(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
15 October 2020 (15.10.2020)

(10) International Publication Number
WO 2020/210846 A2

(51) International Patent Classification:
A61B 17/70 (2006.01)

(21) International Application Number:
PCT/ZA2020/050019

(22) International Filing Date:
09 April 2020 (09.04.2020)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
2019/02202 09 April 2019 (09.04.2019) ZA

(71) Applicant: SOUTHERN MEDICAL (PTY) LTD [ZA/ZA]; Southern Implants Office Park, Building 11, 1 Albert Road, Irene, Gauteng, 0062 Centurion (ZA).

(72) Inventors: ROGINSKY, Andrew; 173 Dahlia Road, Kyalami, Gauteng, 1684 Midrand (ZA). JANSEN, Neville; Unit 57 Savanna, 21 Stansted Street, Highveld, Gauteng, 0169 Centurion (ZA).

(74) Agent: SUSAN, Leon Pierre; Corner of Barry Hertzog Avenue and Empire Road, 2092 Johannesburg (ZA).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, WS, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:
— *without international search report and to be republished upon receipt of that report (Rule 48.2(g))*
— *in black and white; the international application as filed contained color or greyscale and is available for download from PATENTSCOPE*

(54) **Title:** AN INTERBODY SPACER

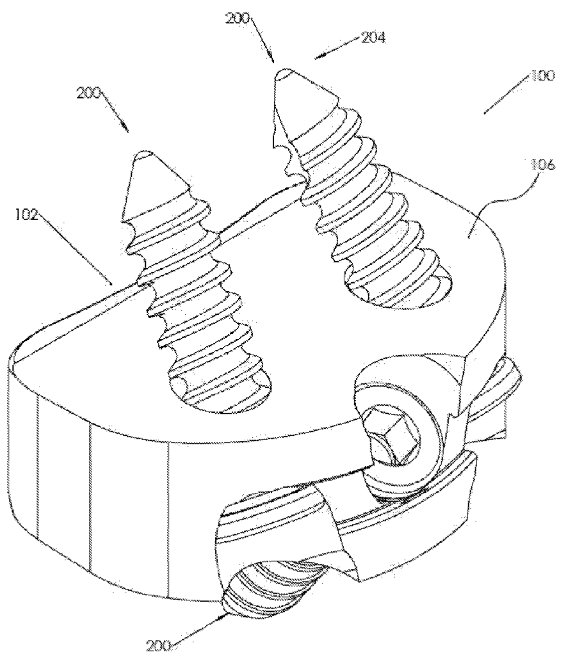

FIGURE 4

(57) Abstract: This invention relates to an interbody spacer and more specifically to a stand-alone interbody spinal fusion spacer. Generally, interbody spacers (also referred to in the industry as cages) are used to stabilize an intervertebral space and to allow for fusion of the adjacent vertebral bodies within a patient's spine. The interbody spacer (100) is implanted between a superior vertebra (502) and an adjacent inferior vertebra (501). The interbody spacer includes a body 106 which is shaped and sized to engage and space apart the adjacent vertebrae, engagement means for inducing engagement between the spacer body (106) and at least one of the vertebrae. The interbody spacer (100) includes a deformable element, in the form of an insert (110), which deforms under the stress of the engagement means to increase engagement between the spacer body (106) and the adjacent vertebra.

WO 2020/210846 A2

AN INTERBODY SPACER

FIELD OF THE INVENTION

This invention relates generally to an interbody spacer and more specifically, but not exclusively, the example embodiment relates to a stand-alone interbody spinal fusion spacer.

BACKGROUND TO THE INVENTION

Generally, interbody spacers (also referred to in the industry as cages) are used to stabilize an intervertebral space and to allow for fusion of the adjacent vertebral bodies within a patient's spine.

It is desired that interbody spacers are osteoconductive, biocompatible, that it retains structural integrity to maintain the intervertebral separation without degradation or deformation, and that the spacers are retained in place until fusion occurs.

Conventional interbody spacers are made of titanium, polyether ether ketone (PEEK), titanium coated PEEK, or titanium alloys.

One of the primary concerns in the industry, irrespective of the type of spacer body material, is the stability and osteo-conductivity of the spacer and has led to various fixation mechanisms to stabilize the spacer in the intervertebral space to enable contact between the spacer and the adjacent vertebra. Some of the fixation features as described in prior art are set out below.

PCT international patent application number PCT/US2012/034627, in the name of Alphatec Spine, Inc., entitled *"Stand Alone Interbody Fixation System"* (published as WO 2012/148838 A1) describes curved blade like structures on the surface of an interbody spacer that makes contact with the adjacent vertebrae where the spacer is placed.

US patent number 8,328,870 in the name of Alphatec Spine Inc., entitled *"Stand-Alone Interbody Fixation System"* describes a stand-alone interbody spacer fixation system having anterior and posterior blades for fixation of adjacent vertebrae to the spacer.

US patent number 8,795,376, in the name of A-Spine Asia Co Ltd entitled *"Positioning Insert for Intervertebral Disc Disorder"* which discloses a plate like device positioned vertically through an interbody spacer wherein, in use, the plate that extends out of the spacer is inserted into adjacent vertebral endplates for fixation of the spacer in the intervertebral space.

US patent number 9,107,760, in the name of Alphatec Spine Inc., entitled *"Stand Alone Interbody Fixation System"* discloses an interbody spacer system that includes a cage and at least one fixation blade as part of the cage body, wherein, in use the fixation blade is rotatable up to 90 degrees to achieve a location of best position, be it in the cervical or lumbar region, and the blade/s assist in fixation of the spacer in the intervertebral space.

An example of a commercial fixation mechanism is a VERTEBRIDGE®, which resembles a nail, in the ROI-A®, a cage for anterior lumbar interbody fusion and produced by Zimmer Biomet.

PCT international patent application number PCT/US2014/025162, in the name of Globus Medical, Inc., entitled *"Interbody Standalone Interverterbral Implant"* (published as WO 2014/151175 A9) discloses a stand-alone intervertebral fusion device, which is suitable for oblique implantation. The device comprises a spacer within the interbody space of adjacent vertebrae and positioned with intervertebral screws, and a plate comprising minor locking screws that can be fixed to the adjacent vertebra which facilitate in preventing the intervertebral screws from being expelled from the vertebral body.

PCT international patent application number PCT/US2011/052462, in the name of DePuy Synthes Products, LLC., entitled *"Stand Alone Intervertebral Fusion Device"* (published as WO 2012/040268 A2) reveals multiple fixation methods with either screws or anchors, each embodiment consisting of a different faceplate including an accommodating thread within the plate which matches that of the faceplate. Other methods include a ridge in the thread of the faceplate to prevent the screw from screwing out of the mechanism. An alternate embodiment describes an anchor which is locked in place with the use of an additional locking plate.

US patent application number 11/695,939, in the name of Warsaw Orthopedic Inc., entitled *"Anchor Member Locking Features"* (published as US 2008/0249575 A1) discloses a stand-alone fusion cage in which the apertures that receive the bone anchors have a locking ring which prevents the anchor member back out by allowing the head of the anchor member to pass past the locking ring by elastically deforming it.

