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(54) **VERTEBRAL IMPLANT INCLUDING
PREFORMED OSTEOCONDUCTIVE INSERT
AND METHODS OF FORMING**

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(57) **ABSTRACT**

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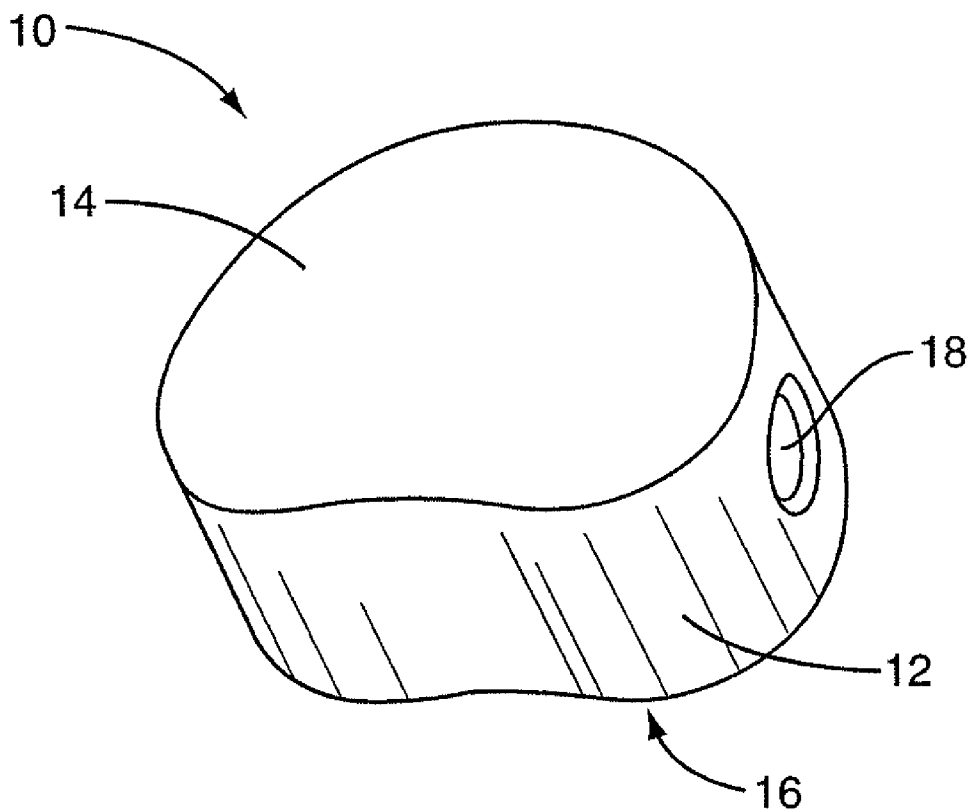
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12, 2006, now Pat. No. 7,951,200.

A vertebral implant for insertion into a patient includes an insert formed from an osteoconductive material and further including a biocompatible polymer body that is formed into the insert. The insert may extend over part of or substantially the entire bone contact surface of the implant. The insert includes a bone contact surface and a substrate interface. The implant may include fibers that extend across the substrate interface from the insert to the body. The insert may be thin relative to the overall thickness of the implant. The insert may be preformed. The insert may be formed using a molding process. The body may be molded onto the insert.



