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(54) Title: SPINAL IMPLANT CONFIGURED FOR LATERAL INSERTION

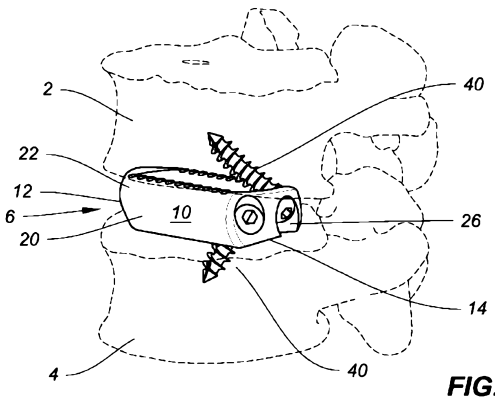

FIG. 1

(57) Abstract: The embodiments provide a spinal implant that is configured for lateral insertion into a patient's intervertebral disc space. The spinal implant may have a body having a tapered anterior portion and one or more apertures. The tapered anterior portion allows for concomitant distraction of soft tissue during insertion of the implant. In addition, at least some of the apertures are designed to permit a predetermined amount of nutation by a fixation element. The fixations elements that allow nutation enable the fixation element to toggle from one position to another, for example, during subsidence of the implant in situ.

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SPINAL IMPLANT CONFIGURED FOR LATERAL INSERTION

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims priority to U.S. Provisional No. 61/259,401, filed November 9, 2009, and entitled "SPINAL IMPLANT CONFIGURED FOR LATERAL INSERTION," which is herein incorporated by reference in its entirety.

FIELD

The present disclosure relates to orthopedic implants, and more particularly to spinal implants that facilitate fusion of bone segments and associated methods. Even more particularly, the present disclosure relates to a spinal fusion implant configured for lateral insertion.

BACKGROUND

The integrity of the spine, including its subcomponents like the vertebral bodies and intervertebral discs that are well known structural body parts forming the spine, are key to a patient's health. These parts may become crushed or damaged as a result of trauma or injury, or damaged by disease (e.g., by tumor, autoimmune disease), or as a result of wear over time or degeneration caused by the normal aging process.

In many instances, one or more damaged structural body parts can be repaired or replaced with a prosthesis or implant. For example, specific to the spine, one method of repair is to remove the damaged vertebra (in whole or in part) and/or the damaged disc (in whole or in part) and replace it with an implant or prosthesis. In some cases, it is necessary to stabilize a weakened or damaged spinal region by reducing or inhibiting mobility in the area to avoid further progression of the damage and/or to reduce or alleviate pain caused by

the damage or injury. In other cases, it is desirable to join together the damaged vertebrae and/or induce healing of the vertebrae. Accordingly, an implant or prosthesis may be configured to facilitate fusion between two adjacent vertebrae. The implant or prosthesis may be placed without attachment means or fastened in position between adjacent structural body parts (e.g., adjacent vertebral bodies).

Typically, an implant or prosthesis is secured directly to a bone structure by mechanical or biological means. One manner of spine repair involves attaching a fusion implant or prosthesis to adjacent vertebral bodies using a fixation element, such as a screw. Most implants and their attachment means are configured to provide an immediate, rigid fixation of the implant to the implantation site. Unfortunately, after implantation the implants tend to subside, or settle, into the surrounding environment as the patient's weight is exerted upon the implant. In some cases, this subsidence may cause the rigidly fixed attachment means to either loosen, dislodge or potentially damage one or more of the vertebral bodies.

Several known surgical techniques can be used to implant a spinal prosthesis. The suitability of any particular technique may depend upon the amount of access available to the implant site. For instance, a surgeon may elect a particular entry pathway depending on the size of the patient or the condition of the patient's spine such as where a tumor, scar tissue, or other obstacle is present. Other times, it may be desirable to minimize intrusion into the patient's musculature and associated ligamentous tissue. In some patients who have had prior surgeries, implants or fixation elements may have already been inserted into the patient's spine and as such, an implant introduction pathway may have to account for these prior existing conditions.

Thus, it is desirable to provide an implant that can be easily inserted in accordance with a specific pathway or approach. For example, in certain situations, it is desirable to provide a spinal implant that can be inserted using a lateral approach. It is further desirable to provide an implant that is configured to reduce insertion forces. In addition, it is desirable to provide an implant and

associated fixation elements that can account for subsidence that occurs with the implant subsequent to implantation while also providing rigid fixation.

Although the following discussion focuses on spinal implants or prostheses, it will be appreciated that many of the principles may equally be applied to other structural body parts within a human or animal body.

SUMMARY

The present disclosure describes a spinal implant that is configured for lateral insertion into a patient's intervertebral disc space. In accordance with one exemplary embodiment, a spinal implant is provided having an upper surface, a lower surface, an anterior portion, a posterior portion and one or more apertures within the posterior portion for receiving at least one fixation element wherein the implant is configured for lateral insertion. For example, the anterior portion or leading edge of the implant may include a sharp, bullet shaped nose or tip. All or some of the apertures may be configured to permit a predetermined amount of nutation by a fixation element, thus allowing the fixation element to toggle from one position to another. The spinal implant may additionally include anti-migration features.

