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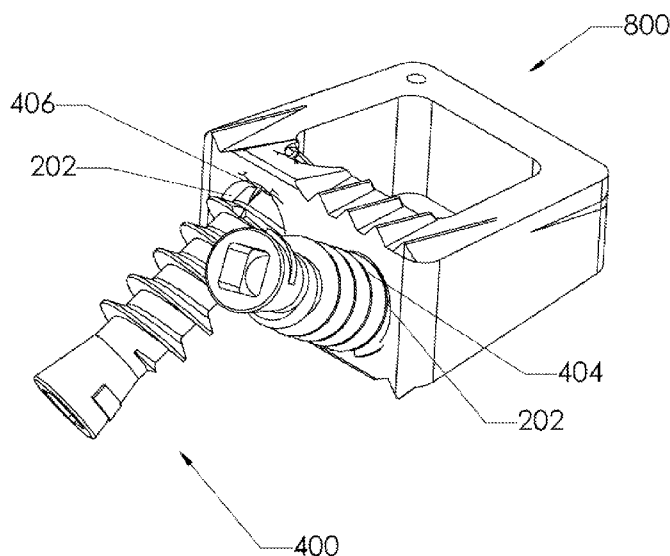


FIG. 8

(57) Abstract: A system, device, and method are disclosed for anterior intervertebral fusion with fixation. An intervertebral fusion with fixation device includes a spacer configured to fit into a disc space between plural vertebrae, the spacer including through holes between and through plural sidewalls. A first fixating element is rigidly preloaded in a first portion of the spacer along a first linear trajectory. A second fixating element is rigidly preloaded in a second portion of the spacer along a second linear trajectory. An integrated drill and screwdriver instrument is adapted to extend through a cannula of the first fixating element and second fixating element and penetrate the vertebra. The instrument is further adapted to drive the head of the first fixating element and second fixating element into the vertebra and lock the first fixating element and second fixating element with respect to the spacer to prevent extrusion from the spacer.



ANTERIOR INTERVERTEBRAL FUSION WITH FIXATION SYSTEM, DEVICE AND METHOD

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Application No. 61/463,239, filed on February 15, 2011, and U.S. Provisional Application No. 61/517,717, filed on April 25, 2011, which are incorporated herein by reference in their entirety.

Field

[0002] The present disclosure relates to spinal implants and associated instrumentation. Various embodiments are directed to an anterior intervertebral fusion with fixation system, device and method.

Description of Related Art

[0003] A healthy spinal disc (intervertebral disc) is a fibroelastic structure with a non-compressible viscous center that articulates adjacent vertebrae. Due to its deformable geometry, the disc not only supports normal functional loads of the human body, but also evenly distributes the stresses applied during body movement and positioning. The disc interfaces with associated superior and inferior vertebrae via large surface areas known as vertebral endplates. Normally, vertebral endplates are thin regions of dense bone (e.g. 1mm – 3mm) that support high stresses at articulating junctions.

[0004] Intervertebral discs and adjacent articulations progressively deteriorate with age. This natural degenerative process results in various degrees of pathological changes, mostly affecting the geometry and elasticity of a vertebral disc. In severe cases, reduced disc volume results in foraminal compression that mechanically irritates nerve roots and causes neurocompressive syndrome. This often causes severe chronic pain that can only be resolved surgically.

[0005] Historically, surgical treatment of degenerative spinal disc disease required fusion, which immobilizes two adjacent vertebral bodies (vertebrae) to prevent motion-sensitive pain and inflammation. This is accomplished by distracting the vertebrae to a healthy disc height, inserting a disc implant and allowing bone to grow between and through the disc implant until

the vertebrae fuse into a solid bony structure. To facilitate proper healing under normal conditions of motion, the disc implant is used to maintain temporary positioning until the bone achieves fusion. The implant is secured to the vertebrae using fixation elements.

[0006] The effectiveness of the disc implant can be evaluated with the following criteria: (i) its ability to restore and maintain normal disc height and curvature; (ii) its ease of delivery and fixation to the disc space; (iii) its ability to facilitate fusion of associated vertebrae; and (iv) its ability to restrict movement of associated vertebrae.

[0007] Disc implants share the same fundamental characteristics to meet the effectiveness criteria. Implants aim to restore disc height through the use of variable geometries. Lordotic curvature is preserved through the use ergonomic designs that conform to spinal curvature and height between the vertebrae. Also, the disc implants are sufficiently porous or hollow to promote the growth of vertebral bone into and through the implant. However, independently, these implants can only restrict spinal flexion and intervertebral compression. Any excessive lateral, sliding, or extension motion may cause device failure and/or extrusion. To avoid this risk, it is customary to provide additional fixation of the disc implant to the vertebrae.

[0008] Devices and systems may integrate fixating members directly into the disc implant. These implants have garnered the nickname “standalone” due to their ability to self-fixate without the use of secondary fixation elements. In the foregoing standalone implants, obtrusive fixation elements are delivered directly through implant pilot openings into the vertebra, which fixate the implant to the vertebrae and prevent implant failure under remaining ranges of motion (e.g., lateral, sliding, extension). Nevertheless, during these motions, connectivity between fixation elements and vertebrae may become weakened causing the fixation elements to slip or extrude out of the implant. To prevent unwanted fixation element slipping or extrusion, it is customary to include a locking mechanism for the implant.

SUMMARY

[0009] In a particular embodiment, an intervertebral fusion with fixation device is disclosed. The device includes a spacer with an insertion wall, a trailing wall opposite to the insertion wall, a first lateral wall, a second lateral wall opposite to the first lateral wall, a top surface, and a

bottom surface opposite to the top surface. The intervertebral fusion with fixation device further includes a first fixating element rigidly preloaded in a first portion of the spacer along a first linear trajectory, the first fixating element configured to penetrate and secure to a first vertebra by advancing along the first linear trajectory. The device also includes a second fixating element rigidly preloaded in a second portion of the spacer along a second linear trajectory that is different from the first linear trajectory, the second fixating element configured to penetrate and secure to a second vertebra by advancing along the second trajectory. Further, the intervertebral fusion with fixation device includes a through opening having an entrance proximate the top surface and an exit proximate the bottom surface to facilitate contact and in-growth of bone fusion material with the first vertebra and second vertebra.

[0010] In another particular embodiment, an integrated drill and screwdriver instrument is disclosed. The integrated drill and screwdriver includes a handle, a driving element configured to engage a head of a bone screw and rotate the bone screw into a vertebra, and a drilling element extending from the from the driving element. The drilling element is configured to extend through a cannula of the bone screw and to penetrate the vertebra. The driving element is configured to engage the head of the bone screw as the drilling element penetrates through a vertebral endplate.