PCT international patent application number PCT/KR2018/007880, in the name of L&K Biomed Co., Ltd., entitled *"Stand-Alone Oblique Vertebral Fusion Cage"* (published as WO 2019013559) discloses a fusion cage, which incorporates a face plate and an additional locking plate with a screw to prevent back out. In this invention a metal bushing is utilised to prevent any damage the screws may cause the PEEK cage body.

A problem, however, remains that when screws or anchors are required to lock into a titanium spacer body, the screws make contact with a rigid titanium surface and are prevented from turning into the surface. Once the screw engages with the thread or similar feature on the cage it locks and there is no flexibility in the system nor, do they provide optimum contact for the spinal cage and vertebral endplate, or compression between the spacer cage and the vertebra. Lack of appropriate contact and compression results in non-union or imperfect fusion which may lead to a reoperation for the patient as the vertebral body is not in contact with either the graft or osteo-conductive surface.

A distinct disadvantage of the fixation systems in the prior art is that the vertebral body isn't guaranteed to be compressed against the spacer fusion cage and, at times, use of screws results in the vertebral body being pushed away from the cage.

Another problem, where an implant uses anchor members to initially secure the implant to the vertebrae, is that over time, due to micro motion of the vertebrae relative to the implant, the anchor members may loosen and start to back-out of vertebrae. In addition to possibly allowing the implant member to become loose and potentially displace within the vertebral space, the anchor members themselves may protrude and cause damage to sensitive tissue and organs in the patient.

It is a further object of this invention to provide an interbody spacer which provides a useful alternative to existing interbody spacers.

None of the above disclosures, taken singly or in combination, describes the present invention as revealed.

OBJECT OF THE INVENTION

It is accordingly an object of the invention to provide an interbody spacer which, at least partially, alleviates some of the problems associated with the prior art.

SUMMARY OF THE INVENTION

According to a first aspect of the invention there is provided an interbody spacer for implantation between adjacent vertebrae comprising:

- a spacer body shaped and sized to space apart adjacent vertebrae;
- engagement means for inducing engagement between the spacer body and a vertebra and securing the spacer body to the vertebra; and
- a deformable element associated with the engagement means wherein deformation of the deformable element increases engagement between the spacer body and the vertebra.

The deformable element may, at least partially, undergo elastic deformation such that a preload is produced in the engagement means to induce engagement between the spacer body and the vertebra.

The deformable element may, at least partially, undergo plastic deformation.

The deformable element may undergo deformation which is wholly elastic, wholly plastic, or a combination of elastic and plastic deformation.

The deformation may increase strain energy in the deformable element.

The deformable element may be an intermediate element wherein the element is located between the engagement means and the spacer body.

Deformation of the intermediate element between the engagement means and the spacer body is greater than the deformation of the spacer body between the intermediate element and the vertebra.

The element may undergo plastic deformation around securing formations in the spacer body and/or engagement means.

The spacer body may have a modulus of elasticity, which is relatively greater than the modulus of elasticity of the deformable element. The spacer body may be made of titanium or titanium alloy.

The spacer body may have a porous internal structure and the spacer body may be produced by an additive manufacturing process such as laser metal deposition or 3D printing.

The engagement means may include a fastener which has a flange on one end and a vertebra engaging formation on an other end.

The fastener may be in the form of a screw wherein the vertebra engaging formation is self-tapping.

The fastener may engage the spacer body thorough a hole on the spacer body. The hole may be threaded. The hole may include a seat which corresponds partially to the shape and size of the flange.

The deformable element may be in the form of an insert between the flange and the seat.

The insert deforms between the flange of the fastener and the seat of the hole.

The insert may be shaped and sized to undergo relatively greater deformation than the portion of the spacer body between the seat and the vertebra.

The insert may be made of a material which has a lower modulus of elasticity than the spacer body such that the insert will undergo relatively greater deformation than the spacer body.

The insert may be made of a polymer such as polyether ether ketone (PEEK).

The insert may be annular such that the inner bore of the annular insert corresponds to the shape and/or size of the fastener.

The seat may include a radial wall, which corresponds in shape and size to a outer wall of the annular insert. The insert may engage the radial wall of the seat. The seat may include securing formations. The securing formations may be barbed protrusions extending radially inward from the radial wall of the seat.

The fastener may include a radial protrusion proximal to the flange wherein the protrusion engages the inner radial wall of the annular insert and induces engagement between the outer radial wall of the insert and the radial wall of the seat.

The engagement means may include two holes which are angled relative to the spacer body such that one hole guides a fastener to one adjacent vertebra and the other guides a fastener to the other adjacent vertebra.

The engagement means may include three or more holes wherein one or more of the holes are angled towards each adjacent vertebra.

The insert may be integrally formed with the body.

The insert may be integrally formed with a fastener.

In accordance with a second aspect of the invention there is provided an insert for use with an interbody spacer for implantation between adjacent vertebrae with a spacer body and a fastener comprising a a deformable element and engagement means for engaging a spacer body and fastener such that deformation of the deformable element increases engagement between the spacer body and an adjacent vertebra.

BRIEF DESCRIPTION OF THE DRAWINGS

An embodiment of the invention is described below, by way of a non-limiting example only, and with reference to the accompanying drawing in which:

Figure 1 is a schematic exploded perspective view of an interbody spacer;

DETAILED DESCRIPTION OF THE DRAWINGS

With reference to the drawings, in which like features are indicated by like numerals, an interbody spacer is generally indicated by reference numeral 100.

The interbody spacer 100 is shown in this example as implanted between a superior vertebra 502 and an adjacent inferior vertebra 501. The interbody spacer includes a body 106 which is shaped and sized to engage and space apart the adjacent vertebrae. Specifically, the superior side of the body 105 engages the superior vertebra 502 and the inferior side 107 engages the inferior vertebra 501. The body 106 is made of titanium or titanium alloy. Preferably, the body is produced by an additive manufacturing process such as laser metal deposition or 3D printing. The height 108 of the body 106 provides the required separation between the vertebrae and the superior surface 105 and inferior surface 107 contact and engage the related vertebrae.

Where the body is manufactured using additive manufacturing method, it is desirable that the engaging surfaces (105 and 107) of the body 106 are shaped to be substantially complementary to the shape of the corresponding vertebra to allow for more uniform contact and distribution of pressure. Further, it is desirable that the body 106 has a porous internal structure and that the density of the body 106 is similar to human bone. The porous internal structure and shaped surfaces (105 and 107) allow for greater osteo-conductivity, bone growth, and fusion between the spacer 100 and the adjacent vertebrae.

The interbody spacer 100 includes engagement means for inducing engagement between the spacer body 106 and at least one of the vertebrae. In the current example, the engagement means includes three fasteners 200. Each fastener 200 has a flange 203 on one end and a vertebra engaging formation, in the form of a self-tapping tip 204, on the other end with helical thread 201 between the flange 203 and tip 204. Proximal to the flange is a radial protrusion 202. The screws 200 engage the adjacent vertebrae through holes 104 in the body 106.

In the current example, the outer holes 104 are angled upwards toward the superior vertebra 502 with the central hole angled downwards toward the inferior vertebra 501. The holes 104 may be threaded and each hole 104 includes a seat 103 with a corresponding radial wall which corresponds roughly to the shape and size of the flange 203. The screws 200, when inserted and fastened through the body 106 to the vertebrae, induces engagement between the spacer body 106 and the vertebrae which creates engagement pressure and secures the spacer body 106 to the vertebrae.