In one embodiment, a spinal implant comprises a body and one or more apertures. The body may comprise an upper surface, a lower surface, a tapered anterior portion, and a posterior portion, wherein the body is configured for lateral insertion between vertebral bodies of a patient's spine. The one or more apertures may be provided within the posterior portion of the body and can receive at least one fixation element. At least one of the apertures is configured to permit a predetermined amount of nutation by a fixation element.

In another embodiment, a method of treating a patient's spine comprises accessing at least a portion of a patient's spine via a lateral approach. A spinal implant is then inserted between vertebral bodies of the patient's spine, wherein the spinal implant comprises a body having an upper surface, a lower surface, a tapered anterior portion, a posterior portion, wherein the body is configured for lateral insertion between vertebral bodies of a patient's spine, the implant further including one or more apertures within the posterior portion of the body for receiving at least one fixation element, and wherein at least one of the apertures is configured to permit a predetermined amount of nutation by a fixation element. The spinal implant is attached with the at least one fixation elements to the vertebral bodies and a predetermined amount of toggling of the fixation element

is permitted based on nutation of the fixation element during subsidence of the spinal implant.

It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only and are not restrictive of the disclosure. Additional features of the disclosure will be set forth in part in the description which follows or may be learned by practice of the disclosure.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate several embodiments of the disclosure and together with the description, serve to explain the principles of the disclosure.

FIG. 1 illustrates a partial cutaway view of a spinal implant of the present disclosure in situ.

FIG. 2A illustrates a superior view of the spinal implant of FIG. 1 with fixation screws.

FIG. 2B illustrates an anterior view of the spinal implant of FIG. 1 with fixation screws.

FIG. 2C illustrates a sagittal view of the spinal implant of FIG. 1 with fixation screws.

FIG. 2D illustrates a perspective view of the spinal implant of FIG. 1 with fixation screws.

FIG. 3 illustrates an enlarged perspective view of an exemplary fixation screw with locking ring of the present disclosure.

FIG. 4 illustrates a partial cutaway view of the spinal implant of FIG. 1 with the fixation screws and locking rings of FIG. 3.

FIG. 5 illustrates a cross-sectional view of the spinal implant with fixation screws of FIG. 4.

FIG. 6A illustrates a perspective view of an alternative embodiment of a spinal implant of the present disclosure with fixation screws.

FIG. 6B illustrates another perspective view of the spinal implant and fixation screws of FIG. 6A.

FIG. 7 illustrates an exemplary embodiment of an imaging marker of the present disclosure.

DESCRIPTION OF THE EMBODIMENTS

Referring now to FIG. 1, a spinal implant 10 of the present disclosure is shown. The spinal implant 10 may be implanted in the intervertebral space 6 between vertebral bodies 2, 4 and secured to the vertebral bodies 2, 4 with fixation screws 40. The spinal implant 10 may be employed in the lumbar or thoracic regions. Alternatively, the spinal implant 10 may be employed in the cervical region of the spine, in a manner similar to the one described for the cervical implant of U.S. Patent Application No. 11/938,476 filed November 12, 2007, entitled "Orthopaedic Implants and Prostheses," which is herein incorporated by reference in its entirety. A cervical version may be provided so long as it is appropriately sized and configured, and the surgical approach takes into account this specific design.

As shown in FIGS. 2A—2D, the spinal implant 10 may include anterior and posterior portions 12, 14 and upper and lower surfaces 16, 18 profiled to correspond with the profile of any bone material to which they are to be secured. A pair of sidewalls 20 extends between the upper and lower surfaces 16, 18 and connects to the anterior and posterior portions 12, 14. The spinal implant 10 may include a central opening or lumen 24 extending between the upper and lower surfaces 16, 18 to facilitate bony ingrowth or fusion between adjacent bone segments, such as vertebral bodies 2, 4. If so desired, the opening 24 may be used to receive and hold bone graft material.

To facilitate ease of insertion, the anterior portion, or leading end12 may be tapered or otherwise shaped for concomitant distraction of soft tissue during insertion. For example, the anterior portion 12 may be a sharp, bullet shaped nose or tip 22. The unique geometry of the implant 10 including this sharpened tip 22 supports reduced insertion forces, and may also help to separate tissue during the insertion. This can be helpful, for example, where scar tissue or other obstructions are present at the implantation site, or where there is stenosis and/or some other anatomic anomaly such as where the endplates have grown together.

The posterior portion, or trailing end 14 of the spinal implant 10 includes holes 26 for receiving fixation elements, such as bone screws 40. In the embodiment shown, the spinal implant 10 includes two screw holes 26, one extending superiorly and one extending inferiorly (see in particular FIG. 2D). However, one skilled in the art will appreciate that the implant 10 may comprise any number of holes in any location on the implant 10. For example, instead of having one superior hole and one inferior hole in the implant 10 as shown in the drawings, the implant may have two superior holes, or may be adapted to have two inferior holes. As previously discussed, the implant 10 may be configured with any number of holes without departing from the spirit of the disclosure. In addition, the implant 10 may include bores 50 for receiving features like a radiologic marker or other imaging marker 70, as shown in FIG. 7. The imaging marker 70 may be rod-shaped, for example, for insertion into the bores 50.

