a predetermined angled trajectory of a screw member through the intervertebral cage.

5. The apparatus of claim 1, wherein the internal screw guide has a 25 degree angulation.

6. The apparatus of claim 1, wherein the top wall has a thickness extending from the top surface of the top wall to the bottom surface of the top wall in a direction of a depth of the intervertebral cage, a height of the intervertebral cage extending in a direction perpendicular to the depth, and

wherein an axis of the internal screw guide extends to a greater extent in the direction of the depth of the intervertebral cage than in a direction of a height of the intervertebral cage in order to facilitate multi-level fusion of adjacent vertebral bodies with multiple intervertebral cages.

7. The apparatus of claim 1, wherein the top wall of the intervertebral cage has a thickness that is greater than a thickness of each of the sidewalls.

8. The apparatus of claim 1, wherein each of the two sidewalls includes a means for receiving placement of bone filling into the open space of the intervertebral cage for the biological bone fusion.

9. The apparatus of claim 1, wherein the intervertebral cages includes indentations formed on surfaces of the two

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sidewalls and on opposite ends of the intervertebral cage for receiving ends of prongs of an implantation tool.

10. The apparatus of claim 1, wherein a surface of each of the two sidewalls includes a plurality of ridges.

11. The apparatus of claim 1, wherein the intervertebral cage is configured to receive a means for securing a second intervertebral cage thereto.

12. The apparatus of claim 11, wherein the intervertebral cage comprises:

a screw insert configured to receive the plate for securing the second intervertebral cage thereto.

13. The apparatus of claim 1, wherein the intervertebral cage is a cervical intervertebral cage configured to fit into a cervical disc space.

14. The apparatus of claim 1, wherein the intervertebral cage is a lumbar intervertebral cage configured to fit into a lumbar disc space.

15. The apparatus of claim 1, wherein the intervertebral cage is a posterior lumbar intervertebral cage configured to fit into a lumbar disc space.

16. The apparatus of claim 1, wherein the intervertebral cage is capable of one of posterior lumbar intervertebral placement, anterior lumbar intervertebral placement, thoracic intervertebral placement, and anterior cervical intervertebral placement.

17. The apparatus of claim 1, wherein the intervertebral cage further comprises:

a second internal screw guide having a second entry opening and a second exit opening, the second entry opening formed at least partially in the top surface of the top wall and the second exit opening formed at least partially in the bottom surface of the top wall and at least partially in a second side surface of the top wall.

18. The apparatus of claim 17, wherein each of the internal screw guide and the second internal screw guide is angled to orient a first screw member and a second screw bi-directionally in opposite directions.

19. The apparatus of claim 18, wherein the internal screw guide is configured to orient the first screw member rostrally and the second internal screw guide is configured to orient the second screw member caudally.

20. The apparatus of claim 17, wherein the internal screw guide and the second internal screw guide are at an angulation with respect to the top surface of the top wall.

21. The apparatus of claim 17, wherein each of the internal screw guide and the second internal screw guide permits only a 25 degree angulation of the first screw member and the second screw member.

22. The apparatus of claim 17, wherein the internal screw guide and the second internal screw guide are aligned along a longitudinal axis of the top wall of the intervertebral cage.

23. The apparatus of claim 17, wherein the internal screw guide and the second internal screw guide are symmetrically disposed on each side of a center point of the intervertebral cage along a longitudinal axis of the top wall of the intervertebral cage.

24. The apparatus of claim 17, wherein the internal screw guide and the second internal screw guide are offset in opposite directions with respect to a center line of a longitudinal extent of the top wall.

25. The apparatus of claim 24, wherein a part of the internal screw guide overlaps a part of the second internal screw guide along the longitudinal extent of the top wall.

26. The apparatus of claim 17, wherein the entry opening of the internal screw guide and the second entry opening of the second internal screw guide are arranged diagonally on the top surface of the top wall.

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27. The apparatus of claim 17, wherein the top wall has four quadrants delineated by a first axis and a second axis each lying in a plane of the top wall, and the first axis is at a right angle with respect to the second axis,

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

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

wherein a majority of an area of the entry opening of the internal screw guide is in the first quadrant and a majority of an area of the second entry opening of the second internal screw guide is in the third quadrant.

28. The apparatus of claim 17, wherein the top wall has four quadrants delineated by a first axis and a second axis each lying in a plane of the first wall, and the first axis is at a right angle with respect to the second axis,

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

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

wherein a center of the entry opening of the internal screw guide is in the first quadrant and a center of the second entry opening of the second internal screw guide is in the third quadrant.

29. The apparatus of claim 17, wherein the top wall includes a first corner and a second corner, the first corner being arranged at an opposite side of the top wall and an opposite end of the top wall with respect to the second corner, and

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

30. The apparatus of claim 17, wherein the intervertebral cage further comprises:

a third internal screw guide having a third entry opening and a third exit opening, the third entry opening formed at least partially in the top surface of the top wall and the third exit opening formed at least partially in the bottom surface of the top wall and at least partially in the side surface of the top wall.

31. The apparatus of claim 30, wherein the intervertebral cage further comprises:

a fourth internal screw guide having a fourth entry opening and a fourth exit opening, the fourth entry opening formed at least partially in the top surface of the top wall and the fourth exit opening formed at least partially in the bottom surface of the top wall and at least partially in the second side surface of the top wall.

32. The apparatus of claim 31, wherein the internal screw guide and the fourth internal screw guide are oriented rostrally and the second internal screw guide and the third internal screw guide are oriented caudally.

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33. The apparatus of claim 31, wherein the second internal screw guide and the third internal screw guide are disposed between the internal screw guide and the fourth internal screw guide along a longitudinal length of the top wall of the intervertebral cage.

34. The apparatus of claim 31, wherein each of the internal screw guide, the second internal screw guide, the third internal screw guide, and the fourth internal screw guide has a 25 degree angulation.

35. The apparatus of claim 1, further comprising:

a second intervertebral cage including:

a top wall, a bottom wall, and two sidewalls defining an open space capable of receiving bone filling for biological bone fusion, and

an internal screw guide having an entry opening and an exit opening, the entry opening of the second intervertebral cage formed at least partially in a top surface of the top wall of the second intervertebral cage and the exit opening formed at least partially in a bottom surface of the top wall of the second intervertebral cage and at least partially in a side surface of the top wall of the second intervertebral cage; and

an attachment member coupling the intervertebral cage to the second intervertebral cage.

36. The apparatus of claim 1, wherein the exit opening is formed at least partially in a surface of one of the two sidewalls.

37. The apparatus of claim 1, wherein the internal screw guide includes:

a counterbore formed at least partially in the top surface of the top wall for accommodating a screw head of a screw member, wherein the internal bore is configured to continuously guide a body of the screw member through the internal screw guide into the open space and into the first vertebral body, wherein the entry opening of the internal bore is formed in a lower surface of the counterbore.

38. The apparatus of claim 37, wherein the internal bore is coaxial with the counterbore.

39. The apparatus of claim 1, wherein the expandable cage is formed from at least first and second parts that combine to form the top wall, the bottom wall, and the two sidewalls, wherein the first part defines the top wall and the second part defines the bottom wall and at least part of the side walls, wherein the surface features are present on both the first and second parts.

40. The apparatus of claim 1, wherein the side surface of the top wall and side surfaces of the side walls are perpendicular to the top surface.

41. The apparatus of claim 1, wherein the plurality of surface features are patterned all the way to the top surface of the top wall such that at least one or more of the surface features are positioned on the side surface of the top wall adjacent to the top surface of the top wall.

42. A universal, intervertebral combination internal screw guide and fixation apparatus configured to be inserted into a disc space between a first vertebral body and a second vertebral body and to provide fusion of the first vertebral body to the second vertebral body via biological bone fusion and screw fusion, the apparatus comprising:

an intervertebral cage including:

a top wall, a bottom wall, and two sidewalls defining an open space capable of receiving bone filling for the biological bone fusion;

an internal screw guide having an internal bore with an entry opening and an exit opening, the entry opening

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of the internal bore formed only in a top surface of the top wall and the exit opening formed at least partially in a bottom surface of the top wall and at least partially in a side surface of the top wall;

a second internal screw guide having a second internal bore with a second entry opening and a second exit opening, the second entry opening of the second internal bore formed only in the top surface of the top wall and the second exit opening formed at least partially in the bottom surface of the top wall and at least partially in a second side surface of the top wall; and

a circular hole extending into the top wall in a direction substantially normal to the top surface of the top wall and positioned between the internal screw guide and the second internal screw guide at the top surface of the top wall,

wherein the expandable cage is formed from at least first and second parts that combine to form the top wall, the bottom wall, and the two sidewalls, wherein the first part defines at least part of the top wall and the side walls and the second part defines the at least part of bottom wall and the side walls.

43. The apparatus of claim 42, wherein the exit opening is formed partially in the surface of the one of the two sidewalls.

44. The apparatus of claim 42, wherein a diameter of the circular hole is smaller than a diameter of the internal screw guide and the second internal screw guide, wherein a rectangular indentation extends into at least part of the top surface of the top wall and is oriented with at least one side of the rectangular indentation being substantially parallel to the side surface of the top wall, and wherein both the circular hole and the rectangular indentation are positioned between the internal screw guide and the second internal screw guide at the top surface of the top wall.

45. The apparatus of claim 42, wherein the side surface of the top wall is patterned with a plurality of surface features to create a rough side surface adjacent the exit opening.

46. The apparatus of claim 42, wherein the open space for receiving bone graft material extends continuously from a first of the two sidewalls to a second of the two sidewalls.

47. A universal, intervertebral combination internal screw guide and fixation apparatus configured to be inserted into a disc space between a first vertebral body and a second vertebral body and to provide fusion of the first vertebral body to the second vertebral body via biological bone fusion and screw fusion, the apparatus comprising:

an intervertebral cage including:

a top wall, a bottom wall, and two sidewalls defining an open space capable of receiving bone filling for the biological bone fusion;

an internal screw guide having an internal bore with an entry opening and an exit opening, the entry opening of the internal bore formed only in a top surface of the top wall and the exit opening formed at least partially in a bottom surface of the top wall and at least partially in a side surface of the top wall, wherein the internal screw guide further includes a counterbore that is larger than and coaxial with the internal bore and has a counterbore entry opening that is formed only in the top surface of the top wall;

a second internal screw guide having a second internal bore with a second entry opening and a second exit opening, the second entry opening of the second internal bore formed only in the top surface of the top wall and the second exit opening formed at least

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partially in the bottom surface of the top wall and at least partially in a second side surface of the top wall; and

a circular hole extending through the top wall in a direction substantially normal to the top surface of the top wall, wherein the circular hole is positioned between the internal screw guide and the second internal screw guide at the top surface of the top wall.

48. The apparatus of claim 47, wherein the intervertebral cage includes a rectangular indentation extending into at least part of the top wall and oriented with at least one side of the rectangular indentation being substantially parallel to the side surface of the top wall, wherein the rectangular indentation is positioned between the internal screw guide and the second internal screw guide at the top surface of the top wall.

49. The apparatus of claim 47, wherein the side surface of the top wall comprises means to facilitate integration and fusion with superior and inferior vertebral bodies.

50. The apparatus of claim 49, wherein the means is positioned at least partially on the side surface closer to the top surface of the top wall than the exit opening.

51. The apparatus of claim 47, wherein an internal surface of the internal screw guide extends continuously from the entry opening to the exit opening.

52. The apparatus of claim 47, wherein the internal screw guide extends through an entire depth of the top wall from the top surface to the bottom surface and exiting at least partially into the open space.

53. The apparatus of claim 47, wherein the internal screw guide permits only a predetermined angled trajectory of a screw member through the intervertebral cage.

54. The apparatus of claim 47, wherein the internal screw guide has a 25 degree angulation.

55. The apparatus of claim 47, wherein the top wall has a thickness extending from the top surface of the top wall to the bottom surface of the top wall in a direction of a depth of the intervertebral cage, a height of the intervertebral cage extending in a direction perpendicular to the depth, and

wherein an axis of the internal screw guide extends to a greater extent in the direction of the depth of the intervertebral cage than in a direction of a height of the intervertebral cage in order to facilitate multi-level fusion of adjacent vertebral bodies with multiple intervertebral cages.

56. The apparatus of claim 47, wherein the top wall of the intervertebral cage has a thickness that is greater than a thickness of each of the sidewalls.

57. The apparatus of claim 47, wherein each of the two sidewalls includes a means for receiving placement of bone filling into the open space of the intervertebral cage for the biological bone fusion.

58. The apparatus of claim 47, wherein the intervertebral cages includes indentations formed on surfaces of the two sidewalls and on opposite ends of the intervertebral cage for receiving ends of prongs of an implantation tool.

59. The apparatus of claim 47, wherein a surface of each of the two sidewalls includes a plurality of ridges.

60. The apparatus of claim 47, wherein the intervertebral cage is a cervical intervertebral cage configured to fit into a cervical disc space.

61. The apparatus of claim 47, wherein each of the internal screw guide and the second internal screw guide is angled to orient a first screw member and a second screw bi-directionally in opposite directions.

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62. The apparatus of claim 61, wherein the internal screw guide is configured to orient the first screw member rostrally and the second internal screw guide is configured to orient the second screw member caudally.

63. The apparatus of claim 47, wherein the internal screw guide and the second internal screw guide are at an angulation with respect to the top surface of the top wall.

64. The apparatus of claim 47, wherein each of the internal screw guide and the second internal screw guide permits only a 25 degree angulation of the first screw member and the second screw member.

65. The apparatus of claim 47, wherein the internal screw guide and the second internal screw guide are aligned along a longitudinal axis of the top wall of the intervertebral cage.

66. The apparatus of claim 47, wherein the internal screw guide and the second internal screw guide are symmetrically disposed on each side of a center point of the intervertebral cage along a longitudinal axis of the top wall of the intervertebral cage.

67. The apparatus of claim 47, wherein the internal screw guide and the second internal screw guide are offset in opposite directions with respect to a center line of a longitudinal extent of the top wall.

68. The apparatus of claim 47, wherein the top wall has four quadrants delineated by a first axis and a second axis each lying in a plane of the top wall, and the first axis is at a right angle with respect to the second axis,

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

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

wherein a majority of an area of the entry opening of the internal screw guide is in the first quadrant and a

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majority of an area of the second entry opening of the second internal screw guide is in the third quadrant.

69. The apparatus of claim 47, wherein the top wall has four quadrants delineated by a first axis and a second axis each lying in a plane of the first wall, and the first axis is at a right angle with respect to the second axis,

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

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

wherein a center of the entry opening of the internal screw guide is in the first quadrant and a center of the second entry opening of the second internal screw guide is in the third quadrant.

70. The apparatus of claim 47, wherein the intervertebral cage further comprises:

a third internal screw guide having a third entry opening and a third exit opening, the third entry opening formed at least partially in the top surface of the top wall and the third exit opening formed at least partially in the bottom surface of the top wall and at least partially in the side surface of the top wall; and

a fourth internal screw guide having a fourth entry opening and a fourth exit opening, the fourth entry opening formed at least partially in the top surface of the top wall and the fourth exit opening formed at least partially in the bottom surface of the top wall and at least partially in the second side surface of the top wall, wherein the internal screw guide and the fourth internal screw guide are oriented rostrally and the second internal screw guide and the third internal screw guide are oriented caudally.

* * * * *

(12) **United States Patent**
Moskowitz et al.

(10) **Patent No.:** **US 8,353,913 B2**
(45) **Date of Patent:** **Jan. 15, 2013**

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

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **13/084,543**

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Related U.S. Application Data

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(60) Provisional application No. 60/670,231, filed on Apr. 12, 2005.

(51) **Int. Cl.**
A61B 17/56 (2006.01)

(52) **U.S. Cl.** **606/86 A**

(58) **Field of Classification Search** 606/86 A,
606/251, 246, 301, 247, 250, 252, 99, 248,
606/279; 623/17.11, 17.15, 17.16

See application file for complete search history.

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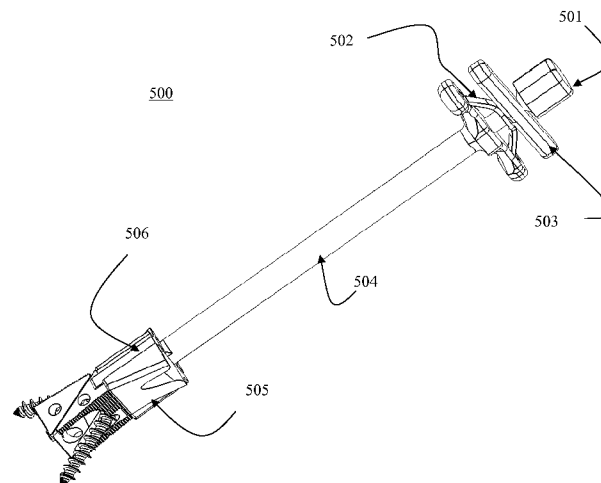
Primary Examiner — Pedro Philogene

(74) *Attorney, Agent, or Firm* — Dresch IP Law, PLLC; John J. Dresch

(57) **ABSTRACT**

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.

44 Claims, 41 Drawing Sheets



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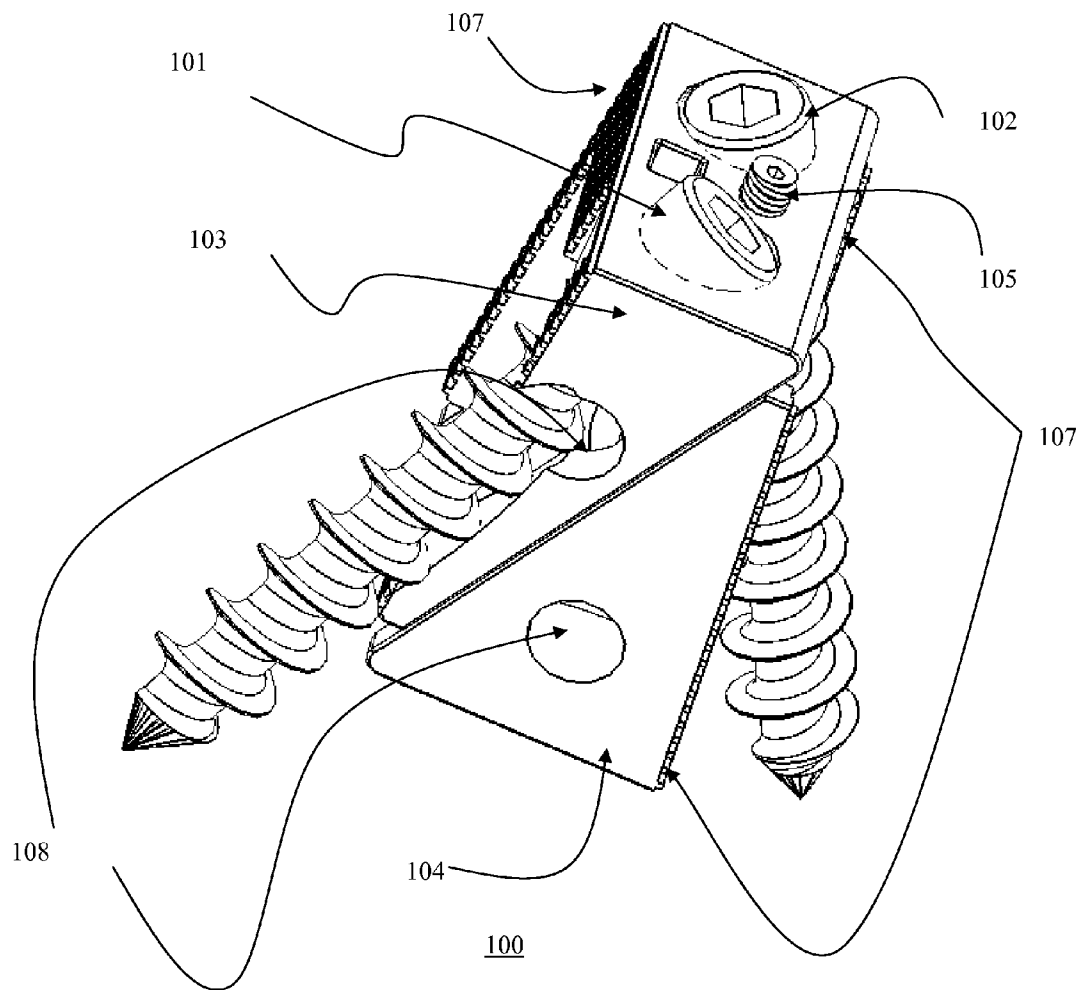