The interbody spacer 100 includes a deformable element, in the current example in the form of an insert 110, which deforms under the stress of the engagement means to increase engagement between the spacer body 106 and the adjacent vertebra. The deformation of the insert 110 is at least partially elastic such that a preload is produced in the engagement means to induce engagement between the spacer body 106 and the vertebra. Such elastic deformation increases the strain energy in the deformable element.

Strain energy is a form of potential energy in an elastic body under loading. Strain is a dimensionless measure of deformation representing the displacement between particles in a body. Colloquially, the term strain is typically used to described linear strain which relates to linear deformation of a solid body under tensile or compressive stress. In the linear sense, the stress-strain relationship is well studied for solid bodies of most materials and strain energy is directly related to the stress through the modulus of elasticity of the material. However, in complex bodies where the shape provides for greater linear deformation (such as a spring) the strain in the solid body is similarly complex and the concept of linear strain is no longer helpful.

There are three main disadvantages as a result of the high stiffness of titanium. The first disadvantage is especially noticeable where the implant is threaded and is caused by the initial displacement of the vertebra when a fastener is inserted. When the fastener reaches the titanium surface such that it cannot be fastened further, at least part of the initial displacement will still be present which creates imperfect engagement. The second disadvantage is that at this point further fastening of the fastener would require a very large torque to be applied to the fastener. The torque which may be applied to the fastener is limited by the strength of the physician, the maximum allowable torque which may be applied to the fasteners, and the tools at the physician’s disposal. The limited torque might not be enough to create the desired engagement pressure between the implant and the vertebra. The third disadvantage is related to the back-out problem. Vibrations and micro-movements would only have to release a small amount of strain in the fastener, and due to the high modulus of elasticity, this would have a very large effect on the engagement pressure.

The deformable element as described herein and embodied by the inserts 110 is aimed at addressing these disadvantages in a novel way. The element increases in and maintains strain energy which is applied thereto through the fasteners 200. For this reason, such elements will typically be intermediate elements and be located between the body 106 and the fastener 200 (specifically between the flange 203 and the seat 103) as is the case for the inserts 110. The strain energy in the insert 110 is a result of the deformation created by the engagement between the element and a vertebra or, in the case where the hole 104 is threaded, between the element and the spacer body 106.

The deformation of the insert 110 under compressive stress from the fastener 200 is greater than the deformation of the corresponding portion of the body 106 between the insert 110 and the relevant vertebra. This may be achieved by using an insert 100 which is manufactured from a material with a relatively lower modulus of elasticity than that of the body 106. Alternatively, the insert may be shaped and sized to undergo relatively greater deformation under compressive stress by, for example, introducing weakened portions in the shape to exaggerate deformation thereof.

Figure 9 shows hypothetical schematic stress-strain curves for the materials of the body 601 and deformable element 602 in the elastic range. The area under each of the curves would represent the strain energy per unit volume. Thus, for the sake of the example, assuming that the volumes are equal, we can clearly observe that for a given peak stress 603 the strain energy in the body 604 is significantly less than the strain energy in the deformable element 605. As the peak stress is increased, the body strain energy 604 will eventually be greater than the deformable element strain energy 605. However, this will require large peak stress 603 which would not be desirable or would not be possible to apply with available torque to the fasteners.

In reality, the total strain energy will be shared between portions of the fastener 200, body 106, insert 110, and the vertebra. The relation will be complex and from the example above it can be seen that the addition of an insert 110 with a greater strain energy capacity will increase the total strain energy capacity.

The disadvantages discussed earlier are thus addressed in the following manner. The initial displacement of the vertebra may be compensated for by the deformation of the insert 110. As the insert 110 deforms, the fastener can achieve extra rotation such than the initial displacement is negated. The limited torque disadvantage is alleviated as a physician may use lower torque over greater rotation of the fastener whilst the insert 110 deforms to achieve the desired engagement pressure between the spacer body 106 and the vertebra. Lastly, the deformation of the insert 110 serves as a barrier to back-out, as vibrations or micro movements would have to overcome, collectively, a larger energy barrier. In addition thereto, the smaller gradient of the curve allows the stress to decrease slightly for a given deformation allowing the engagement pressure to be substantially maintained for small changes in the deformation.

In the current example the inserts 110 are made of PEEK. The inserts 110 have an annular shape with a substantially rectangular cross section and a central bore corresponding to the size of the threaded portion 201 of the fasteners 200. On one side, the outer edge of the insert 110 is chamfered. The shape and size of the seat 103 corresponds to the shape and size of the insert 110 such that the outer wall of the insert 110 and within the radial wall of the seat 103 forms an interference fit. This provides an advantage in that, under deformation of the inserts 110, a radial force will be exerted on the radial wall of the seat 103 and the fastener 200 creating frictional resistance which prevents the fastener 200 from rotating or backing out. The radial protrusion 202 on each fastener has an effective diameter which is slightly larger than the outer diameter of the threaded portion 201. This increases the resistive force between the fastener 200 and the radial wall, essentially locking the fastener in place.

At least part of the deformation of the inserts 110 will be plastic deformation. In the current example, the radial wall of the seat 103 includes securing formations 109 extending inward from the radial wall. The securing formations 109 have a barbed profile to allow the insert 110 to be inserted more easily than it may be removed. The plastic deformation may be linear in the direction of the fasteners or caused by protrusions 202. As the insert 110 deforms in the seat, the stress in the insert 110 at the protrusion 202 and the securing formations 109 will exceed the yield strength of the insert and the insert will conform to the shape of the cavity around the protrusion 202 and the securing formations 109. This essentially locks the insert 110 in place in the seat preventing the insert from backing out and maintaining the resistive force between the fastener 200 and the radial wall.

The example described herein utilizes a combination of plastic and elastic deformation of the insert to achieve the desired effect. However, the deformable element may be made in such a manner that many if the effects and advantages may be achieved using a deformable element which undergoes wholly plastic or wholly elastic deformation. Those skilled in the art will recognize from the description herein, that the invention may be easily adapted such that the deformable element may be incorporated into, or integrally formed with, the fastener 200 or body 106. A second aspect of the invention therefore provides for an insert 110 for use with an interbody spacer 101 for implantation between adjacent vertebrae (501 and 502) with a spacer body 106 and a fastener 200 comprising a deformable element and engagement means for engaging a spacer body 106 and fastener 200 such that the insert 110 increases engagement between the spacer body 106 and an adjacent vertebra.

It is envisaged that the invention will provide an interbody spacer which creates increased engagement between the spacer and adjacent vertebra and prevents back-out of fasteners.

The invention is not limited to the precise details as described herein. For example, instead of having an annular insert, a rectangular or hexagonal insert may be employed. Further, instead of self-tapping screw fasteners, the engagement means may include bolts or anchors to achieve the same result.

CLAIMS

1. An interbody spacer for implantation between adjacent vertebrae comprising: a spacer body shaped and sized to space apart adjacent vertebrae; engagement means for inducing engagement between the spacer body and a vertebra and securing the spacer body to the vertebra; and a deformable element associated with the engagement means wherein deformation of the deformable element increases engagement between the spacer body and the vertebra.