The holes 26 provide a path through which securing means (e.g., fixation elements such as bone screws 40) may be inserted so as to secure the implant 10 to respective superior and inferior vertebral bodies 2, 4. The holes 26 may be configured to accommodate a variety of securing means, such as screws, pins, staples, or any other suitable fastening device. In one embodiment, the fixation screws 40 may be self-tapping and/or self-drilling and may be of a bone-screw-type, such as those well known to skilled artisans. In some embodiments, the head portion 42 of the fixation screws 40 extends into an elongate body 44 that terminates at a tip 46. While the implant 10 is shown with screws 40 sized and shaped for unicortical bone fixation, it is contemplated that bone screws sized and shaped for bicortical bone fixation may also be employed with the present disclosure.

The holes 26 of the spinal implant 10 may be configured to permit a predetermined amount of screw toggle (i.e., angular skew) and enable a lag effect when the fixation screw 40 is inserted and resides inside the hole or lumen 26. In other words, the holes 26 permit a certain degree of nutation by the screw 40 and thus the screws 40 may toggle from one position to one or more different positions, for instance, during subsidence. As depicted in FIG. 5, the holes 26 may be configured with a conical range of motion (i.e., angular clearance) of

about 25 to about 35 degrees, although it is contemplated that an even larger range may be possible such as 20 to 40 degrees, or 15 to 45 degrees. In one embodiment, the range is about 22 to 28 degrees. It is also believed that the predetermined screw toggle (permitted by the clearance between the lumen, or hole 26 and the screw 40) promotes locking of the screw 40 to the implant 10 after subsidence subsequent to implantation. Alternatively, the holes 26 of implant 10 may be configured with little or no clearance to achieve rigid fixation, for example, when implant 10 is to be implanted into sclerotic bone.

As shown in FIG. 2C, the spinal implant 10 may have non-parallel upper and lower surfaces 16, 18 to form a wedge-shaped implant 10. However, one skilled in the art will appreciate that the spinal implant 10 may also be provided with parallel upper and lower surfaces 16, 18. The spinal implant 10 may have any suitable shape or size to allow it to be used under lodortic or kyphotic conditions. For instance, in one example, the spinal implant 10 may have a 12 degree lodortic profile from an anterior—posterior (A—P) view.

In some situations, after insertion into the vertebral body, the fixation element or screw 40 may work itself loose and/or back out, i.e., withdraw from the vertebral body. The consequence of back out or loosening includes improper or incomplete fusion, loss of stability, potential risk to the patient, and a separate costly and often painful revision surgery. FIG. 3 shows a fixation screw 40 of the present disclosure, along with an anti-backout element to avoid such problems. As illustrated, the anti-backout element comprises a split ring 60 that acts like a locking ring. FIG. 4 shows the split ring 60 residing between the head 42 of the fixation screw 40 and the hole 26 of the spinal implant 10.

The spinal implant 10 and its components may be formed of any suitable medical grade material, such as biocompatible metals like stainless steel, titanium, titanium alloys, etc. or a medical grade plastic such as polyetheretherketone (PEEK) or another radiolucent material, ultra high molecular weight polyethylene (UHMWPE), etc. If so desired, the implant 10 may also be formed of a bioresorbable material. The bioresorbable material may preferably be osteoconductive or osteoinductive (or both).

In one exemplary method of inserting the spinal implant 10, the surgeon prepares the implantation site by removing some disc material from the disc space 6 between two adjacent vertebrae 2, 4. Because the spinal implant 10 is configured for lateral insertion (i.e., as opposed to midline insertion), less disc material needs to be removed to accommodate the implant 10, which has a slim profile. This provides the benefit of preserving more of the patient's natural anatomy and more specifically, preserves the soft tissue and ligament surrounding the site. The spinal implant 10 may be provided to the surgeon with the screws 40 pre-attached, or separately, as desired. After the surgeon places the implant 10 in the desired location, such as the cervical region of a patient's spine, the surgeon can tighten the screws 40 into the surrounding bone tissue, thereby securing the implant 10.

As noted, the implant 10 may be configured to permit a predetermined amount of screw toggle and enable a lag effect when the fixation screw 40 is inserted and resides inside the hole or lumen 26. Upon tightening, the lag effect may be observed whereby the implant 10 draws bone tissue towards itself, which may promote better fusion.

As further noted, the predetermined screw toggle promotes locking of the screw 40 to the implant 10 after subsidence subsequent to implantation. For example, after surgery, the patient's natural movement will result in settling and subsidence of bone tissue and the implant 10 in situ. It is believed that during this process, the weight exerted upon the implant 10 causes the fixation screws 40 to toggle and eventually lock against one or more surfaces of the holes 26 of the implant 10.

Some practitioners prefer to allow some degree of movement between the implant and the adjacent vertebral body after implantation. In that case the screw heads 42 may be provided with contours on its underside that allow the screws 40 to toggle with respect to the contoured opening 26 of the implant 10. Other practitioners may prefer a more rigid implant that is firmly locked to the adjacent vertebral body. The embodiments of implant 10 allow either preference.