Fig. 1A

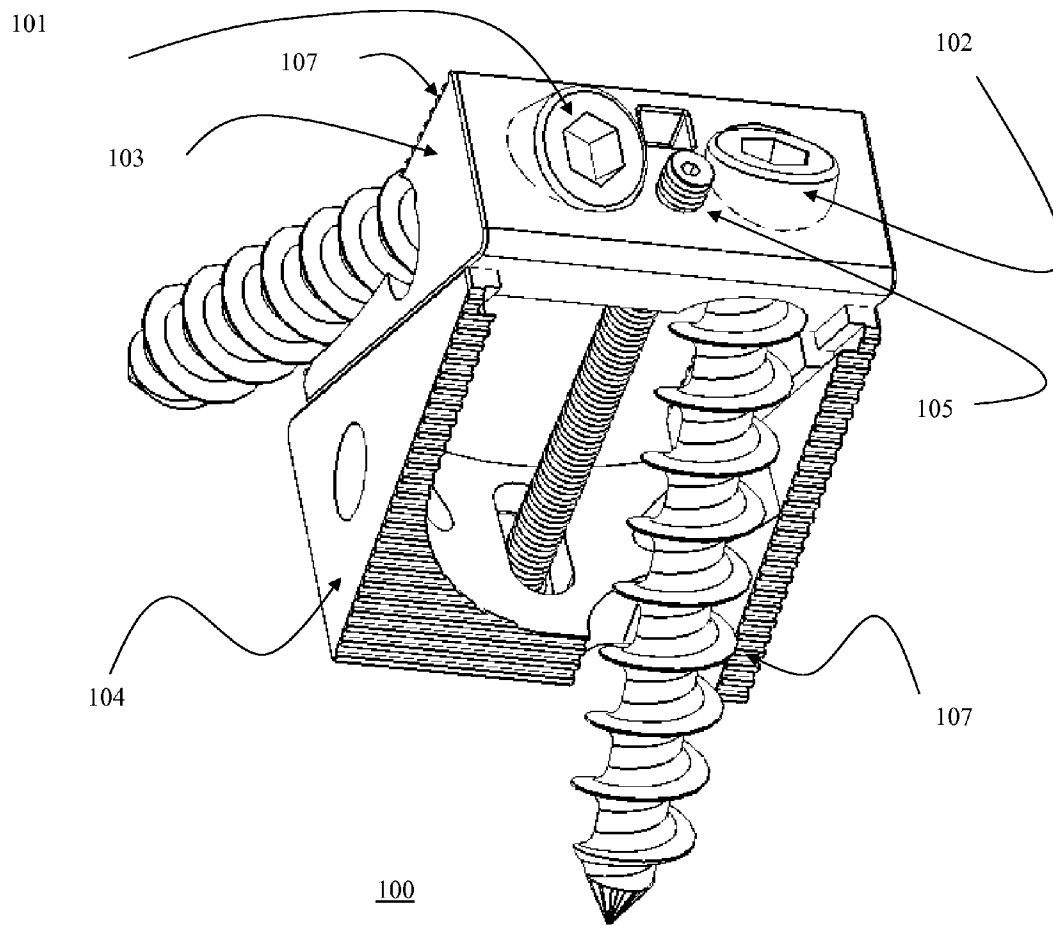


Fig. 1B

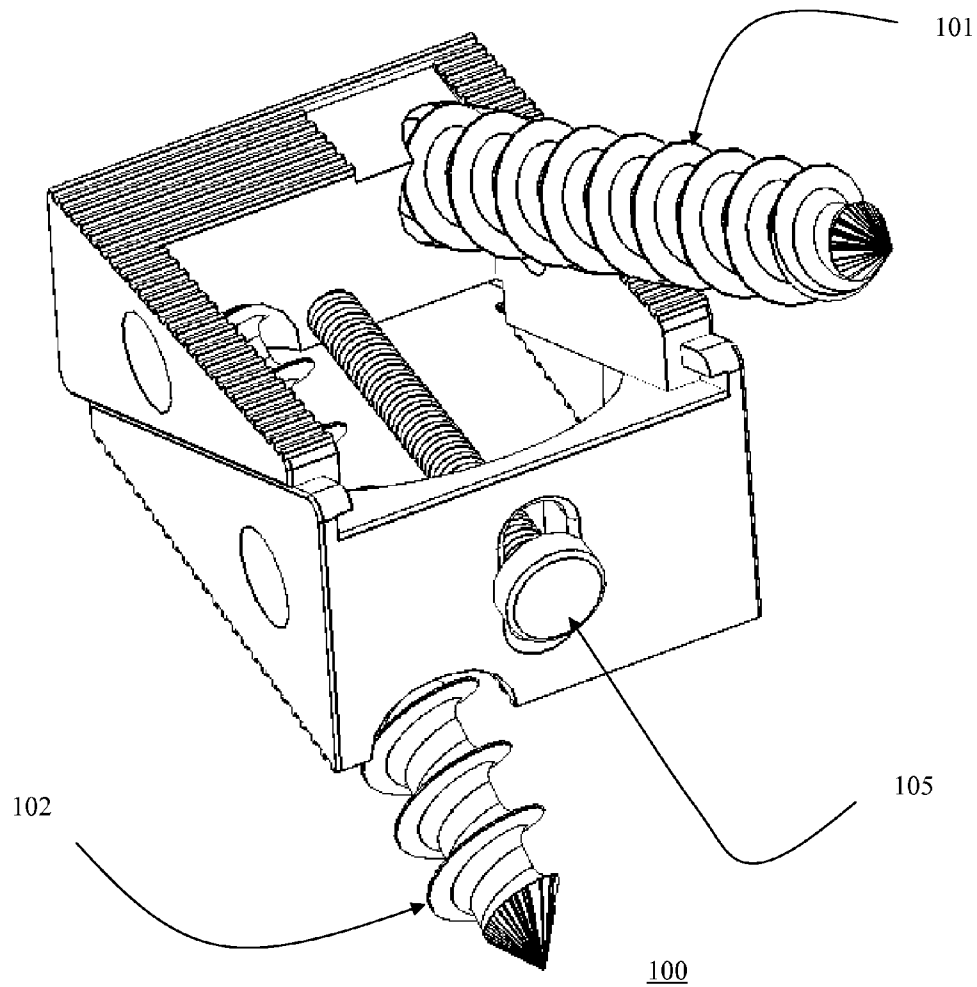


Fig. 1C

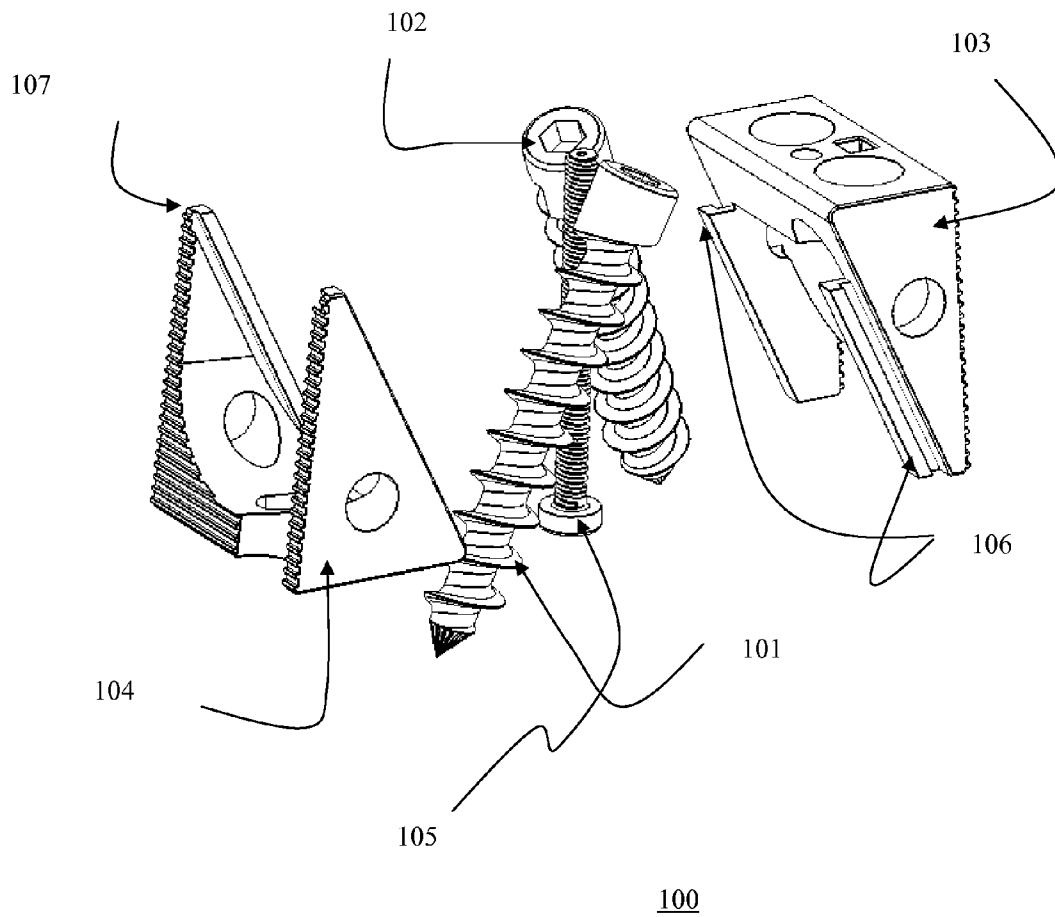


Fig. 1D

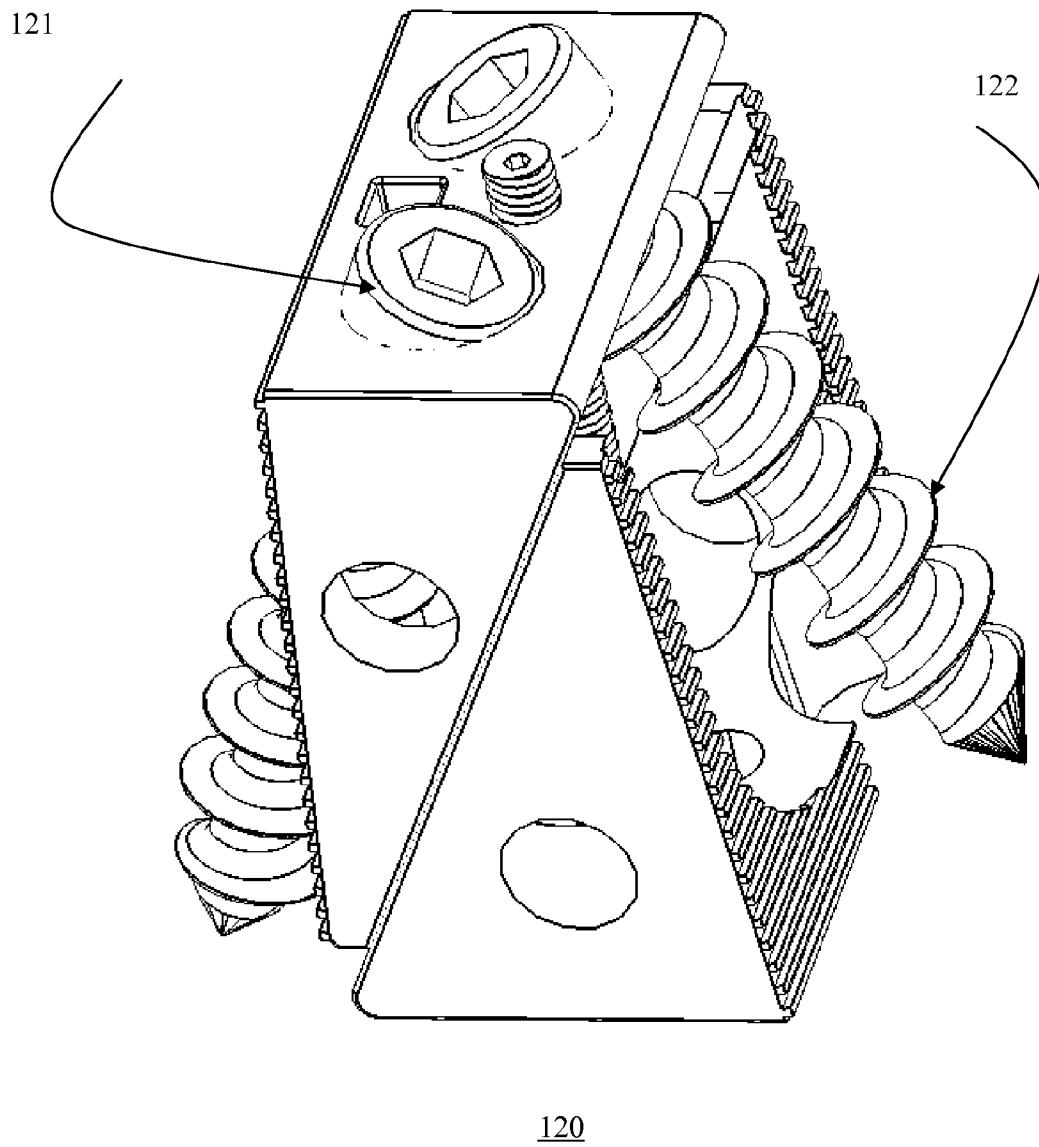


Fig. 1E



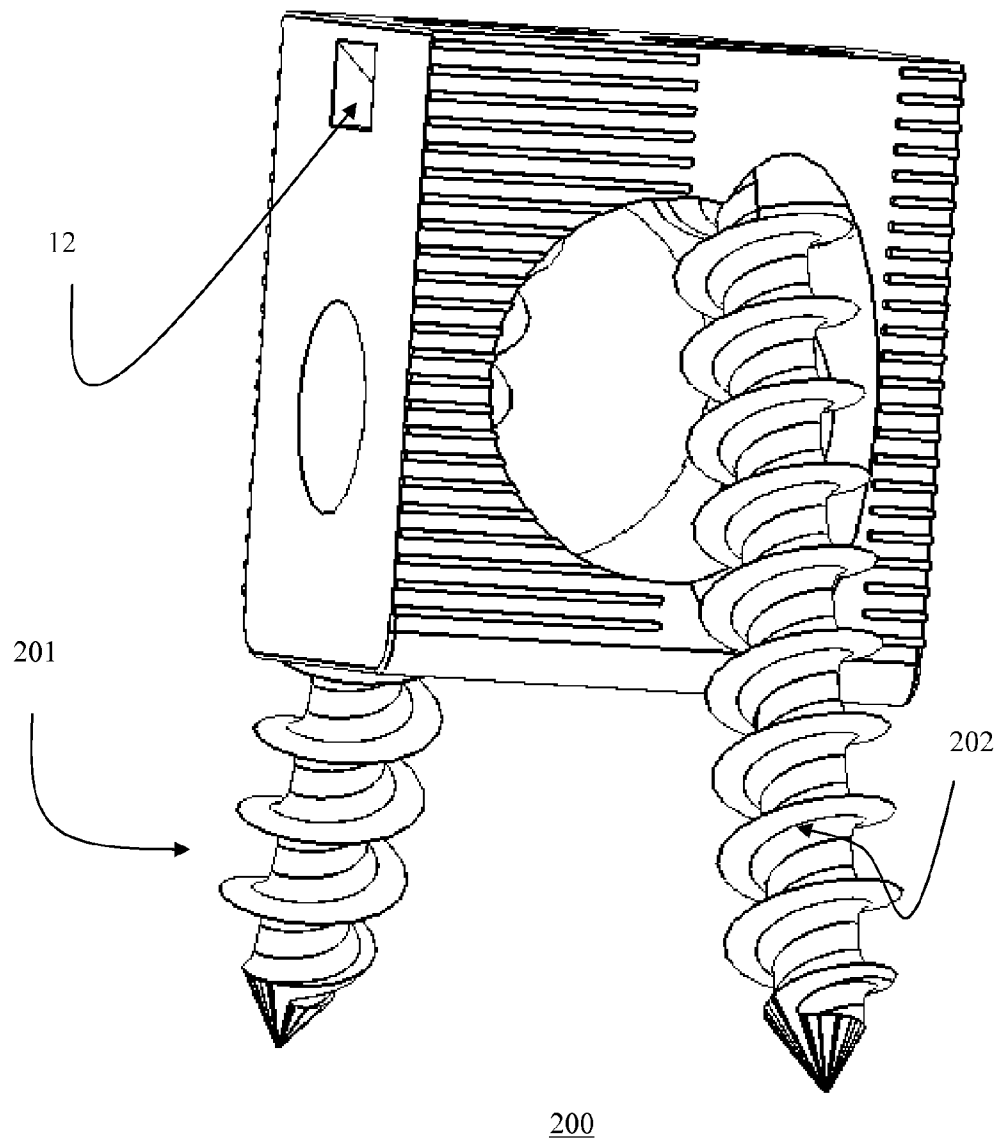


Fig. 2B

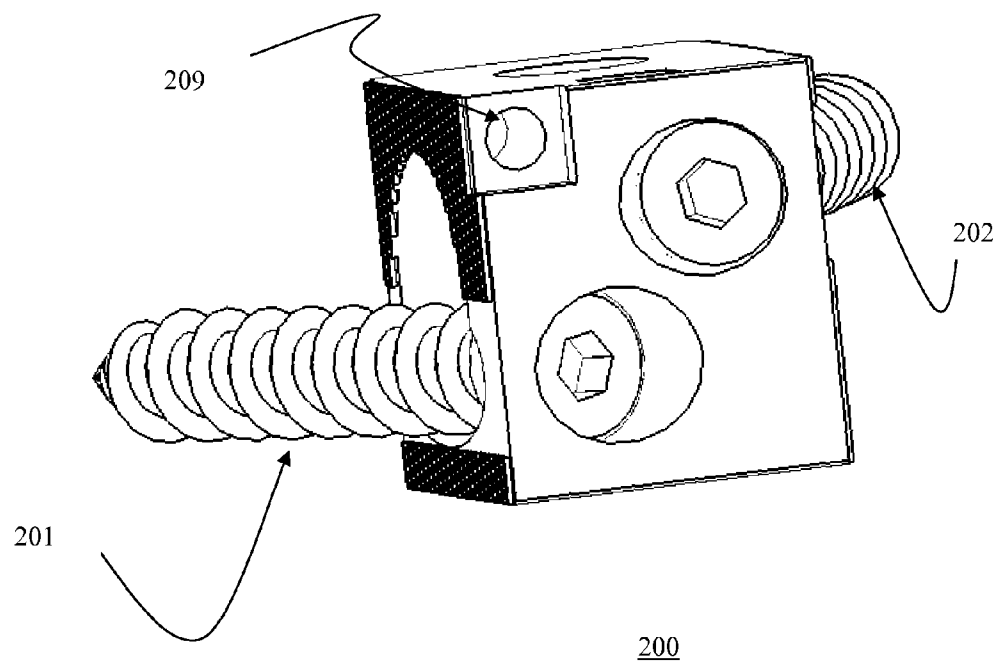


Fig. 2C

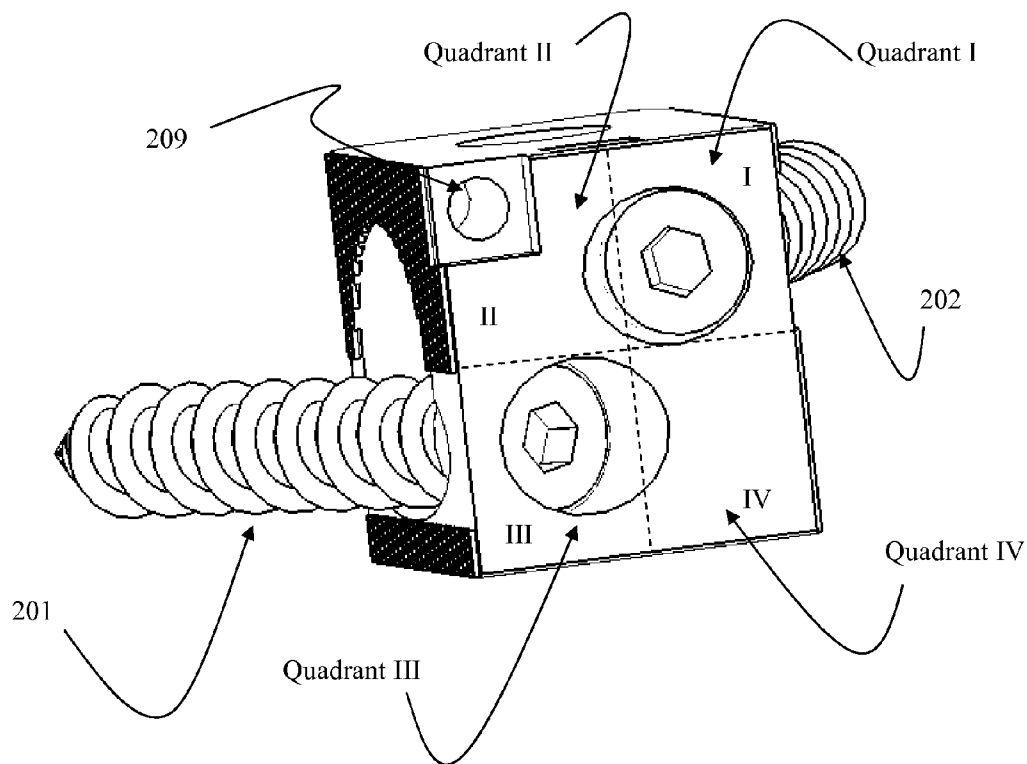


Fig. 2D

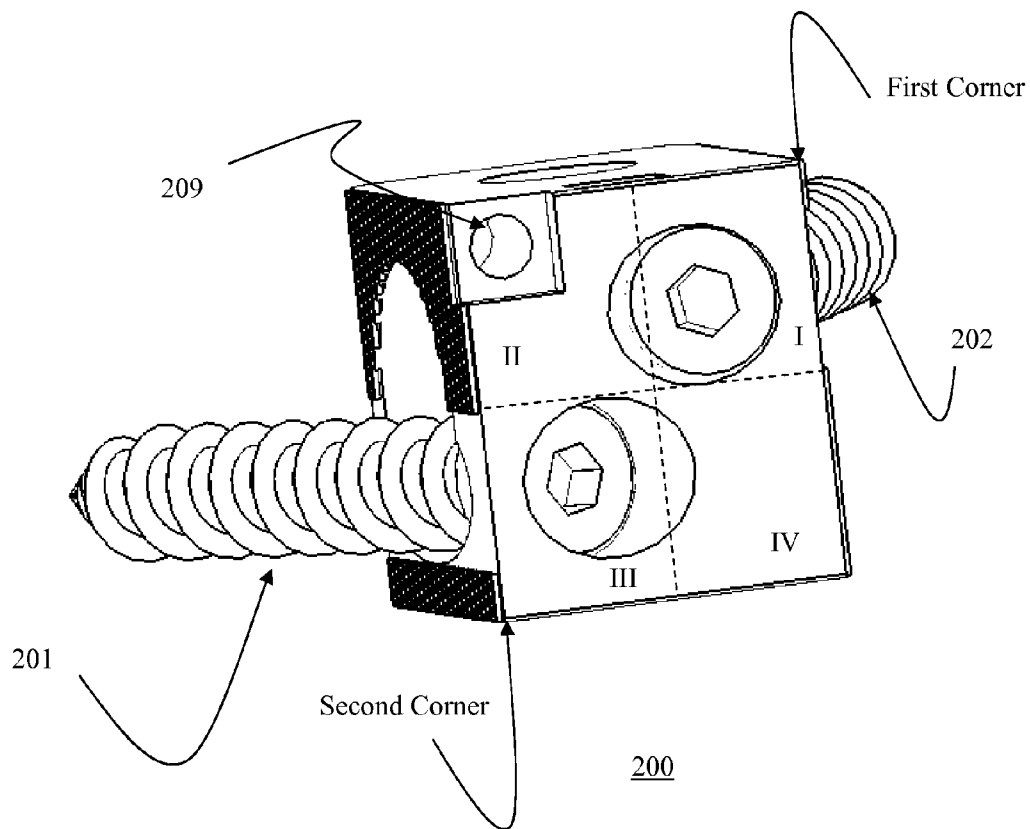


Fig. 2E

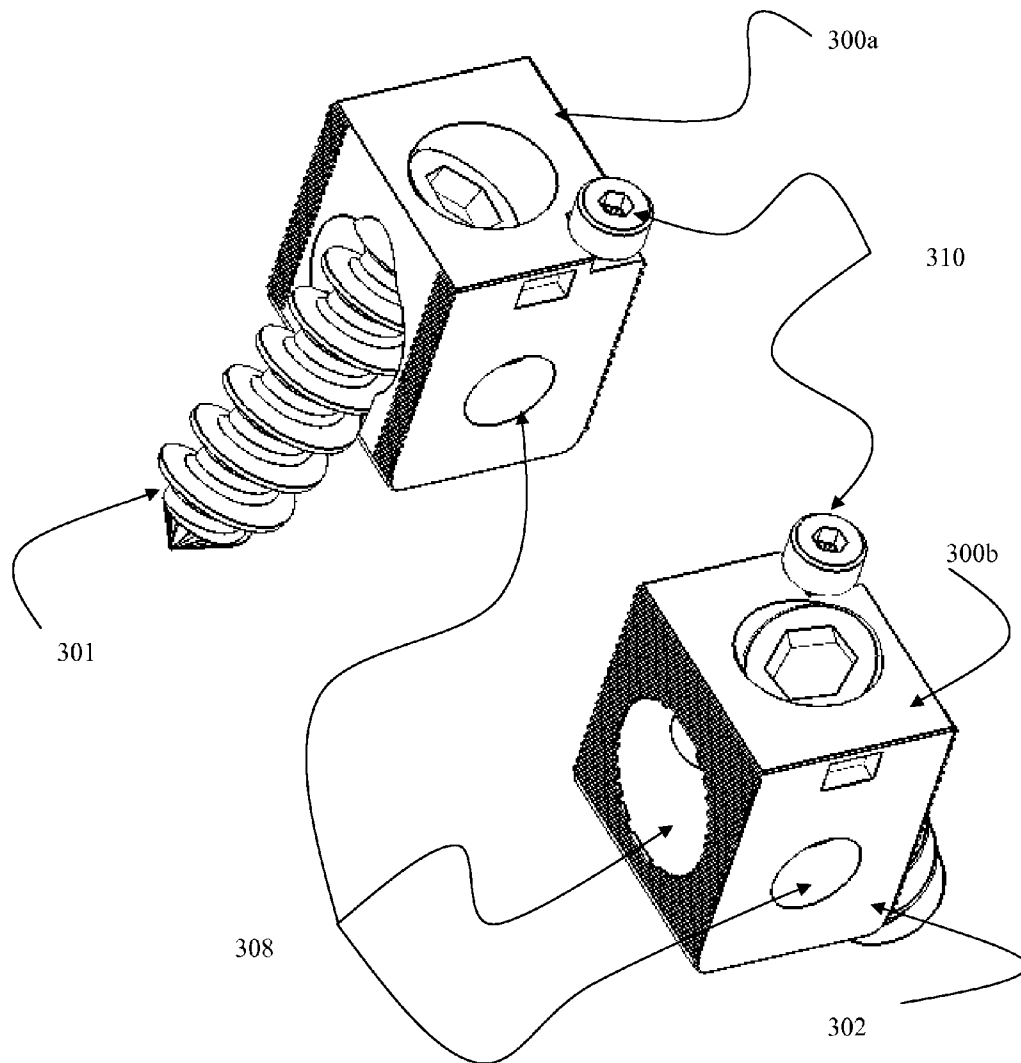


Fig. 3

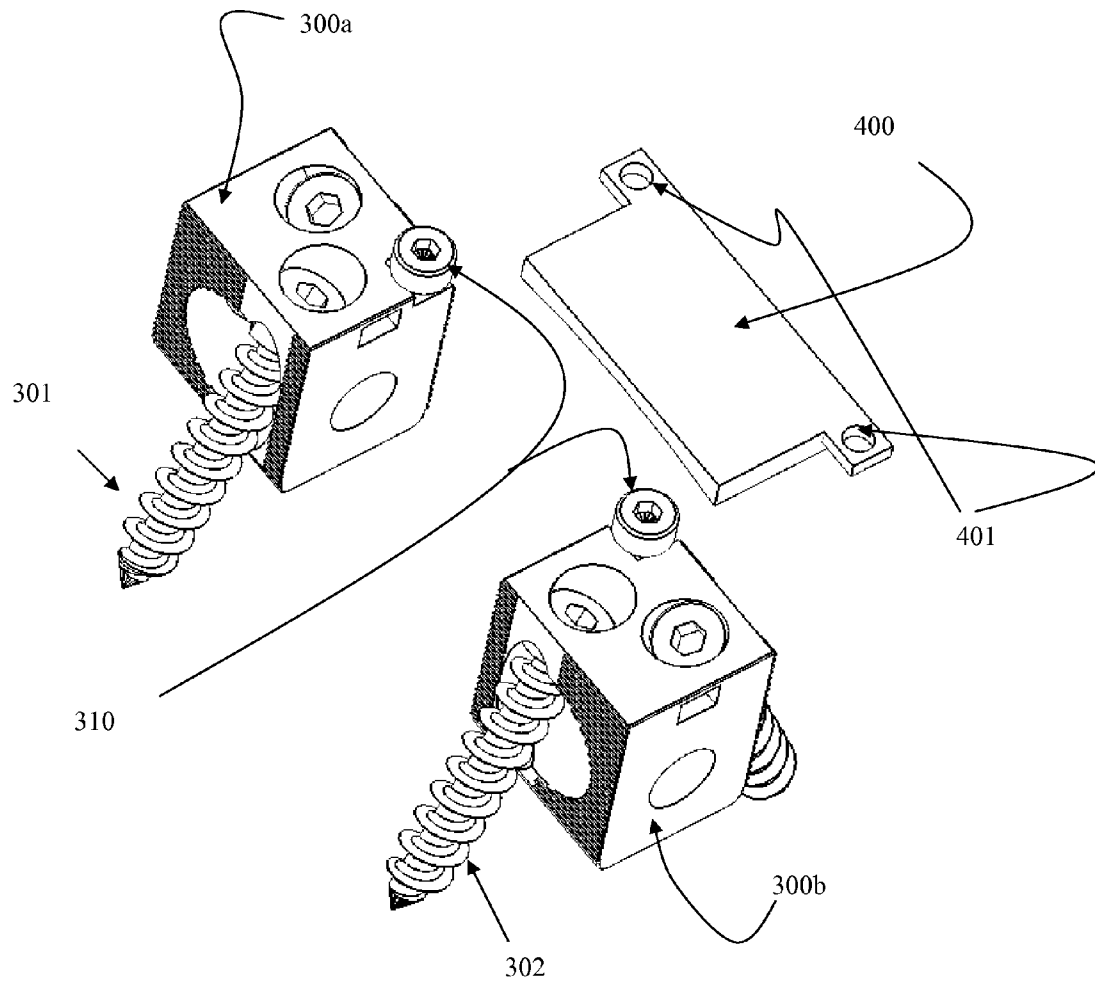


Fig. 4A

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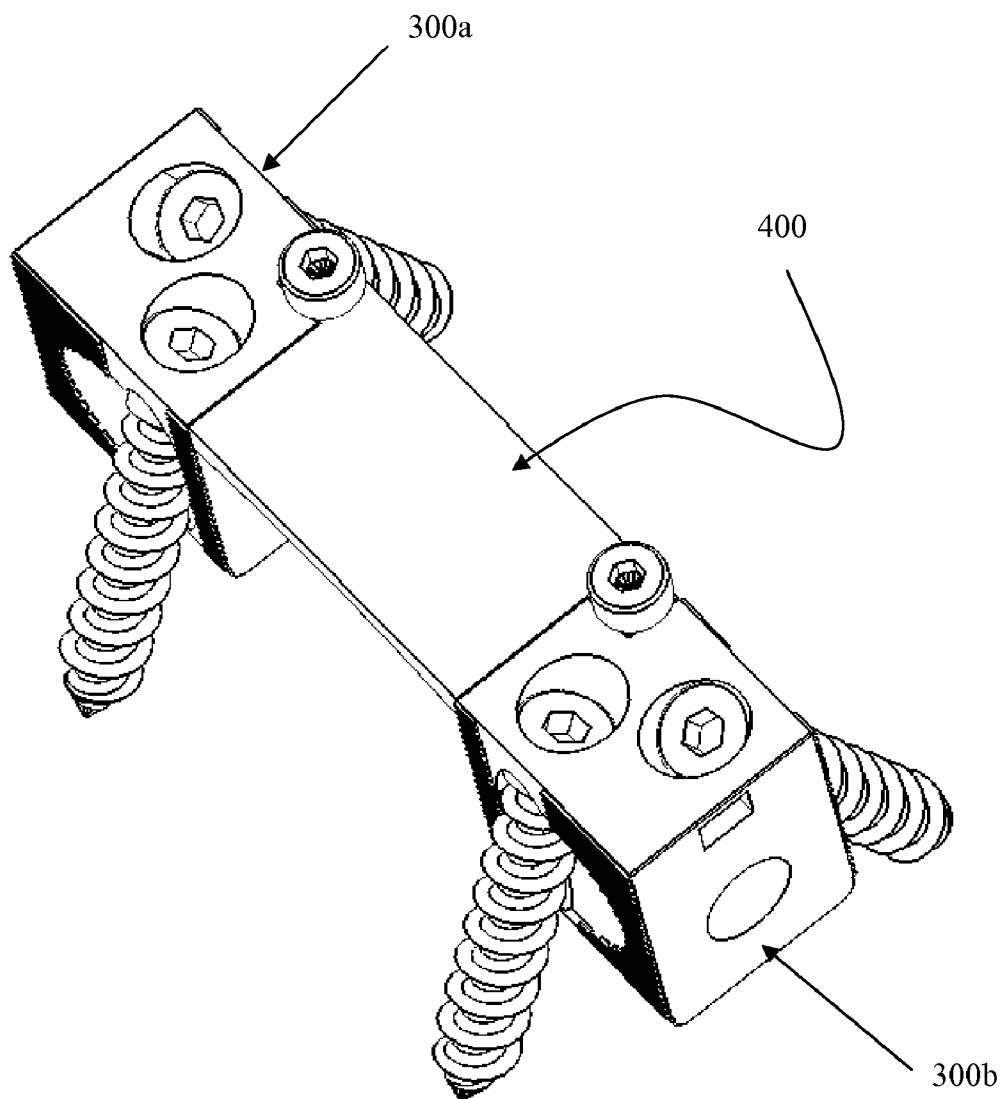


Fig. 4B

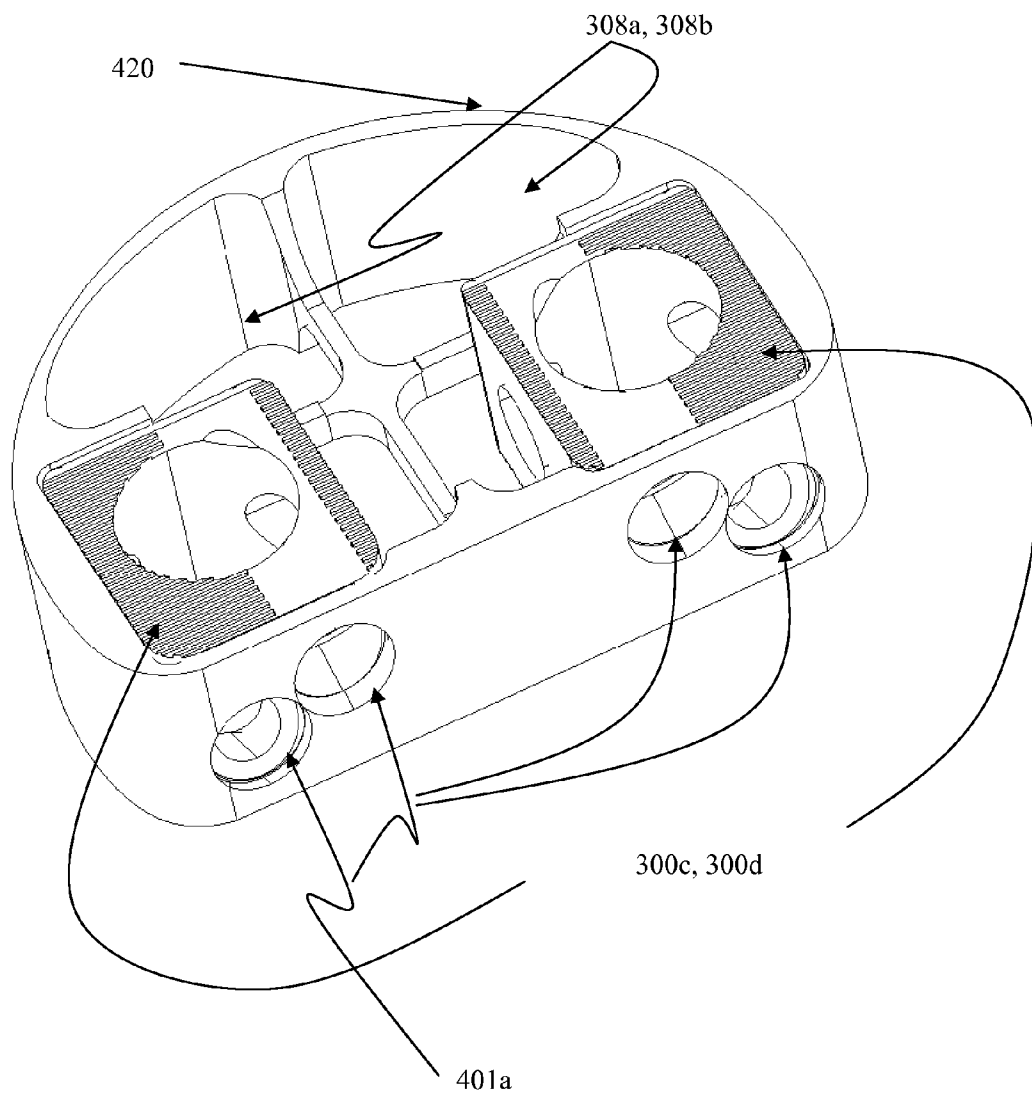


FIG. 4C

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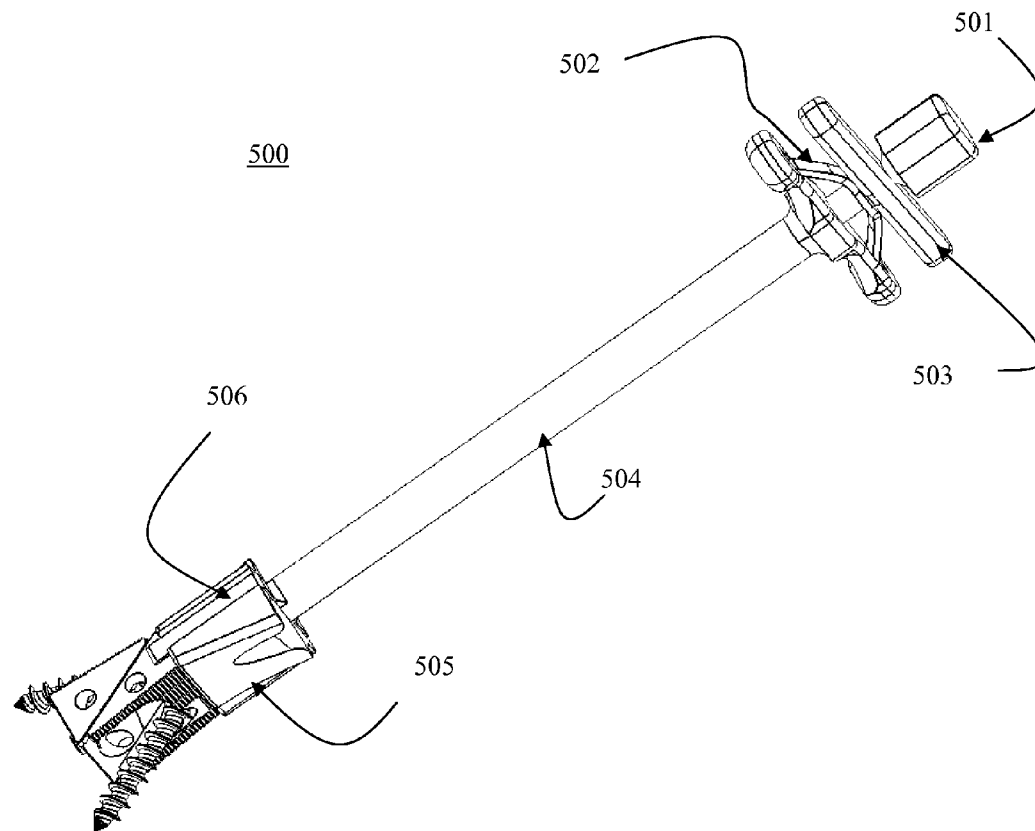


Fig. 5A

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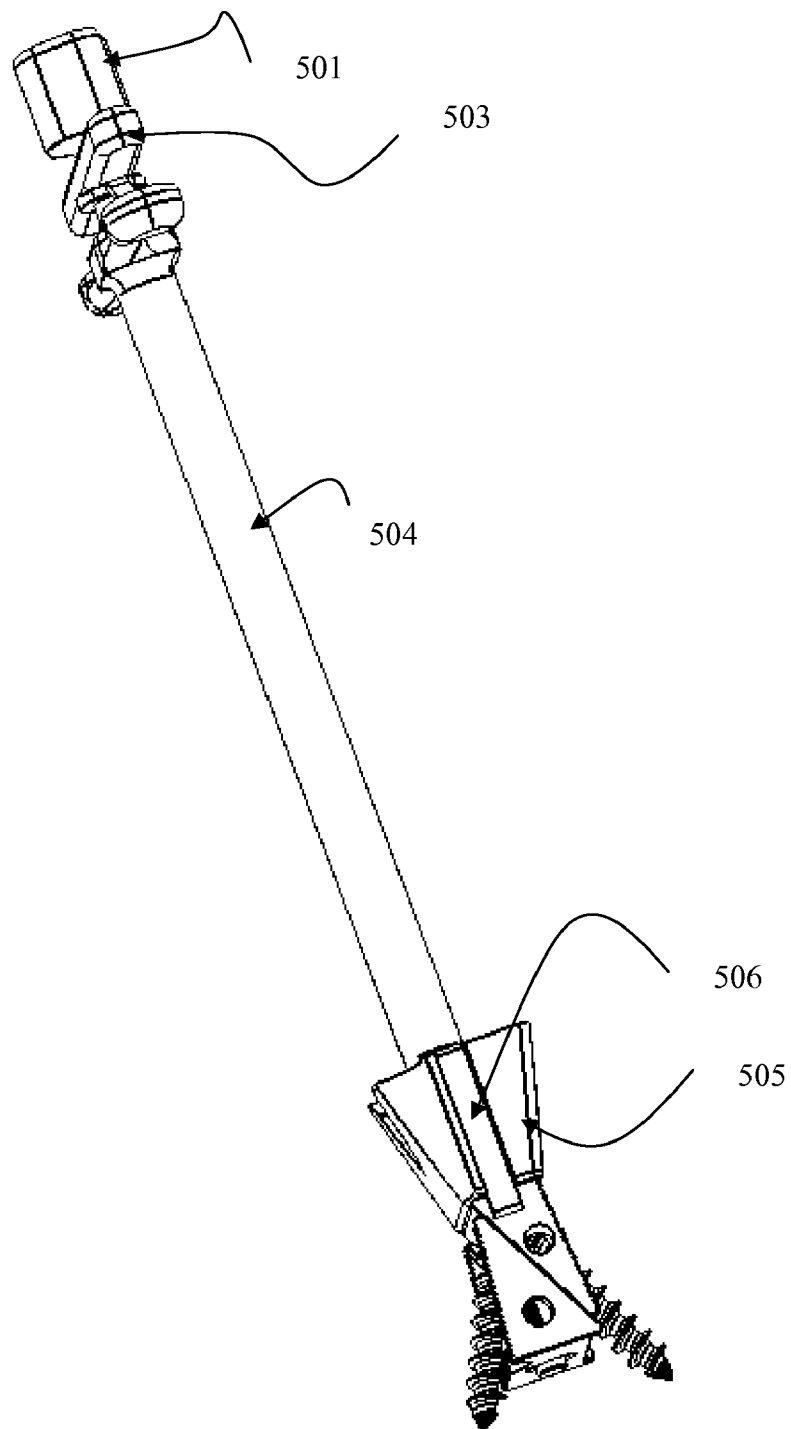