2. The interbody spacer of claim 1 wherein the deformable element, at least partially, undergoes elastic deformation such that a preload is produced in the engagement means to induce engagement between the spacer body and the vertebra.

3. The interbody spacer of claim 1 wherein the deformable element, at least partially, undergoes plastic deformation.

4. The interbody spacer of claim 1 wherein the deformable element undergoes deformation which is wholly elastic.

5. The interbody spacer of claim 1 wherein the deformable element undergoes deformation which is wholly plastic.

6. The interbody spacer of claim 1 wherein the deformable element undergoes deformation which is a combination of elastic and plastic deformation.

7. The interbody spacer of claim 1 wherein the deformation of the deformable element increases strain energy in the deformable element.

8. The interbody spacer of claim 1 wherein the deformable element is an intermediate element located between the engagement means and the spacer body.

9. The interbody spacer of claim 8 wherein deformation of the intermediate element between the engagement means and the spacer body is greater than the deformation of the spacer body between the intermediate element and the vertebra.

10. The interbody spacer of claim 8 wherein the element undergoes plastic deformation around securing formations in the spacer body.

11. The interbody spacer of claim 8 wherein the element undergoes plastic deformation around the engagement means.

12. The interbody spacer of claim 1 wherein the spacer body has a modulus of elasticity which is relatively greater than the modulus of elasticity of the deformable element.

13. The interbody spacer of claim 1 wherein the spacer body is made of titanium.

14. The interbody spacer of claim 1 wherein the spacer body is made of titanium alloy.

15. The interbody spacer of claim 1 wherein the spacer body has a porous internal structure

16. The interbody spacer of claim 15 wherein the spacer body is produced by an additive manufacturing process

17. The interbody spacer of claim 16 wherein the additive manufacturing process is 3D printing.

18. The interbody spacer of claim 16 wherein the additive manufacturing process is laser metal deposition.

19. The interbody spacer of claim 1 wherein the engagement means includes a fastener with a flange on one end and a vertebra engaging formation on an opposing end.

20. The interbody spacer of claim 19 wherein the fastener is a screw and the vertebra engaging formation is self-tapping.

21. The interbody spacer of claim 19 wherein the fastener engages the spacer body thorough a hole on the spacer body.

22. The interbody spacer of claim 21 wherein the hole is threaded.

23. The interbody spacer of claim 21 wherein the hole includes a seat which corresponds to the shape and size of the flange.

24. The interbody spacer of claim 23 wherein the deformable element is an insert between the flange and the seat.

25. The interbody spacer of claim 24 wherein the insert deforms between the flange of the fastener and the seat of the hole.

26. The interbody spacer of claim 24 wherein the insert is shaped and sized to operatively undergo relatively greater deformation than the portion of the spacer body between the seat and the vertebra.

27. The interbody spacer of claim 26 wherein the insert is made of a material which has a lower modulus of elasticity than the spacer body such that the insert will undergo relatively greater deformation than the spacer body.

28. The interbody spacer of claim 27 wherein the insert is made of a polymer.

29. The interbody spacer of claim 28 wherein the polymer is polyether ether ketone (PEEK).

30. The interbody spacer of claim 24 wherein the insert is annular such that the inner bore of the annular insert corresponds to the shape and size of the fastener.

31. The interbody spacer of claim 24 wherein the seat includes a radial wall corresponding in shape and size to an outer wall of the annular insert.

32. The interbody spacer of claim 31 wherein the insert operatively engages the radial wall of the seat.

33. The interbody spacer of claim 23 wherein the seat includes securing formations.

34. The interbody spacer of claim 31 wherein the securing formations are barbed protrusions extending radially inward from the radial wall of the seat.

35. The interbody spacer of claim 31 wherein the fastener includes a radial protrusion proximal to the flange which operatively engages the inner radial wall of the annular insert and induces engagement between the outer radial wall of the insert and the radial wall of the seat.

36. The interbody spacer of claim 19 wherein the engagement means includes two holes in the spacer body which are angled relative to the spacer body such that one hole guides a fastener to one adjacent vertebra and the other guides a fastener to the other adjacent vertebra.

37. The interbody spacer of claim 19 wherein the engagement means includes three or more holes wherein one or more of the holes are angled towards each adjacent vertebra.

38. The interbody spacer of claim 24 wherein the insert is integrally formed with the body.

39. The interbody spacer of claim 24 wherein the insert is integrally formed with a fastener.

40. An insert for use with an interbody spacer for implantation between adjacent vertebrae with a spacer body and a fastener comprising a deformable element and engagement means for engaging a spacer body and fastener such that deformation of the deformable element increases engagement between the spacer body and an adjacent vertebra.