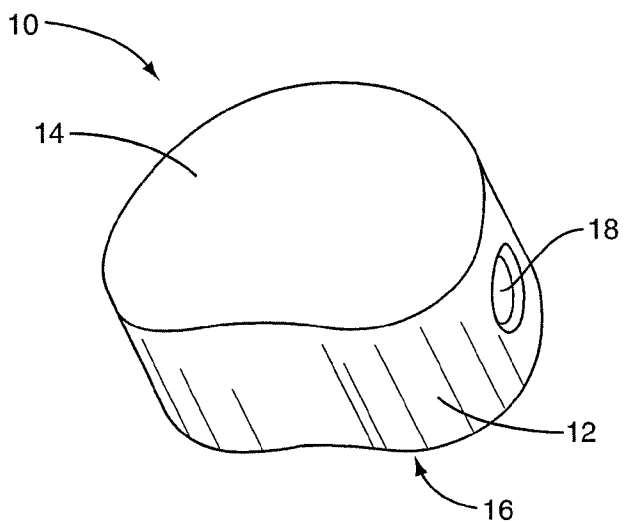


FIG. 1

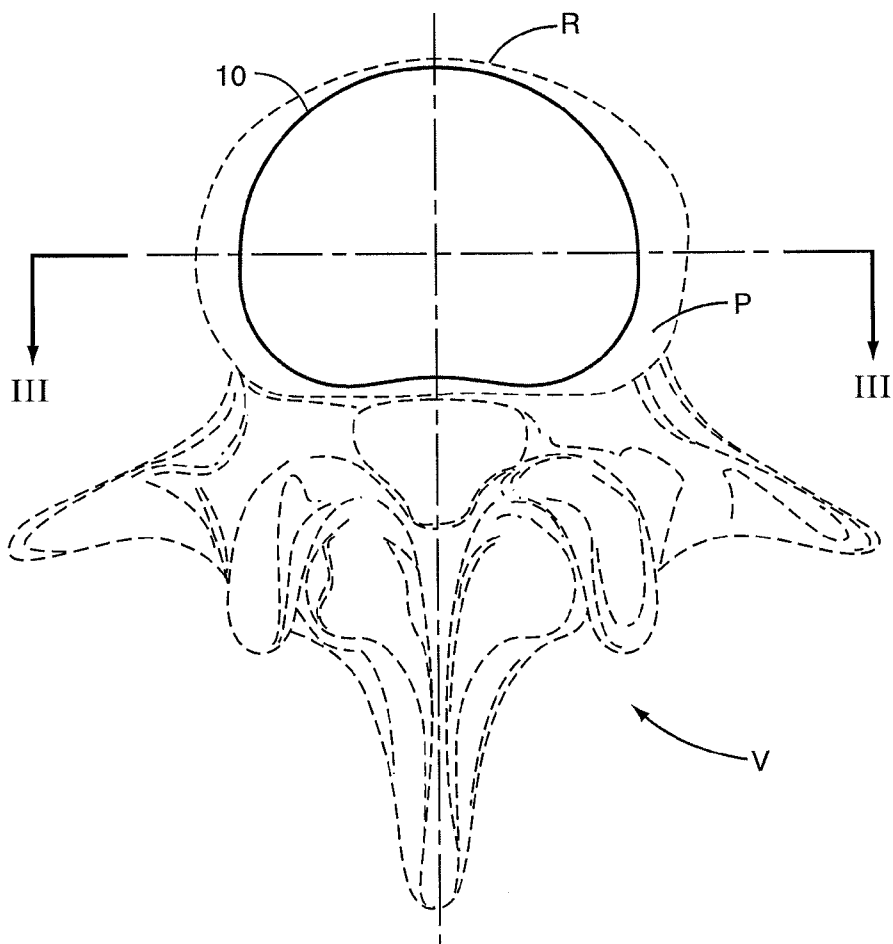


FIG. 2

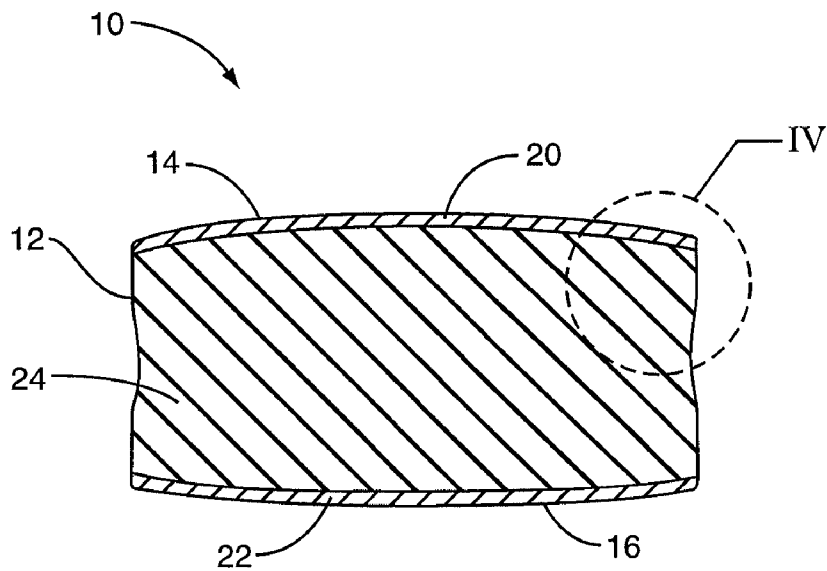


FIG. 3

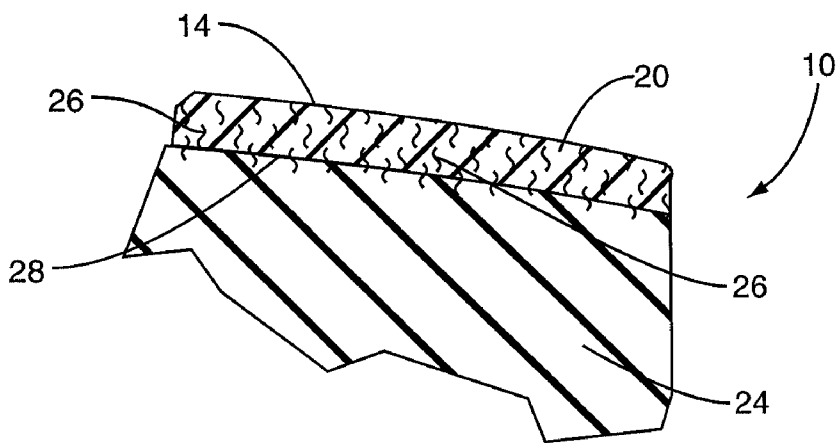


FIG. 4

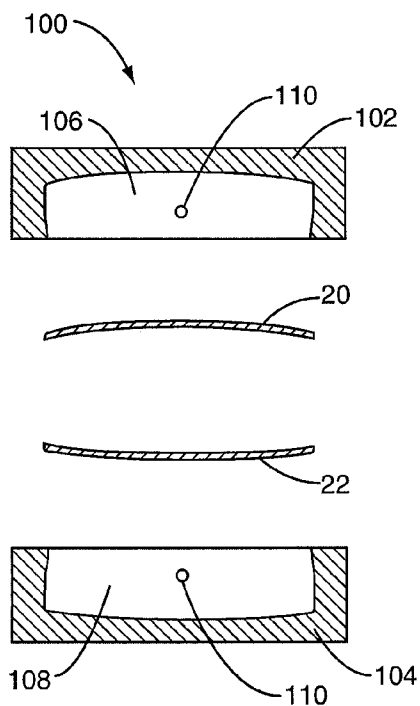


FIG. 5A

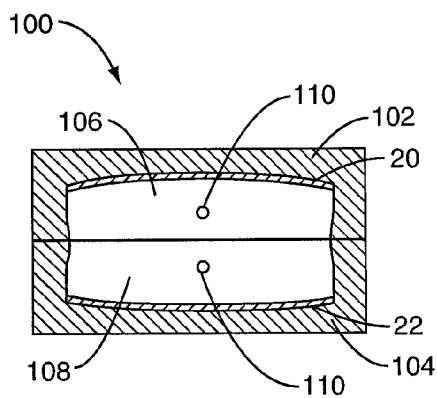


FIG. 5B

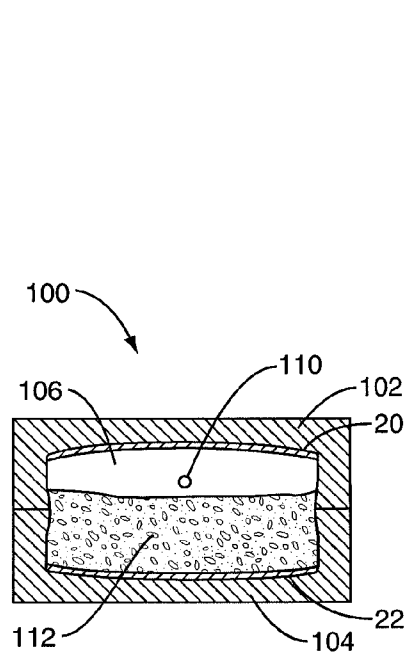


FIG. 5C

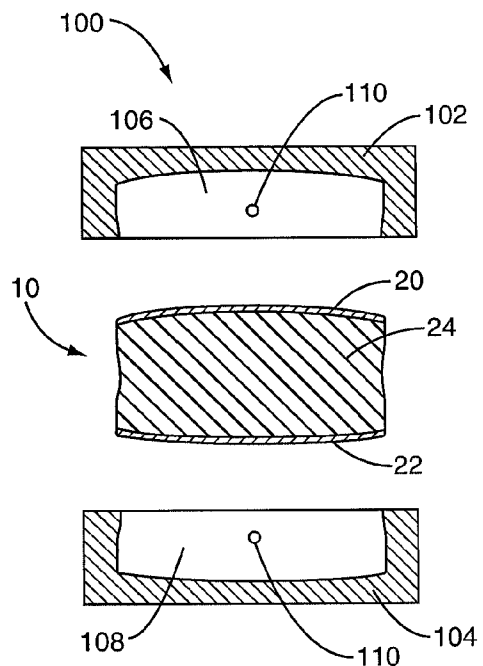


FIG. 5D

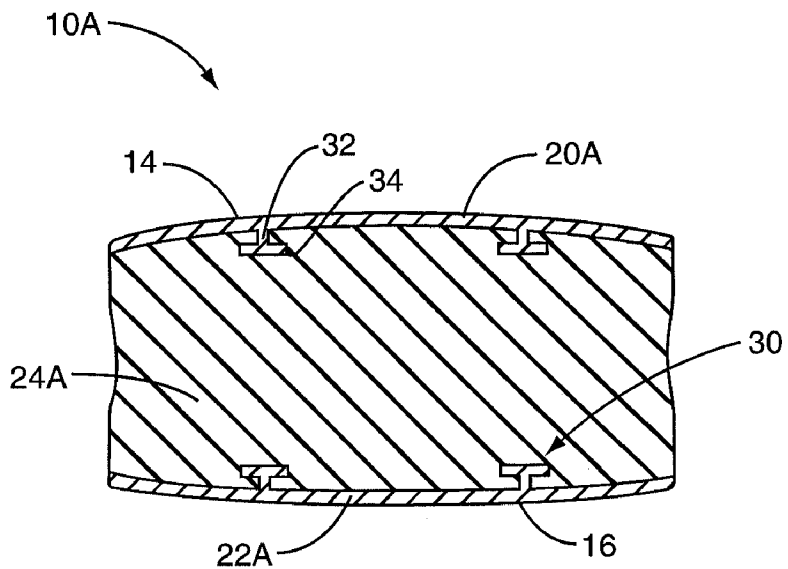


FIG. 6

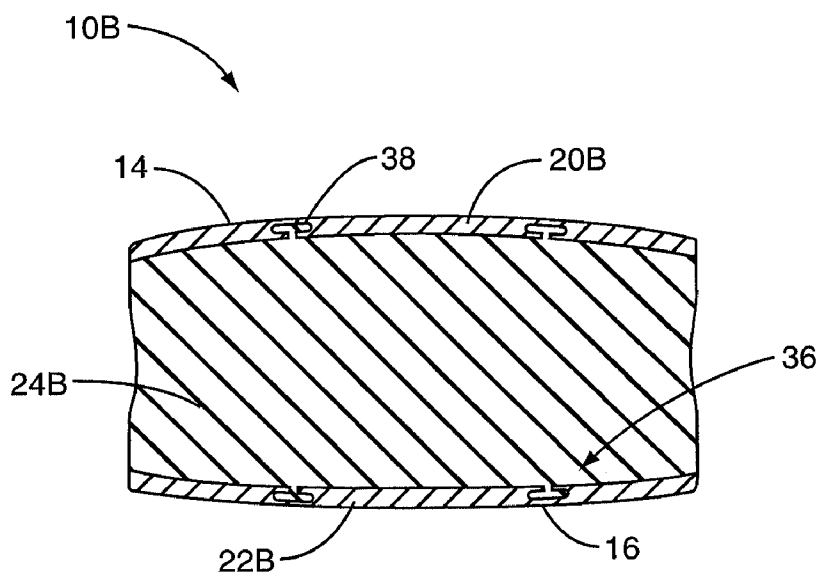


FIG. 7

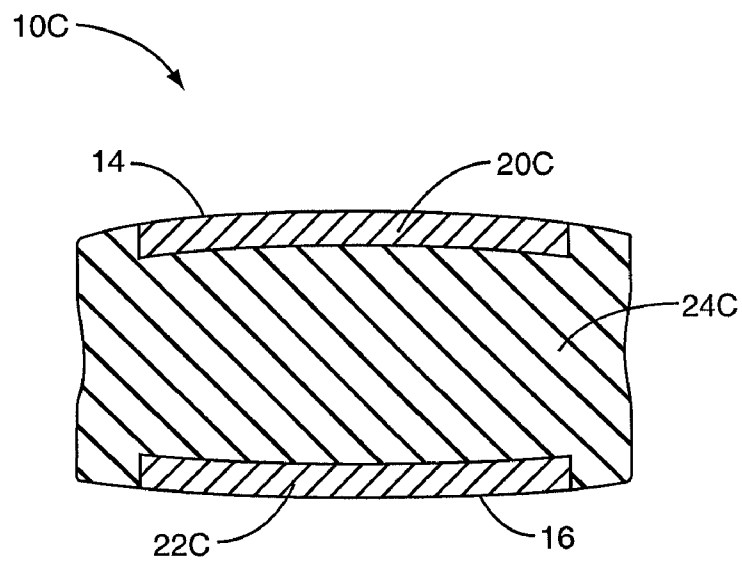


FIG. 8

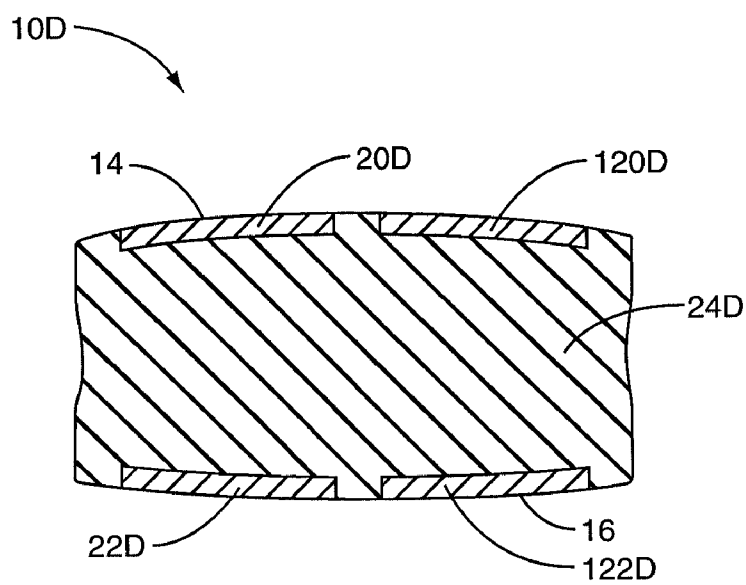


FIG. 9

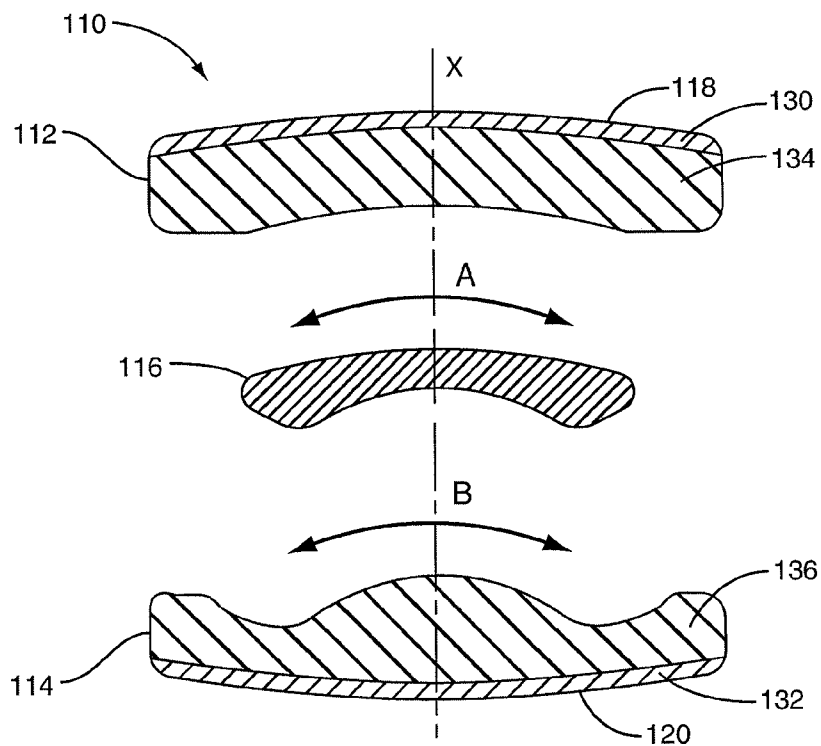


FIG. 10

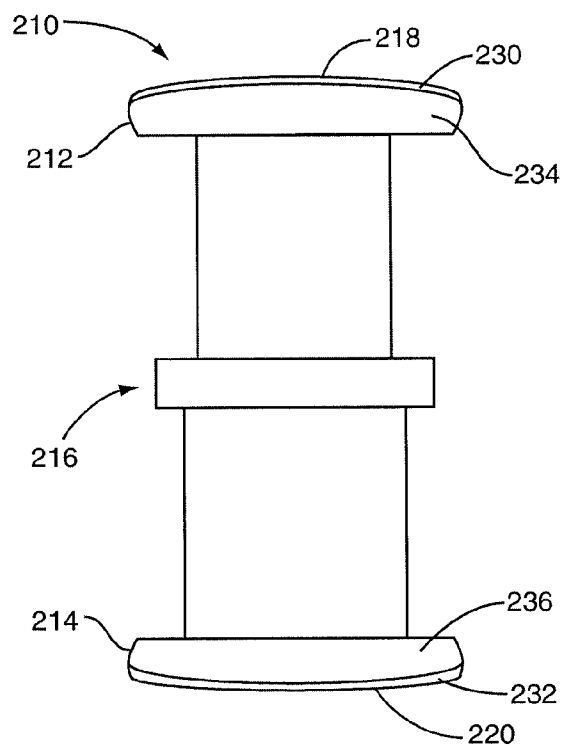


FIG. 11

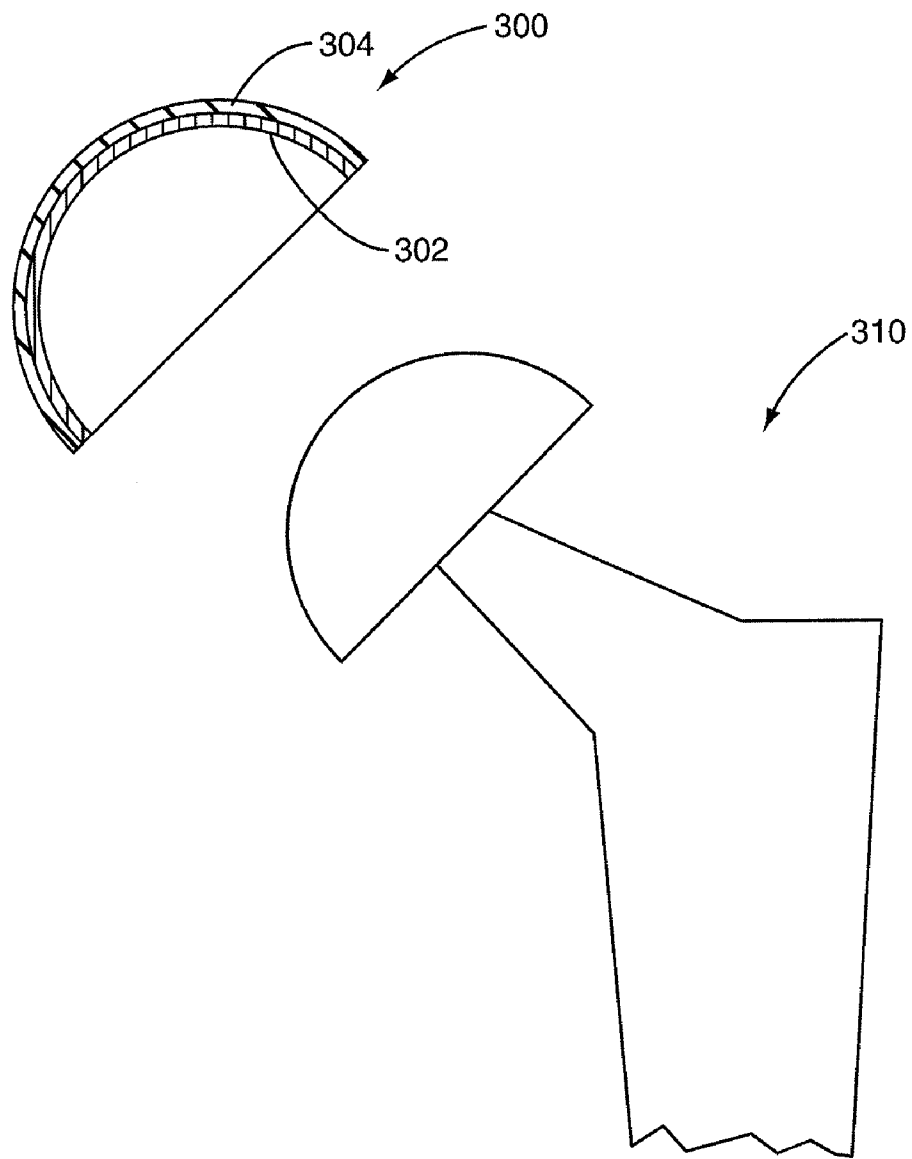


FIG. 12

**VERTEBRAL IMPLANT INCLUDING
PREFORMED OSTEOCONDUCTIVE INSERT