[0011] In a further particular embodiment, an intervertebral fusion with fixation system is disclosed. The system includes an intervertebral fusion with fixation device configured to be implanted between plural vertebrae. The device includes a spacer with an insertion wall, a trailing wall opposite to the insertion wall, a first lateral wall, a second lateral wall opposite to the first lateral wall, a top surface, and a bottom surface opposite to the top surface. The device further includes a first fixating element rigidly preloaded in a first portion of the spacer along a first linear trajectory, the first fixating element configured to penetrate and secure to a first vertebra by advancing along the first linear trajectory. Additionally, the device also includes a second fixating element rigidly preloaded in a second portion of the spacer along a second linear trajectory that is different from the first linear trajectory, the second fixating element configured to penetrate and secure to a second vertebra by advancing along the second trajectory. The system also includes an integrated integrated drill and screwdriver instrument. The integrated instrument includes a handle, a driving element configured to engage a head of a bone screw and

rotate the bone screw into a vertebra, and a drilling element extending from the from the driving element. The drilling element is configured to extend through a cannula of the bone screw and to penetrate the vertebra. The driving element is configured to engage the head of the bone screw as the drilling element penetrates through a vertebral endplate.

[0012] In yet another particular embodiment, a method to secure plural vertebrae is disclosed. The method includes implanting an intervertebral fusion with fixation device between plural vertebrae. The fusion with fixation device includes a spacer, a first fixating element rigidly preloaded in a first portion of the spacer along a first linear trajectory, and a second fixating element rigidly preloaded in a second portion of the spacer along a second linear trajectory that is different from the first linear trajectory. The method further includes driving the first fixating element along the first linear trajectory to penetrate the first vertebra and to secure the spacer to a first vertebra, and driving the second fixating element along the second linear trajectory to penetrate the second vertebra and to secure the spacer to a second vertebra. The method also includes extending an integrated drill and screwdriver instrument through a cannula of the first fixating element and a cannula of the second fixating element, drilling the plural vertebrae with a drilling element, engaging the first fixating element and second fixating element with a driving element as the drilling element penetrates through a vertebral endplate of the plural vertebrae, and rotating the first fixating element and second fixating element via the driving element to penetrate the plural vertebrae and to secure the spacer to the plural vertebrae. The method further includes locking the first fixation element and second fixation element with respect to the spacer to prevent the first fixation element and second fixation element from extruding from the plural vertebrae and from the spacer.

[0013] In a further embodiment, a method to assemble an intervertebral fusion with fixation device is disclosed. The method includes rigidly preloading a first fixating element in a first portion of a spacer along a first linear trajectory and a second fixating element in a second portion of the spacer along a second linear trajectory, the first linear trajectory being different from the second linear trajectory.

BRIEF DESCRIPTION OF DRAWINGS

- [0014] FIG. 1 is a perspective view of an example spacer of an intervertebral fusion with fixation device;
- [0015] FIG. 2 is a front view of the example spacer shown in FIG. 1;
- [0016] FIG. 3 is a side view of the example spacer shown in FIG. 1;
- [0017] FIG. 4 is a perspective view of an example fixation element of the intervertebral fusion with fixation device;
- [0018] FIG. 5 is a cross-sectional side view of the example fixation element show in FIG. 4;
- [0019] FIG. 6 is a side view of an example integrated drill and screwdriver driving instrument;
- [0020] FIG. 7 is a perspective exploded view of a tip of the example integrated drill and screwdriver drilling tip shown in FIG. 6;
- [0021] FIG. 8 is a perspective view of an example intervertebral fusion with fixation device with the example fixation elements shown in FIG. 4 preloaded in the example spacer shown in FIG. 1;
- [0022] FIG. 9 is a perspective view of the example intervertebral fusion with fixation device of FIG. 8 with the example integrated drill and screwdriver of FIG. 6 actuating a fixation element shown in FIG. 4.
- [0023] FIG. 10 is a translucent perspective view of an example intervertebral fusion with fixation device with the example fixation element of FIG. 4 in a locked position within a vertebra.

DETAILED DESCRIPTION

[0024] FIG. 1 is a perspective view of an example spacer **100** of an intervertebral fusion with fixation device. The intervertebral fusion with fixation device is illustrated in FIG. 8. The spacer **100** is made of a weight-bearing material, such as a polymer, metal, ceramic, biological material, or composite thereof, that is capable of withstanding the normal stresses of bodily movement and positioning, while also allowing sufficient elasticity. The material can have a flexural modulus and tensile strength comparable to bone. For example, the spacer **100** can be made of

polyetheretherketone (PEEK), a thermoplastic with a flexural modulus of 4.2 GPa and a tensile strength of 95 MPa. Another benefit of PEEK is its high level of biocompatibility in a dynamic and immunoreactive environment. Other materials and combinations of materials are possible.

[0025] The spacer **100** includes an insertion wall **110**, trailing wall **112**, lateral walls **106**, **108**, top surface **102**, bottom surface **104**, and through opening **114** extending between and through the top surface **102** and bottom surface **104** for bone graft insert.

[0026] In various embodiments, the dimensions of the spacer **100** are approximately the following: the length of the spacer **100** between an insertion wall **110** and trailing wall **112** is between about 10mm and 80mm; the width of the spacer **100** between a first lateral wall **106** and second lateral wall **108** is between about 10mm and 80mm; and the height of the spacer **100** between a top surface **102** and bottom surface **104** is between about 4mm and 30mm. The foregoing dimensions are non-limiting and are intended to be adjusted depending on the specific spinal anatomy of the patient.

[0027] The opening **114** can have a volume approximately between 0 cm^3 and 8 cm^3 . Other volumes can be provided. While the insertion wall **110**, trailing wall **112**, and lateral walls **106**, **108** are generally flat surfaces, the top surface **102** and bottom surface **104** may be tapered or curved with respect to one another to conform to intervertebral lordosis or curvature. The lateral walls **106**, **108** can also have a tapered geometry to conform to intervertebral space. In some embodiments, the angle between the lateral surfaces **106**, **108** can be from about 0 degrees to about 16 degrees.

[0028] The trailing wall **112** includes a plurality of through holes **202** (shown in FIG. 2) extending from the central opening **114** to the exterior of the spacer **100** to receive, secure, and guide plural fixation elements **400** (shown in FIG. 4). Each of the foregoing holes **202** is oriented to provide a trajectory for a fixation element (shown in FIG. 4). The trajectories of the holes **202** can be oriented in directions lateral, medial, superior, inferior, or any combination thereof to the spacer to provide multi-axial fixation to the vertebrae. In some embodiments, the holes **202** can direct the fixation elements **400** in divergent trajectories to counterbalance one another from any opposing torques or shear stresses initiated by vertebral motion. The dimensions of the holes **202**

are approximately the following: the medial and/or lateral angle in respect to lateral walls **106**, **108** is between about 0 degrees and 25 degrees, and the superior and/or inferior angle in respect to surfaces **102**, **104** is between about 30 degrees and 50 degrees. The diameters of the foregoing holes **202** are approximately between 0.5mm and 10mm.

[0029] FIG. 2 is a front view of the example spacer **100** shown in FIG. 1. Now with reference to FIGS. 1 and 2, the spacer **100** includes ridges **116** on surfaces **102**, **104** proximate the holes **202** to reinforce the spacer **100** during advancement of the fixation elements **400**. For example, ridges **116** can be provided about the exits to the outside of the spacer **100** and can be of various dimensions and tapers along the surfaces **102**, **104**. In some embodiments, the ridges **116** can be omitted. The spacer **100** further includes ridges **118** along the surfaces **102**, **104** that penetrate surrounding vertebrae during implantation and provide stability to the spacer **100** through micro-scale contact with the vertebral plates.