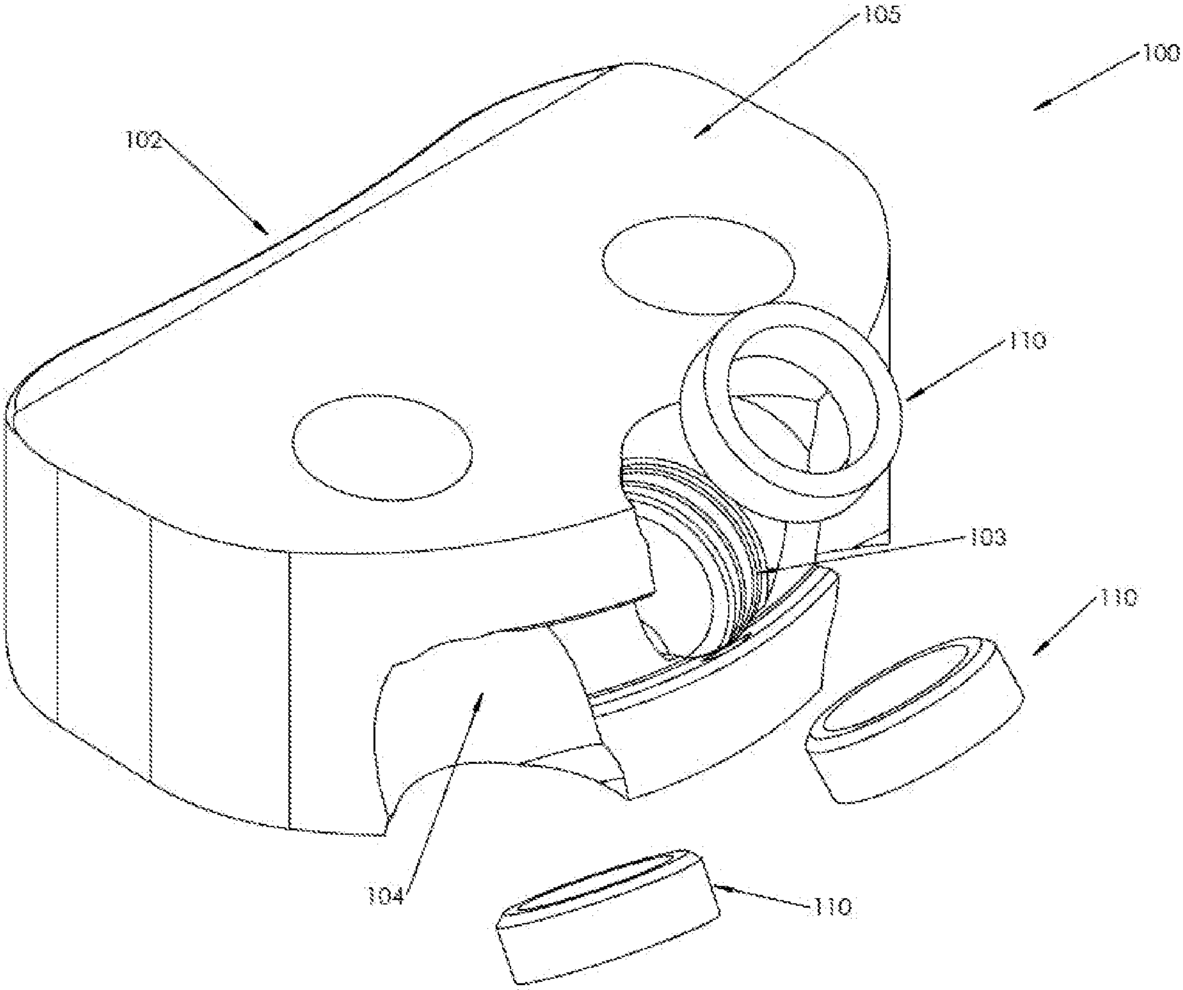

FIGURE 1

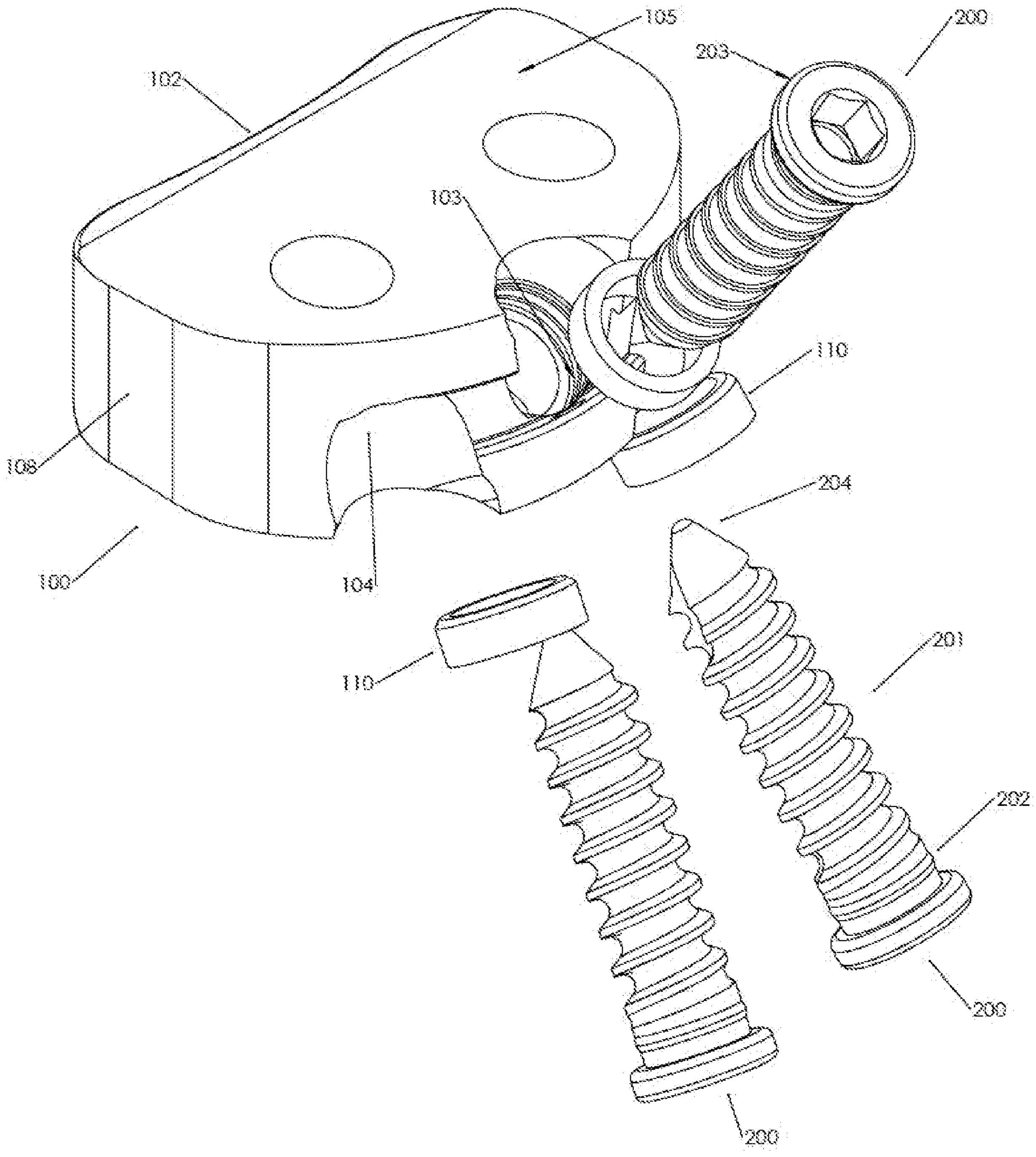

FIGURE 2