In the rigidly fixed version, the screws 40 may be provided without the contour on its underside (i.e., a relatively flat underside) while the opening 26 of the implant 10 would likewise not include a contour. Thus, when secured together, the screws 40 and implant 10 form a rigidly locked construct. Where rigid fixation is desired (i.e., no toggle), the underside of the screws 40 may also include surfaces features as well in order to provide secure attachment to the implant 10.

While a toggle and a rigidly fixed version of the implant 10 and screws 40 are described, it is understood that a combination of toggling and rigid fixation may be accomplished in a single implant 10. For example, it is possible to provide an implant 10 that allows toggling of one or more screws 40, while also allowing rigid fixation of the other of the screws 40.

It will also be appreciated that the angular positioning of the various holes, as described above, allows the present implant 10 to be of a relatively small size and therefore insertable from a lateral approach within the intervertebral spaces of the spine. Thus, it will be appreciated that the angular positioning of the holes is important to the effective operation of the implant 10 and the ability to "stack" implants in adjacent multilevel procedures without the securing means interfering with each other, which can be of major significance in some situations.

As illustrated, the spinal implant 10 may have any variety of surface features, such as anti-migration and bone attachment features. For example, it is contemplated that the implant may have threads, teeth, barbs, surface roughenings, etc. to assist in bone attachment. Further, biological agents such as bone growth factors, for example, may be employed to enhance bone attachment. FIGS. 6A and 6B illustrate exemplary embodiments of a spinal implant 10 of the present disclosure having teeth 30 on the upper and lower surfaces 16, 18 to prevent migration after implantation and enhance securement to bone tissue.

Other embodiments of the disclosure will be apparent to those skilled in the art from consideration of the specification and practice of the disclosure

provided herein. It is intended that the specification and examples be considered as exemplary only.

What is claimed is:

1. A spinal implant comprising:

a body having an upper surface, a lower surface, a tapered anterior portion, and a posterior portion, wherein the body is configured for lateral insertion between vertebral bodies of a patient's spine; and

one or more apertures within the posterior portion of the body for receiving at least one fixation element, wherein at least one of the apertures is configured to permit a predetermined amount of nutation by a fixation element.

2. The spinal implant of claim 1, further comprising one or more bores for receiving an imaging marker.

3. The spinal implant of claim 2, wherein the imaging marker is rod-shaped.

4. The spinal implant of claim 1, wherein at least one of the apertures is configured to permit about 25 to about 35 degrees of nutation by the fixation element.

5. The spinal implant of claim 1, wherein at least one of the apertures is configured to permit about 20 to about 40 degrees of nutation by the fixation element.

6. The spinal implant of claim 1, wherein at least one of the apertures is configured to permit about 15 to about 45 degrees of nutation by the fixation element.

7. The spinal implant of claim 1, wherein at least one of the apertures is configured to permit about 22 to about 28 degrees of nutation by the fixation element.

8. The spinal implant of claim 1, wherein the one or more apertures comprises a superior aperture extending superiorly and an inferior aperture extending inferiorly.

9. The spinal implant of claim 8, wherein the superior aperture is configured to permit about 15 to about 45 degrees of nutation by a first fixation element and the inferior aperture is configured to rigidly lock to a second fixation element.

10. The spinal implant of claim 8, wherein the inferior aperture is configured to permit about 15 to about 45 degrees of nutation by a first fixation element and the superior aperture is configured to rigidly lock to a second fixation element.

11. The spinal implant of claim 1, further being configured to have a lordotic profile.

12. The spinal implant of claim 1, wherein the tapered anterior portion is configured for concomitant distraction of soft tissue during implantation of the spinal implant.

13. The spinal implant of claim 1, further including anti-migration features.

14. The spinal implant of claim 13, wherein the anti-migration features include teeth on the upper and lower surfaces of the body.

15. A method of treating a patient's spine comprising:

accessing at least a portion of a patient's spine via a lateral approach;

inserting a spinal implant between vertebral bodies of the patient's spine, wherein the spinal implant comprises a body having an upper surface, a lower surface, a tapered anterior portion, a posterior portion, wherein the body is configured for lateral insertion between vertebral bodies of a patient's spine, the implant further including one or more apertures within the posterior portion of the body for receiving at least one fixation element, wherein at least one of the apertures is configured to permit a predetermined amount of nutation by a fixation element;

attaching the spinal implant with the at least one fixation element to the vertebral bodies; and

permitting a predetermined amount of toggling of the fixation element based on nutation of the fixation element during subsidence of the spinal implant.

16. The method of claim 15, wherein the spinal implant comprises one or more bores for receiving an imaging marker, and further including the step of inserting the spinal implant based on visual cues provided by the imaging marker.

17. The method of claim 15, wherein inserting the spinal implant comprises inserting the spinal implant based on visual cues provided by a radiopaque imaging marker on an intraoperative image.

18. The method of claim 15, wherein inserting the spinal implant also includes distracting soft tissue with the tapered anterior portion.