AND METHODS OF FORMING**

RELATED APPLICATION

[0001] The present application is a divisional application of co-pending application Ser. No. 11/485,259, filed on Jul. 12, 2006, and incorporated by reference herein in its entirety.

BACKGROUND

[0002] Spinal implants are often used in the surgical treatment of spinal disorders such as degenerative disc disease, disc herniations, curvature abnormalities, and trauma. Many different types of treatments are used. In some cases, spinal fusion is indicated to inhibit relative motion between vertebral bodies. In other cases, dynamic implants are used to preserve motion between vertebral bodies. In yet other cases, relatively static implants that exhibit some degree of flexibility may be inserted between vertebral bodies.

[0003] Implants such as these may be positioned between vertebral bodies, with superior and inferior surfaces placed in contact with the vertebral bodies. Often, the bone-contact surfaces of these implants are configured with a surface texture, surface features, and natural or synthetic bone growth stimulators to promote osseointegration of the implant. Recent innovations in implant materials have produced a new generation of implants constructed from polymers such as UHMWPE or PEEK. These polymer materials may offer a variety of advantages, including improved strength, reduced weight, and desirable mechanical characteristics. Unfortunately, the polymers are not naturally osteoconductive. Thus, implant constructed from these polymers may not sufficiently fuse with the vertebral bodies. Ineffective fusion at the bone-contact surface may lead to subsidence of the vertebral implants over time, and often leads to spinal instability, angular deformities, and planar translations.

SUMMARY

[0004] Illustrative embodiments disclosed herein are directed to a vertebral implant device for insertion into a patient. One embodiment of a vertebral implant device may include an insert with a first bone contact surface and an opposing second surface. The insert may be constructed from an osteoconductive material with fibers with some of the fibers including a first section positioned in the insert and a second section that extends outward from the second surface. The insert may also include an anchor that extends outward from the second surface a greater distance than the second sections of the fibers. A non-osteoconductive body may be attached to the second surface of the insert and may be formed from a different material than the insert. The second sections of the fibers and the anchor may be positioned in the body. The insert and the anchor may have a unitary construction formed from the osteoconductive material.

[0005] An embodiment of the vertebral implant device may include a body constructed from a first material with a first side and an opposing second side. An insert may be attached to the first side of the body and may be constructed from a second material having a plurality of fibers. An anchor may extend outward from the insert into the body and may include a stem adjacent to the insert and a head spaced away from the insert and positioned at an end of the stem. The stem may include a smaller width than the head. The anchor and a

portion of the fibers may be positioned to extend outward from the insert and into the body to improve adhesion between the body and the insert.