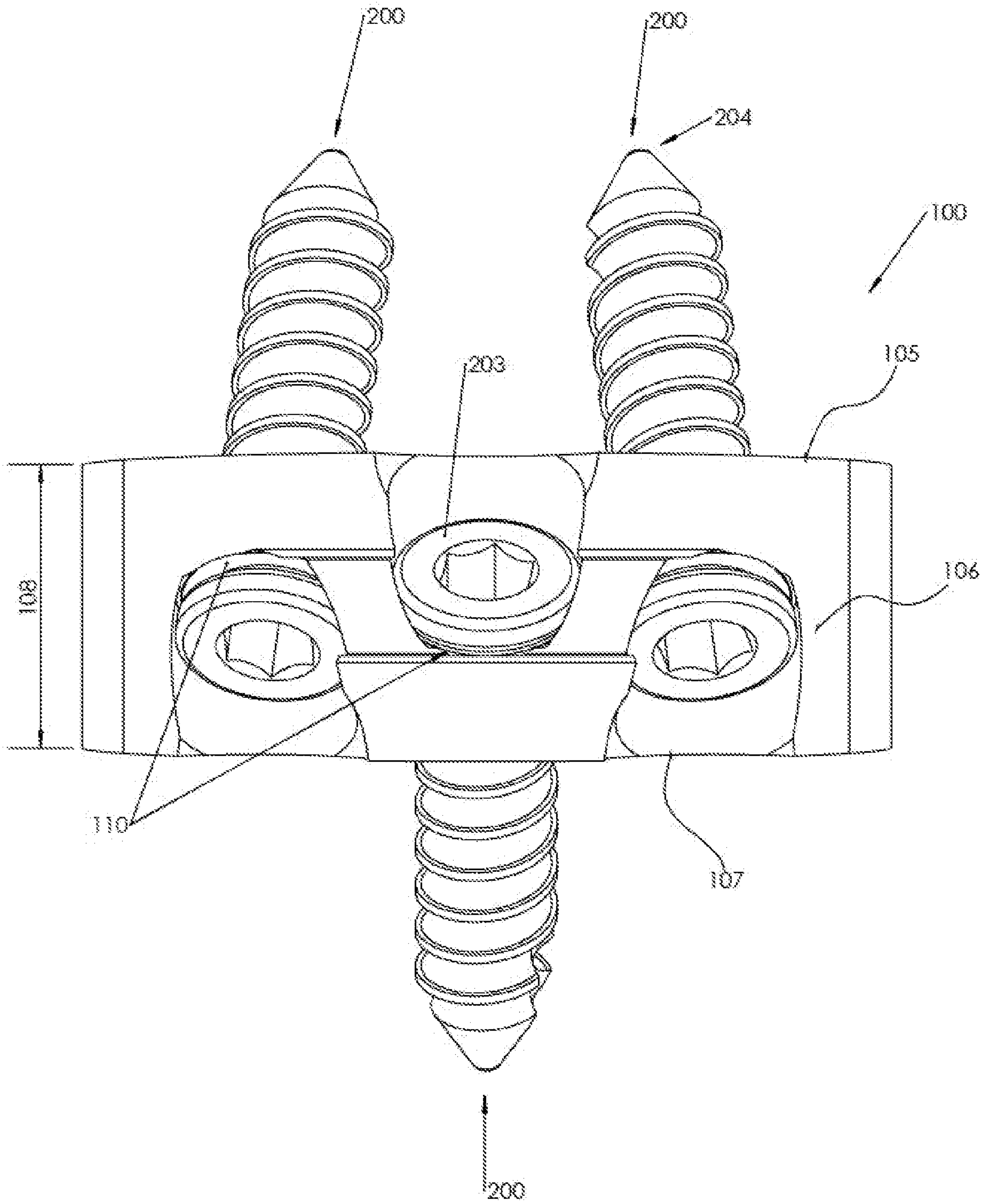

FIGURE 3

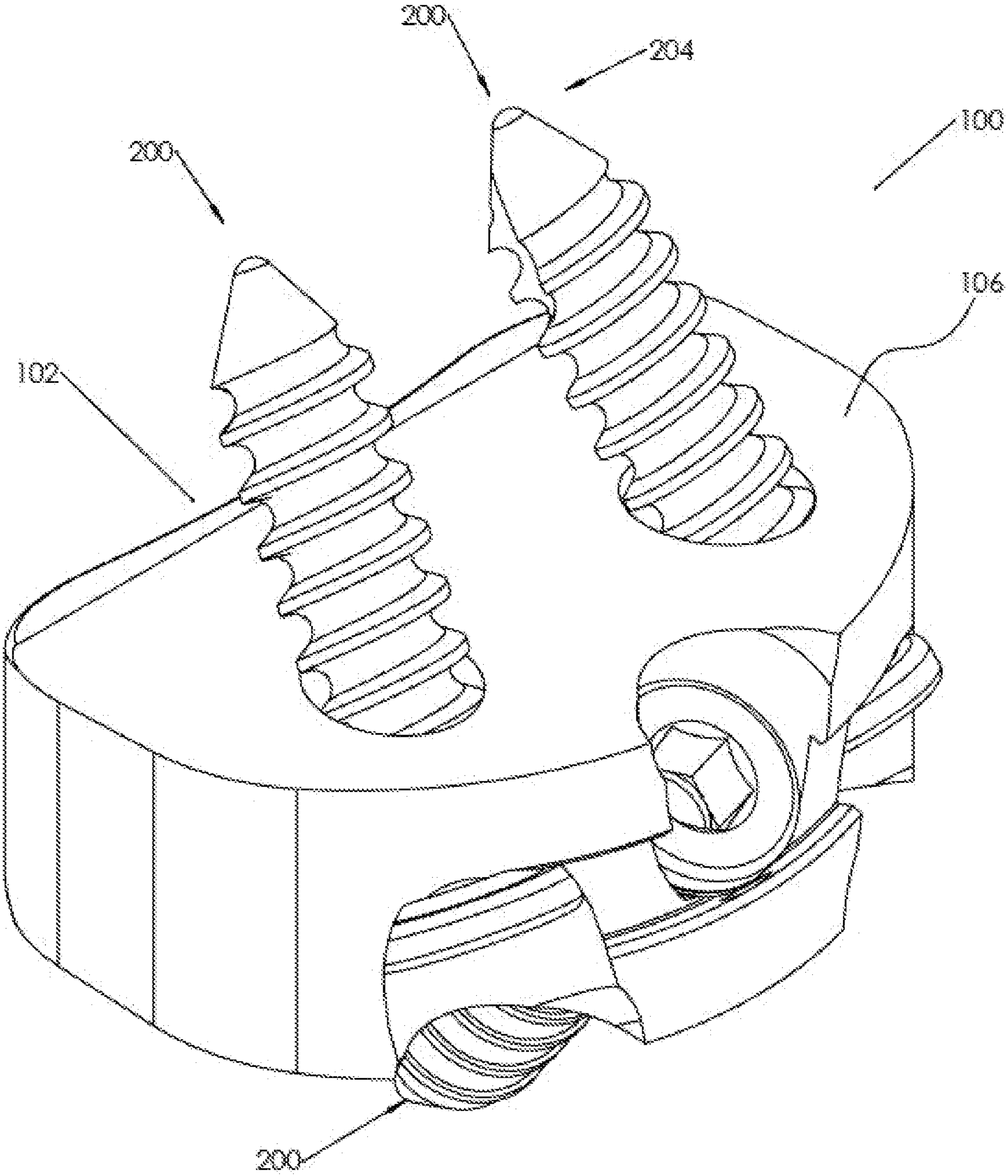

FIGURE 4

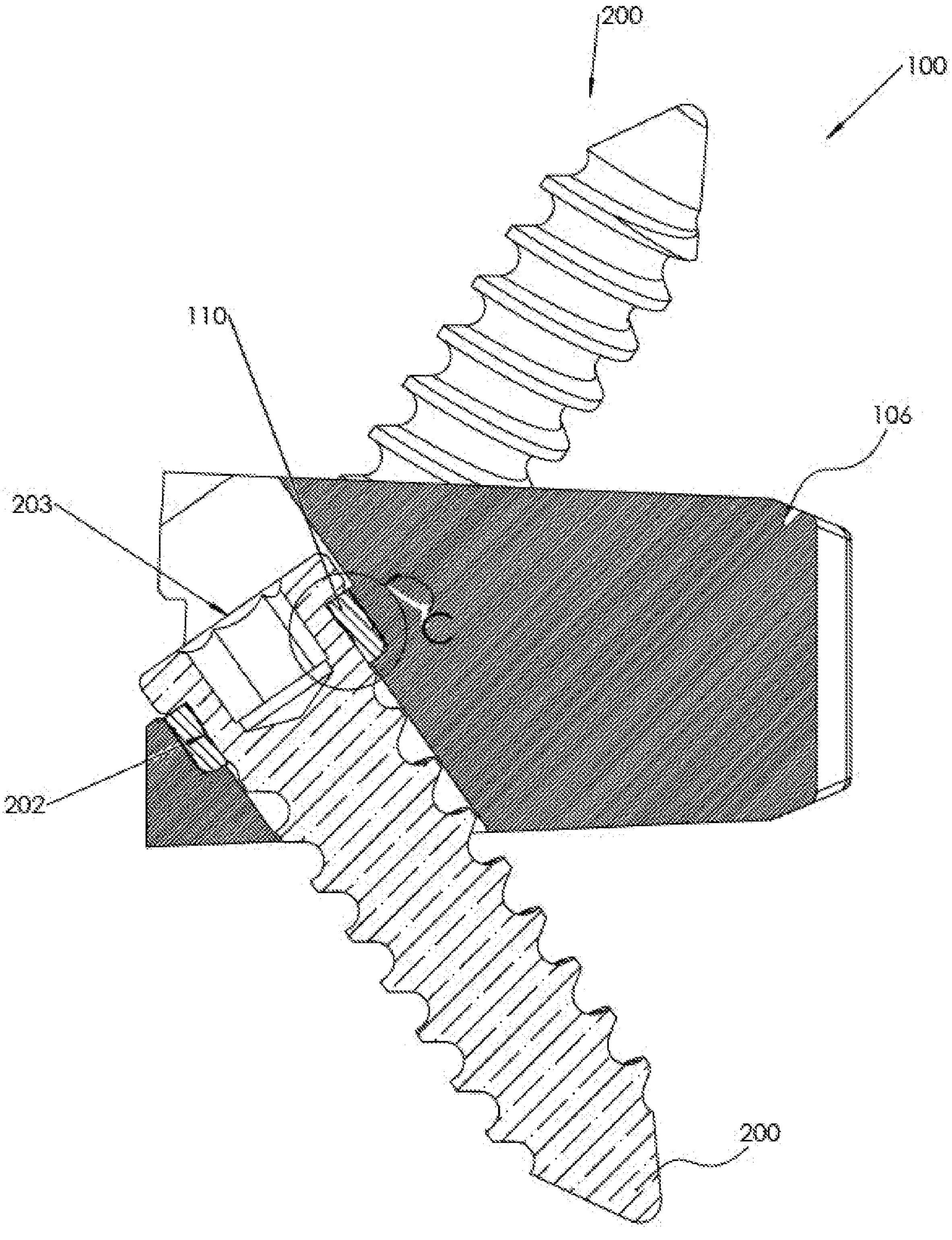