Fig. 5B

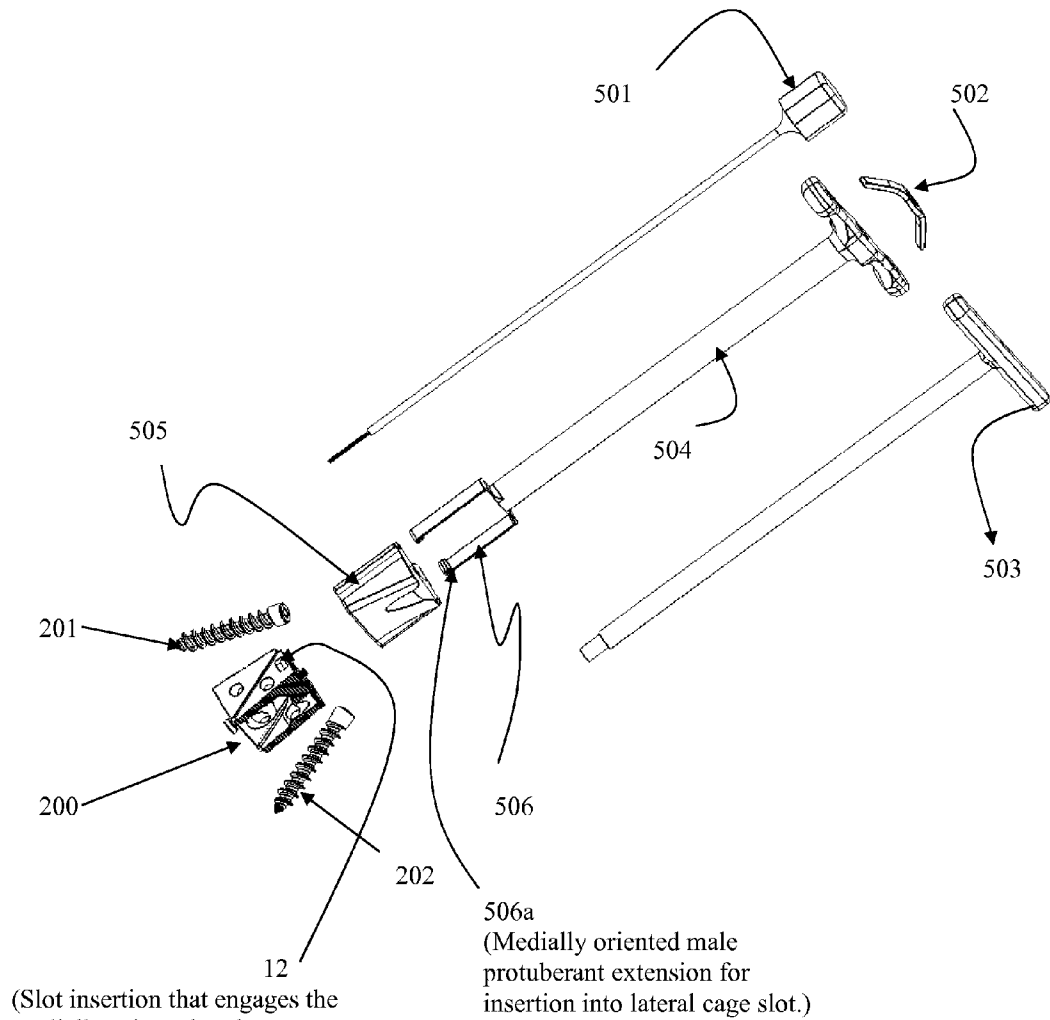


Fig. 5C

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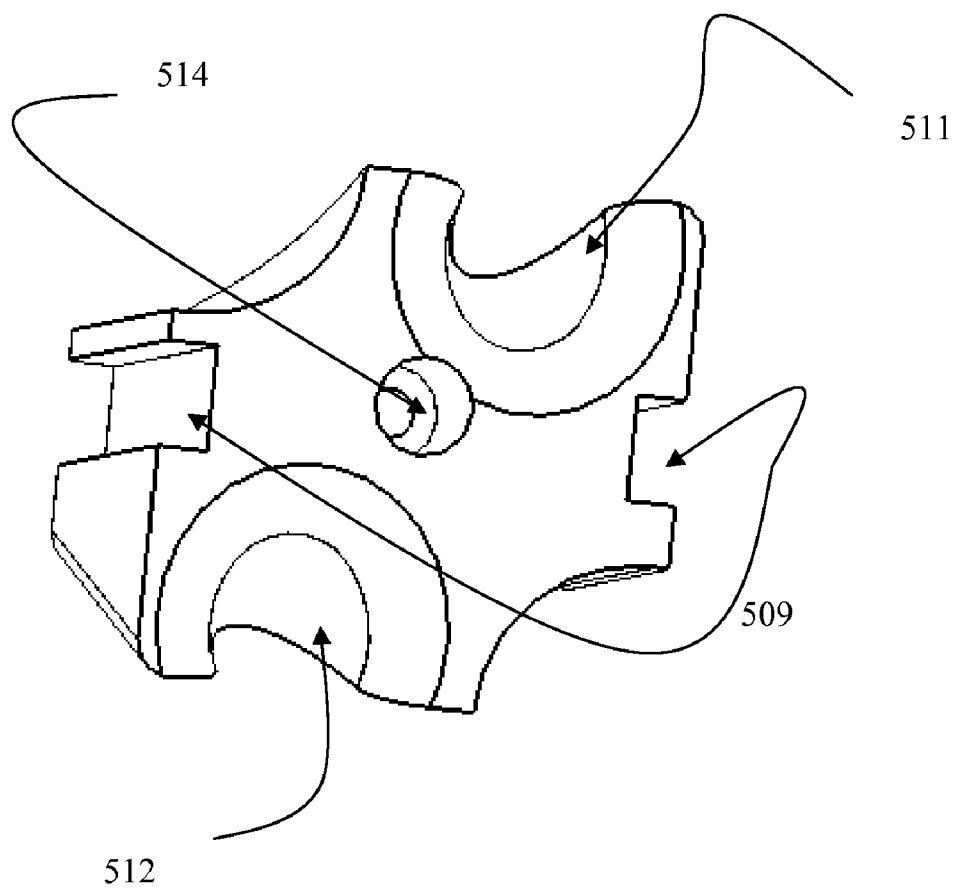


Fig. 5D

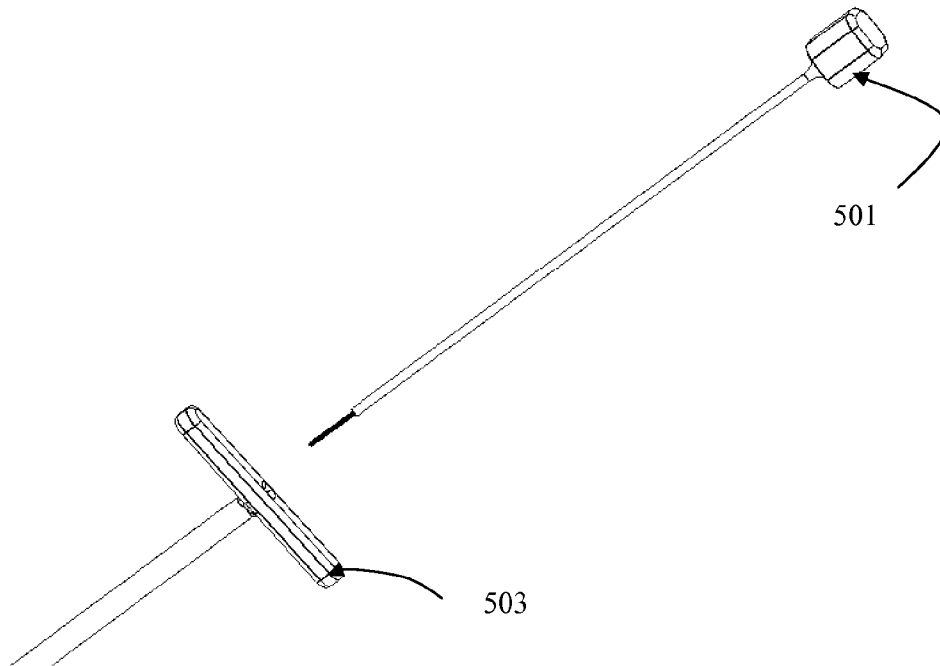


Fig. 5E

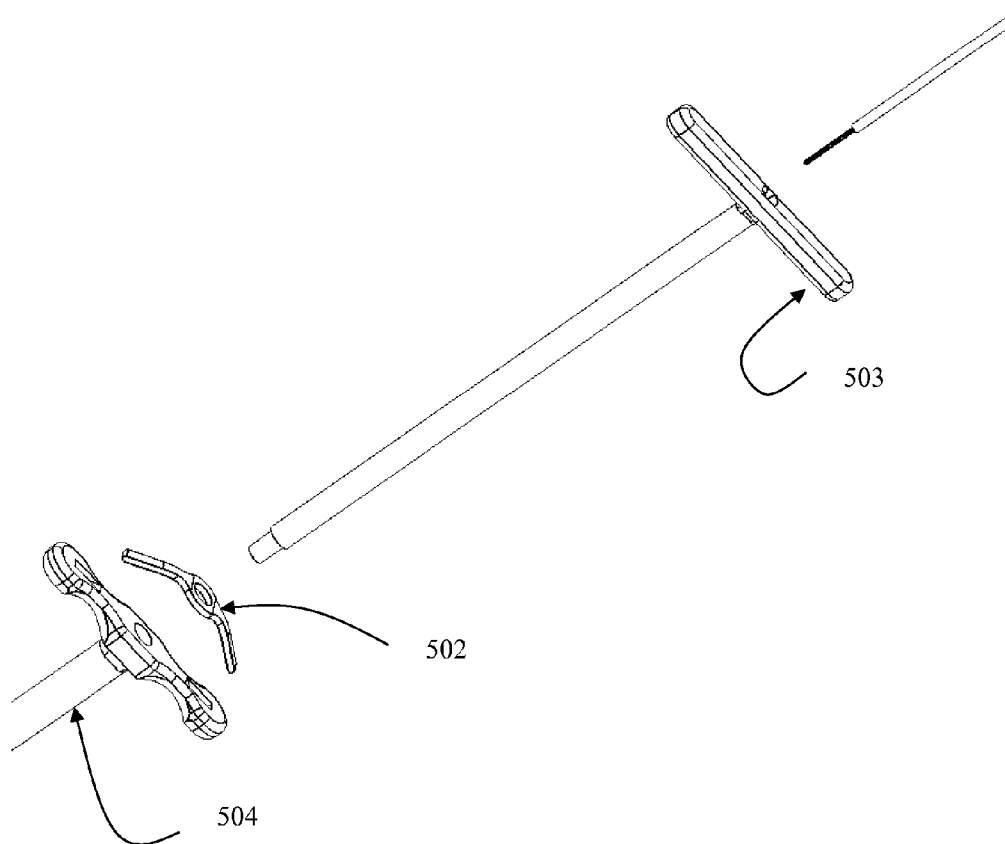


Fig. 5F

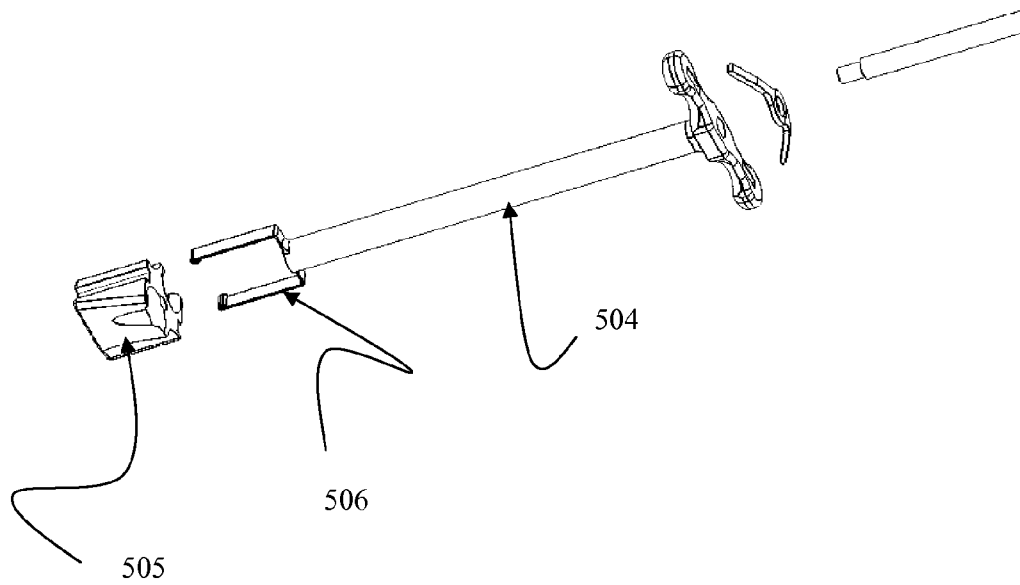


Fig. 5G

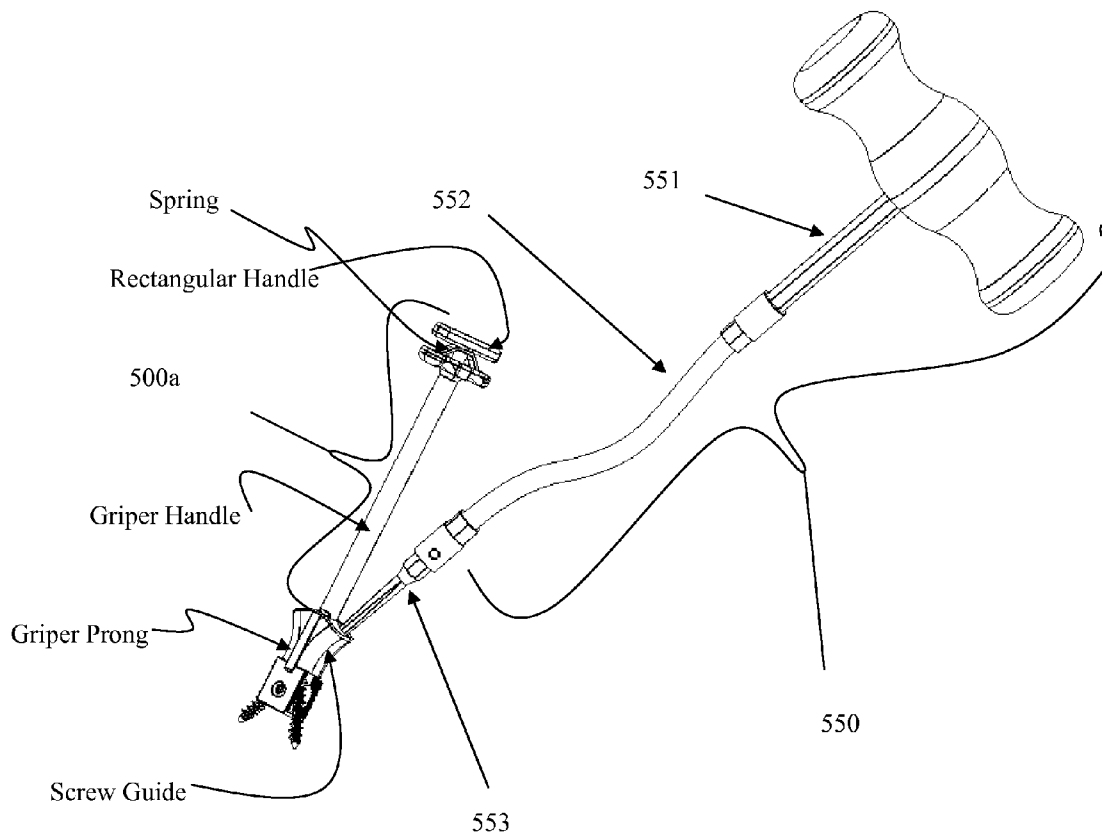


FIG. 5H

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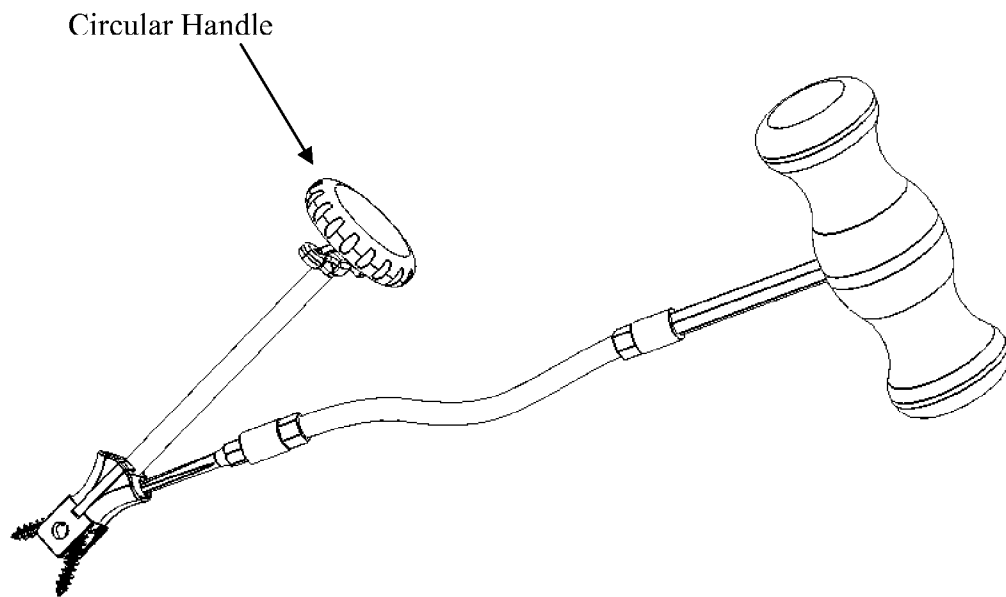


FIG. 5I

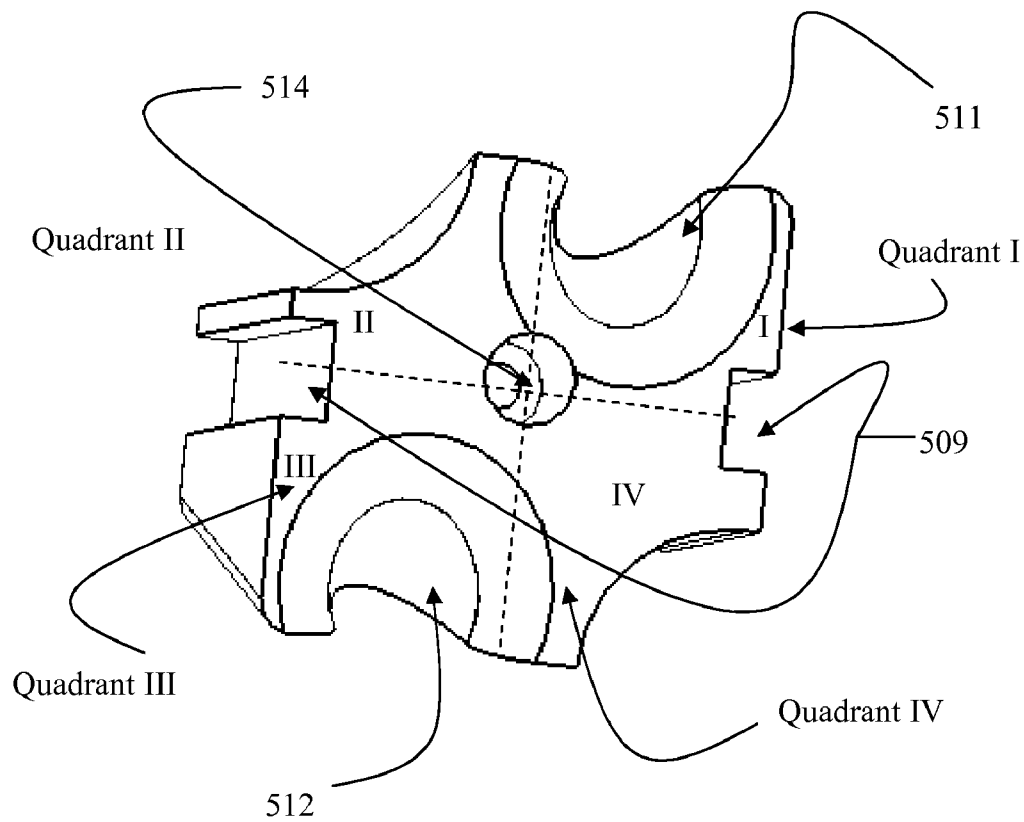


Fig. 5J

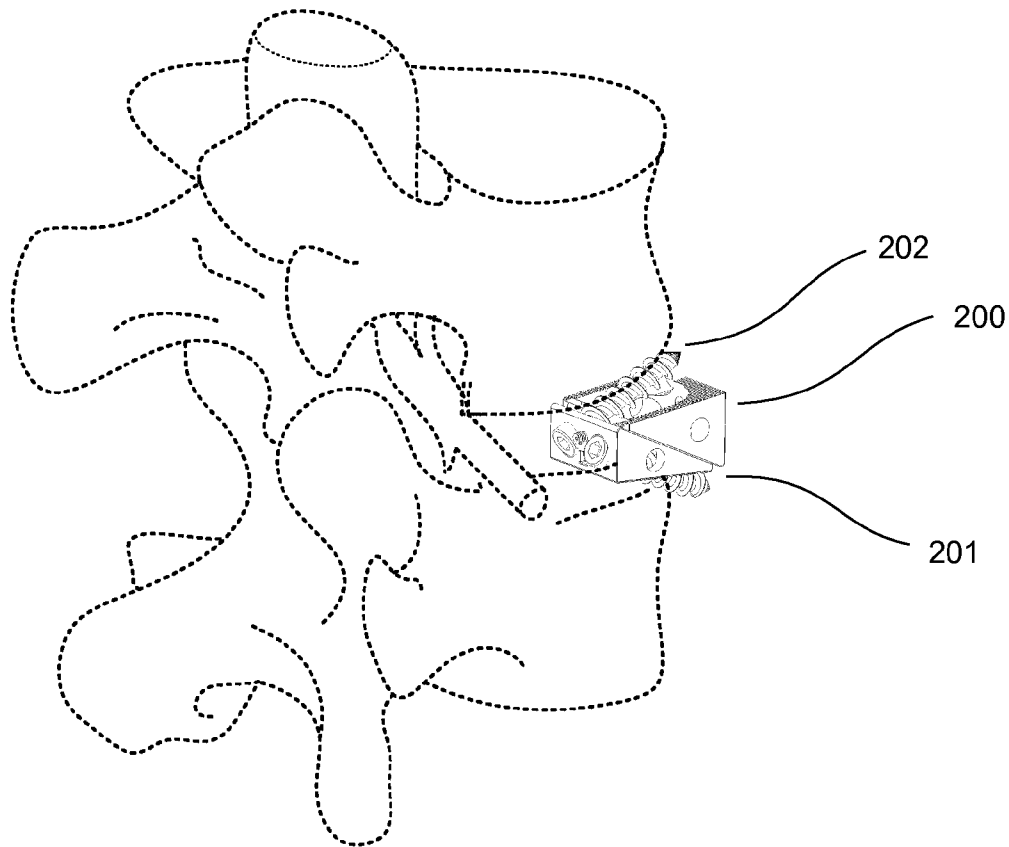


Fig. 6A

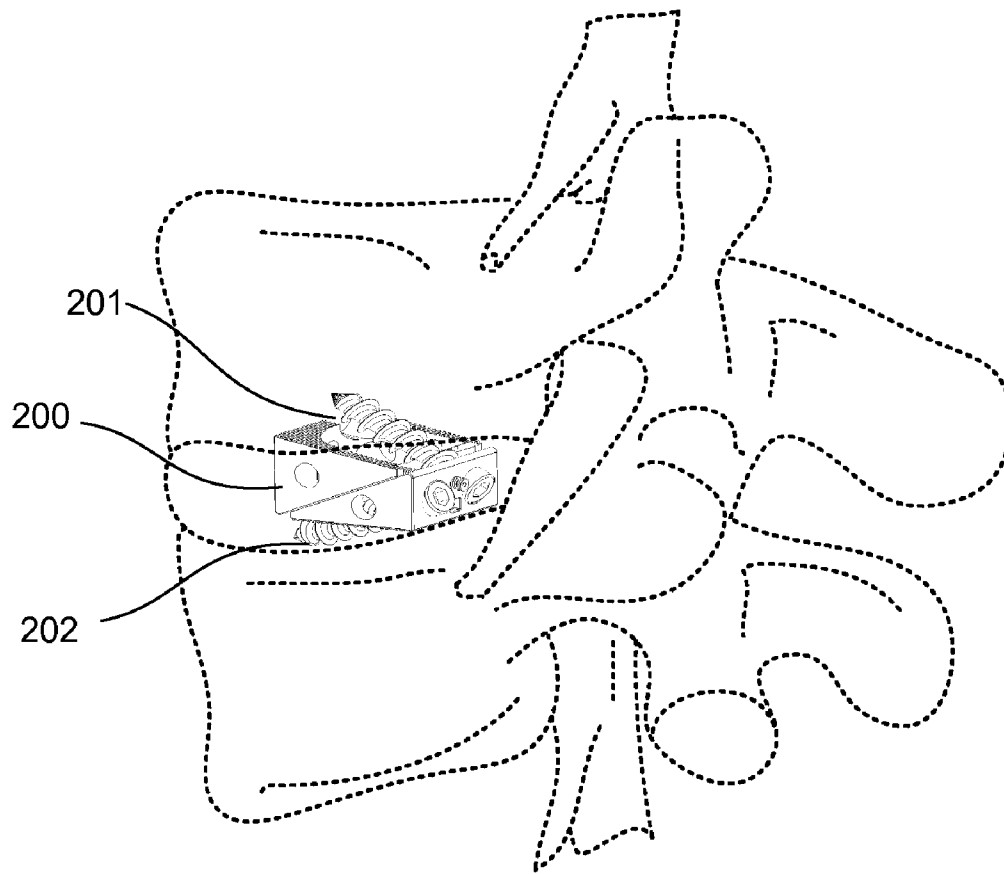


Fig. 6B

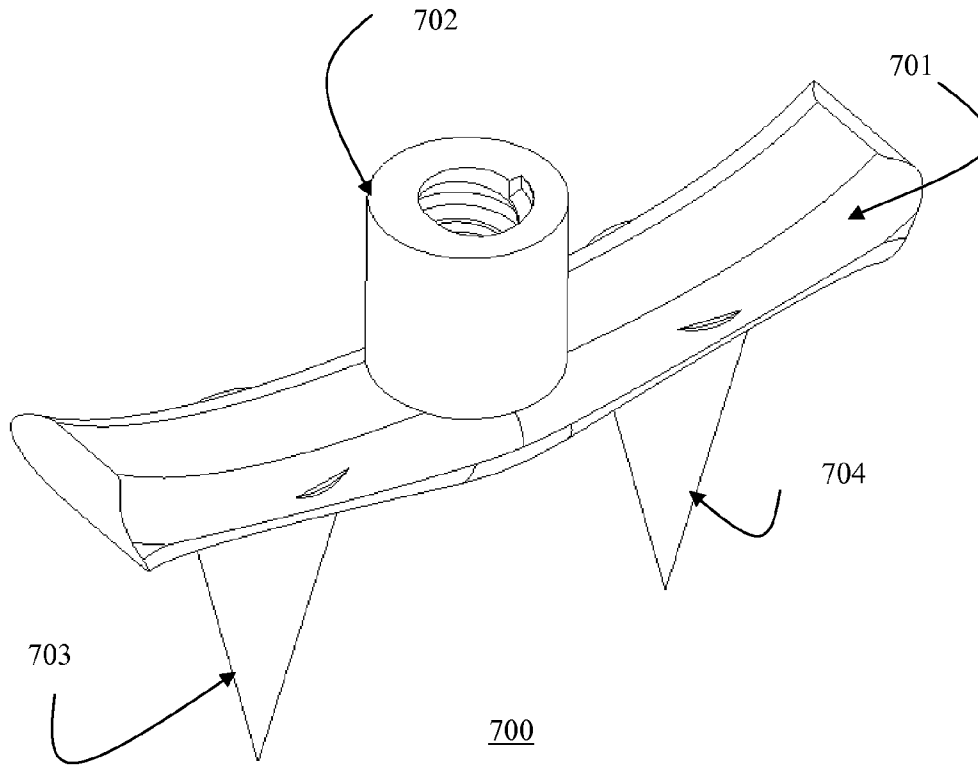


Fig. 7A

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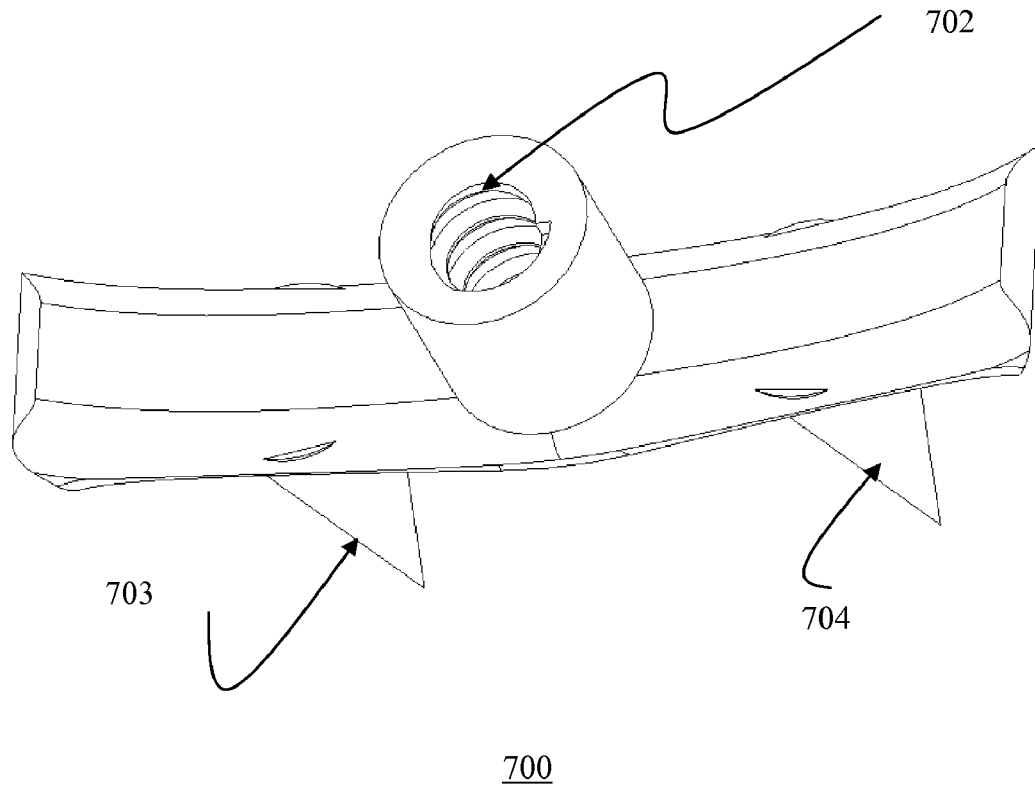