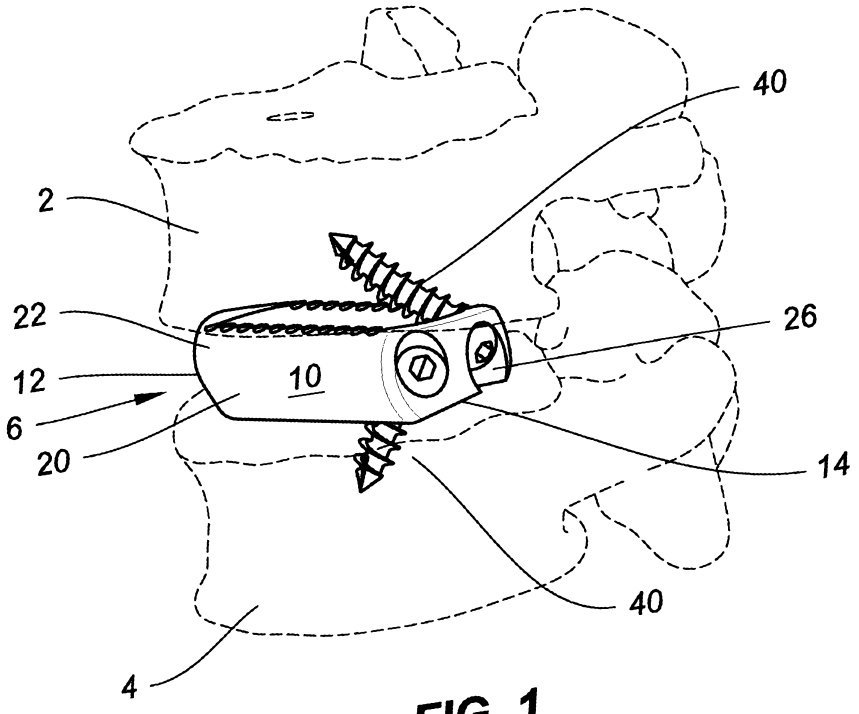

FIG. 1

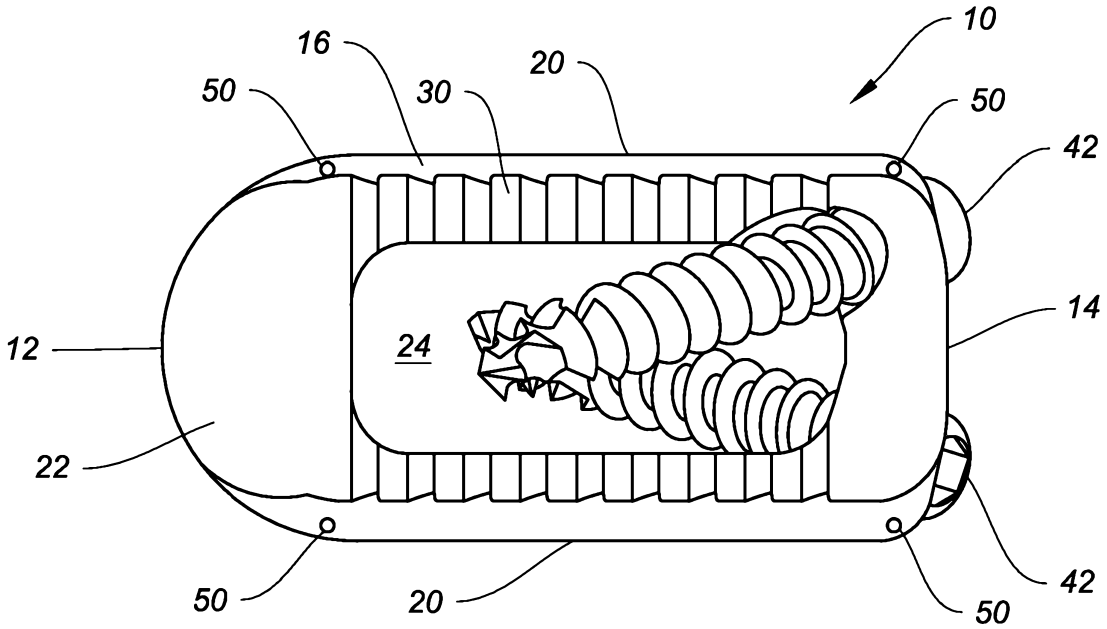
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FIG. 2A