[0030] The spacer **100** can include plural radiopaque markers **120** to enhance radiographic visualization of the spacer **100**. The markers **120** can be made of a biocompatible radiopaque material, such as tantalum, platinum alloys, gold alloys, or palladium alloys. Other applicable materials may also be employed. Plural markers **120** can be provided near the walls **106**, **108**, **110**, **112** and surfaces **102**, **104** to provide additional visual references of the spacer **100** for clinicians during radiographic imaging. Furthermore, the markers **120** can assume various geometries and volumes within the spacer **100** depending on visualization requirements. In various embodiments, the markers **120** can be omitted.

[0031] FIG. 3 is a side view of an example spacer **100** of an intervertebral fusion with fixation device of FIG. 8. In a particular embodiment, the trailing height **302** gradually decreases to the insertion height **304** at a taper to approximate natural lordosis. Additionally, the ridges **116** can be also tapered to minimize friction during insertion and facilitate smooth entry of the spacer **100** into the intervertebral space.

[0032] FIG. 4 is a perspective view of an example fixation element **400**. In a particular embodiment, the fixation element **400** can be made of a biocompatible metal, such as a titanium alloy. Other applicable materials may also be employed. The fixation element **400** includes a tip

405 that locks into and interfaces with the holes **202** during assembly to maintain a preloaded position, and penetrates bone during engagement with vertebral endplates. The fixation element **400** has a minor diameter **402** that is between about 1mm and 10mm. The fixation element **400** also includes a major diameter **404** of threading that is between 2mm and 15mm to provide cutting during engagement.

[0033] Additionally, the tip **405** includes flutes **406** to facilitate penetration into the vertebra during initial engagement. The fixation element **400** further includes a head **407** with a conically shaped body **408** to pressure-fit into the holes **202** after advancement via an instrument receiver **410**. The instrument receiver **410** can interface with a driving instrument (shown in FIG. 6). In a particular embodiment, the head **407** includes a hook protrusion **412** with a sharp edge that can cut into the hole **202** after the fixation element **400** is advanced (e.g., fully) into the vertebra and the head **407** is in contact with the spacer **100**. The contact between the sharp edge of the hook protrusion **412** and the hole **202** functions as a locking mechanism to prevent extrusion of the fixation element **400**.

[0034] FIG. 5 is a cross-sectional side view of an example fixation element **400** of FIG. 4. As illustrated, the fixation element **400** includes a cannula **502** that allows a drilling tip of the driving instrument (shown in FIG. 6) to pass into and through the fixation element **400** to facilitate vertebral endplate pre-drilling and preparation for advancement of the fixation element **400**. The fixation element **400** further includes a platform **504** that connects or interfaces the driving instrument receiver **410** and cannula **502** to contact and limit the depth of motion of the driving instrument (shown in FIG. 6) in relation to the fixation element **400**.

[0035] FIG. 6 is a side view of an example integrated drill and screwdriver driving instrument (driving instrument) **600**. In a particular embodiment, the driving instrument **600** can be made of a metal, such as titanium. Other applicable materials may also be employed. The driving instrument **600** includes an integrated tip **614** that can penetrate and pre-drill vertebral endplates with a drill tip **606** as well as engage the driving instrument receiver **410** of a fixation element **400** with a fixation element interface **604**.

[0036] The drill tip **606** of the integrated tip **614** can pass into and through the cannula **502** of the fixation element **400** in order to penetrate and pre-drill a vertebral endplate. The fixation element interface **604** can contact the driving instrument receiver **410** once the drill tip **606** has penetrated through the vertebral endplate into the softer bony layer. In a particular embodiment, both the fixation element interface **604** and corresponding driving instrument receiver **410** are of a quadrilateral shape to facilitate rigid contact between the surfaces and allow engagement of the fixation element **400**.

[0037] The driving instrument **600** includes a body **602** to increase operational distance from the spacer **100** and provide access under various angulations. The body **602** is smoothly mated to the integrated tip **614** with a conical transition element **610**. Furthermore, the driving instrument **600** includes a handle **612** that can be operated manually or by an electrical or mechanical tool. In a particular embodiment, the handle **612** can be constructed as a hexagonal bit to fit a standard screwdriver. The handle **612** is smoothly mated to the body **602** with a conical transition element **603**.

[0038] FIG. 7 is an exploded perspective view of the example integrated tip **614**. The integrated tip **614** includes cutting blades **702** to facilitate vertebral penetration during advancement. The integrated tip **614** further includes a rounded transition element **704** between the fixation element interface **604** and the drill tip **606** to allow smooth contact between the fixation element interface **604** and driving instrument receiver **410** during the initial engagement of the fixation element **400**.

[0039] FIG. 8 is a perspective view of an example intervertebral fusion with fixation device **800** with the plural example fixation elements **400** of FIG. 4 preloaded in the example spacer **100** of FIG. 1. As illustrated, the fixation elements **400** can be preloaded into the spacer **100** via holes **202**. The flutes **406** and threading **404** cut into and secure the fixation elements **400** to the spacer **100** via holes **202** to maintain a preloaded assembly. This preloaded assembly ensures fixed trajectories for the fixation elements **400** during delivery of the device **800** and eliminates the need for alignment post-implantation.

[0040] FIG. 9 is a perspective view of an example intervertebral fusion with fixation device of FIG. 8 with an example driving instrument 600 of FIG. 6 actuating a fixation element 400 of FIG. 4. As illustrated, the integrated tip 614 is delivered into and through the cannula 502 of the fixation element 400 to pre-drill the vertebral endplate with the cutting blades 702 of the fixation element 400. The penetration of the integrated tip 614 through the vertebral endplate combined with the linear force applied to the handle 612 drives the fixation element interface 604 into contact with the driving instrument receiver 410 of the fixation element 400. Simultaneously, the torque from the handle 612 engages the fixation element interface 604, which in turn actuates the driving instrument receiver 410 and advances the fixation element 400 into vertebral endplate. Additionally, the fixation element flutes 406 and major threading 404 penetrate and secure the fixation element 400 to the endplate of the vertebra.

[0041] FIG. 10 is a translucent perspective view of an example intervertebral fusion with fixation device 800 with the plural example fixation elements 400 of FIG. 4 in a locked position and secured to a vertebra 1001. In a particular embodiment, the hook protrusion 412 of the fixation element 400 pressure fits the holes 202 of the spacer 100 to prevent the fixation element 400 from toggling and backing-out. Furthermore, the hook protrusion 412 rigidly cut into the spacer 100 via its sharp edge to limit the ability of the fixation element 400 to torque towards the trailing wall 112 of the device 800 and away from the vertebra 1001. Additionally, the ridges 118 penetrate adjacent vertebral endplates and provide ancillary stability.

[0042] Other apparent modifications and configurations of the invention will be appreciated by those skilled in the art to allow varying applications of the disclosed embodiments without departing from the scope of the embodiments described herein. The disclosed specifications and principles are intended to be used for illustrative purposes only, with the true scope and spirit of the patent document being defined by the following claims.