FIGURE 5

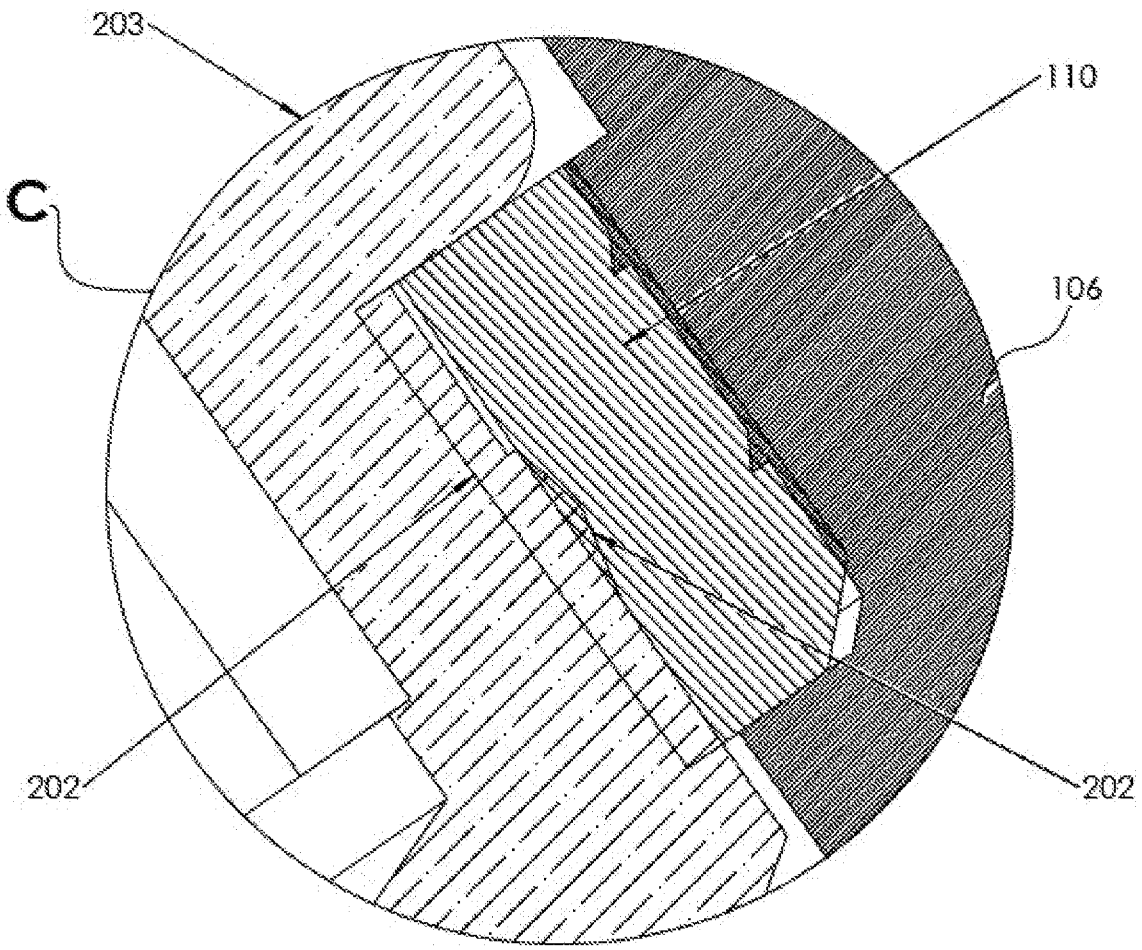

FIGURE 6

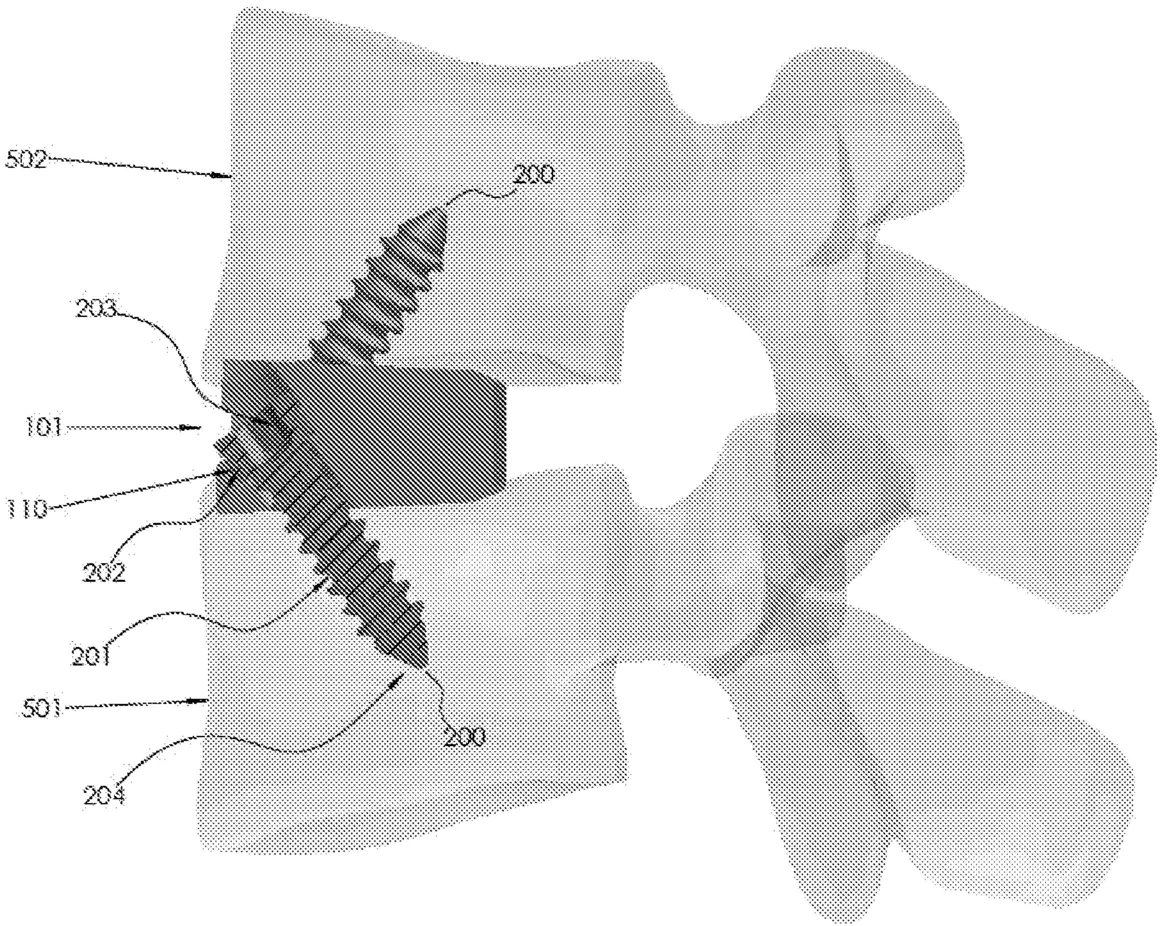