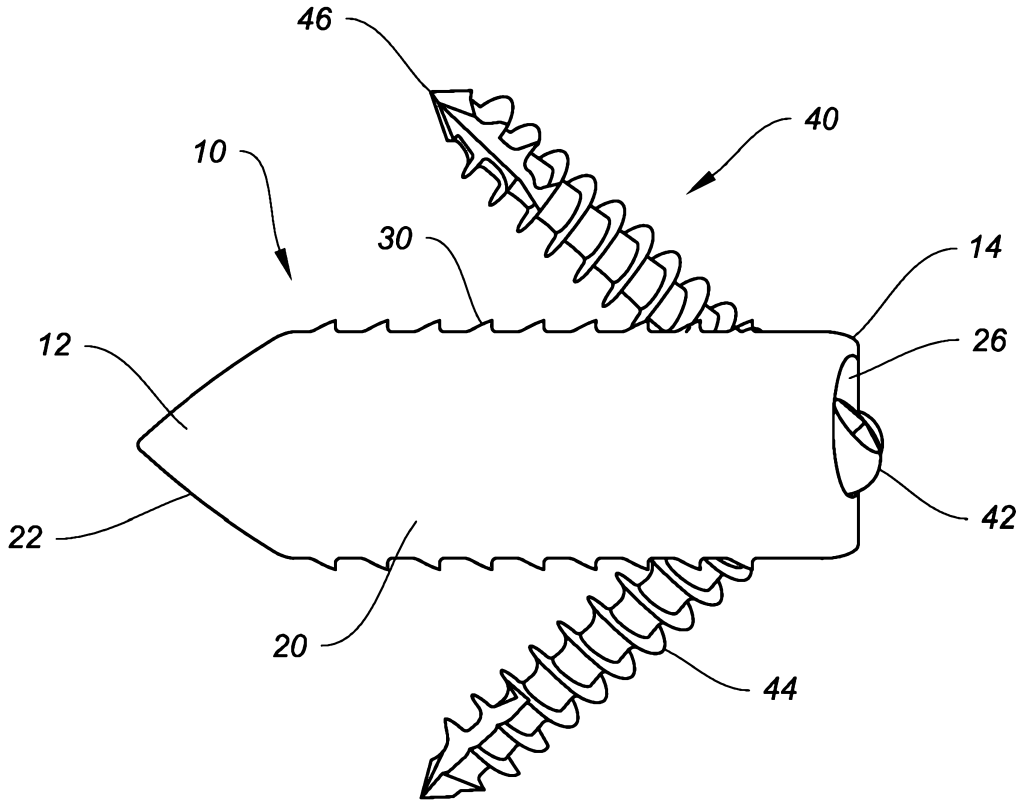
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FIG. 2B