What is claimed is:

1. An intervertebral fusion with fixation device configured to be implanted between plural vertebrae, the device comprising:

a spacer with an insertion wall, a trailing wall opposite to the insertion wall, a first lateral wall, a second lateral wall opposite to the first lateral wall, a top surface, and a bottom surface opposite to the top surface;

a first fixating element rigidly preloaded in a first portion of the spacer along a first linear trajectory, the first fixating element configured to penetrate and secure to a first vertebra by advancing along the first linear trajectory; and

a second fixating element rigidly preloaded in a second portion of the spacer along a second linear trajectory that is different from the first linear trajectory, the second fixating element configured to penetrate and secure to a second vertebra by advancing along the second trajectory.

2. The intervertebral fusion with fixation device of claim **1**, wherein the spacer includes a through opening having an entrance proximate the top surface and an exit proximate the bottom surface to facilitate contact and in-growth of bone fusion material with the first vertebra and second vertebra.

3. The intervertebral fusion with fixation device of claim **1**, wherein the spacer is made of polyetheretherketone (PEEK), other polymers, metal, ceramics, or composites.

4. The intervertebral fusion with fixation device of claim **1**, wherein at least one of the first fixating element and the second fixating element is a cannulated bone screw.

5. The intervertebral fusion with fixation device of claim **4**, wherein the cannulated bone screw includes a head that is configured to integrate with a driving instrument.

6. The intervertebral fusion with fixation device of claim 4, wherein the cannulated bone screw includes a head that has a locking mechanism configured to penetrate and lock into spacer to prevent screw toggling and extrusion.

7. An integrated drill and screwdriver instrument, the instrument comprising:

a handle;

a driving element configured to engage a head of a bone screw and to rotate the bone screw into a vertebra,

a drilling element extending from the driving element, the drilling element configured to extend through a cannula of the bone screw and to penetrate the vertebra, the driving element engaging the head of the bone screw as the drilling element penetrates through a vertebral endplate.

8. An intervertebral fusion with fixation system, the system comprising:

an intervertebral fusion with fixation device configured to be implanted between plural vertebrae, the device comprising:

a spacer with an insertion wall, a trailing wall opposite to the insertion wall, a first lateral wall, a second lateral wall opposite to the first lateral wall, a top surface, and a bottom surface opposite to the top surface;

a first fixating element rigidly preloaded in a first portion of the spacer along a first linear trajectory, the first fixating element configured to penetrate and secure to a first vertebra by advancing along the first linear trajectory; and

a second fixating element rigidly preloaded in a second portion of the spacer along a second linear trajectory that is different from the first linear trajectory, the second fixating element configured to penetrate and secure to a second vertebra by advancing along the second trajectory; and

an integrated drill and screwdriver instrument, the instrument comprising:

a handle;

a driving element configured to engage a head of a bone screw and to rotate the bone screw into a vertebra; and

a drilling element extending from the driving element, the drilling element configured to extend through a cannula of the bone screw and to penetrate the vertebra, the driving element engaging the head of the bone screw as the drilling element penetrates through a vertebral endplate.

9. A method to secure plural vertebrae, the method comprising:

implanting an intervertebral fusion with fixation device between plural vertebrae, the device comprising:

a spacer with an insertion wall, a trailing wall opposite to the insertion wall, a first lateral wall, a second lateral wall opposite to the first lateral wall, a top surface, and a bottom surface opposite to the top surface;

a first fixating element rigidly preloaded in a first portion of the spacer along a first linear trajectory; and

a second fixating element rigidly preloaded in a second portion of the spacer along a second linear trajectory that is different from the first linear trajectory, the second fixating element configured to penetrate and secure to a second vertebra by advancing along the second trajectory;

driving the first fixating element along the first linear trajectory to penetrate the first vertebra and to secure the spacer to the first vertebra; and

driving the second fixating element along the second linear trajectory to penetrate the second vertebra and to secure the spacer to the second vertebra.

10. The method of claim 9, the method comprising:

introducing an integrated drill and screwdriver instrument to the first fixating element of the intervertebral fusion with fixation device, the instrument comprising:

a handle;

a driving element configured to engage a head of the first fixating element; and

a drilling element extending from the driving element, the drilling element configured to extend through a cannula of the first fixating element; and

drilling the first vertebra with the drilling element;

engaging the first fixating element with the driving element as the drilling element penetrates through a vertebral endplate of the first vertebra; and

rotating the first fixating element via the driving element to penetrate the first vertebra and to secure the spacer to the first vertebra.

11. The method of claim 10, the method comprising:

locking the first fixating element with respect to the spacer to prevent the first fixating element from extruding from the spacer.

12. The method of claim 9, the method comprising:

introducing the instrument to the second fixating element of the intervertebral fusion with fixation device;

drilling the second vertebra with the drilling element;

engaging the second fixating element with the driving element as the drilling element penetrates through a vertebral endplate of the second vertebra; and

rotating the second fixating element via the driving element to penetrate the second vertebra and to secure the spacer to the second vertebra.

13. The method of claim 12, the method comprising:

locking the second fixating element with respect to the spacer to prevent the second fixating element from extruding from the spacer .

14. A method to assemble an intervertebral fusion with fixation device, the method comprising:

providing a spacer that includes an insertion wall, a trailing wall opposite to the insertion wall, a first lateral wall, a second lateral wall opposite to the first lateral wall, a top surface, and a bottom surface opposite to the top surface;

preloading a first fixating element rigidly in a first portion of the spacer along a first linear trajectory, the first fixating element configured to penetrate and secure to a first vertebra by advancing along the first linear trajectory; and

preloading a second fixating element rigidly in a second portion of the spacer along a second linear trajectory that is different from the first linear trajectory, the second fixating element configured to penetrate and secure to a second vertebra by advancing along the second trajectory.

What is claimed is:

1. An intervertebral fusion with fixation device configured to be implanted between plural vertebrae, the device comprising:

a spacer with an insertion wall, a trailing wall opposite to the insertion wall, a first lateral wall, a second lateral wall opposite to the first lateral wall, a top surface, and a bottom surface opposite to the top surface;

a first fixating element rigidly preloaded in a first portion of the spacer along a first linear trajectory, the first fixating element configured to penetrate and secure to a first vertebra by advancing along the first linear trajectory; and

a second fixating element rigidly preloaded in a second portion of the spacer along a second linear trajectory that is different from the first linear trajectory, the second fixating element configured to penetrate and secure to a second vertebra by advancing along the second trajectory.

2. The intervertebral fusion with fixation device of claim **1**, wherein the spacer includes a through opening having an entrance proximate the top surface and an exit proximate the bottom surface to facilitate contact and in-growth of bone fusion material with the first vertebra and second vertebra.

3. The intervertebral fusion with fixation device of claim **1**, wherein the spacer is made of polyetheretherketone (PEEK), other polymers, metal, ceramics, or composites.

4. The intervertebral fusion with fixation device of claim **1**, wherein at least one of the first fixating element and the second fixating element is a cannulated bone screw.

5. The intervertebral fusion with fixation device of claim **4**, wherein the cannulated bone screw includes a head that is configured to integrate with a driving instrument.

6. The intervertebral fusion with fixation device of claim 4, wherein the cannulated bone screw includes a head that has a locking mechanism configured to penetrate and lock into spacer to prevent screw toggling and extrusion.