[0006] An embodiment of the vertebral implant device may also include an intermediate portion constructed of a first material and including a first side and a second side. A first insert may be attached to the first side of the intermediate portion and may include a first contact surface configured to contact against the first vertebral body when the vertebral implant device is inserted in the patient. A second insert may be attached to the second side of the intermediate portion and may include a second contact surface configured to contact against the second vertebral body when the vertebral implant device is inserted in the patient. Each of the inserts may be constructed from a second material with a plurality of fibers. A portion of the plurality of fibers of each of the first and second inserts may extend into the intermediate portion. A plurality of anchors may extend outward from the first and second inserts and into the intermediate portion. Each of the plurality of anchors may include a stem adjacent to the insert and a head spaced away from the insert and positioned at an end of the stem.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] FIG. 1 is a perspective view of a vertebral implant according to one or more embodiments;

[0008] FIG. 2 is a top view of a vertebral implant according to one or more embodiments shown relative to a vertebral body;

[0009] FIG. 3 is a section view of a vertebral implant according to one or more embodiments;

[0010] FIG. 4 is a detail view of the vertebral implant of FIG. 3;

[0011] FIGS. 5A-D illustrate exemplary process steps by which osteoconductive inserts may be formed onto an implant according to one embodiment;

[0012] FIG. 6 is a section view of a vertebral implant according to one or more embodiments;

[0013] FIG. 7 is a section view of a vertebral implant according to one or more embodiments;

[0014] FIG. 8 is a section view of a vertebral implant according to one or more embodiments;

[0015] FIG. 9 is a section view of a vertebral implant according to one or more embodiments;

[0016] FIG. 10 is a section view of a vertebral arthroplasty implant according to one or more embodiments;

[0017] FIG. 11 is a side view of a corpectomy implant according to one or more embodiments; and

[0018] FIG. 12 is a side section view of an acetabular implant according to one or more embodiments.

DETAILED DESCRIPTION

[0019] The various embodiments disclosed herein relate to a vertebral implant in which bone-contact surfaces are constructed with an osteoconductive insert. The number 10 in FIG. 1 generally identifies one example of an implant including an osteoconductive insert. The representative vertebral implant 10 is a disc replacement implant that is inserted between vertebral bodies of a patient as part of a disc replacement surgery. The vertebral implant 10 may be constructed, at least partially, from biocompatible polymers, such as polyethylene, UHMWPE, and implantable grade polyetheretherketone (PEEK) or other similar materials (e.g., PAEK,

PEKK, PEK, PEEKK and PEKEKK). The exemplary vertebral implant **10** includes a perimeter wall **12** that extends between a superior surface **14** and an inferior surface **16**. The superior surface **14** and inferior surface **16** are bone-contact surfaces in that they are positioned adjacent to and facing a vertebral endplate once the vertebral implant **10** is inserted into a patient.

[0020] The vertebral implant **10** shown in FIG. **1** includes a kidney shape, though other shapes may be used. In further embodiments, the vertebral implant **10** may take on other types of configurations, such as, for example, a circular shape, semi-oval shape, bean-shape, D-shape, elliptical-shape, egg-shape, or any other shape that would occur to one of skill in the art. The vertebral implant **10** may take on substantially solid configurations, such as, for example, block-like or plate-like configurations that do not define an open inner region. In other embodiments, the vertebral implant **10** could also be described as being annular, U-shaped, C-shaped, V-shaped, horseshoe-shaped, semi-circular shaped, semi-oval shaped, or other similar terms defining an implant including at least a partially open or hollow construction.

[0021] The exemplary vertebral implant **10** includes one or more apertures **18** disposed about the perimeter wall **12** that provide a location at which to grasp the vertebral implant **10** during surgical installation. In some instances, the vertebral implant **10** is constructed of a material that is solid, but somewhat flexible or compressible. Thus, the apertures **18** may contribute to the overall flexibility and/or compressibility of the vertebral implant **10**.

[0022] FIG. **2** depicts a top view of the exemplary vertebral implant **10** oriented relative to a vertebral body **V**, which is depicted in dashed lines. The vertebral implant **10** is positioned substantially within the cortical rim **R** of the vertebral body **V**. Further, the vertebral implant **10** is positioned in contact with one of the end plates **P** of the vertebral body **V**. Accordingly, the vertebral implant **10** includes a superior surface **14** and an inferior surface **16** that contact the bony end plates **P** of vertebral bodies **V**. Improved results may be obtained if the superior surface **14** and inferior surface **16** of the implant **10** fuse with the end plates **P**.