Fig. 7B

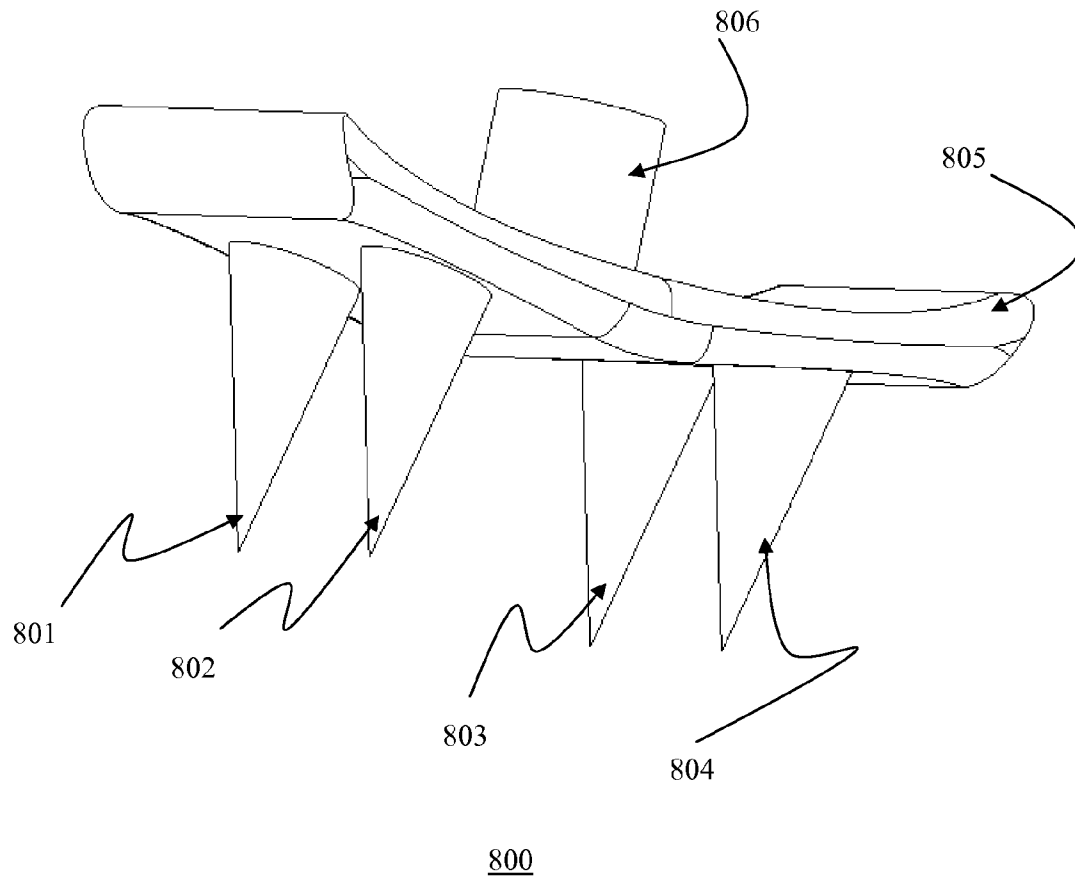


Fig. 8A

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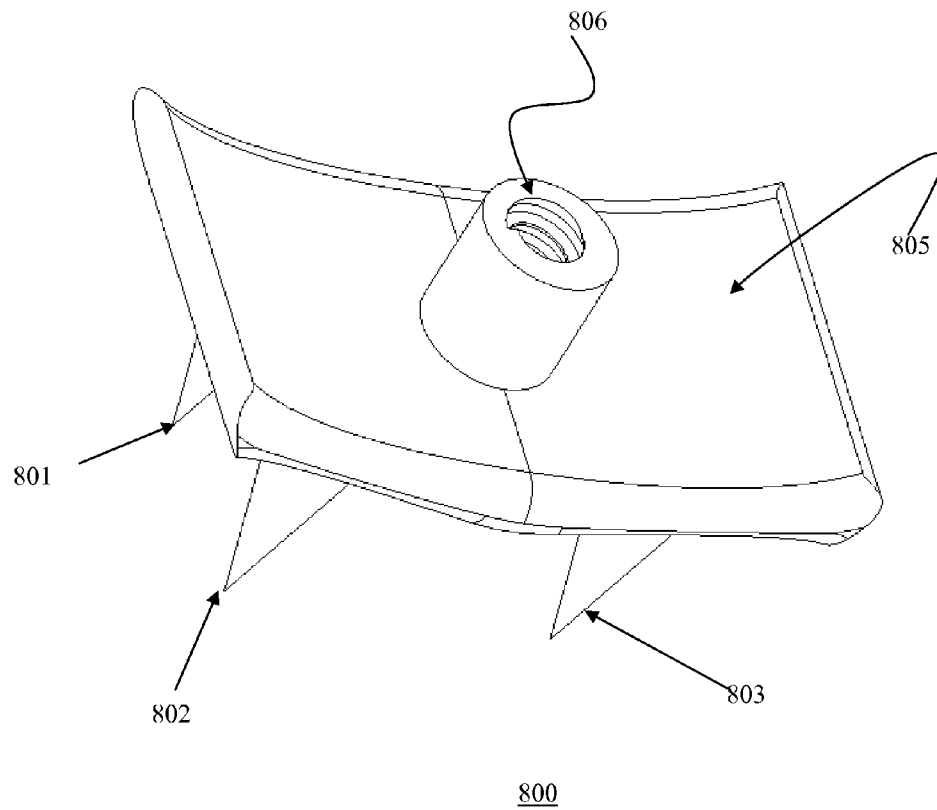


Fig. 8B

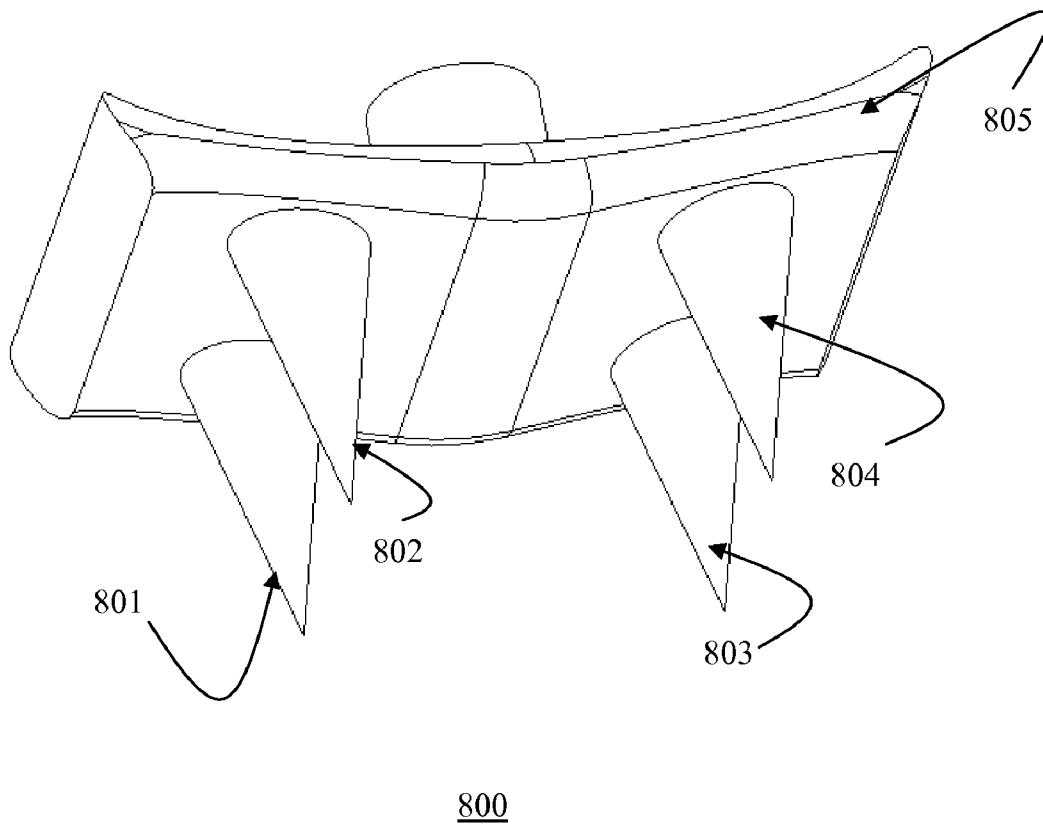


Fig. 8C

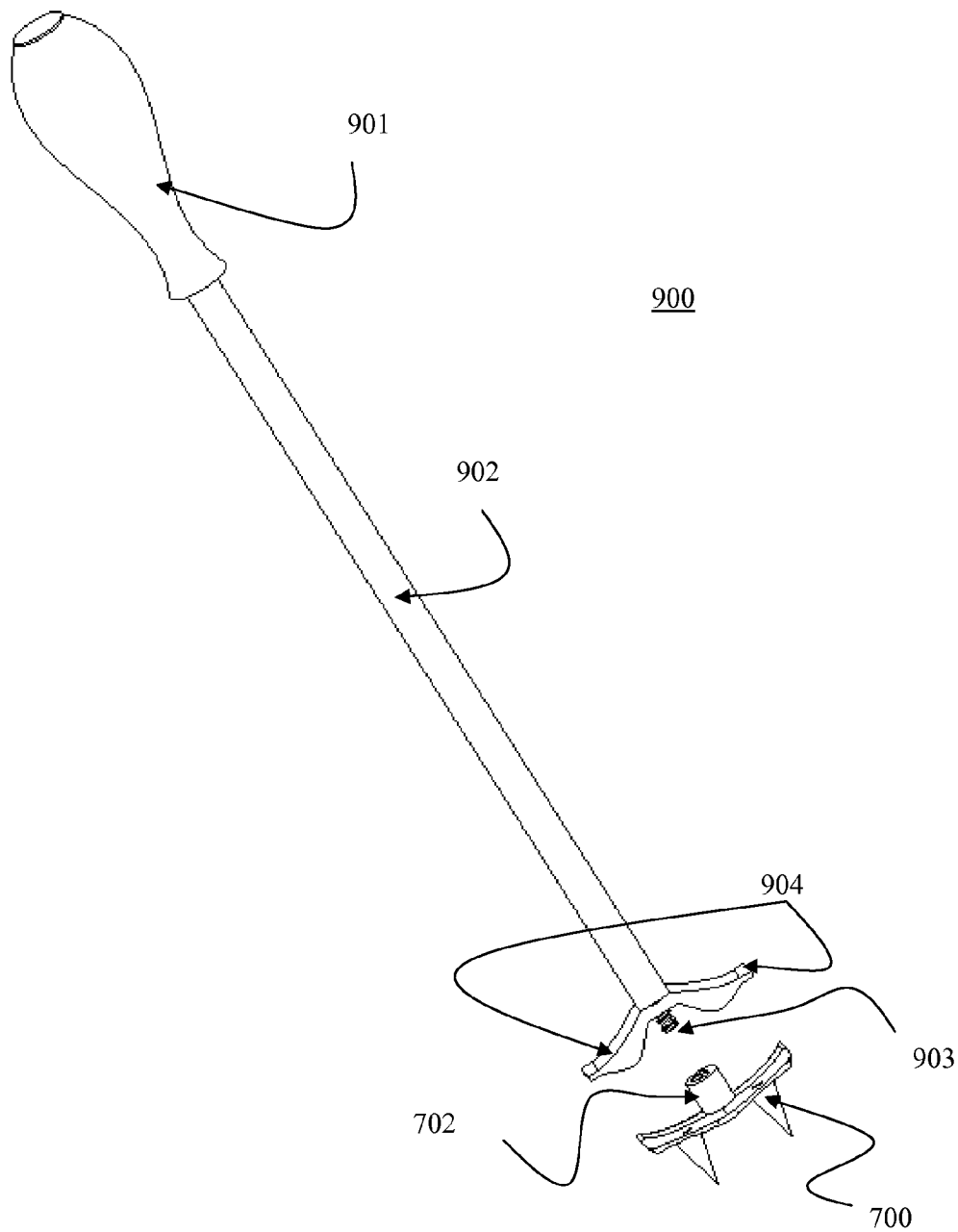


Fig. 9A

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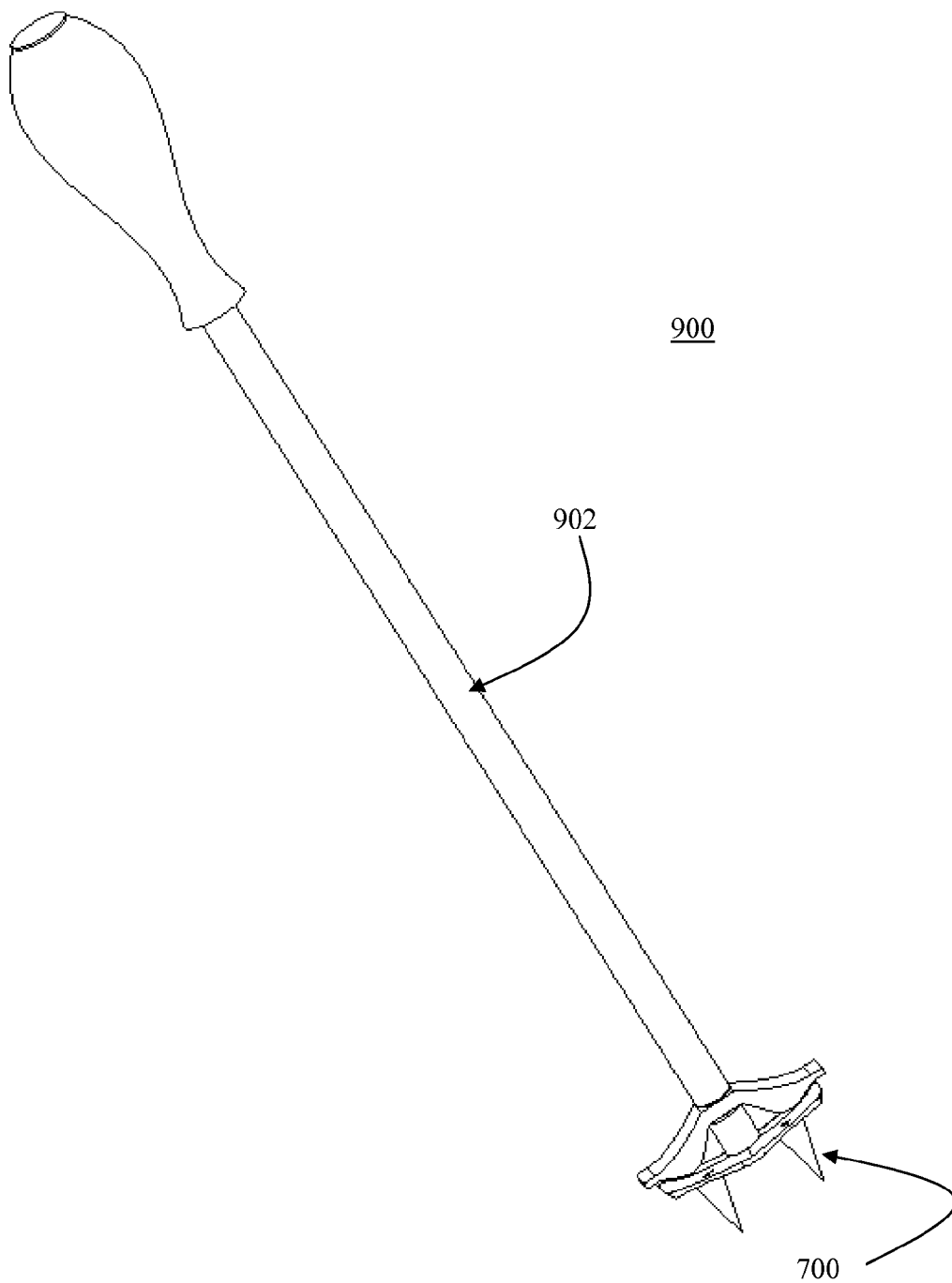


Fig. 9B

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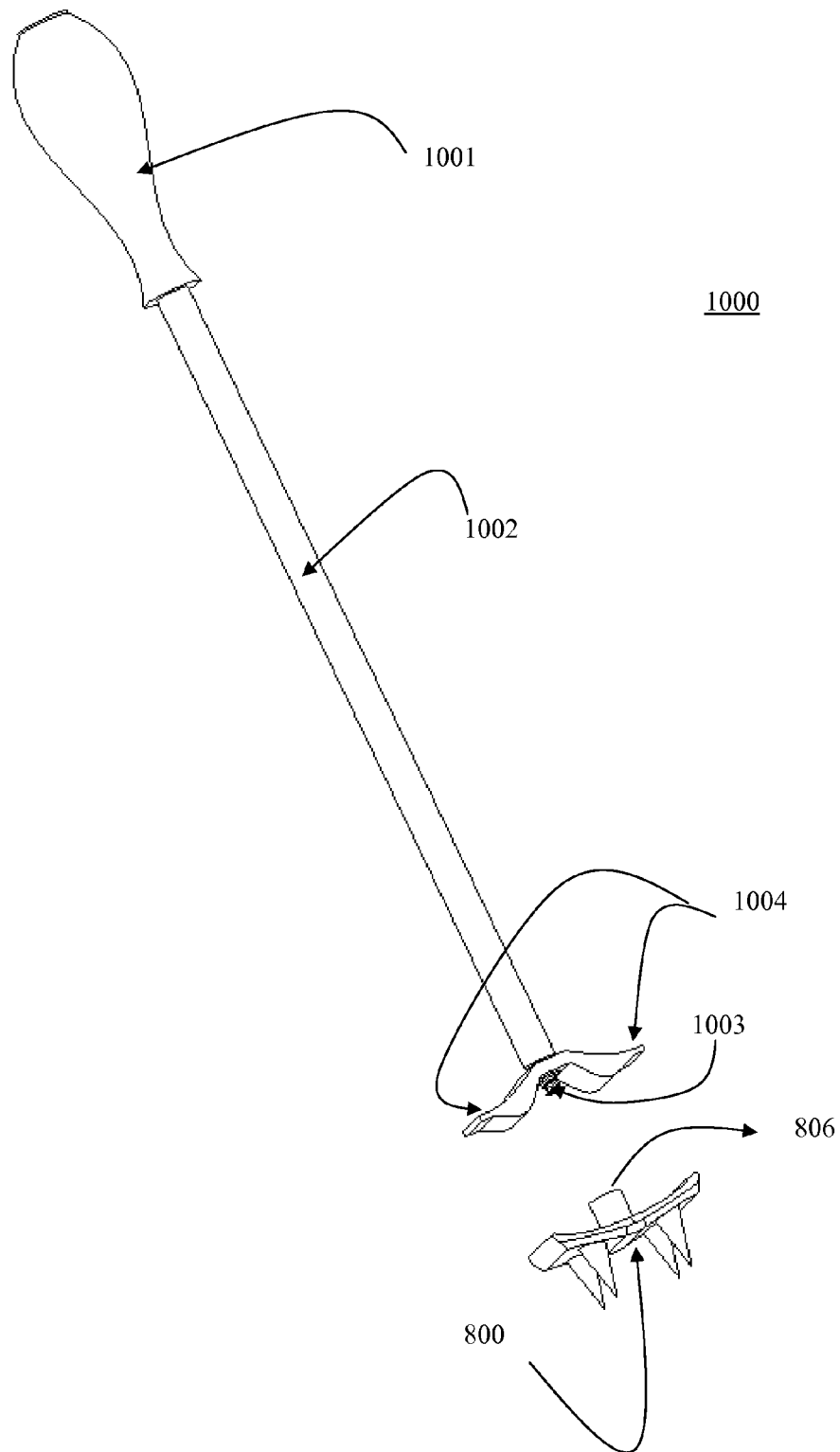


Fig. 10A

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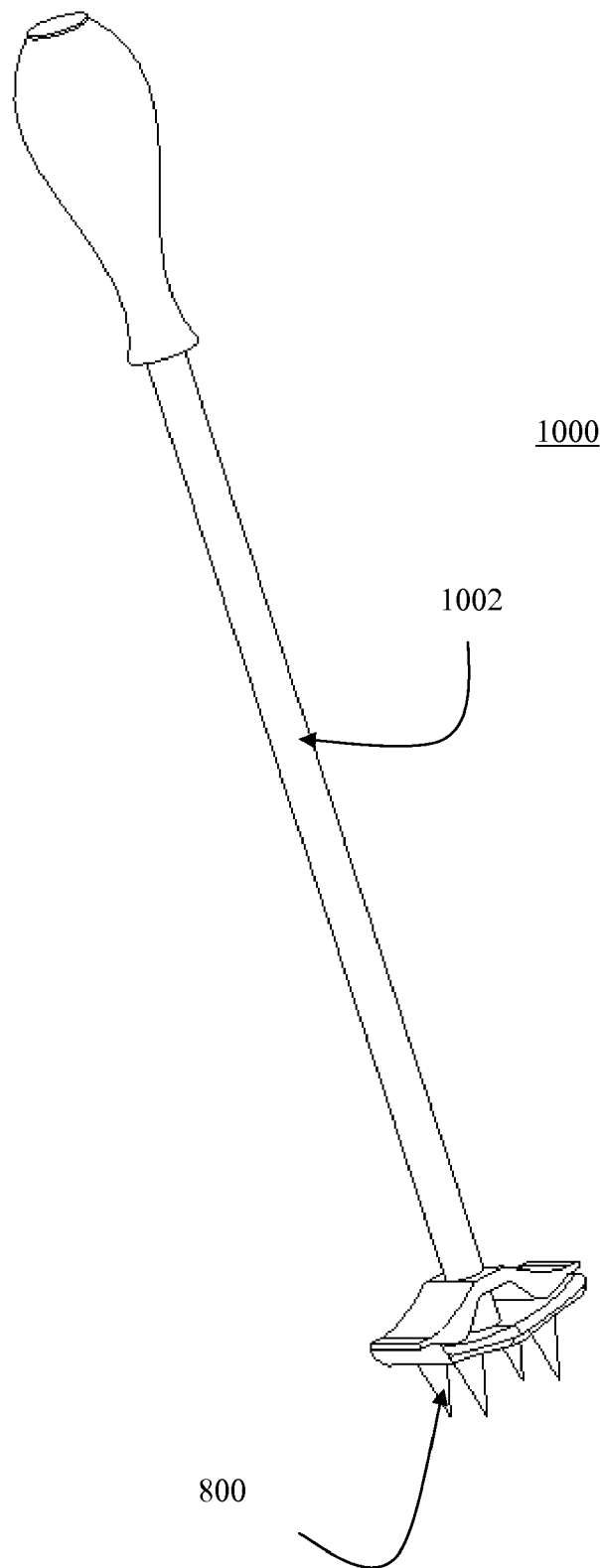


Fig. 10B

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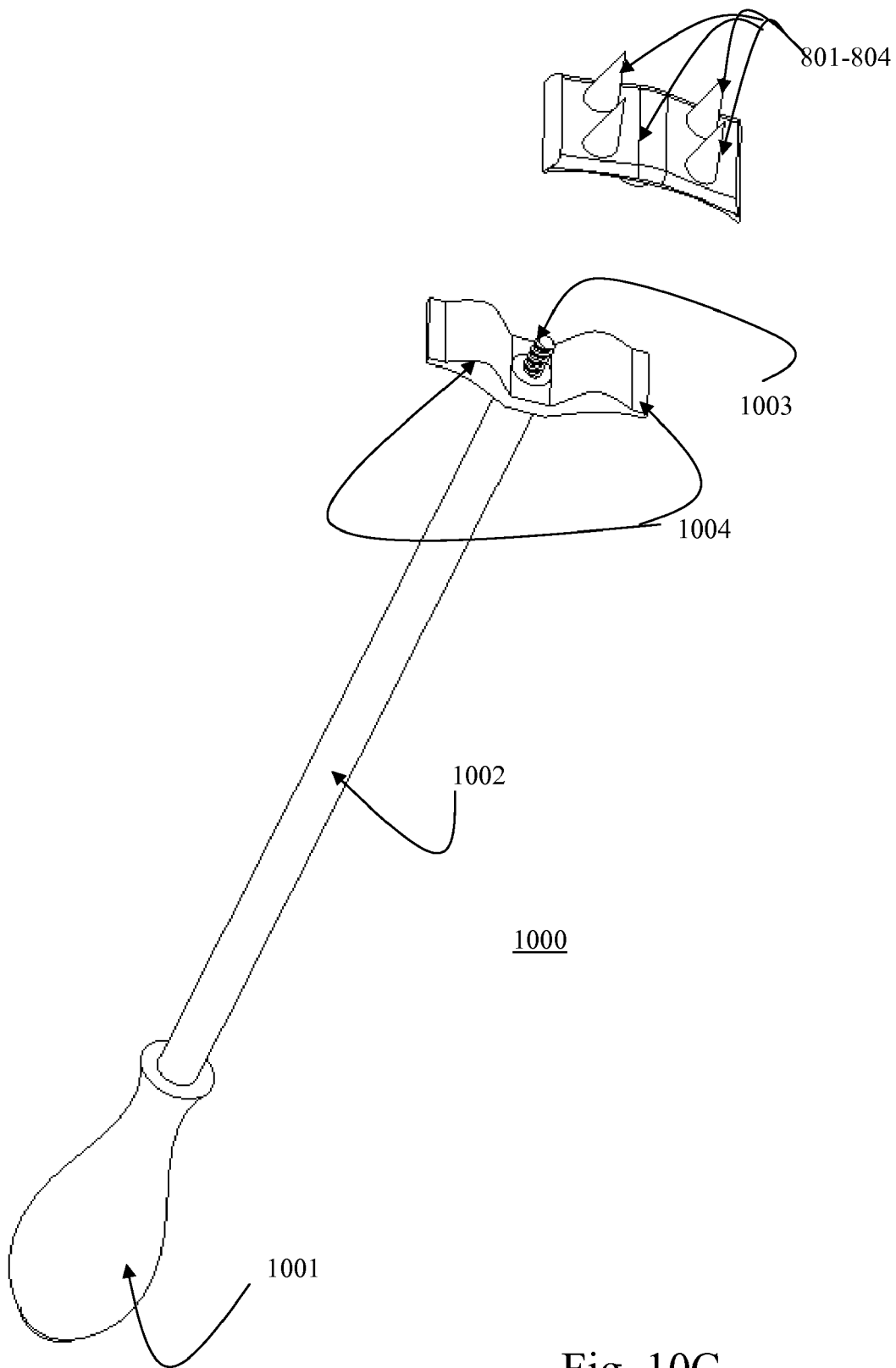


Fig. 10C

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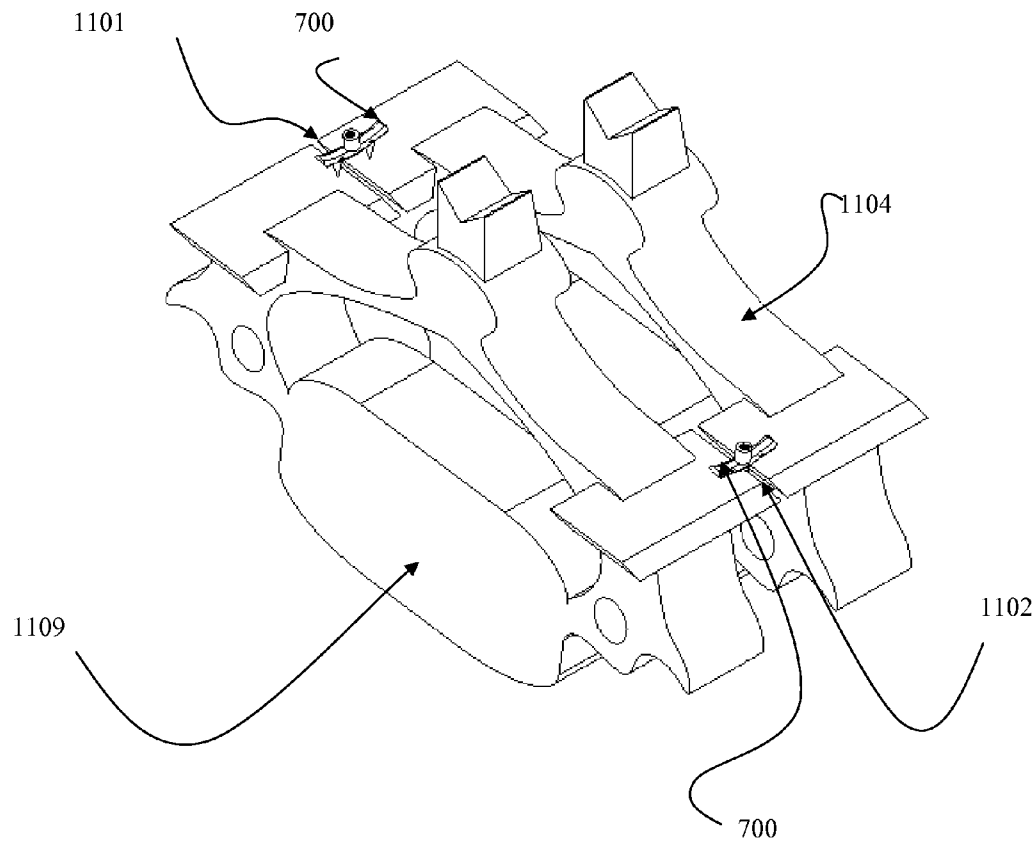


Fig. 11A

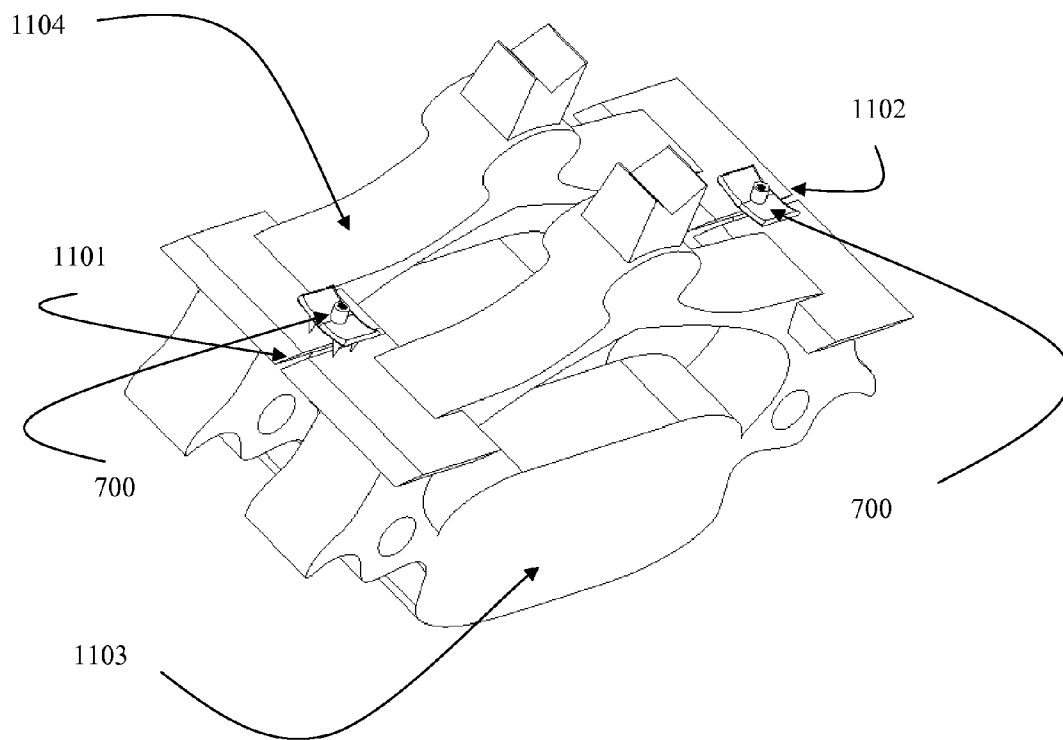


Fig. 11B

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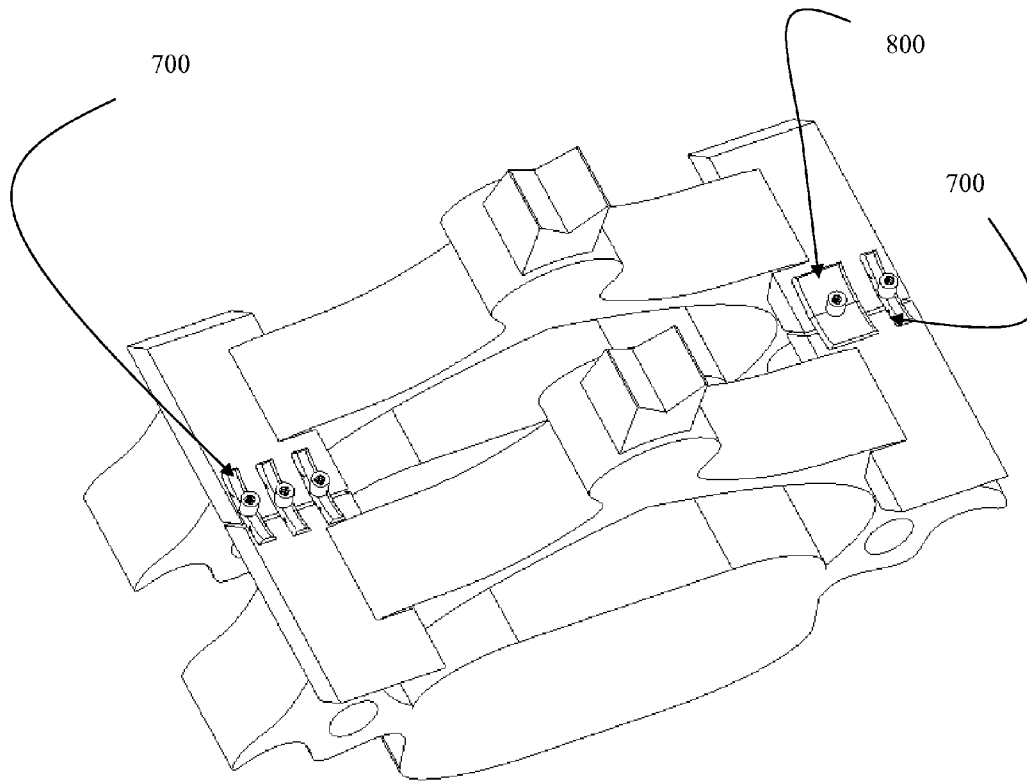