7. An integrated drill and screwdriver instrument, the instrument comprising:

a handle;

a driving element configured to engage a head of a bone screw and to rotate the bone screw into a vertebra,

a drilling element extending from the driving element, the drilling element configured to extend through a cannula of the bone screw and to penetrate the vertebra, the driving element engaging the head of the bone screw as the drilling element penetrates through a vertebral endplate.

8. An intervertebral fusion with fixation system, the system comprising:

an intervertebral fusion with fixation device configured to be implanted between plural vertebrae, the device comprising:

a spacer with an insertion wall, a trailing wall opposite to the insertion wall, a first lateral wall, a second lateral wall opposite to the first lateral wall, a top surface, and a bottom surface opposite to the top surface;

a first fixating element rigidly preloaded in a first portion of the spacer along a first linear trajectory, the first fixating element configured to penetrate and secure to a first vertebra by advancing along the first linear trajectory; and

a second fixating element rigidly preloaded in a second portion of the spacer along a second linear trajectory that is different from the first linear trajectory, the second fixating element configured to penetrate and secure to a second vertebra by advancing along the second trajectory; and

an integrated drill and screwdriver instrument, the instrument comprising:

a handle;

a driving element configured to engage a head of a bone screw and to rotate the bone screw into a vertebra; and

a drilling element extending from the driving element, the drilling element configured to extend through a cannula of the bone screw and to penetrate the vertebra, the driving element engaging the head of the bone screw as the drilling element penetrates through a vertebral endplate.

9. A method to secure plural vertebrae, the method comprising:

implanting an intervertebral fusion with fixation device between plural vertebrae, the device comprising:

a spacer with an insertion wall, a trailing wall opposite to the insertion wall, a first lateral wall, a second lateral wall opposite to the first lateral wall, a top surface, and a bottom surface opposite to the top surface;

a first fixating element rigidly preloaded in a first portion of the spacer along a first linear trajectory; and

a second fixating element rigidly preloaded in a second portion of the spacer along a second linear trajectory that is different from the first linear trajectory, the second fixating element configured to penetrate and secure to a second vertebra by advancing along the second trajectory;

driving the first fixating element along the first linear trajectory to penetrate the first vertebra and to secure the spacer to the first vertebra; and

driving the second fixating element along the second linear trajectory to penetrate the second vertebra and to secure the spacer to the second vertebra.

10. The method of claim 9, the method comprising:

introducing an integrated drill and screwdriver instrument to the first fixating element of the intervertebral fusion with fixation device, the instrument comprising:

a handle;

a driving element configured to engage a head of the first fixating element; and

a drilling element extending from the driving element, the drilling element configured to extend through a cannula of the first fixating element; and

drilling the first vertebra with the drilling element;

engaging the first fixating element with the driving element as the drilling element penetrates through a vertebral endplate of the first vertebra; and

rotating the first fixating element via the driving element to penetrate the first vertebra and to secure the spacer to the first vertebra.

11. The method of claim 10, the method comprising:

locking the first fixating element with respect to the spacer to prevent the first fixating element from extruding from the spacer.

12. The method of claim 9, the method comprising:

introducing the instrument to the second fixating element of the intervertebral fusion with fixation device;

drilling the second vertebra with the drilling element;

engaging the second fixating element with the driving element as the drilling element penetrates through a vertebral endplate of the second vertebra; and

rotating the second fixating element via the driving element to penetrate the second vertebra and to secure the spacer to the second vertebra.

13. The method of claim 12, the method comprising:

locking the second fixating element with respect to the spacer to prevent the second fixating element from extruding from the spacer .

14. A method to assemble an intervertebral fusion with fixation device, the method comprising:

providing a spacer that includes an insertion wall, a trailing wall opposite to the insertion wall, a first lateral wall, a second lateral wall opposite to the first lateral wall, a top surface, and a bottom surface opposite to the top surface;

preloading a first fixating element rigidly in a first portion of the spacer along a first linear trajectory, the first fixating element configured to penetrate and secure to a first vertebra by advancing along the first linear trajectory; and

preloading a second fixating element rigidly in a second portion of the spacer along a second linear trajectory that is different from the first linear trajectory, the second fixating element configured to penetrate and secure to a second vertebra by advancing along the second trajectory.