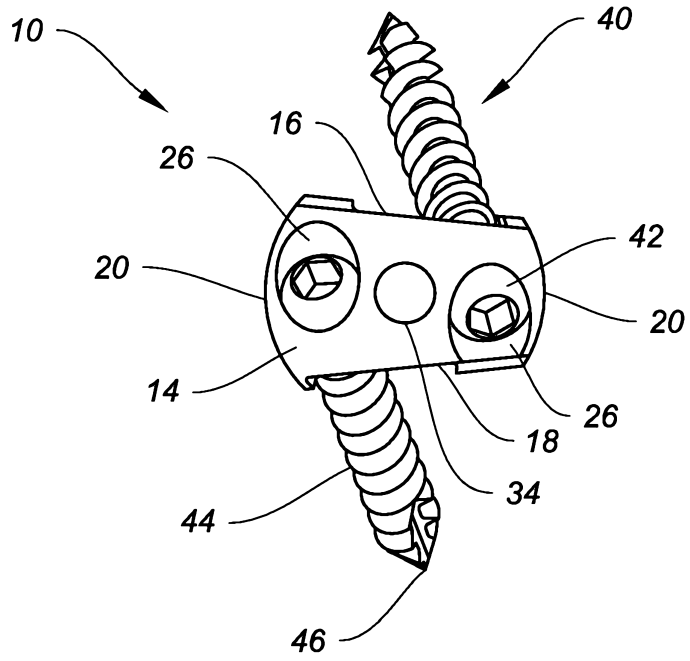

FIG. 2C

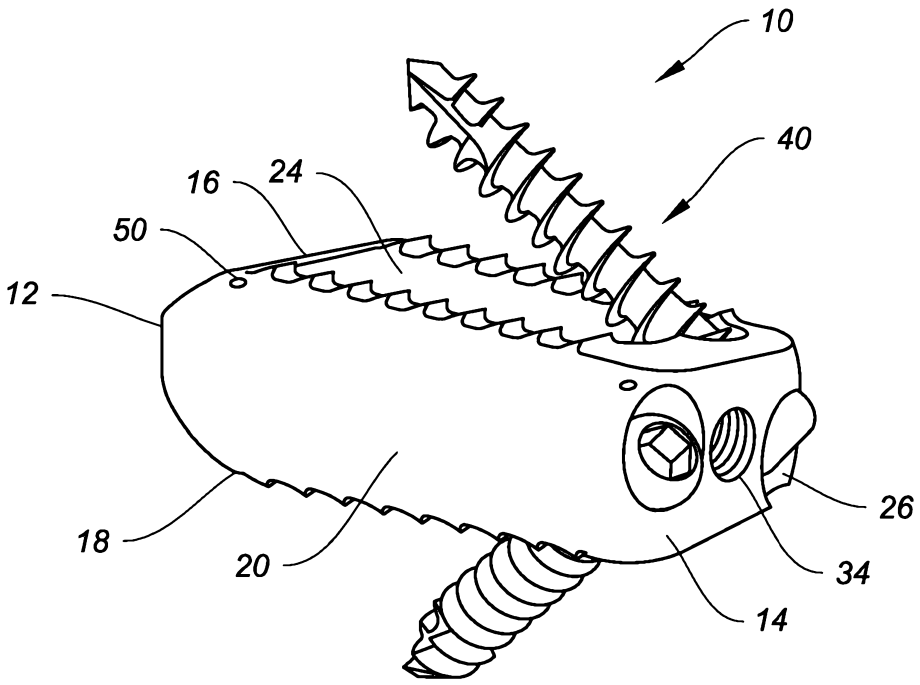

FIG. 2D

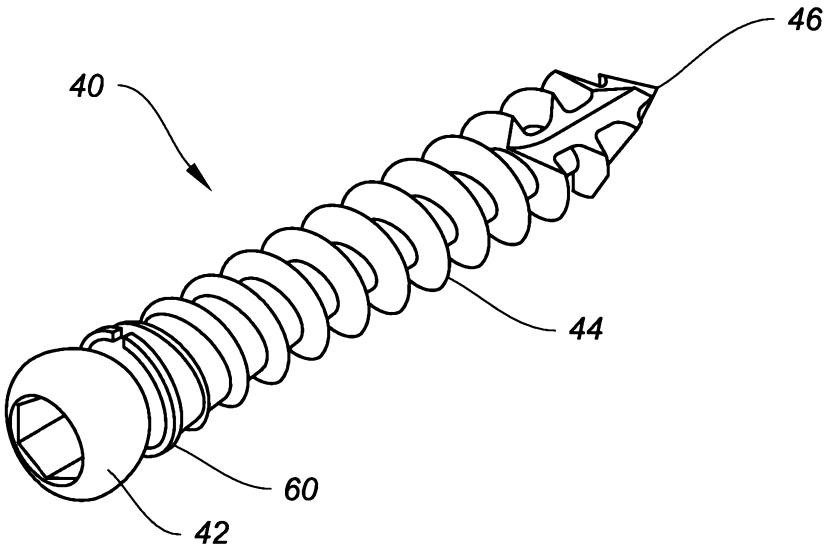

FIG. 3

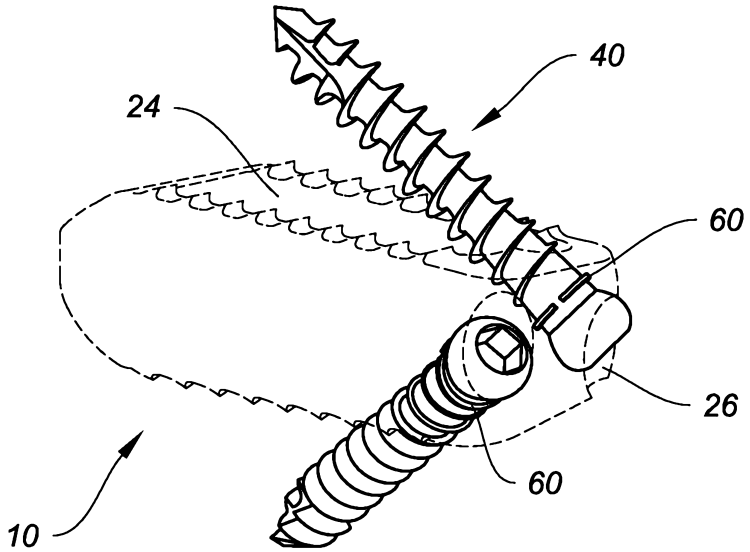

FIG. 4