Fig. 11C

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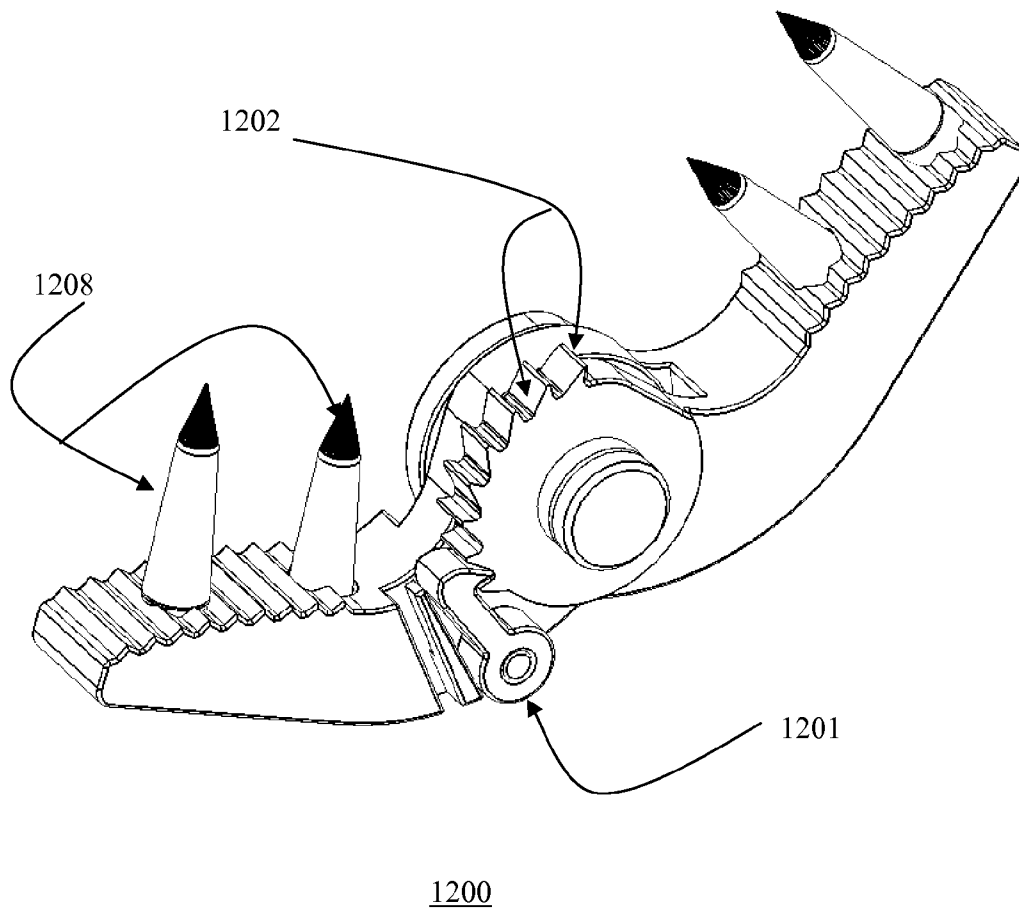


Fig. 12A

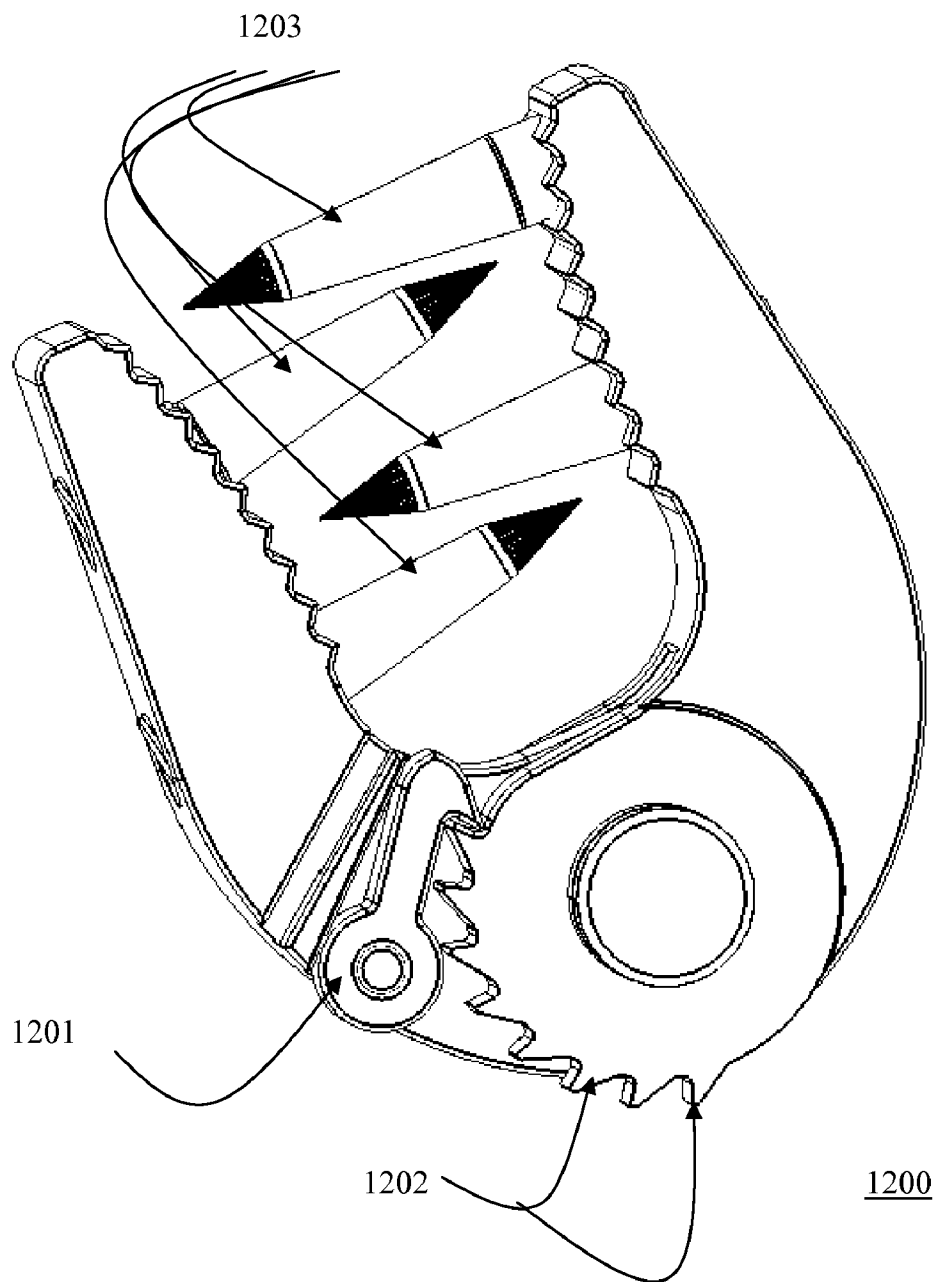


Fig. 12B

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

CROSS-REFERENCE TO RELATED
APPLICATIONS

This application is a Continuation Application of application Ser. No. 11/842,855, filed on Aug. 21, 2007, now U.S. Pat. No. 7,942,903 issued on May 17, 2011, which is a Continuation-In-Part Application of application Ser. No. 11/536,815, filed on Sep. 29, 2006, now U.S. Pat. No. 7,846,188 issued on Dec. 7, 2010, which is a Continuation-In-Part Application of application Ser. No. 11/208,644, filed on Aug. 23, 2005, now U.S. Pat. No. 7,704,279 issued on Apr. 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 Apr. 12, 2005; the entire contents of all the above identified patent applications are hereby incorporated by reference.

BACKGROUND OF THE INVENTION

1. Field of Invention

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.

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.

2. Description of the Relevant Art

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.

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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

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.

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.

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.

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

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.

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

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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.

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.

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

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.

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

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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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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

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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.

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.

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.

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.

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.

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.

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.

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.

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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.

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.

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.

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.

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

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

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

FIGS. 2A-2E 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.

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

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.

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.

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

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

FIGS. 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).

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

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

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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.

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

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

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

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

FIG. 10A illustrates the four pronged cervical facet staple inserter/impactor (Embodiment II).

FIG. 10B illustrates the four pronged cervical facet staple inserter/impactor inserted into the cervical facet staple (Embodiment II).

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

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

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

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.

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

DETAILED DESCRIPTION OF THE INVENTION

1. The Medical Device

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.

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).

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.

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

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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.

FIGS. 2A-2E 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 FIGS. 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 FIGS. 5A-5J).

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.

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).

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).

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.

The key components of this device include an Allen key **501**, a spring **502**, a handle **503**, a gripper **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 gripper **504** has gripper prongs **506** which insert into grooves of the screw guide **505**. The gripper prongs **506** include medially oriented male protu-

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berant extensions **506a** that engage the slot or indentation **12** of and the screw box **200** (FIGS. 5A-D) thus perfectly aligning them.

FIGS. 5D and 5J illustrate 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**.

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**.

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.

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

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.

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.

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.

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.

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**.

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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.

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.

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.

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.

2. The Surgical Method

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

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.

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.

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

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entered and a circumferential discectomy is performed. The disc space is prepared and the endplates exposed.

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.

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.

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.

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.

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.

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.

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

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facets, and then impacted into the joint. To achieve modular calibrated fusion different combinations and permutations of cervical facet staples 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.

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.

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.

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.

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.

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 tool for manipulating and inserting a universal, intervertebral bone fusion spacer into a disc space between a first vertebral body and a second vertebral body for providing 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 includes an intervertebral cage having a first integral screw guide and a second integral screw guide, 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 gripper having a plurality of prongs,

wherein a distal end of each of the plurality of prongs is capable of engaging a respective slot or indentation of the intervertebral cage; and

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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. 5

2. The tool of claim 1, further comprising:
 wherein the plurality of prongs engage and hold the screw guide in place.

3. The tool of claim 1, wherein the screw guide includes a slot or indentation for receiving one of the plurality of prongs. 10

4. The tool of claim 1, wherein the screw guide includes slots or indentations on opposing sides for receiving the plurality of prongs.

5. The tool of claim 1, wherein the screw guide includes an integral trajectory guide that is capable of receiving and guiding one of the screws of the universal, intervertebral bone fusion spacer. 15

6. The tool of claim 1, further comprising a handle wherein the gripper includes a tubular portion that is capable of receiving and guiding a portion of the handle therein. 20

7. The tool of claim 1, further comprising a handle, wherein an end of the handle includes a rectangular handle portion.

8. The tool of claim 1, further comprising a handle, wherein an end of the handle includes a circular handle portion.

9. The tool of claim 1, further comprising: 25
 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 screws of the universal, intervertebral bone fusion spacer. 30

10. The tool of claim 1, 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, 35
 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 50
 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 55
 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.

11. The tool of claim 1, 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, 60
 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, 65

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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.

12. The tool of claim 1, 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, 20
 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.

13. The tool of claim 1, 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, 25
 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.

14. The tool of claim 1, wherein the intervertebral cage includes an arcuate wall.

15. A tool assembly comprising:
 a universal, intervertebral bone fusion spacer 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 comprising:
 an intervertebral cage including a first integral screw guide and a second integral screw guide; and
 a first screw disposed in the first integral screw guide and at least partially within the intervertebral cage;
 a second screw disposed in the second integral screw guide and at least partially within the intervertebral cage, 30
 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 bone fusion spacer 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 35

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vertebral body via biological bone fusion and screw fusion, the tool comprising:

a gripper 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.

16. The tool assembly of claim 15,

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

17. The tool assembly of claim 15, wherein the screw guide includes a slot or indentation for receiving one of the plurality of prongs.

18. The tool assembly of claim 15, wherein the screw guide includes slots or indentations on opposing sides for receiving the plurality of prongs.

19. The tool assembly of claim 15, wherein the screw guide includes an integral trajectory guide that is capable of receiving and guiding one of the first screw and the second screw of the universal, intervertebral bone fusion spacer.

20. The tool assembly of claim 15, further comprising a handle, wherein the gripper includes a tubular portion that is capable of receiving and guiding a portion of the handle therein.

21. The tool assembly of claim 15, further comprising a handle, wherein an end of the handle includes a rectangular handle portion.

22. The tool assembly of claim 15, further comprising a handle, wherein an end of the handle includes a circular handle portion.

23. The tool assembly of claim 15, 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 and the second screw of the universal, intervertebral bone fusion spacer.

24. The tool assembly of claim 15, wherein each of the first internal screw guide and the second internal screw guide is angled to orient the first screw and the second screw bidirectionally in opposite directions.

25. The tool assembly of claim 15, wherein the first screw is a self-tapping and self-drilling screw having a tapered end and a threaded body, and

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

26. The tool assembly of claim 15, further comprising:

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

27. The tool assembly of claim 15, wherein the intervertebral cage includes a side having a plurality of ridges.

28. The tool assembly of claim 15, 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.

29. The tool assembly of claim 28, wherein a first angulation of the first integral screw guide is opposed to a second angulation of the second integral screw guide.

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30. The tool assembly of claim 15, 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.

31. The tool assembly of claim 30, 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.

32. The tool assembly of claim 30, 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.

33. The tool assembly of claim 32, 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.

34. The tool assembly of claim 15, 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.

35. The tool assembly of claim 15, wherein the first integral screw guide and the second integral screw guide diverge from each other.

36. The tool assembly of claim 15, 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.

37. The tool assembly of claim 26, 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 and the second screw passes from the bone graft cavity to an exterior of the intervertebral cage.

38. A method of inserting a universal, intervertebral bone fusion spacer into a disc space between a first vertebral body and a second vertebral body using a tool for manipulating and inserting the universal, intervertebral bone fusion spacer into the disc space between the first vertebral body and the second vertebral body,

wherein the universal, intervertebral bone fusion spacer 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 gripper having a plurality of prongs,

wherein a distal end of each of the plurality of prongs is capable of engaging 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

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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 bone fusion spacer 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 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 bone fusion spacer into a midline of the disc space using the tool until the selected universal, intervertebral bone fusion spacer 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 bone fusion spacer relative to the first vertebral body and the second vertebral body.

39. A method of inserting a universal, intervertebral bone fusion spacer 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 bone fusion spacer into the disc space between the first vertebral body and the second vertebral body,

wherein the universal, intervertebral bone fusion spacer includes:

an intervertebral cage including:

a first integral screw guide;

a second integral screw guide; and

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

a second screw disposed in the second integral screw guide 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 gripper 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 bone fusion spacer 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 bone fusion spacer into a midline of the disc space using the tool until the selected universal, intervertebral bone fusion spacer is flush or countersunk relative to the first vertebral body and the second vertebral body;

inserting the first screw into the first internal screw guide of the selected universal, intervertebral bone fusion spacer;

inserting the second screw into the second internal screw guide of the selected universal, intervertebral bone fusion spacer;

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

confirming a position and placement of the universal, intervertebral bone fusion spacer relative to the first vertebral body and the second vertebral body.

40. A tool assembly comprising:

a universal, intervertebral bone fusion spacer 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 comprising:

an intervertebral cage including:

a first integral screw guide;

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

a second screw disposed in the second integral screw guide 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 and the second screw, and a predetermined angled trajectory of the first internal screw guide is different than a 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

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integral screw guide, the exit being adjacent to or formed in an edge of the bone graft cavity, wherein the first screw is a self-tapping and self-drilling screw having a tapered end and a threaded body, and wherein the second screw is a self-tapping and self-drilling screw 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 bone fusion spacer 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 gripper 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.

41. A tool assembly comprising:

- a universal, intervertebral bone fusion spacer for insertion into a disc space between a first vertebral body and a

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second vertebral body for fusion of the first vertebral body to the second vertebral body via biological bone fusion and screw fusion, the universal, intervertebral bone fusion spacer 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 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 disposed in each of the plurality of internalized screw guides and at least partially within the intervertebral cage; and
- a tool for manipulating and inserting the universal, intervertebral bone fusion spacer into the disc space between the first vertebral body and the second vertebral body for providing fusion of the first vertebral body to the second vertebral body via biological bone fusion and screw fusion, the tool comprising:
 - a gripper 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 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, 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.

42. The tool assembly of claim **41**, wherein the distal tunnel-guide portion that is partially encased by the walls of the intervertebral cage is parabola shaped.

43. The tool assembly of claim **42**, wherein the screw 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.

44. The tool assembly of claim **41**, 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 passes from the bone cavity to an exterior of the intervertebral cage.

* * * * *

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**THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM
THE RECORDS OF THIS OFFICE OF:****U.S. PATENT: 10,478,319****ISSUE DATE: November 19, 2019**

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Certifying Officer

JOINT EXHIBIT**JTX-008**

Case No. 1:16-cv-00570-RGA



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(12) **United States Patent**
Moskowitz et al.

(10) **Patent No.:** **US 10,478,319 B2**
(45) **Date of Patent:** ***Nov. 19, 2019**

(54) **SYSTEM WITH TOOL ASSEMBLY AND EXPANDABLE SPINAL IMPLANT**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

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(Continued)

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(58) **Field of Classification Search**

CPC **A61F 2/4611**; **A61F 2/4465**; **A61F 2/447**;
A61F 2002/2835; **A61F 2002/30133**;
(Continued)

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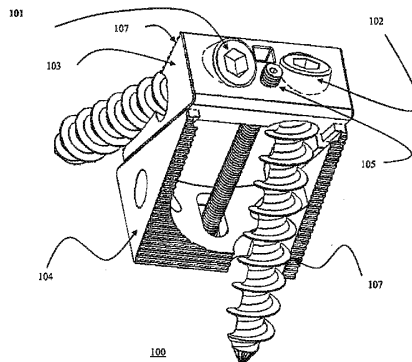
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(57) **ABSTRACT**

A system includes a tool assembly and an expandable spinal implant. The tool assembly includes a first tool and a second adjusting tool. The first tool has first and second engagement prongs positioned at a first distal end and the first tool defines an adjusting tool passage. The second adjusting tool can extend through the adjusting tool passage of the first tool. The expandable spinal implant includes a first expandable spinal implant structure, a second expandable spinal implant structure, and an adjusting screw having a screw head and a threaded portion. The expandable spinal implant defines first and second tool engagement indentations. The adjusting screw is positioned within the expandable spinal implant such that the second adjusting tool can extend through the adjusting tool passage to engage the screw head

(Continued)



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while the first and second engagement prongs are engaged with the first and second tool engagement indentations.

21 Claims, 38 Drawing Sheets

Related U.S. Application Data

No. 13/210,157, filed on Aug. 15, 2011, now Pat. No. 9,889,022, which is a continuation of application No. 13/108,982, filed on May 16, 2011, now Pat. No. 9,005,293, and a continuation of application No. 13/084,543, filed on Apr. 11, 2011, now Pat. No. 8,353,913, which is a continuation of application No. 11/842,855, filed on Aug. 21, 2007, now Pat. No. 7,942,903, said application No. 13/108,982 is a continuation of application No. 11/842,855, filed on Aug. 21, 2007, now Pat. No. 7,942,903, which is a continuation-in-part of application No. 11/536,815, filed on Sep. 29, 2006, now Pat. No. 7,846,188, which is a continuation-in-part of application No. 11/208,644, filed on Aug. 23, 2005, now Pat. No. 7,704,279.

(60) Provisional application No. 60/670,231, filed on Apr. 12, 2005.

(51) Int. Cl.

A61B 17/80 (2006.01)
A61B 17/86 (2006.01)
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A61F 2/44 (2006.01)
A61F 2/46 (2006.01)
A61F 2/28 (2006.01)
A61F 2/30 (2006.01)
A61B 17/92 (2006.01)
A61B 17/00 (2006.01)
A61B 17/17 (2006.01)

(52) U.S. Cl.

CPC *A61B 17/809* (2013.01); *A61B 17/8635* (2013.01); *A61B 17/8875* (2013.01); *A61B 17/8894* (2013.01); *A61B 17/92* (2013.01); *A61F 2/447* (2013.01); *A61F 2/4465* (2013.01); *A61B 17/0644* (2013.01); *A61B 17/1757* (2013.01); *A61B 17/86* (2013.01); *A61B 2017/00407* (2013.01); *A61B 2017/0641* (2013.01); *A61B 2017/0648* (2013.01); *A61B 2017/922* (2013.01); *A61F 2002/2835* (2013.01); *A61F 2002/3055* (2013.01); *A61F 2002/30133* (2013.01); *A61F 2002/30387* (2013.01); *A61F 2002/30448* (2013.01); *A61F 2002/30507* (2013.01); *A61F 2002/30579* (2013.01); *A61F 2002/30604* (2013.01); *A61F 2002/30772* (2013.01); *A61F 2002/30878* (2013.01); *A61F 2002/30879* (2013.01); *A61F 2002/30904* (2013.01); *A61F 2002/448* (2013.01); *A61F 2002/4475* (2013.01); *A61F 2002/4627* (2013.01); *A61F 2002/4681* (2013.01); *A61F 2002/4687* (2013.01); *A61F 2220/005* (2013.01); *A61F 2220/0025* (2013.01); *A61F 2230/0015* (2013.01); *A61F 2250/0007* (2013.01)

(58) Field of Classification Search

CPC .. *A61F 2002/30387*; *A61F 2002/30448*; *A61F 2002/30507*; *A61F 2002/3055*; *A61F 3002/30579*; *A61F 2002/30604*; *A61F*

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USPC 623/17.11–17.16; 606/246–289, 606/300–308, 86 A, 99, 96, 100; 227/175.1, 176.1

See application file for complete search history.

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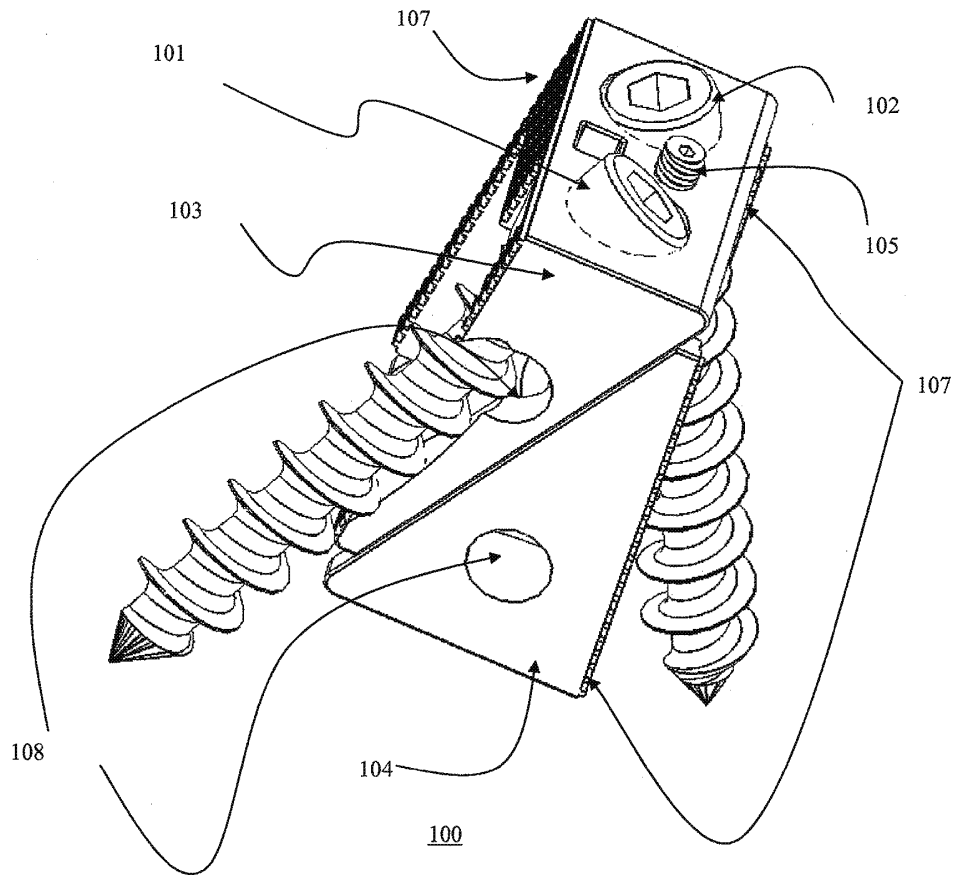


Fig. 1A

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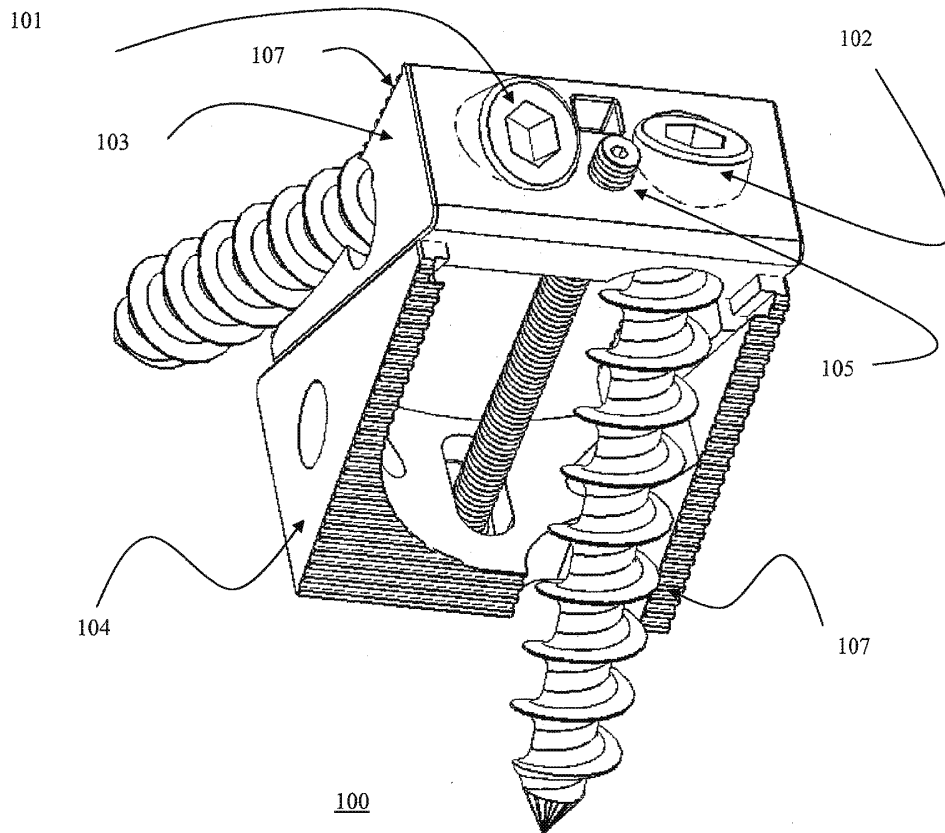


Fig. 1B

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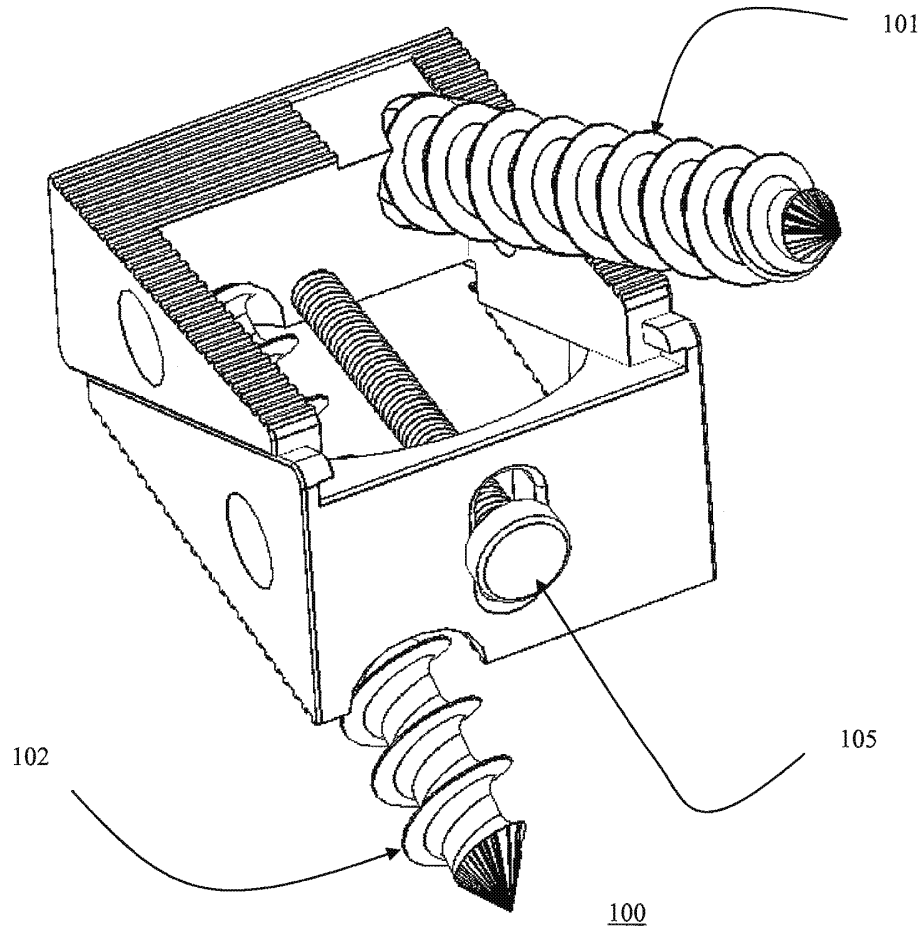


Fig. 1C

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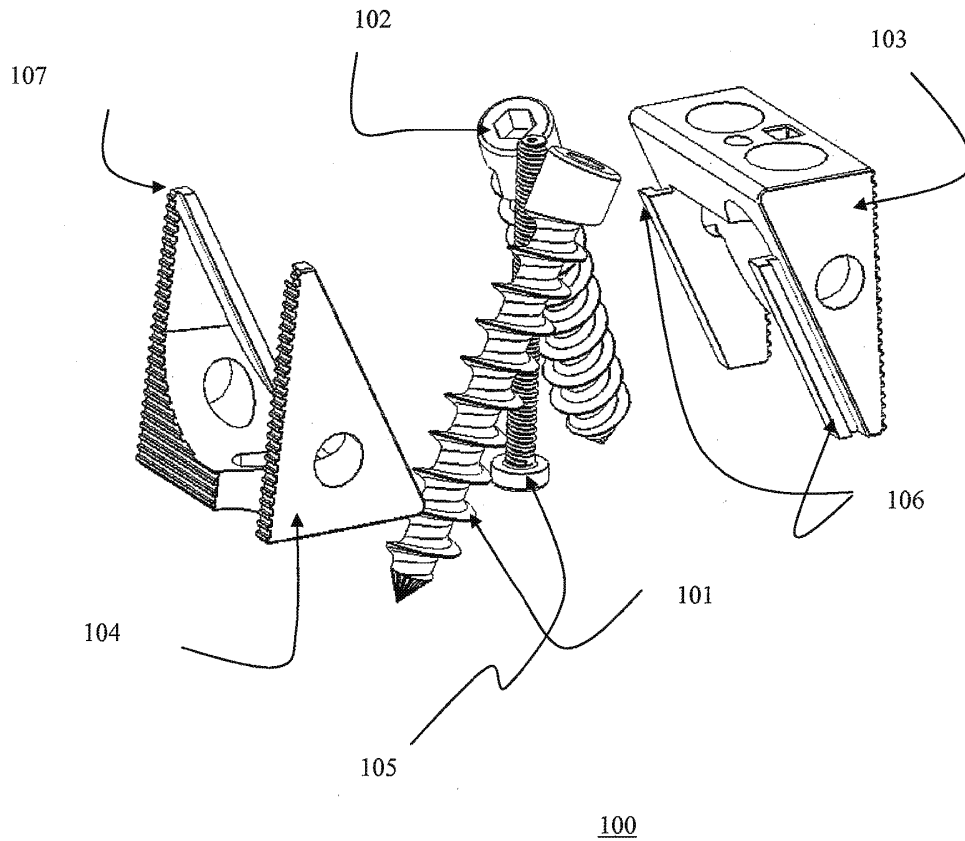