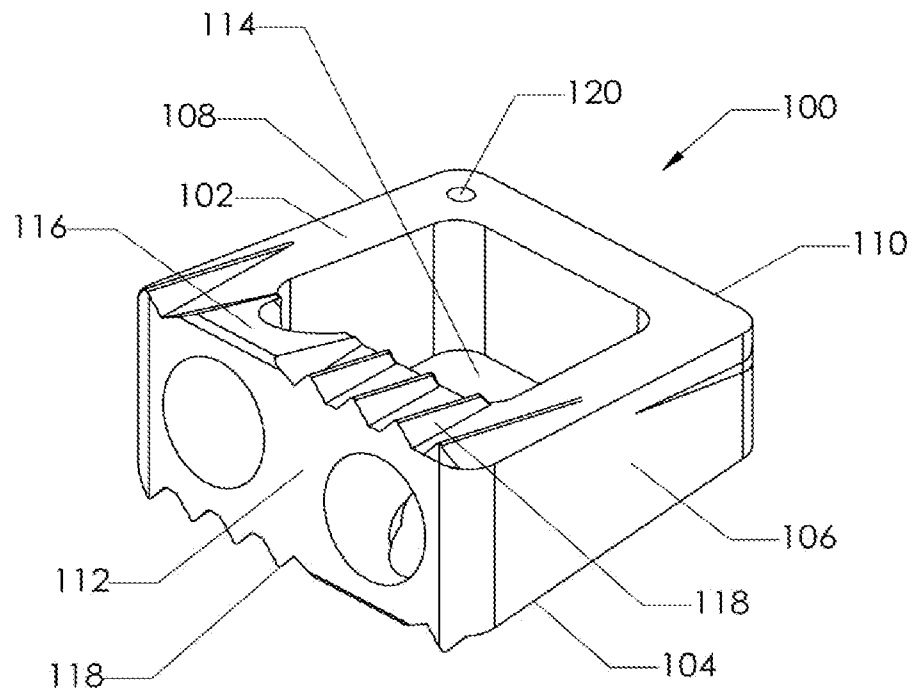


FIG. 1

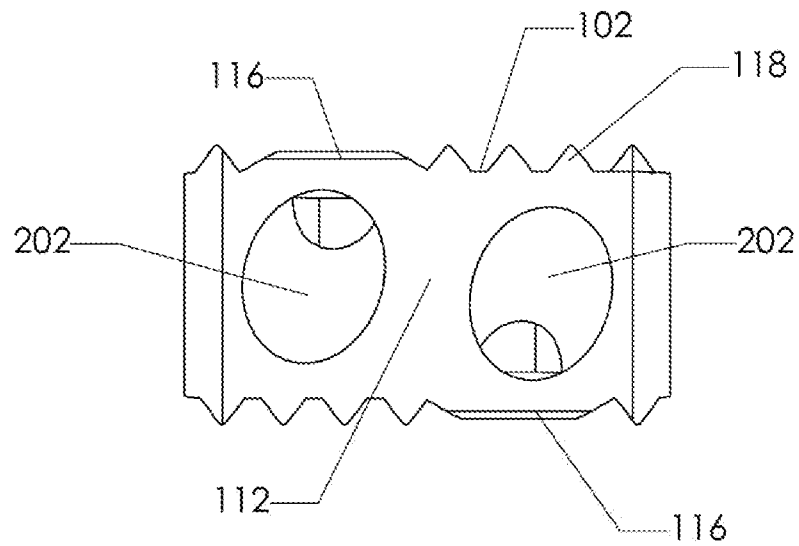


FIG. 2

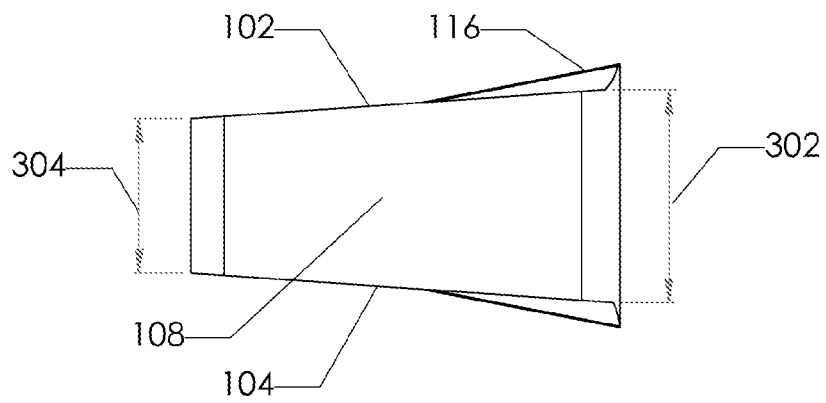


FIG. 3