FIGURE 7

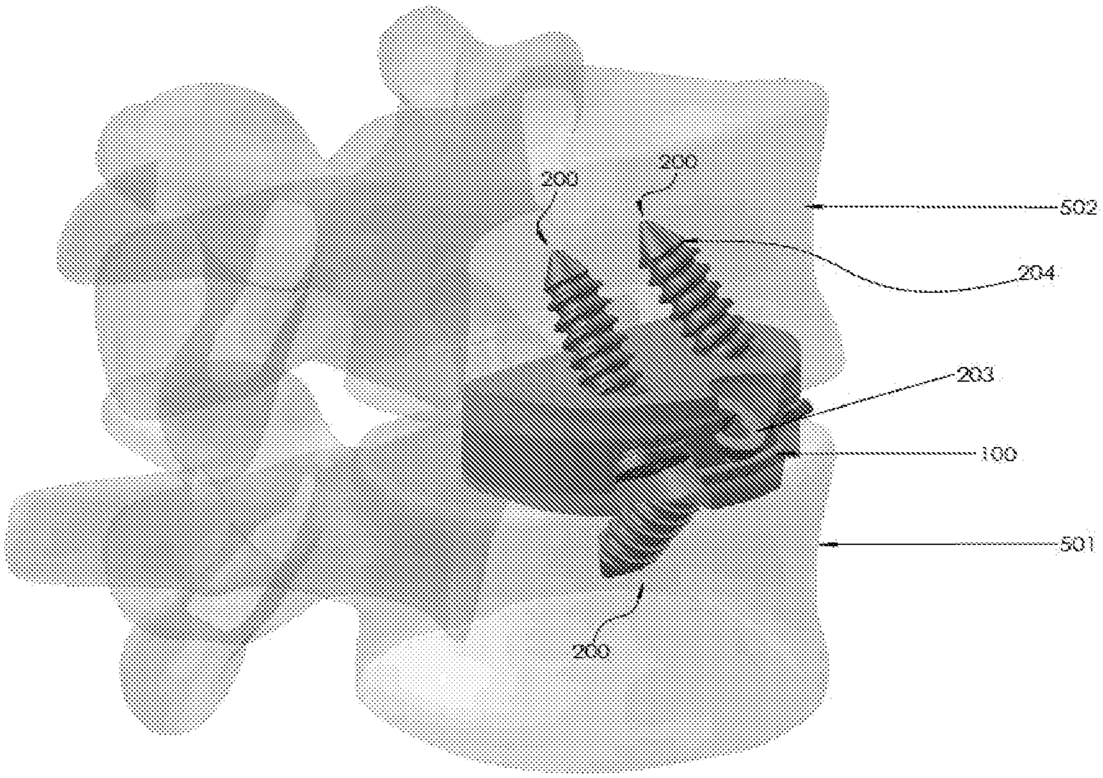

FIGURE 8

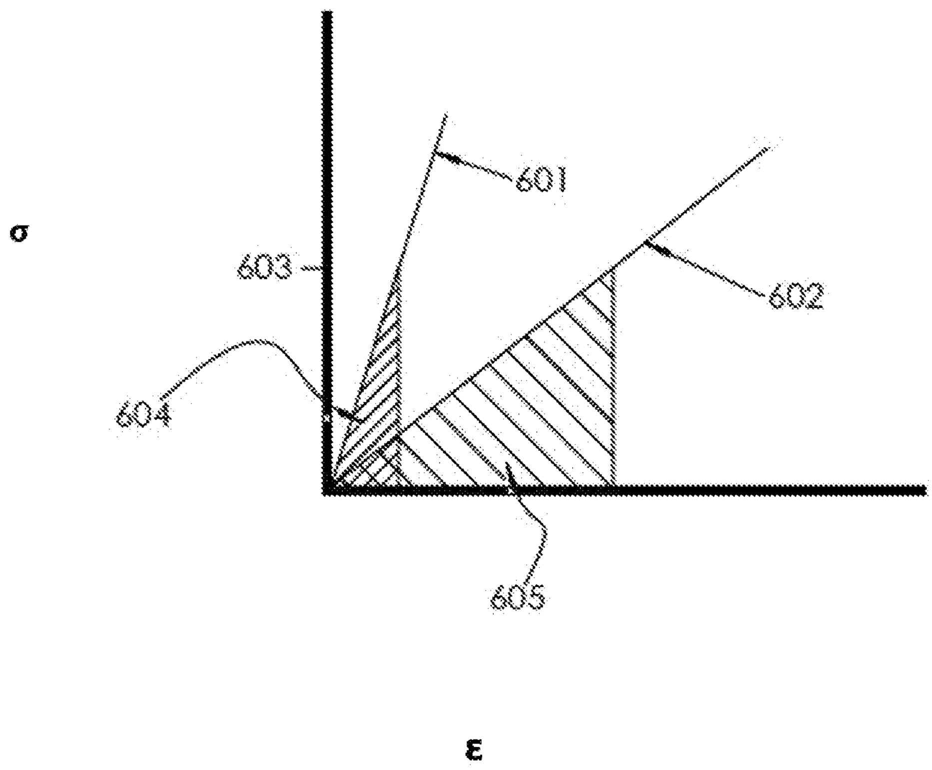

FIGURE 9