Fig. 1D

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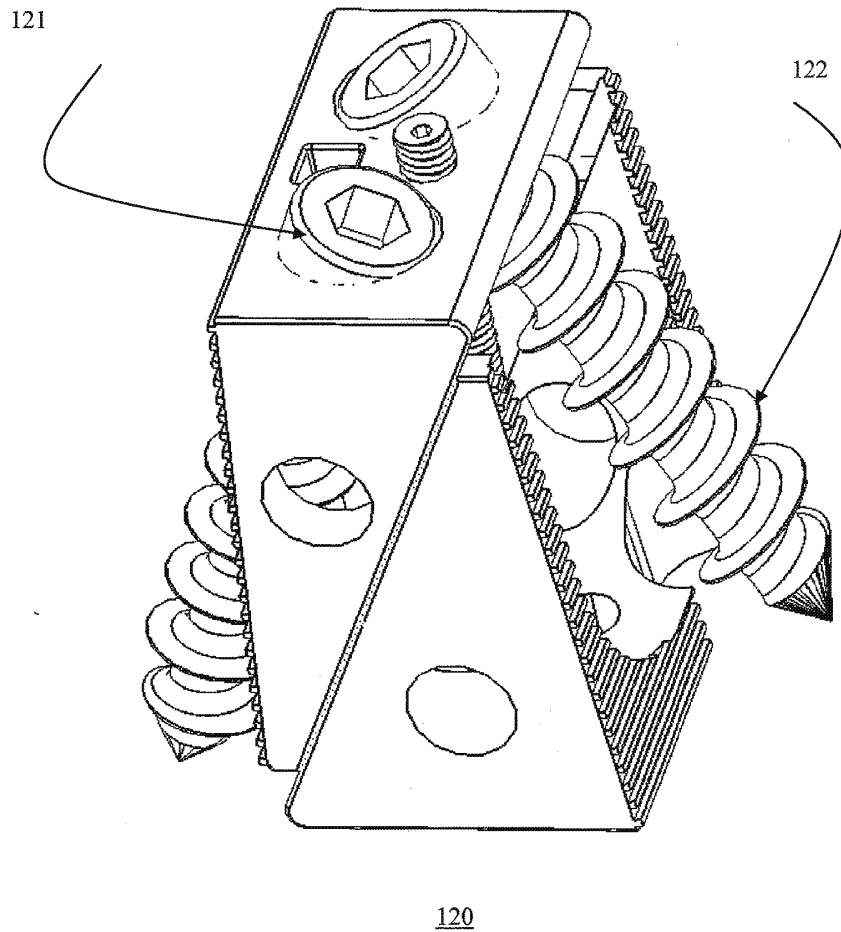


Fig. 1E

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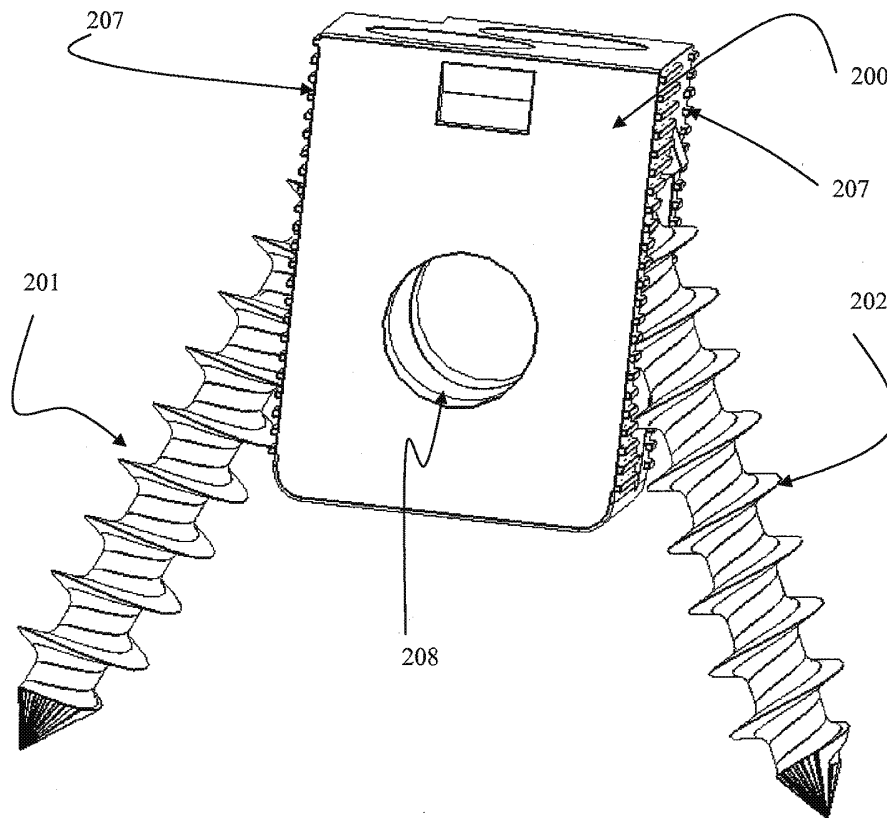


Fig. 2A

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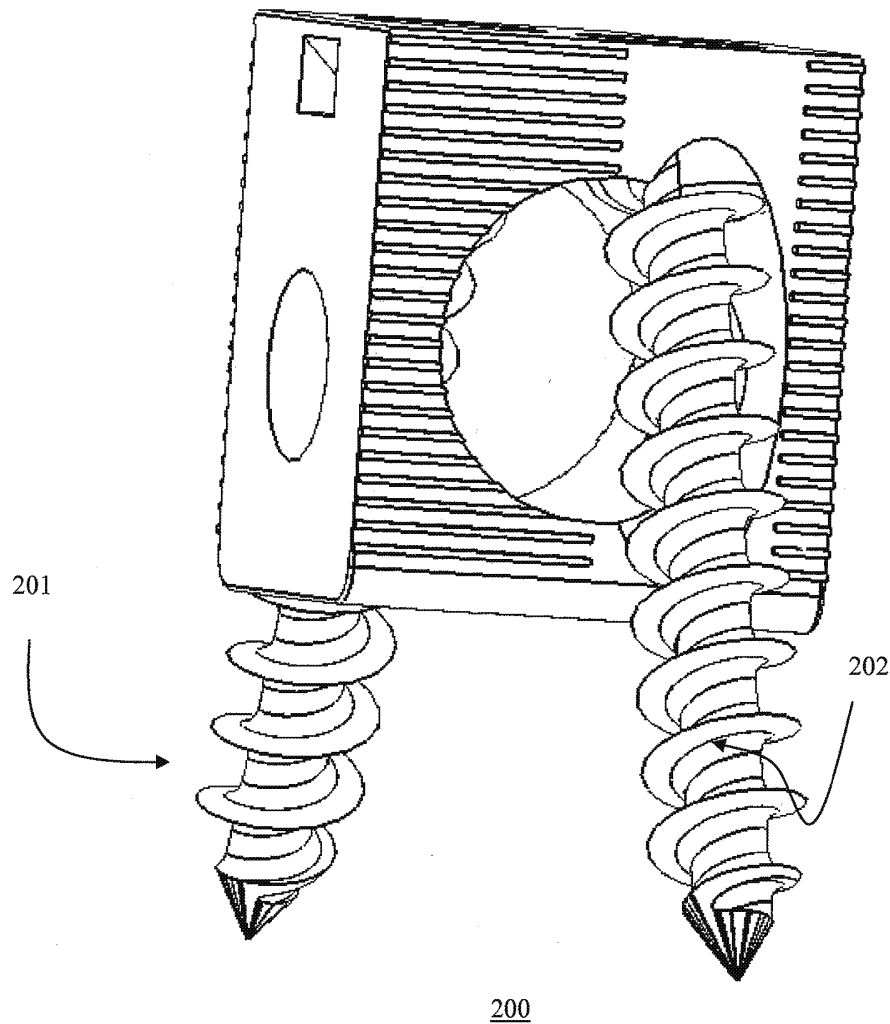


Fig. 2B

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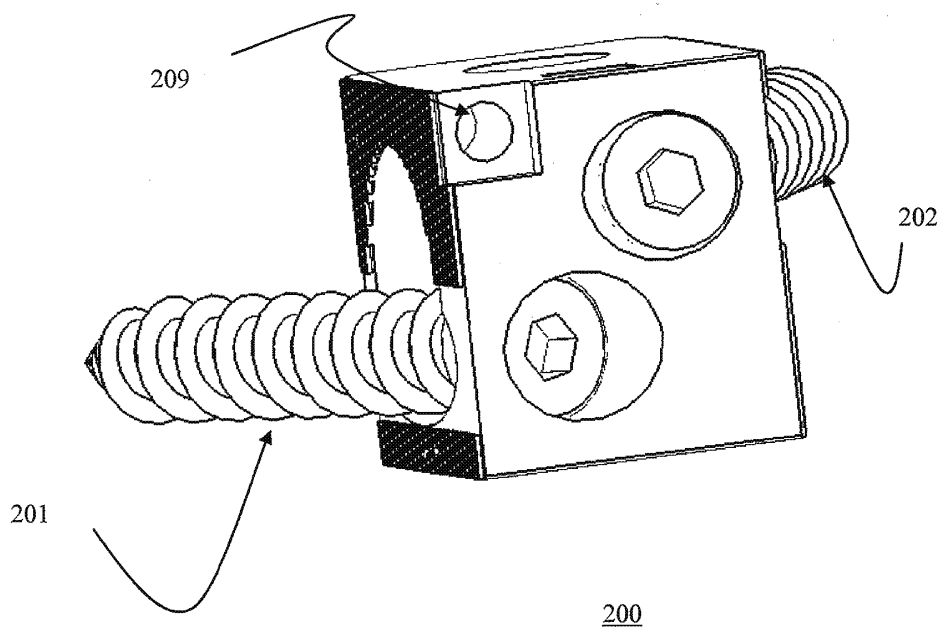


Fig. 2C

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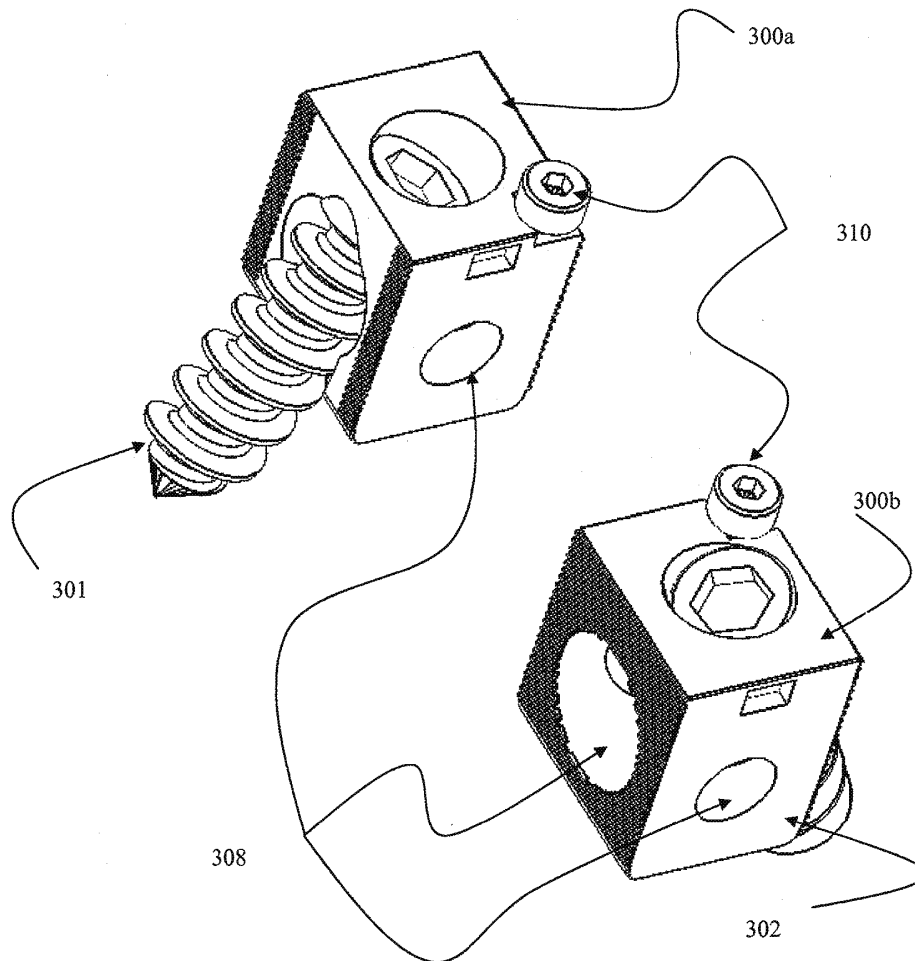


Fig. 3

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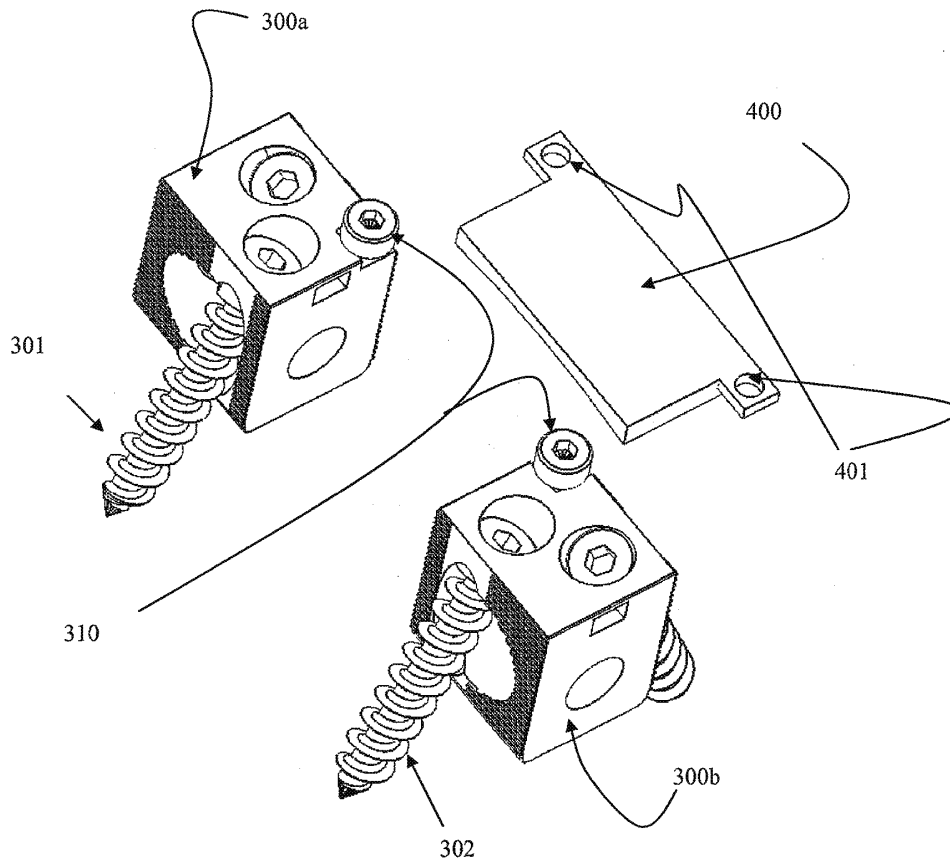


Fig. 4A

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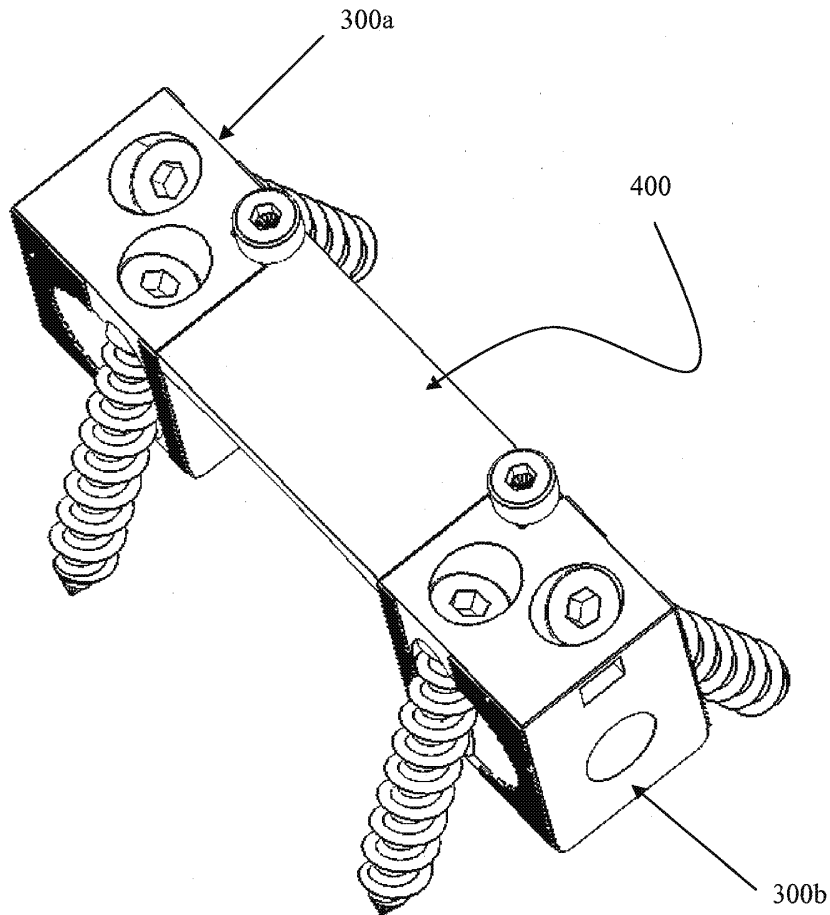


Fig. 4B

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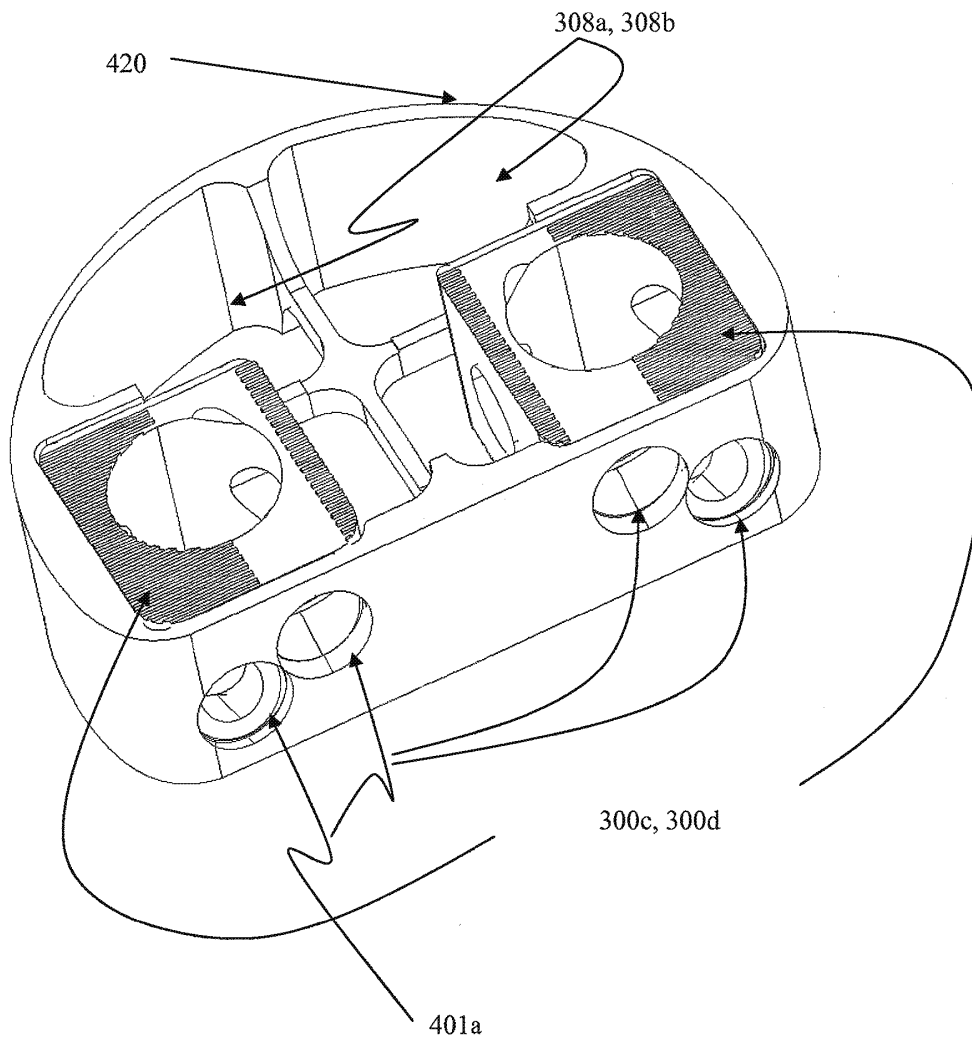


FIG. 4C

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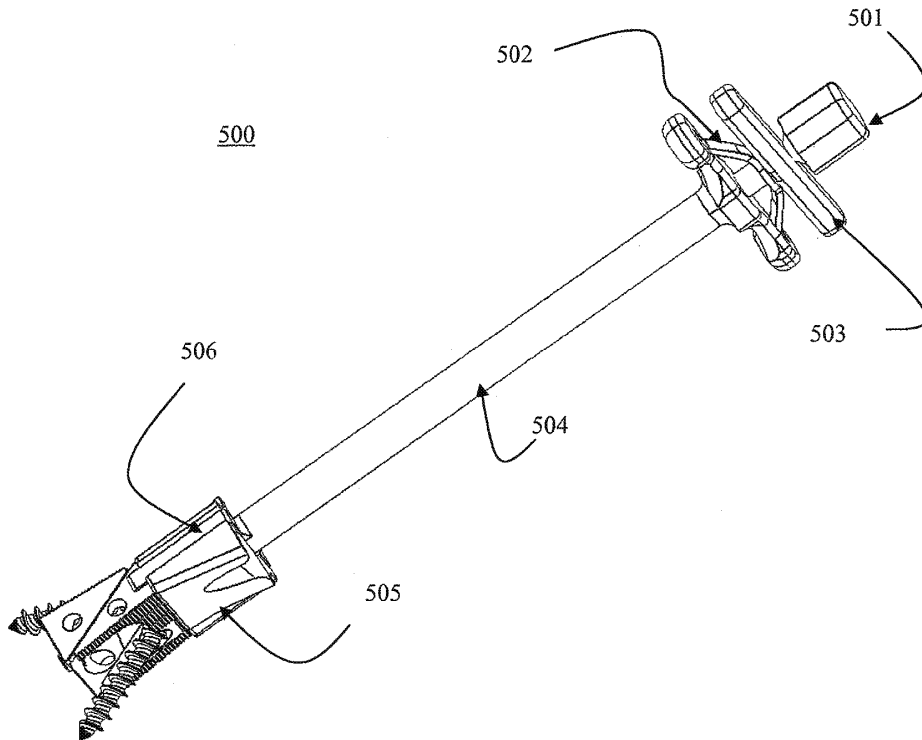


Fig. 5A

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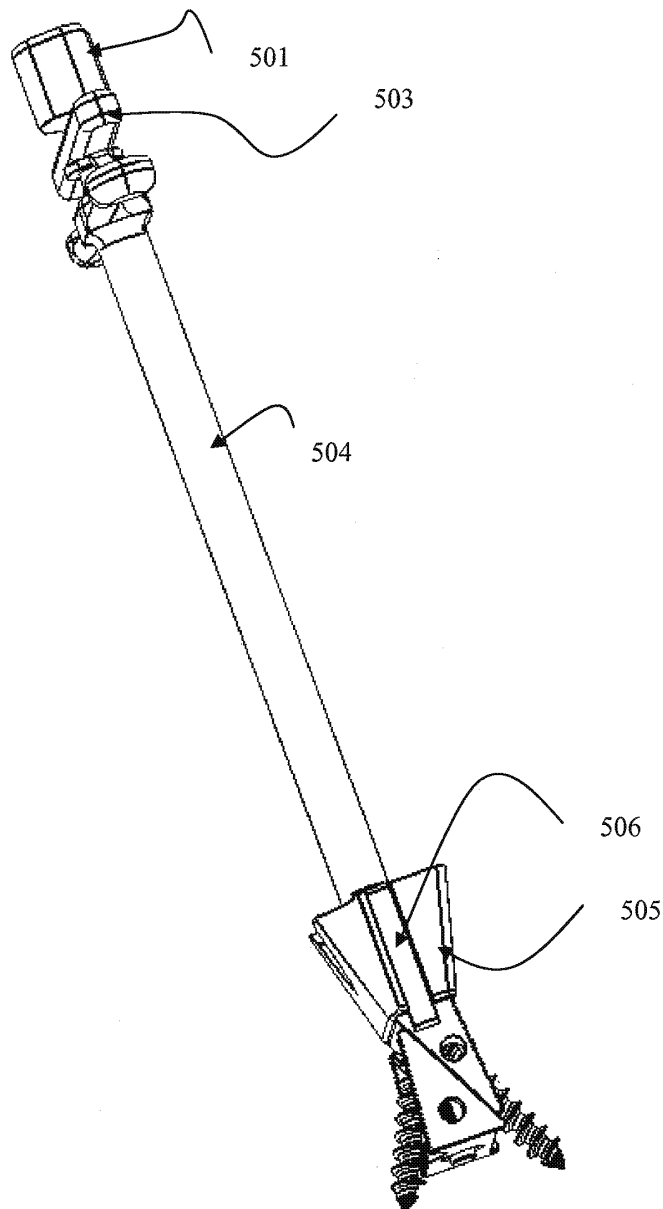


Fig. 5B

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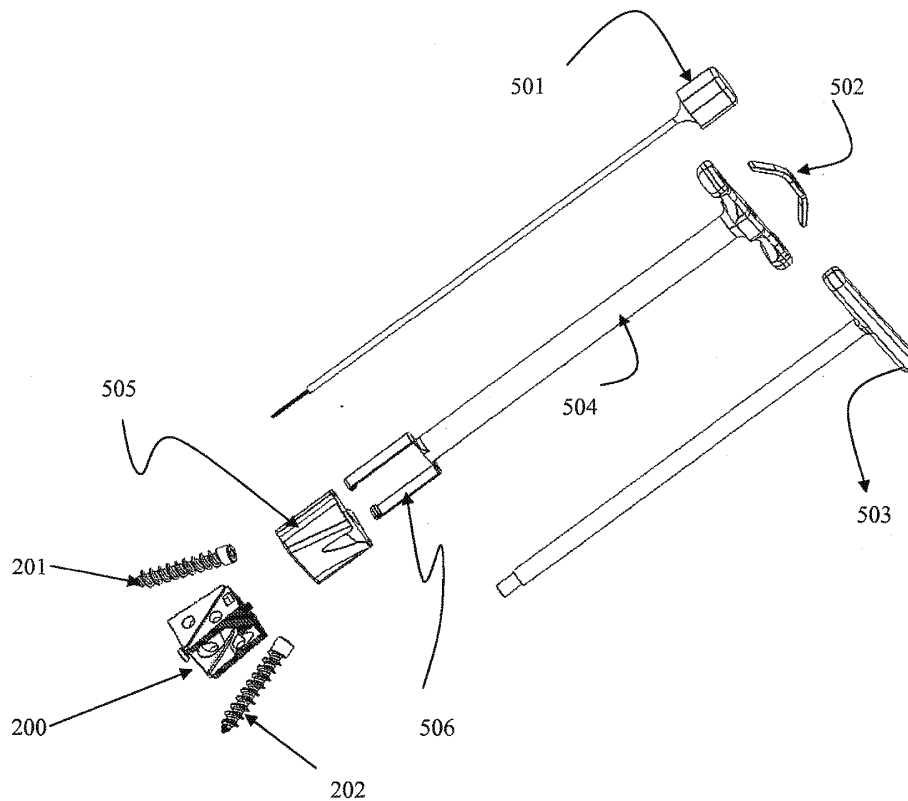


Fig. 5C

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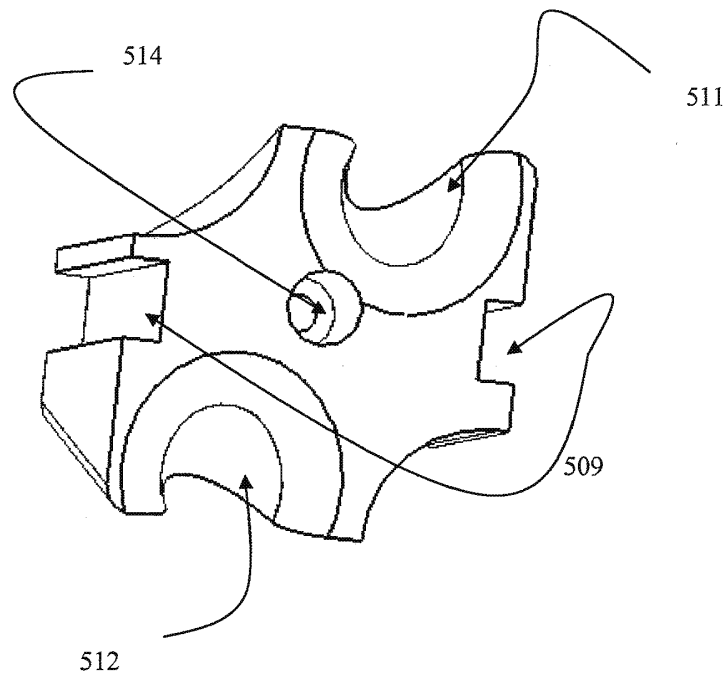


Fig. 5D

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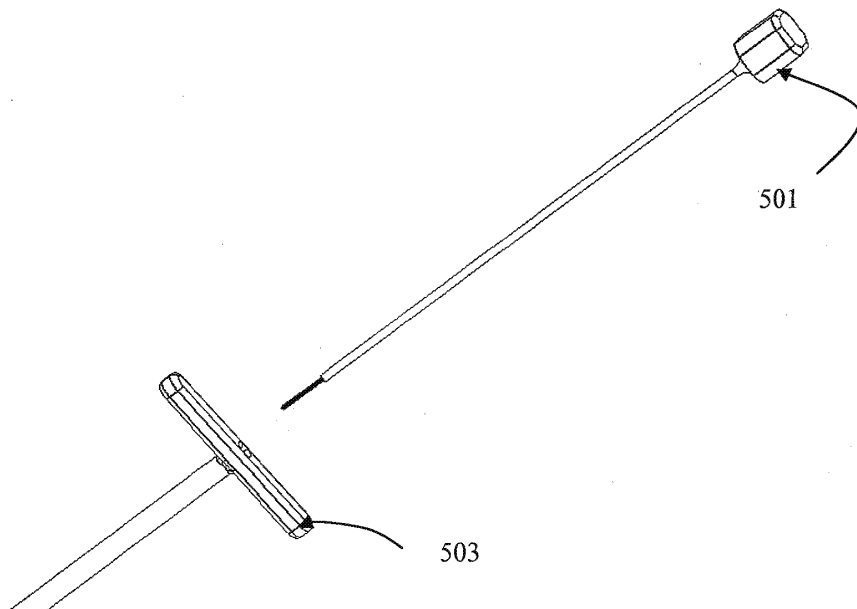


Fig. 5E

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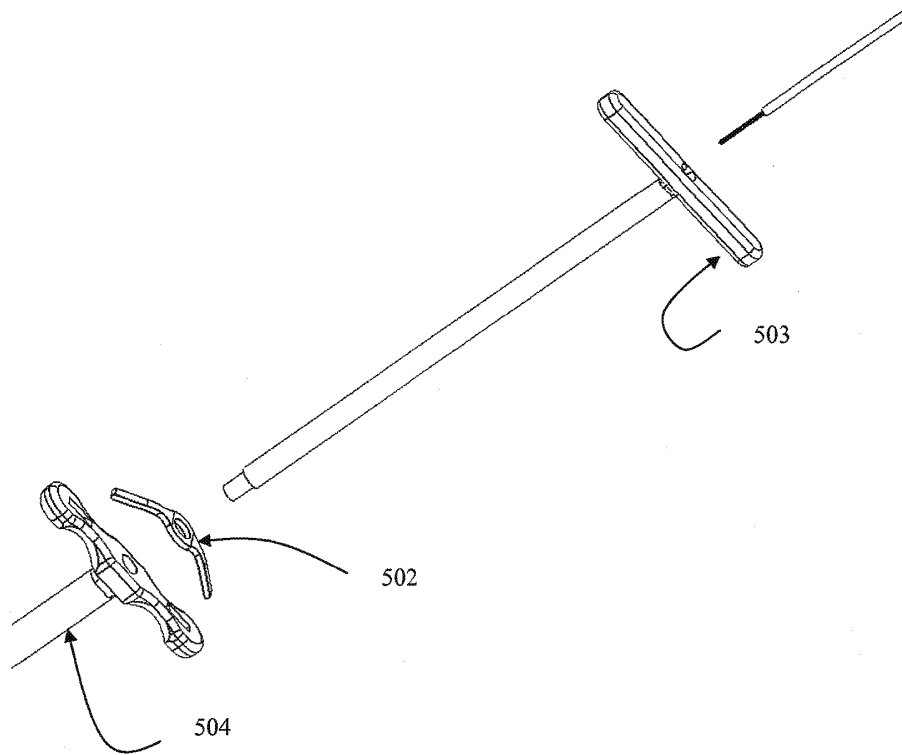