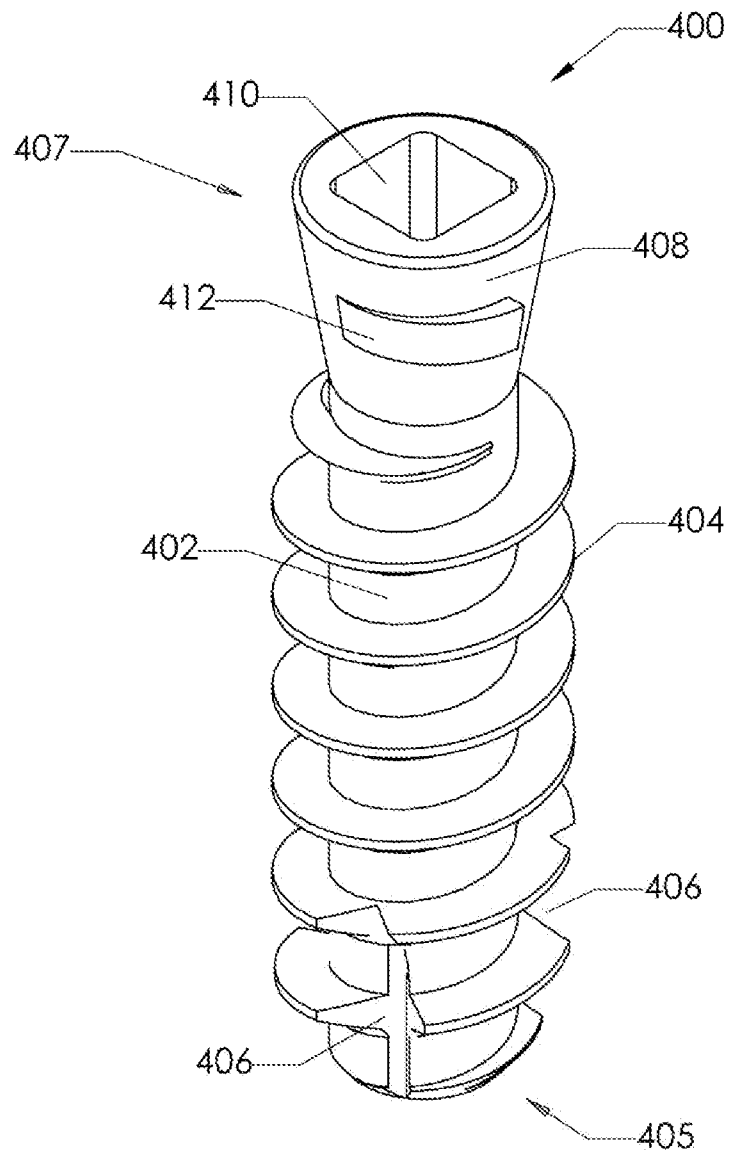


FIG. 4

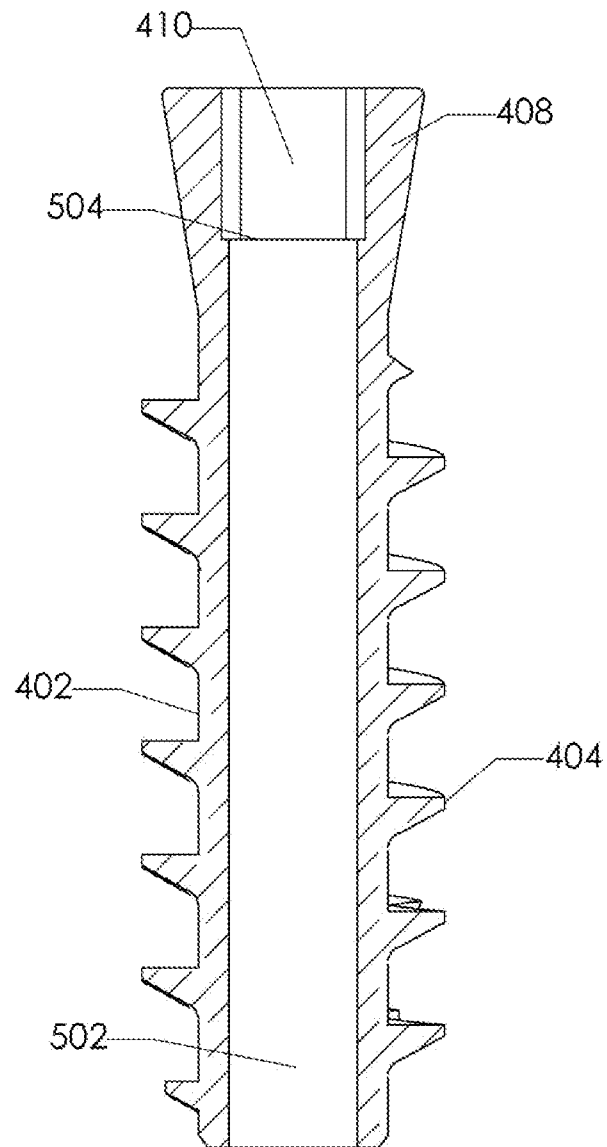


FIG. 5

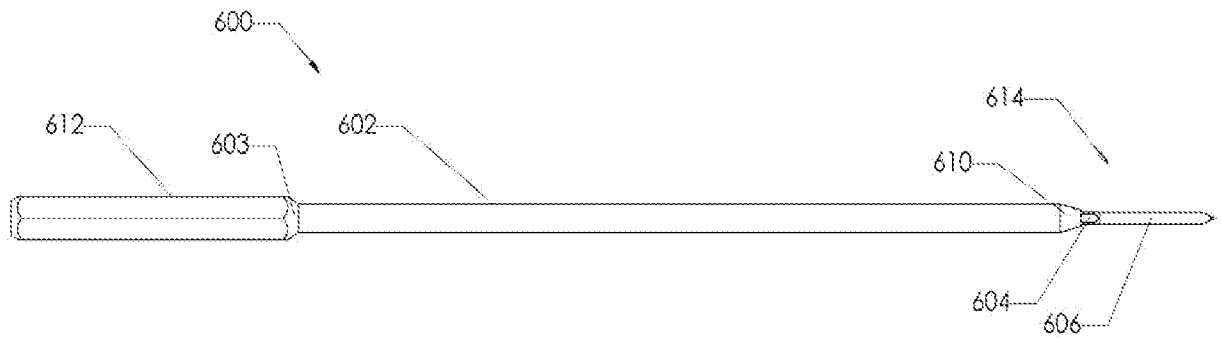


FIG. 6

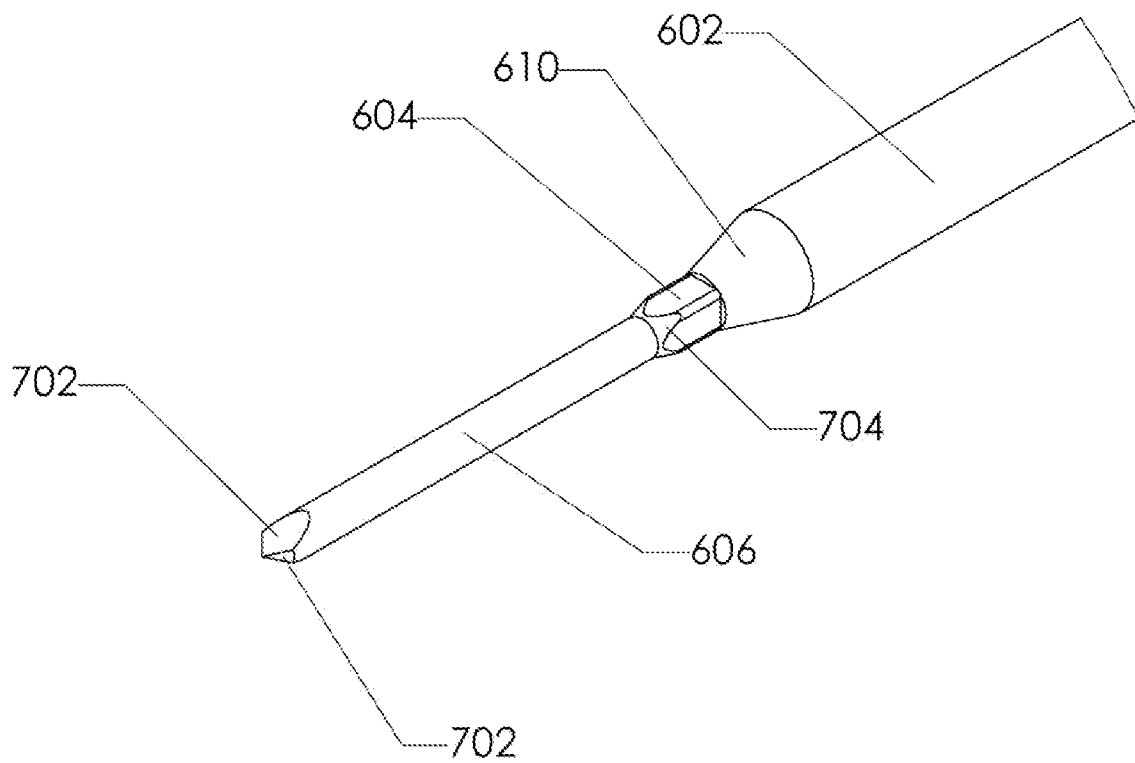