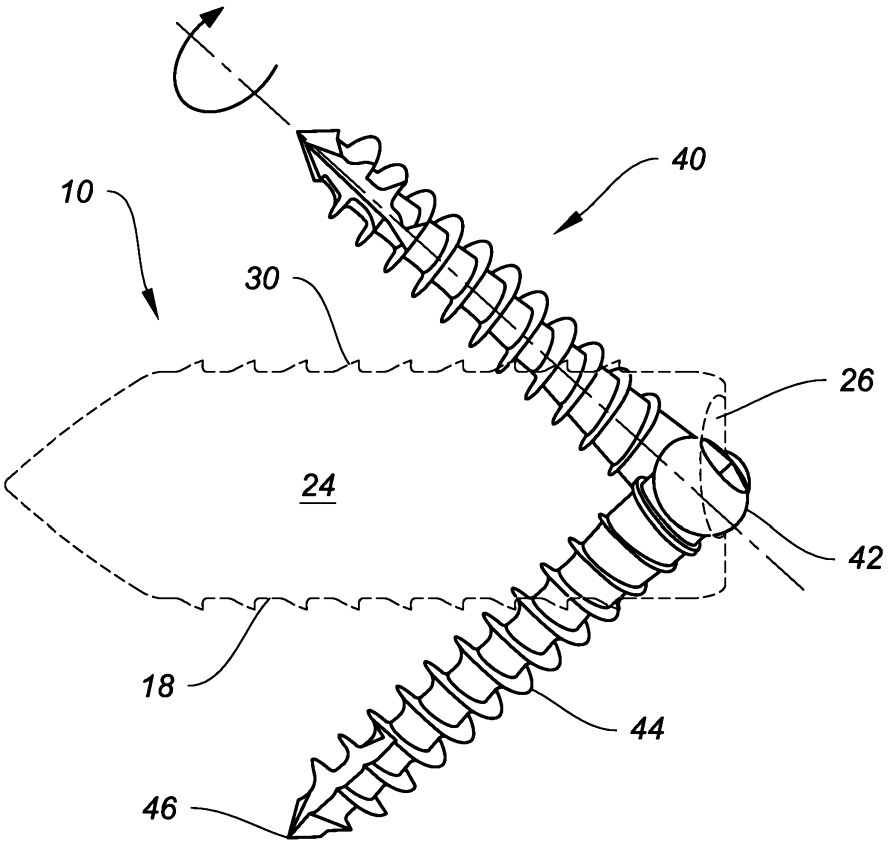

FIG. 5

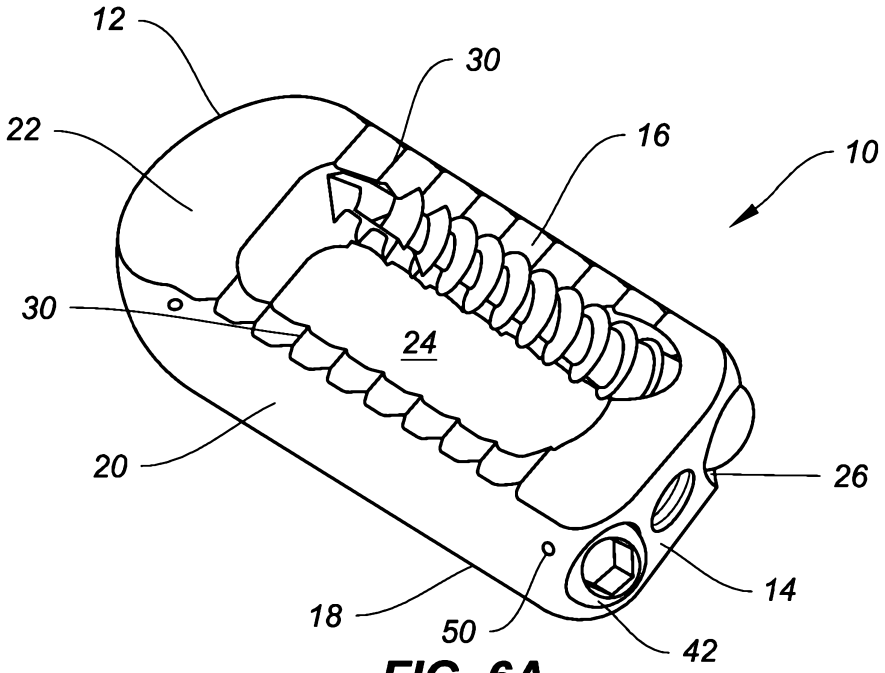

FIG. 6A

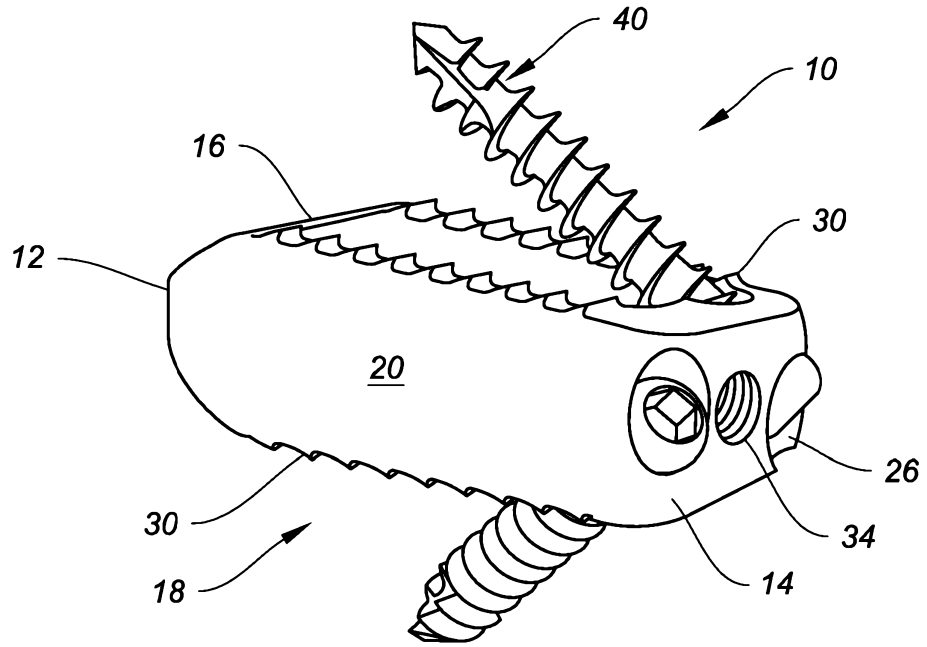

FIG. 6B

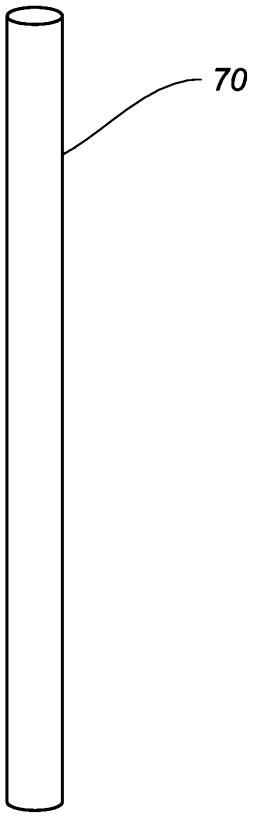

FIG. 7