Fig. 5F

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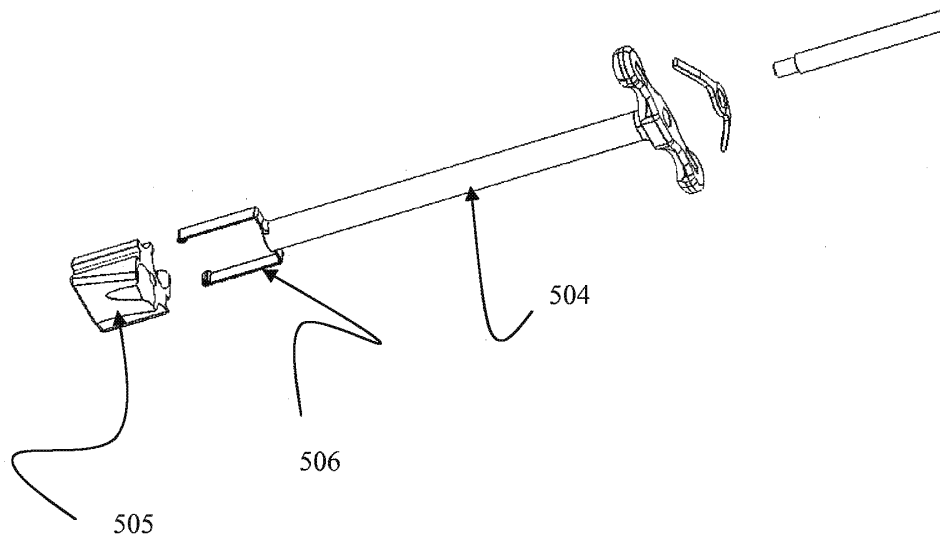


Fig. 5G

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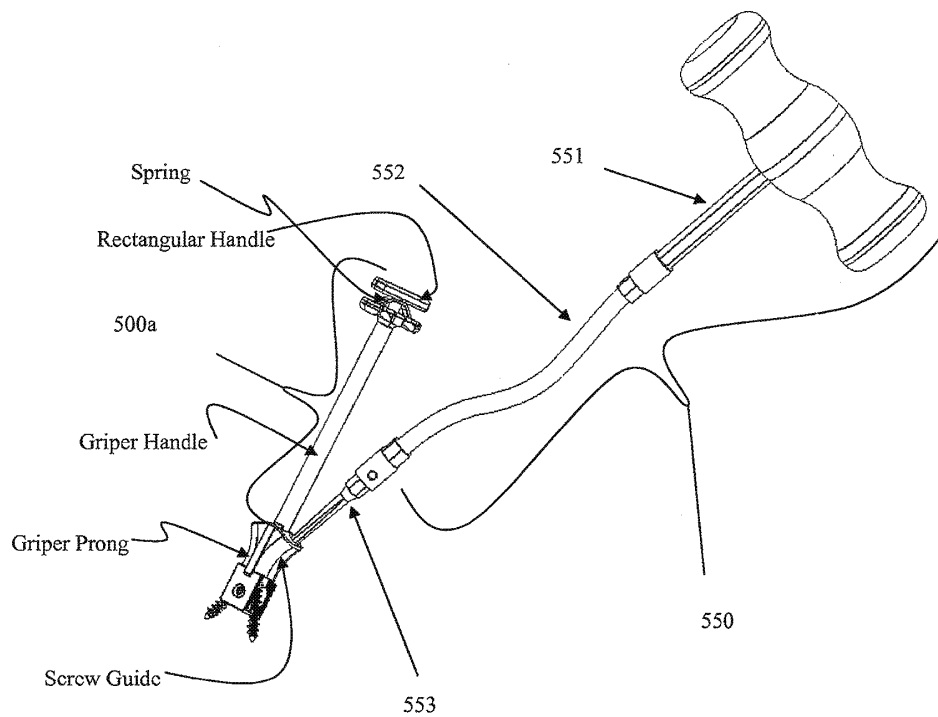


FIG. 5H

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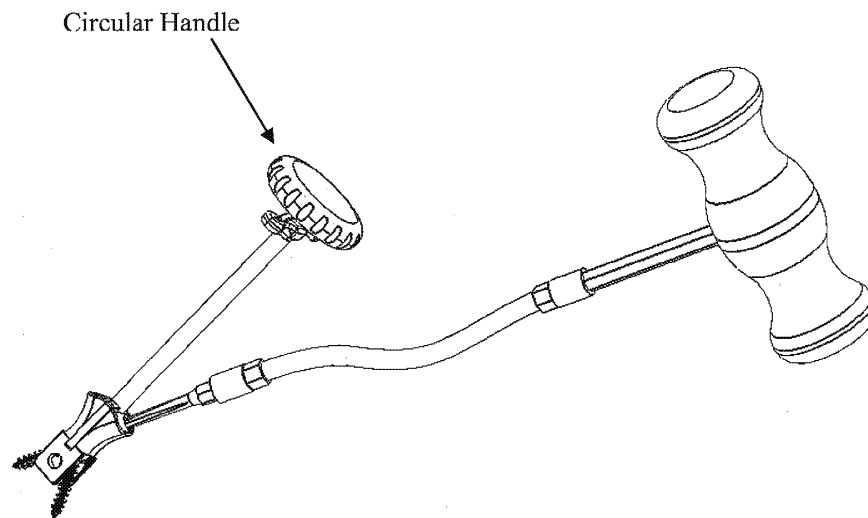


FIG. 5I

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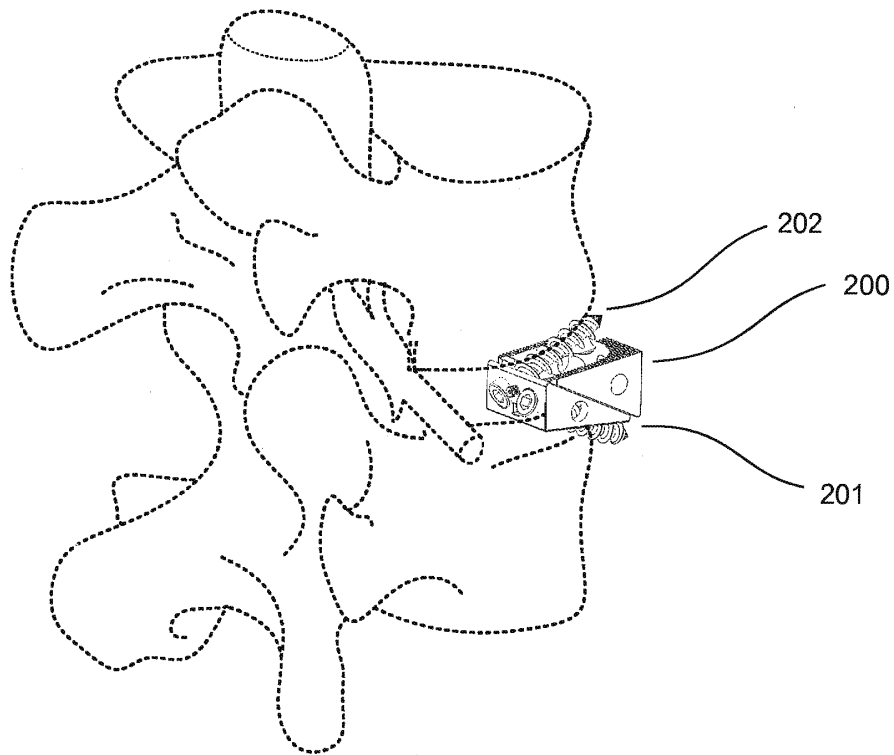


Fig. 6A

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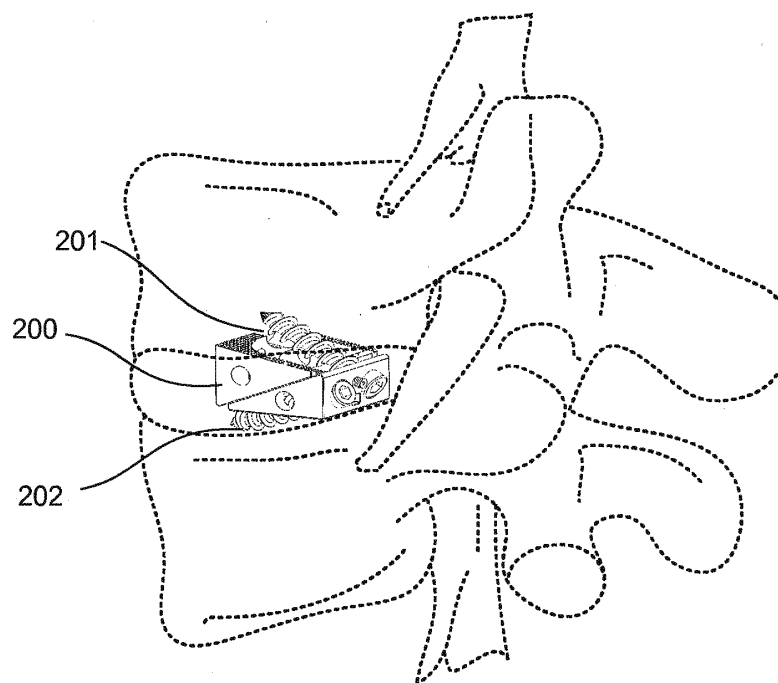


Fig. 6B

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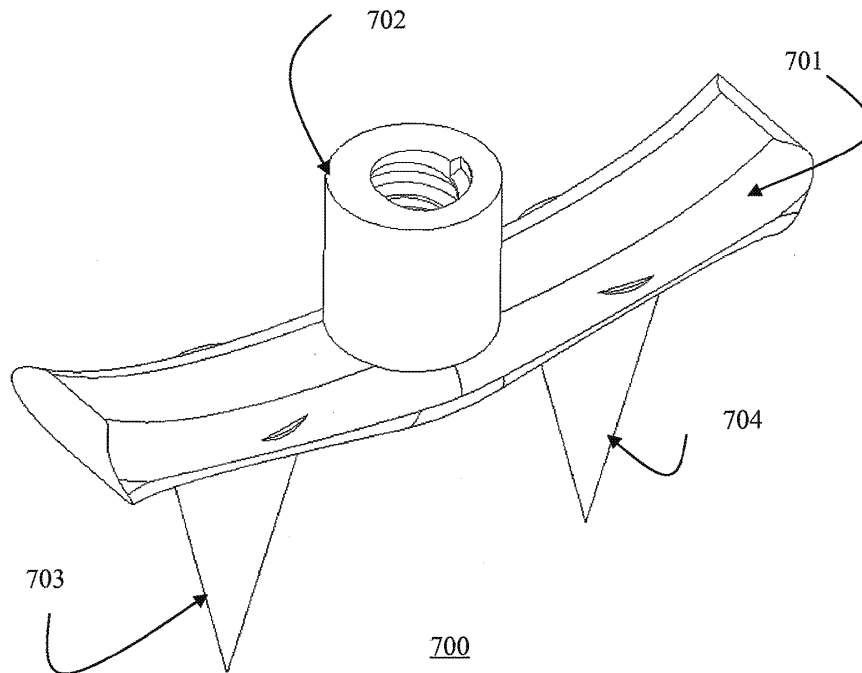


Fig. 7A

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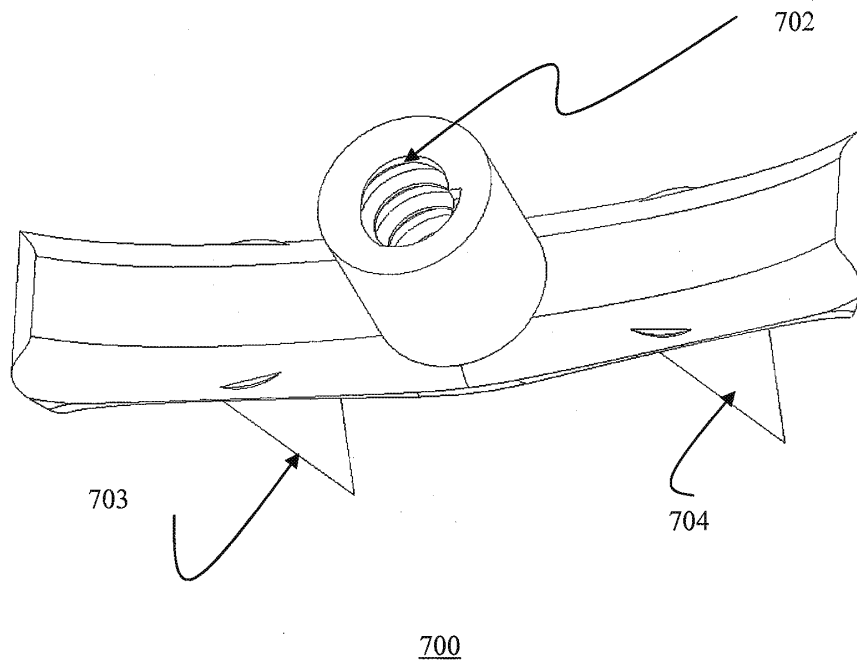


Fig. 7B

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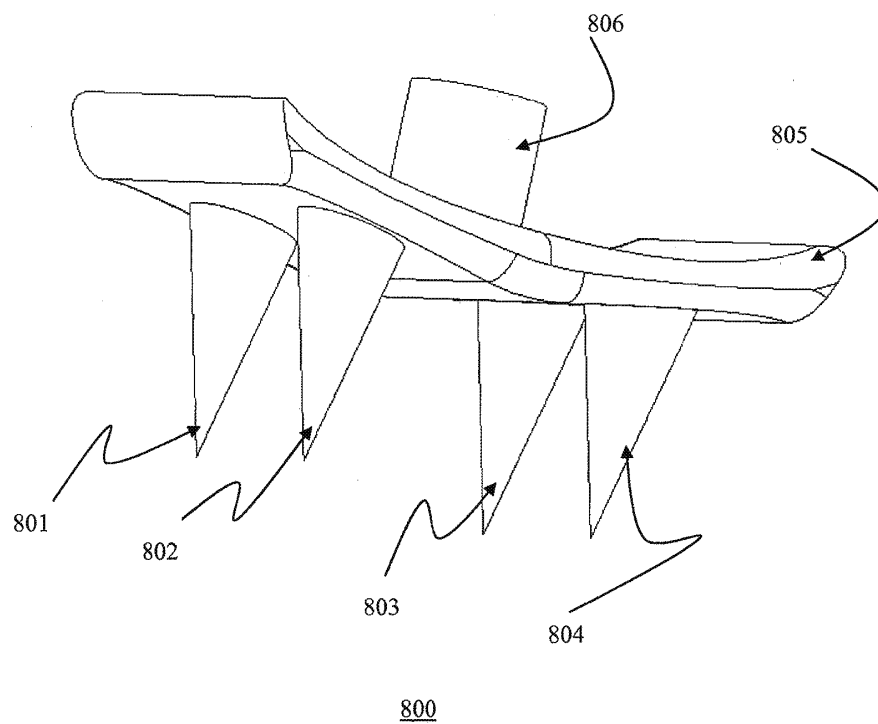


Fig. 8A

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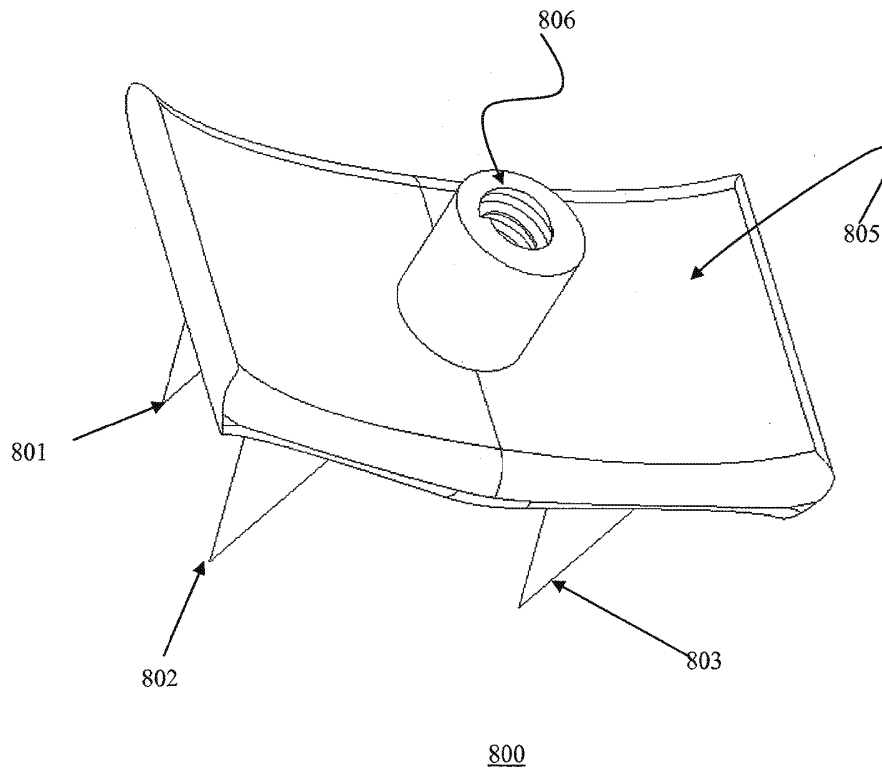


Fig. 8B

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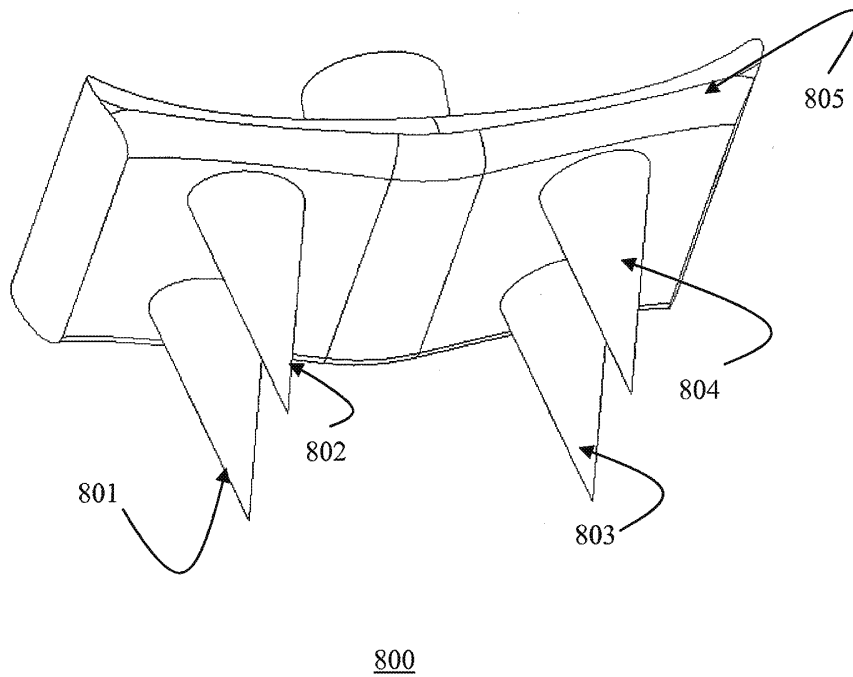


Fig. 8C

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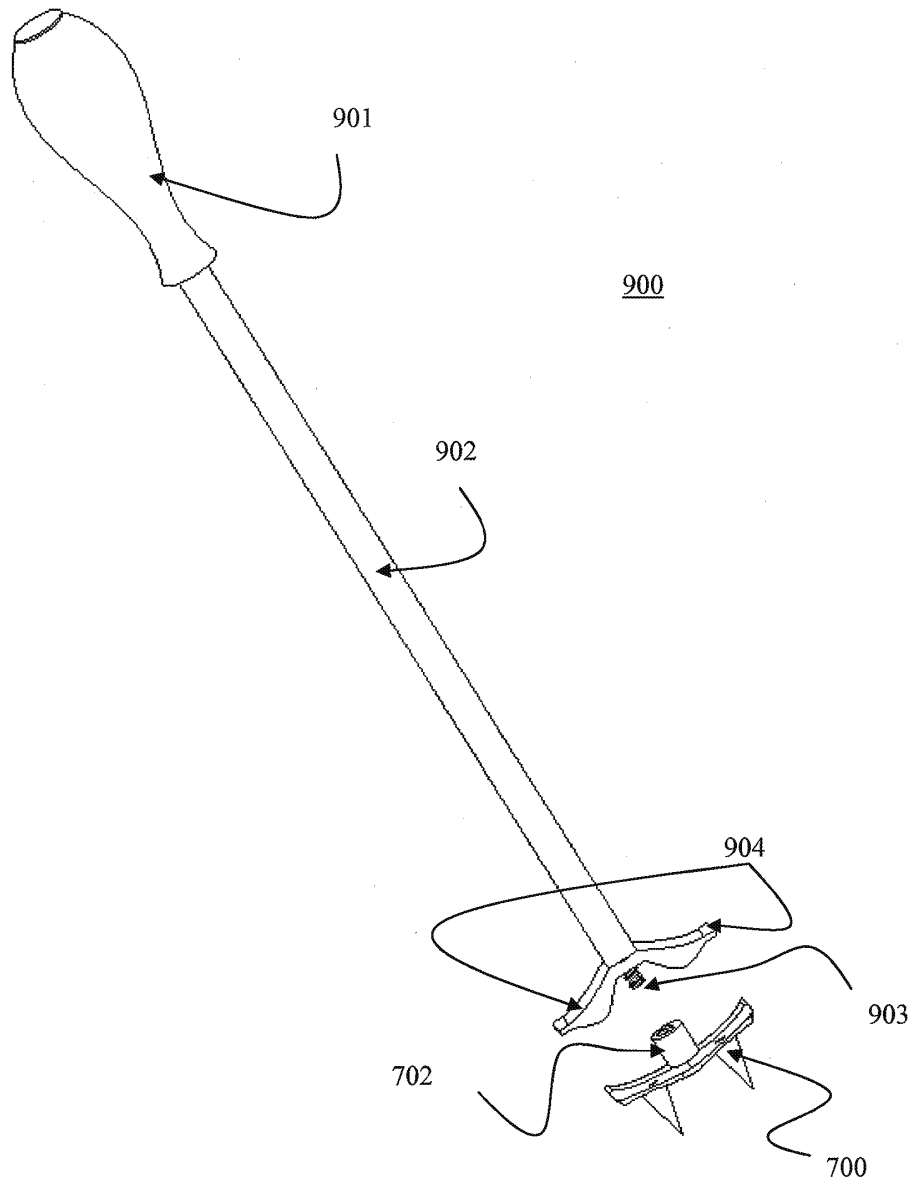


Fig. 9A

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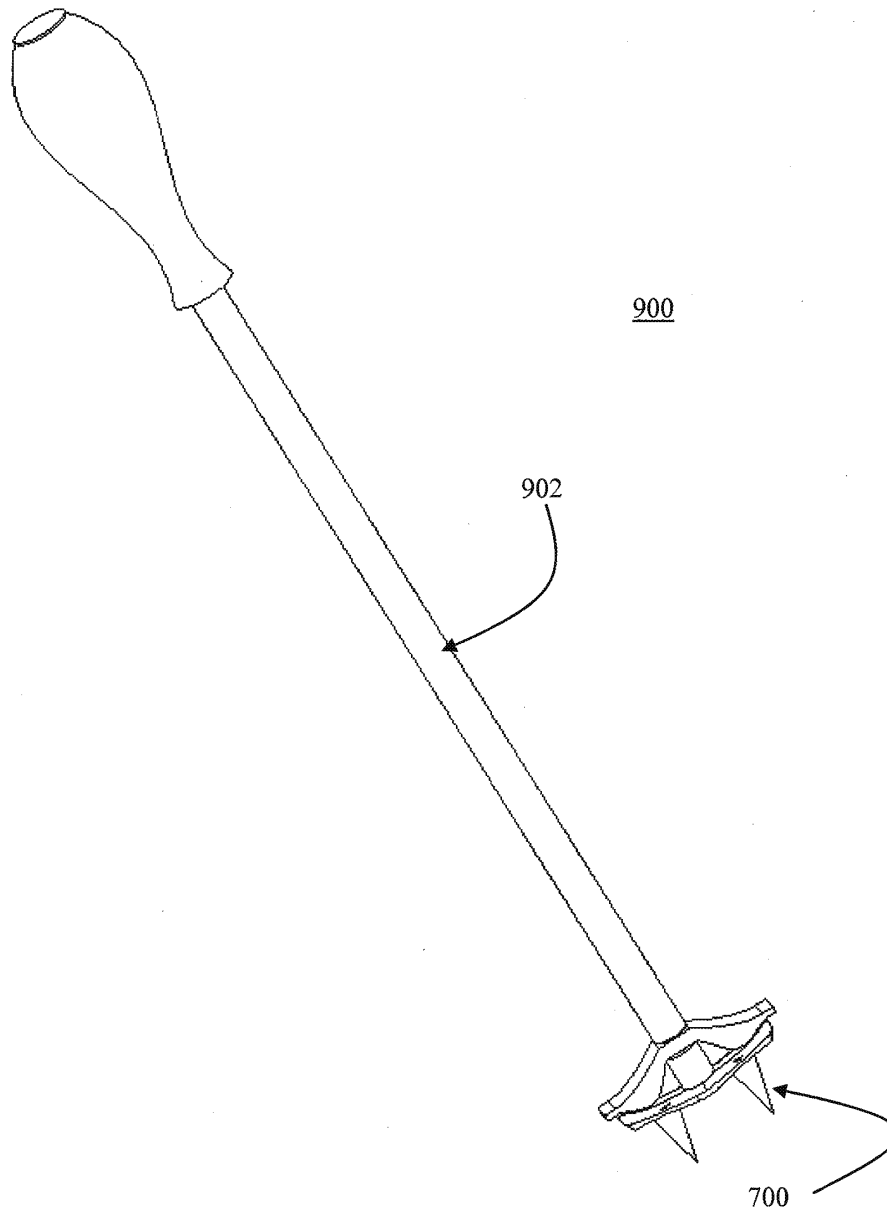


Fig. 9B

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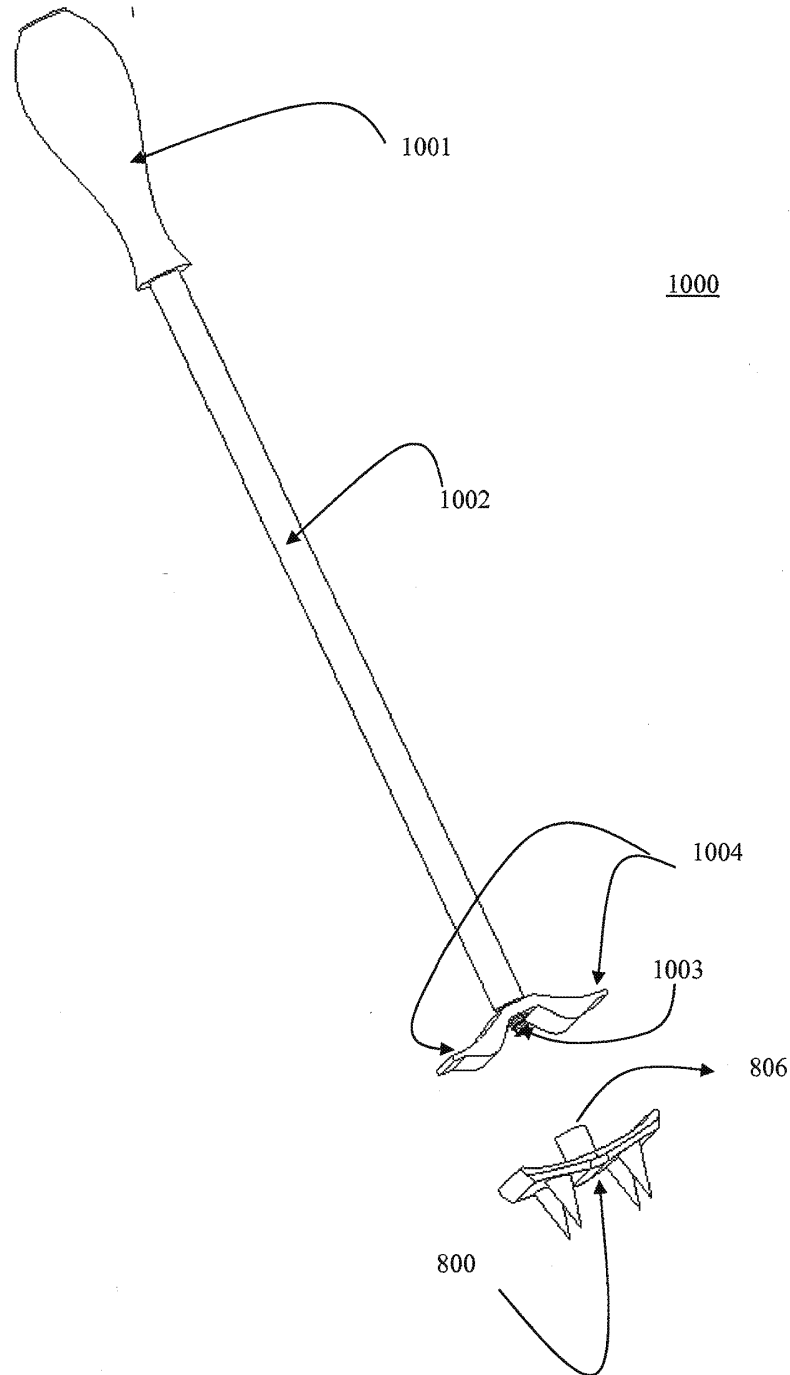


Fig. 10A

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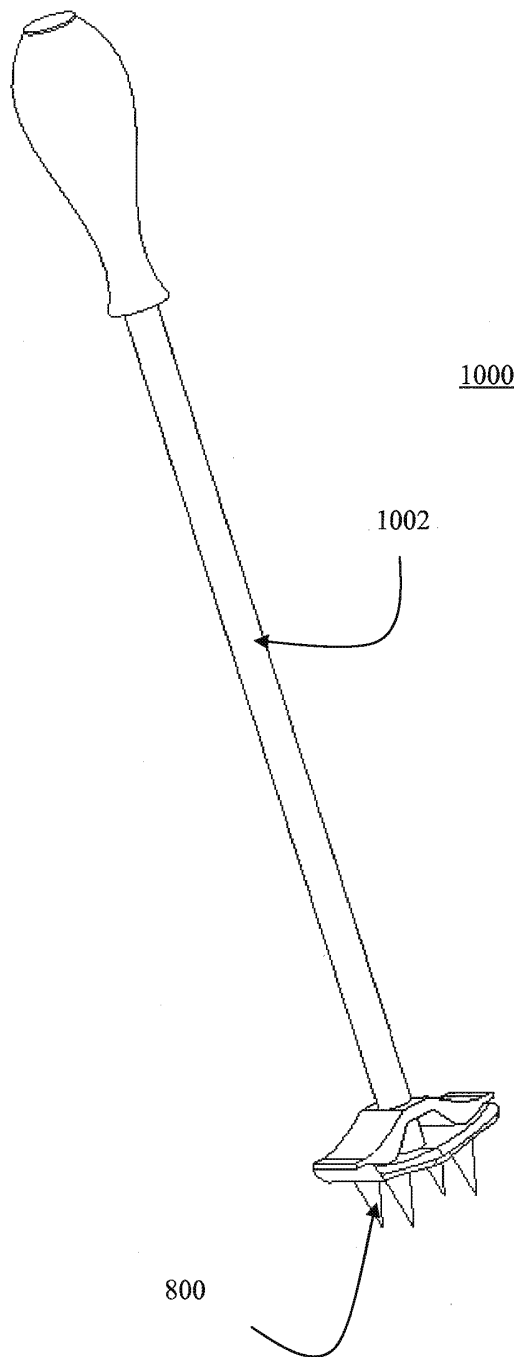