FIG. 7

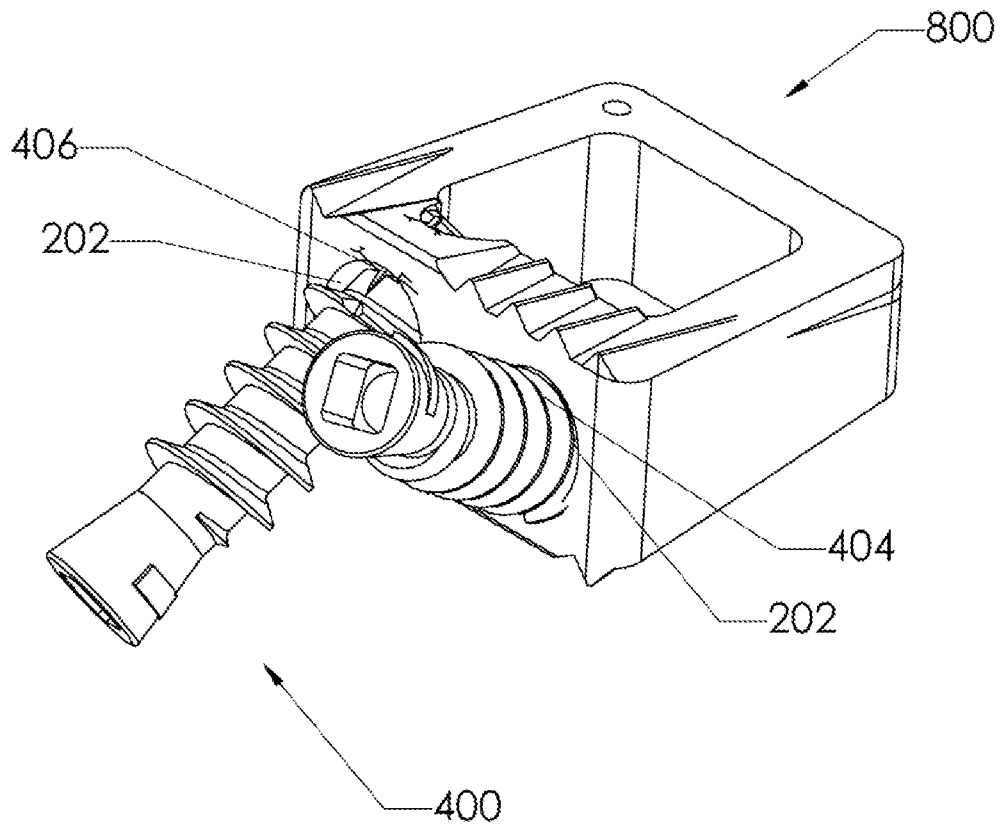


FIG. 8

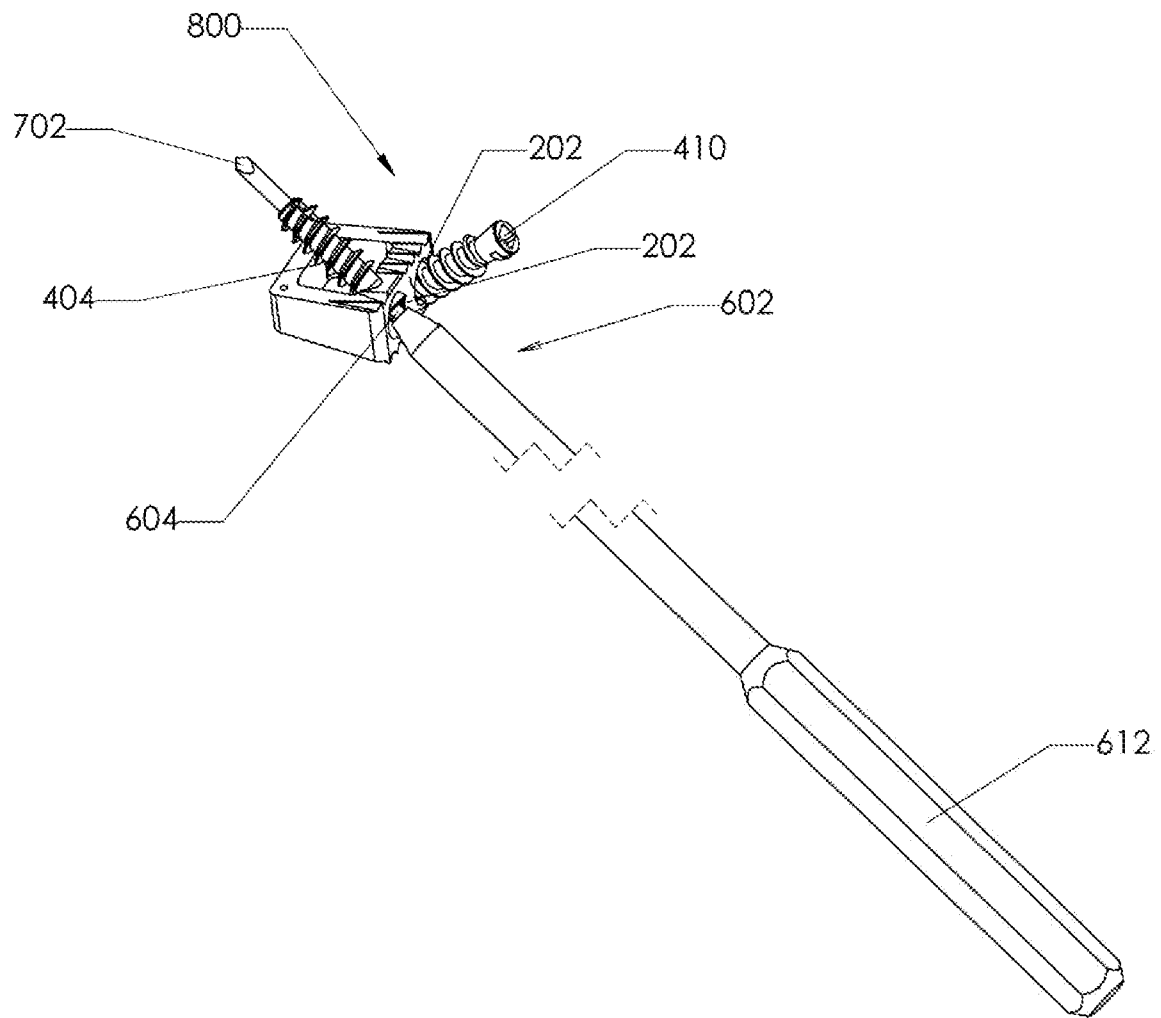


FIG. 9

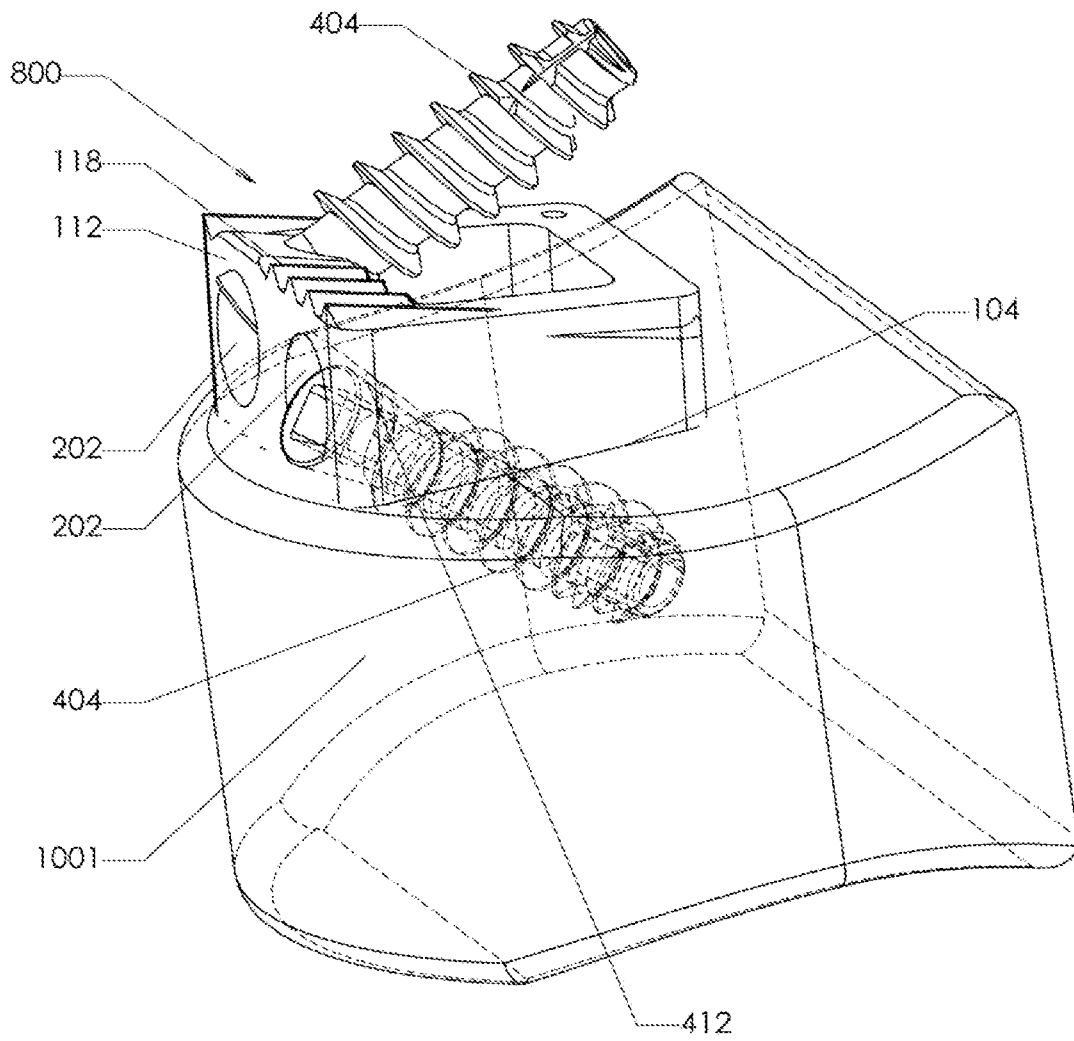


FIG. 10