Fig. 10B

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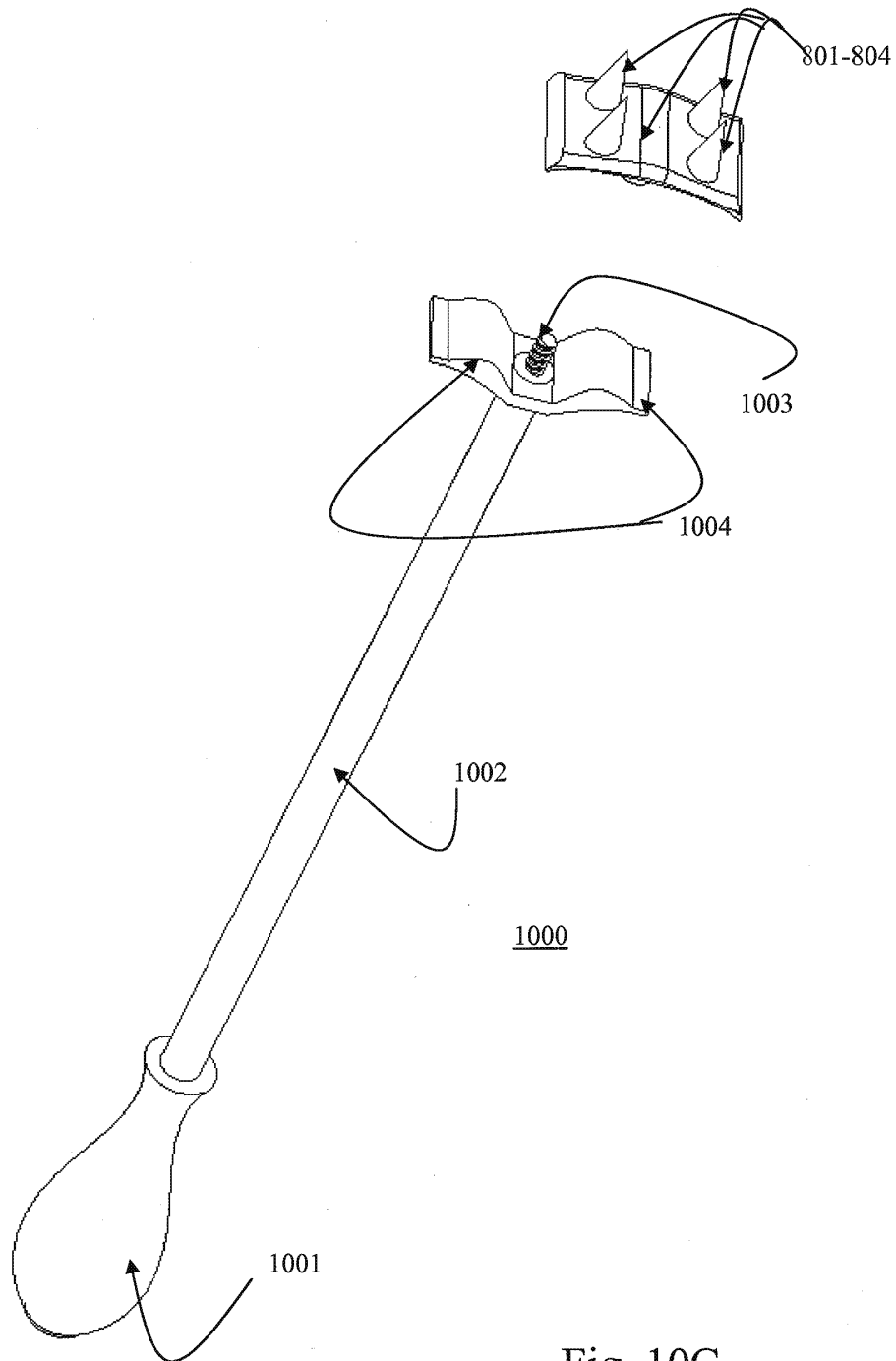


Fig. 10C

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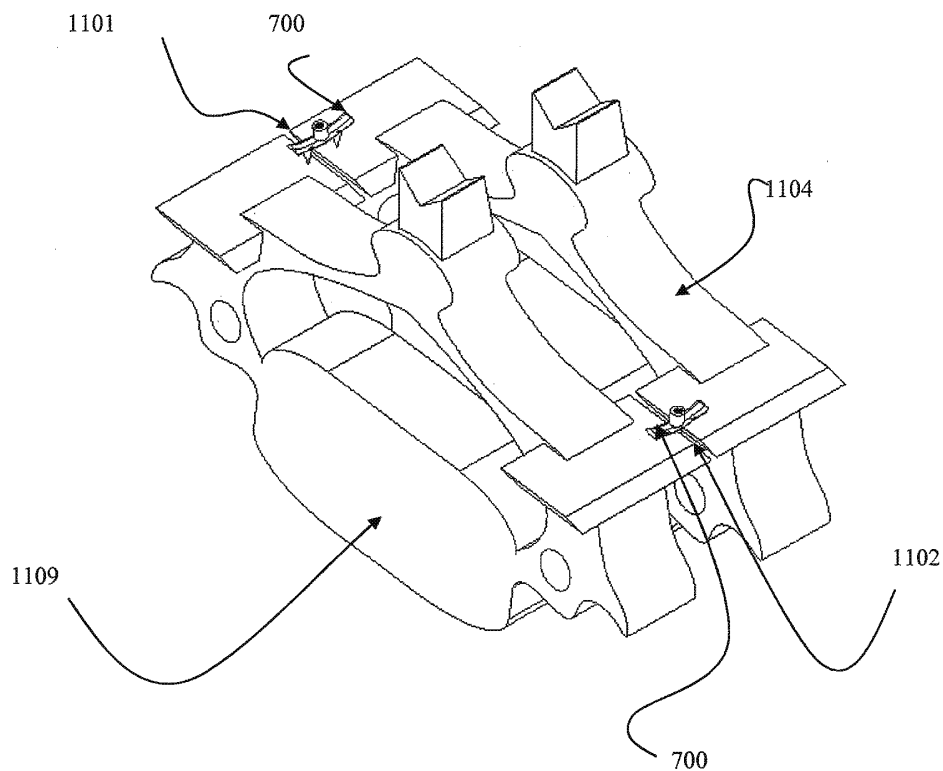


Fig. 11A

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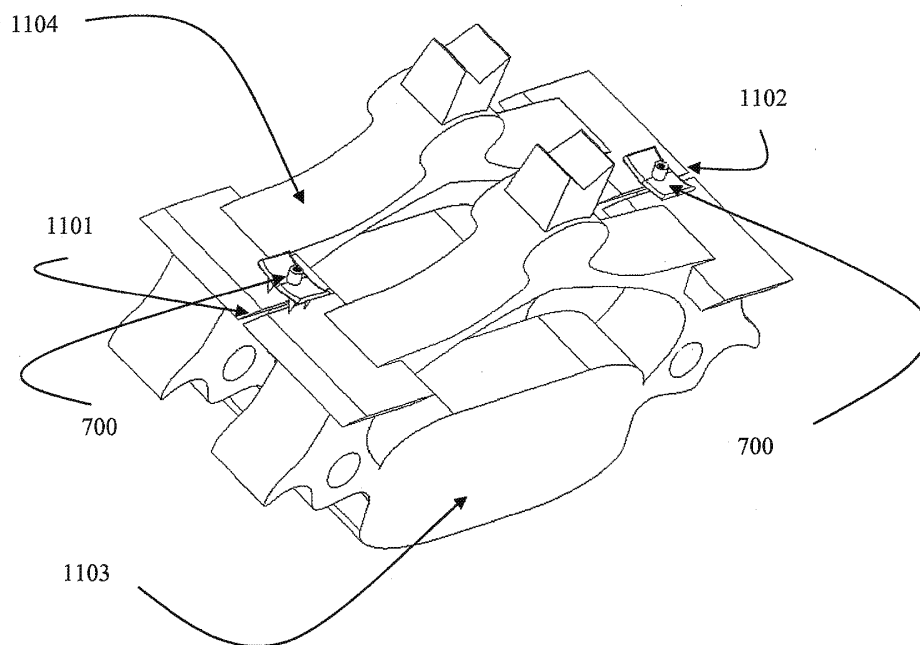


Fig. 11B

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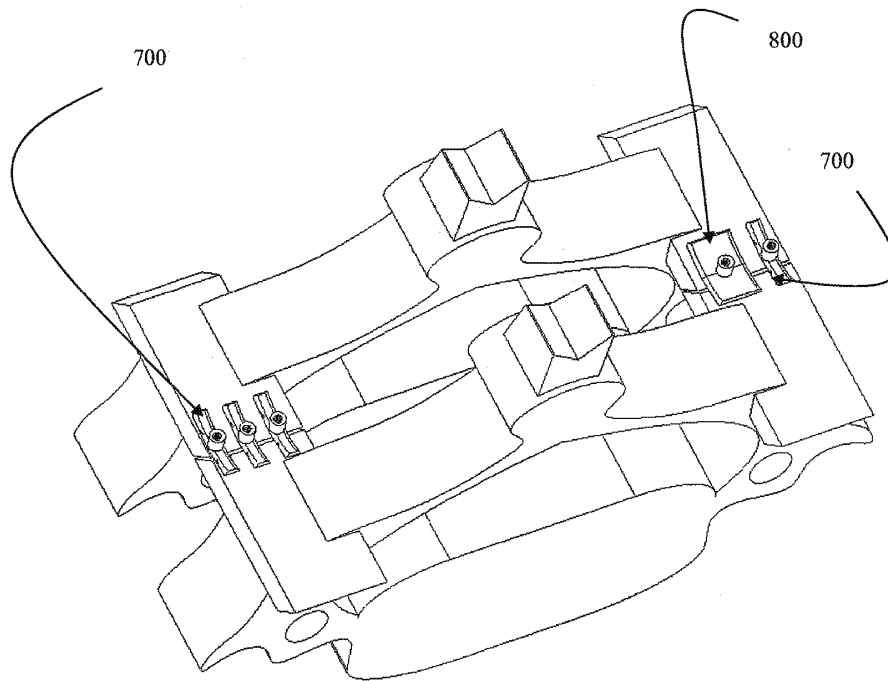


Fig. 11C

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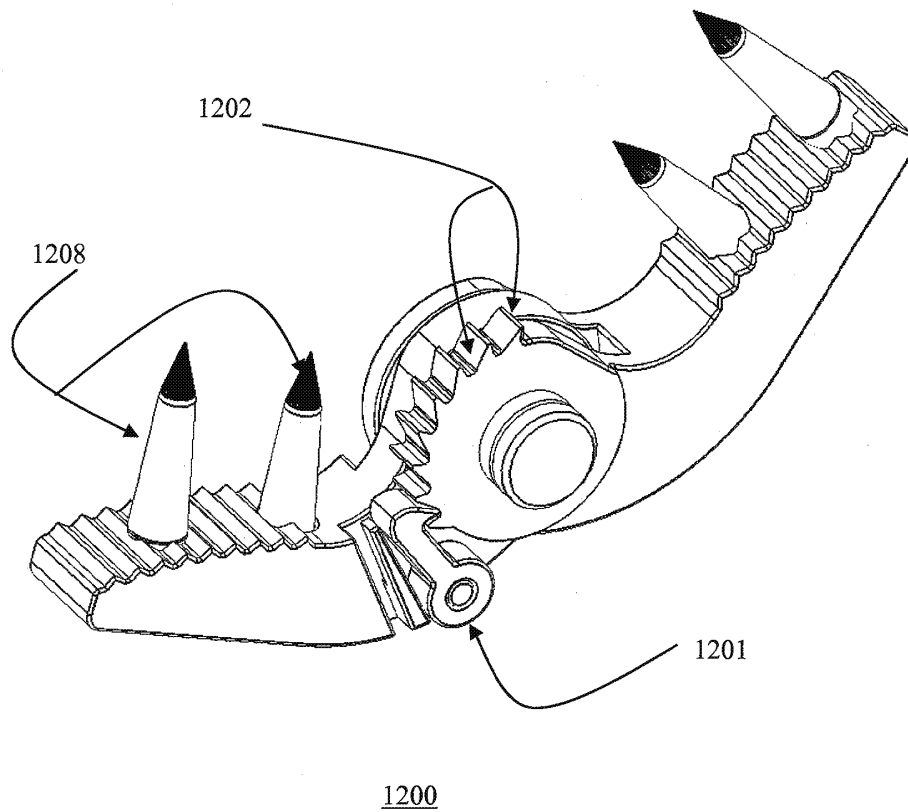


Fig. 12A

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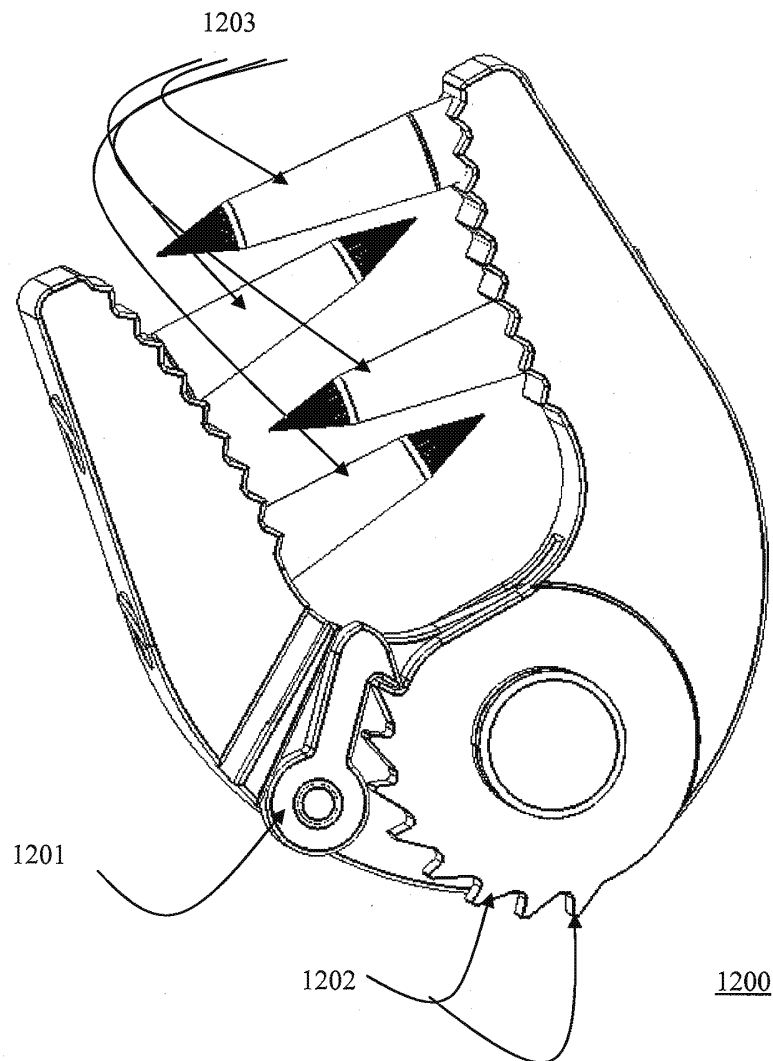


Fig. 12B

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SYSTEM WITH TOOL ASSEMBLY AND
EXPANDABLE SPINAL IMPLANT

This application is a Continuation-In-Part application of copending application Ser. No. 11/536,815, filed on Sep. 29, 2006, which is a Continuation-In-Part application of copending application Ser. No. 11/208,644, filed on Aug. 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 Apr. 12, 2005; the entire contents of all the above identified patent applications are hereby incorporated by reference.

FIELD OF INVENTION

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.

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

DESCRIPTION OF THE RELEVANT ART

The history and evolution of instrumented spinal fusion in the entire human spine has been reviewed in our two prior copending application Ser. No. 14/536,815, 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.

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

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into the thecal sac causing neural compression, in the absence of a physical barrier between the fusing growing bone, and the thecal sac.

SUMMARY

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.

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.

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.

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

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.

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.

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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.

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

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.

It is believed that BDFT-screw constructs provide as strong or stronger segmental fusion as pedicle screws without the complications arising from pedicle screw placement which include screw misplacement with potential nerve and/or vascular injury, violation of healthy facets, possible pedicle destruction, blood loss, and overly rigid fusions. By placing screws across the intervertebral space from vertebral body to vertebral body, engaging anterior and middle spinal columns, and not the vertebral bodies via the transpedicular route, the healthy facet joints, if they exist, are preserved. Because this technique accomplishes both anterior and

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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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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

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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.

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.

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.

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.

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.

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.

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.

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

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boxes may be joined by or include an attachment member, such as a plate and/or a circumferential cage.

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.

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.

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.

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.

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

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

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

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.

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

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.

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.

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

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

FIGS. 5E-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).

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).

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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.

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

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

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

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

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

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

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

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

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

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.

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

1. The Medical Device

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.

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).

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.

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

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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.

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.

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.

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).

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).

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.

The key components of this device include an Allen key 501, a spring 502, a handle 503, a gripper 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 gripper 504

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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.

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.

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.

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.

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

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.

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.

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.

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.

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.

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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.

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.

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.

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. 14/536,815, 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.

2. The Surgical Method

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

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.

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.

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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.

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.

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.

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.

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.

The anterior thoracic and lumbar spine implantation of one, two or three screw box constructs 100, 200, 300 and BDFT screws can be performed in a similar manner to the posterior application. Likewise, a horizontal mini-plate 400 can be used to cap two or three screw box constructs 100, 200, 300 (one placed midline deeply, one placed left and one placed right, forming a triangulation). Alternatively two screw box constructs may be placed into a circumferential ring for anterior placement. Anterior placement of these devices can be performed into the L4/5 and L5/S1 spaces on the supine anesthetized patient via previously described open microscopic or endoscopic techniques. Once the disc space is exposed and discectomy and space preparation are performed, placement of one, two or three screw box embodiments 100, 200, 300 (I-III) or a 2 in 1 construct can be placed. The screw placement is facilitated by the internal screw guides, and different positioning tools (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.

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.

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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 staples can be inserted ranging from a single unilateral two pronged staple providing a high degree of flexibility to a total of four bilaterally placed four pronged staples 800 (16 prongs) leading to the highest degree of rigidity. Additional bone may or may not be placed in its vicinity to facilitate permanent and solid fusion. This procedure can be performed open, closed, percutaneously, tubular, endoscopically or microscopically. FIGS. 11 A-C illustrates placement of the staples 700, 800 in the cervical spine.

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.

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.

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.

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.

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 system comprising:

a tool assembly which comprises:

a first tool having a first proximal end and a first distal end with a first handle and a gripper, the gripper

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being positioned at the first distal end, cooperating with the first handle, and having first and second engagement prongs positioned at the first distal end, wherein the first tool defines an adjusting tool passage through the first tool; and

a second adjusting tool having a second proximal end and a second distal end with a second handle positioned at the second proximal end, a screw engagement portion positioned at the second distal end, and a shaft extending from the second handle to the screw engagement portion, wherein the shaft of the second adjusting tool is sized with a smaller diameter than that of the adjusting tool passage such that the second adjusting tool can extend through the adjusting tool passage of the first tool; and

an expandable spinal implant sized and configured to be implanted in a human spine, the expandable spinal implant comprising a first expandable spinal implant structure, a second expandable spinal implant structure, and an adjusting screw having a screw head and a threaded portion, wherein the expandable spinal implant is configured to expand the first expandable spinal implant structure with respect to the second expandable spinal implant structure in response to turning of the adjusting screw, wherein the expandable spinal implant defines first and second tool engagement indentations sized and configured for receiving the first and second engagement prongs of the first tool, wherein the adjusting screw is positioned within the expandable spinal implant in a screw location such that the second adjusting tool can extend through the adjusting tool passage of the first tool to engage the screw head of the adjusting screw while the first and second engagement prongs of the first tool are engaged with the first and second tool engagement indentations of the expandable spinal implant.

2. The system of claim 1, wherein the screw engagement portion of the second adjusting tool comprises a key for engaging the head of the adjusting screw to turn the adjusting screw and controlling height of the expandable spinal implant.

3. The system of claim 1, wherein the expandable spinal implant defines a longitudinal axis, wherein the first and second expandable spinal implant structures have first and second angled wedge surfaces that engage one another, wherein the adjusting screw is connected to the second expandable spinal implant structure so as to move the second expandable spinal implant structure along the longitudinal axis and slide the first angled wedge surface with respect to the second angled wedge surface to push the first expandable spinal implant structure in a direction that is substantially away from the longitudinal axis of the expandable spinal implant.

4. The system of claim 1, wherein the first expandable spinal implant structure defines a first angled wedge portion that comprises a first inwardly-facing rail and a second inwardly-facing rail, wherein a first inwardly-facing slot is defined at a location adjacent the first inwardly-facing rail, wherein a second inwardly-facing slot is defined at a location adjacent the second inwardly-facing rail, wherein the second expandable spinal implant structure defines a second angled wedge portion that comprises a first outwardly-facing rail and a second outwardly-facing rail that faces outwardly in a direction opposite that of the first outwardly-facing rail, wherein a first outwardly-facing slot is defined at a location adjacent the first outwardly-facing rail, wherein a second outwardly-facing slot is defined at a location adjacent the

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

5. The system of claim 1, and further comprising first and second anchors, wherein the expandable spinal implant comprises first and second anchor guides angled to guide the first and second anchors bidirectionally into first and second vertebral bodies.

6. The system of claim 5, wherein the first tool defines third and fourth anchor guides configured to align with the first and second anchor guides of the expandable spinal implant when the first and second engagement prongs are engaged with the first and second tool engagement indentations so as to guide the first and second anchors through the third and fourth anchor guides into the first and second anchor guides.

7. A method of using the system of claim 1, the method comprising:

connecting the first tool to the expandable spinal implant with the first and second engagement prongs engaged with the first and second tool engagement indentations; implanting the expandable spinal implant into a disc space in the human spine via the first tool;

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

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

8. The system of claim 1, and further comprising bone graft material configured to be placed inside and outside of the expandable spinal implant.

9. A system comprising:
a tool assembly comprising:

a first tool having a first proximal end, a first distal end, and a first elongate body between the first proximal end and the first distal end, wherein the first tool defines a first tool axis from the first proximal end to the first distal end, wherein the first tool includes first and second engagement prongs positioned at the first distal end on opposite sides of the first tool axis, wherein the first tool defines an adjusting tool passage through the first tool; and

a second adjusting tool having a second proximal end and a second distal end, wherein the second adjusting tool includes a second handle positioned at the second proximal end, a screw engagement portion positioned at the second distal end, and a shaft extending from the second handle to the screw engagement portion, wherein the shaft of the second adjusting tool is sized with a smaller diameter than that of the adjusting tool passage such that the

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second adjusting tool can extend through the adjusting tool passage of the first tool; and
 an expandable spinal implant sized and configured to be implanted in a human spine, the expandable spinal implant comprising a first expandable spinal implant structure defining a first engagement surface sized and configured to engage a first vertebral body, a second expandable spinal implant structure defining a second engagement surface sized and configured to engage a second vertebral body, and an adjusting screw having a screw head and a threaded shaft, wherein the expandable spinal implant is configured to expand the first expandable spinal implant structure with respect to the second expandable spinal implant structure in response to turning of the adjusting screw, wherein the expandable spinal implant defines first and second tool engagement indentations sized and configured for receiving the first and second engagement prongs of the first tool, wherein the adjusting screw is positioned within the expandable spinal implant in a screw location such that the second adjusting tool can extend through the adjusting tool passage of the first tool to engage the screw head of the adjusting screw while the first and second engagement prongs of the first tool are engaged with the first and second tool engagement indentations of the expandable spinal implant.

10. The system of claim 9, wherein the expandable spinal implant includes ridges on each of the first and second engagement surfaces, wherein the first indentation extends into a first side of the first expandable spinal implant structure, wherein the second indentation extends into a second side of the expandable spinal implant structure.

11. The system of claim 9, wherein the expandable spinal implant comprises first and second angled wedge surfaces, wherein rotation of the adjustment screw by the second adjusting tool drives relative motion of the first angled wedge surface with respect to the second angled wedge surface to expand the expandable spinal implant.

12. The system of claim 9, wherein the first expandable spinal implant structure defines an end gap between the first and second opposing side surfaces at a first end of the first vertebral body engagement surface, wherein the first vertebral body engagement surface comprises a plurality of ridges extending from the first vertebral body engagement surface, wherein at least some of the ridges are positioned on the first vertebral body engagement surface on opposite sides of the end gap.

13. The system of claim 9, and further comprising first and second anchors, wherein the expandable spinal implant comprises first and second anchor guides angled to guide the first and second anchors bidirectionally into the first and second vertebral bodies, wherein the first tool defines third and fourth anchor guides configured to align with the first and second anchor guides of the expandable spinal implant so as to guide the first and second anchors through the third and fourth anchor guides into the first and second anchor guides when the first and second engagement prongs are engaged with the first and second tool engagement indentations.

14. The system of claim 9, wherein a distal end of the adjusting screw has a distal diameter, wherein the head of the adjusting screw has a head diameter, and wherein the distal diameter is larger than the head diameter.

15. The system of claim 9, wherein the first tool comprises a first handle positioned proximate the first proximal end and extending in a direction that is substantially perpendicular to the first proximal axis, wherein the second handle of the

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second adjusting tool is substantially circular when viewed along the first proximal axis when the second adjusting tool is positioned in the adjusting tool passage.

16. The system of claim 9, wherein the first expandable spinal implant structure and the first engagement surface move with respect to the second expandable spinal implant structure and the second engagement surface at least partially along a direction of the first tool axis when the second adjusting tool turns the adjusting screw.

17. The system of claim 9, wherein the expandable spinal implant has a proximal end, a distal end, and first and second sides, wherein the screw head of the adjusting screw is positioned at the proximal end of the expandable spinal implant, wherein the first and second tool indentations are positioned on the first and second sides proximate to the proximal end, wherein the expandable spinal implant defines a proximal screw hole at the proximal end of the expandable spinal implant and a distal screw hole at the distal end of the expandable spinal implant and wherein the adjusting screw extends through both the proximal and the distal screw holes.

18. The system of claim 9, wherein the first tool indentation extends into a first side of the expandable spinal implant with a first substantially rectangular shape as viewed from a direction perpendicular to the first side and the second tool indentation extends into a second side of the expandable spinal implant with a second substantially rectangular shape as viewed from a direction perpendicular to the second side.

19. A method of using the system of claim 9, the method comprising:

connecting the first tool to the expandable spinal implant with the first and second engagement prongs engaged with the first and second tool engagement indentations; implanting the expandable spinal implant into a disc space in the human spine via the first tool;

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

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

20. A system comprising:

a tool assembly comprising:

a first tool having a first proximal end, a first distal end, and a first elongate body between the first proximal end and the first distal end, wherein the first tool defines a first tool axis from the first proximal end to the first distal end, wherein the first tool includes a gripper having one or more engagement prongs positioned at the first distal end axially offset from the first tool axis, wherein the first tool defines an adjusting tool passage through the first tool; and

a second adjusting tool having a second proximal end and a second distal end, wherein the second adjusting tool includes a screw engagement portion positioned at the second distal end and a shaft extending from the second proximal end to the screw engagement portion, wherein the shaft of the second adjusting tool is sized with a smaller diameter than that of the adjusting tool passage such that the second adjusting tool can extend through and turn within the adjusting tool passage of the first tool; and

an expandable spinal implant sized and configured to be implanted in a human spine, the expandable spinal implant comprising a first expandable spinal implant structure defining a first engagement surface sized and

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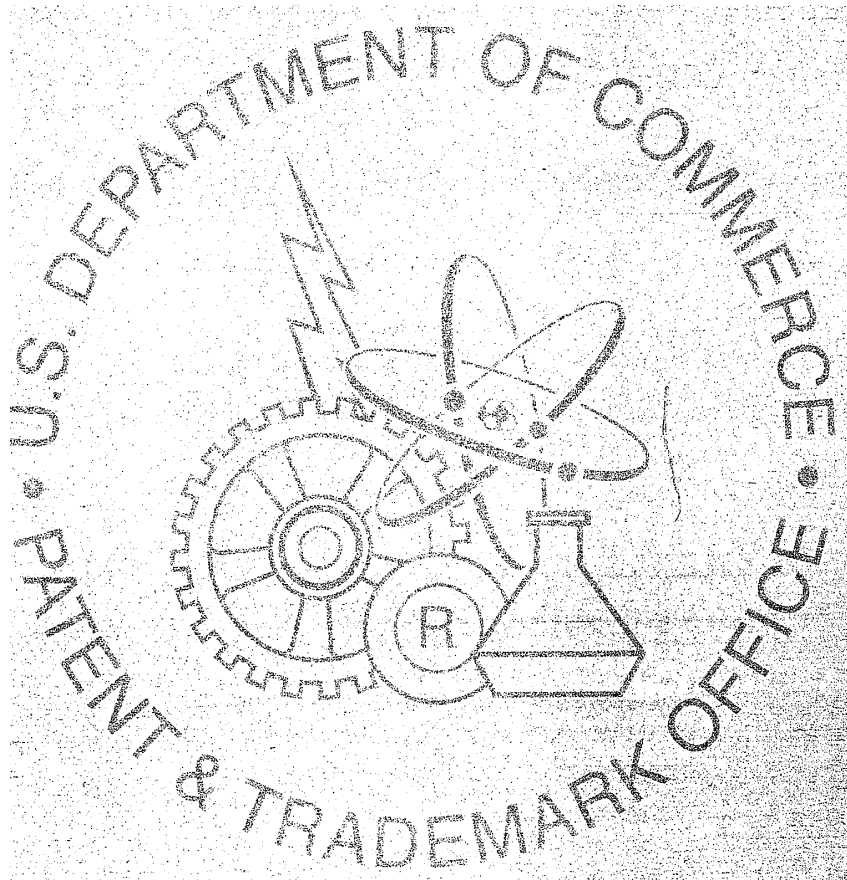
configured to engage a first vertebral body, a second expandable spinal implant structure defining a second engagement surface sized and configured to engage a second vertebral body, and an adjusting screw having a screw engagement portion and a threaded portion, wherein the expandable spinal implant is configured to expand the first expandable spinal implant structure with respect to the second expandable spinal implant structure in response to turning of the adjusting screw, wherein the expandable spinal implant defines one or more tool engagement indentations sized and configured for engaging with the gripper of the first tool, wherein the adjusting screw is positioned within the expandable spinal implant in a screw location such that the second adjusting tool can extend through the adjusting tool passage of the first tool to engage the screw engagement portion of the adjusting screw while one or more engagement prongs of the first tool are engaged with the one or more engagement indentations of the

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expandable spinal implant, wherein at least one of the one or more engagement indentations of the expandable spinal implant is positioned on one or more side surfaces of the expandable spinal implant such that the one or more engagement prongs of the gripper is positioned on the one or more side surfaces of the expandable spinal implant when the first tool is engages with the expandable spinal implant.

21. The system of claim 20, wherein the expandable spinal implant comprises a substantially cylindrical side hole extending through a side of the expandable spinal implant into an interior cavity of the expandable spinal implant and is sized and configured to allow for bone placement through the side hole into the interior cavity, wherein the expandable spinal implant comprises an angled wedge portion having rails and slots configured to allow for relative movement and expansion of the expandable spinal implant during expansion of the expandable spinal implant.

* * * * *



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CERTIFICATE OF SERVICE AND FILING

I certify that on January 30, 2025, I electronically filed the foregoing **PRINCIPAL BRIEF** of Plaintiff-Appellant using the Court's CM/ECF filing system. Counsel for Defendant-Cross-Appellant were electronically served by and through the Court's CM/ECF filing system per Fed. R. App. P. 25 and Fed. Cir. R. 25(e).

/s/ Lauren A. Degnan

Lauren A. Degnan

CERTIFICATE OF COMPLIANCE

The **PRINCIPAL BRIEF** of Plaintiff-Appellant is submitted in accordance with the type-volume limitation of Fed. Cir. R. 32(b). The brief contains 13,999 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f) and Fed. Cir. R. 32(b)(2). This brief has been prepared in a proportionally spaced typeface using Microsoft® Word for Microsoft 365 in Times New Roman, 14 Point.

Dated: January 30, 2025

/s/ Lauren A. Degnan
Lauren A. Degnan