[0023] Where the implant **10** is constructed of a generally non-osteoconductive material, an osteoconductive insert may be formed into the implant to promote bone growth at the superior **14** and inferior **16** surfaces of the implant **10**. To that end, FIG. **3** shows a section view of the vertebral implant **10** taken from the direction indicated by the section lines in FIG. **2**. The section view in FIG. **3** shows that the implant **10** is constructed of an intermediate portion **24** and two inserts **20**, **22**. Generally, the intermediate portion **24** may be constructed of a non-osteoconductive polymer while inserts are constructed from osteoconductive materials. In one embodiment, the inserts **20**, **22** are formed from a material or with a construction that provides a greater degree of osteoconduction than the intermediate portion **24**. The inserts **20**, **22** are disposed at the superior **14** and inferior **16** surfaces of the implant **10** and provide an interface surface into which bone growth is permissible.

[0024] The inserts **20**, **22** may be constructed from an osteoconductive or osteoinductive matrix that includes materials such as collagen, carbon fibers, including continuous or chopped carbon fibers. The inserts may include carbon nanofibers, or metallic filaments including titanium, tantalum, or stainless steel. The inserts **20**, **22** may be constructed from a composite matrix of non-osteoconductive polymers filled

with osteoconductive materials. The inserts **20**, **22** may be constructed from a braided or woven fabric of biocompatible material. In general, the inserts **20**, **22** may be thin relative to the overall height of the implant **10**. For example, the inserts **20**, **22** may have a thickness between about 1 and 10 mm. In one embodiment, the inserts **20**, **22** have a thickness between about 3 mm and about 5 mm. The relatively thin nature of the inserts advantageously permits osseointegration while preserving the overall structural characteristics of the implant **10**.

[0025] As indicated, the inserts **20**, **22** may include osteoconductive fibers. These fibers **26** are depicted graphically in FIG. **4**, which shows a detailed portion of the section view provided in FIG. **3**. In one embodiment, the fibers **26** are oriented randomly. In one embodiment, the fibers **26** are oriented at least partially transverse to an interface surface **28** between the insert **20** (or **22**) and the intermediate portion **24**. In one embodiment, the fibers **26** extend through the interface surface **28** so that they are anchored in each of the insert **20** and the intermediate portion **24**. The fibers **26** may include carbon fibers, metal filaments, or fibers from a woven or braided biocompatible material.

[0026] For the various embodiments disclosed herein, FIGS. **5A-5D** depict exemplary process steps that may be performed to join the osteoconductive inserts **20**, **22** to the intermediate portion. The process steps generally illustrate a molding process whereby the intermediate portion **24** is molded onto pre-formed inserts **20**, **22**. The inserts **20**, **22** may be formed through a separate molding process, including compression molding, injection molding, or a machining operation where the inserts are cut from stock material.

[0027] The exemplary process contemplates a mold **100** that is used to injection mold the intermediate portion **24** onto the inserts **20**, **22**. Other techniques may be used and the present illustration is provided merely as one possible approach. In a first step shown in FIGS. **5A** and **5B**, the preformed inserts **20**, **22** are positioned within a mold cavity **106**, **108** of respective mold halves **102**, **104**. Once the inserts **20**, **22** are positioned as desired, the mold is closed as illustrated in FIG. **5B**. In the embodiment depicted, the mold halves **102**, **104** are substantially equilateral. That is, the mold halves **102**, **104** form a parting line near the midline of the implant **10**. Those skilled in the art will recognize that more complex mold configurations including multiple components may be required depending on implant complexity and geometry. The illustrated mold halves **102**, **104** include injection ports **110** through which resin material is forced to fill the mold **100**.

[0028] Once the mold **100** is closed, resin material **112** from which the intermediate portion is formed is injected through the injection ports **110** and into the mold cavities **106**, **108**. FIG. **5C** illustrates the resin material **112** in fluid form partially filling the mold cavities **106**, **108**. After a sufficient amount of additional resin material **112** is added to completely fill the mold cavities **106**, **108**, the resin material **112** is allowed to set and harden. Once the resin material **112** has cured, the mold **100** is separated and the implant **10** may be removed as shown in FIG. **5D**.

[0029] In the embodiment illustrated in FIGS. **3-5**, the inserts **20**, **22** about the intermediate portion **24**. Adhesion between the components **20**, **22**, **24** may be improved via fiber orientation as shown above. Adhesion may be improved where the inserts **20**, **22** are at least partially porous so that resin material may expand into the inserts **20**, **22** during the process of forming the intermediate portion **24** onto the

inserts 20, 22. Alternately, the inserts 20, 22, may include anchor features as depicted in the embodiments shown in FIGS. 6 and 7.

[0030] FIG. 6 shows an implant 10A including inserts 20A, 22A, and an intermediate portion 24A. In the illustrated embodiment, the inserts 20A, 22A include a plurality of anchors 30 comprising a stem portion 32 and an enlarged head portion 34. In embodiments where the injectable resin 112 comprises a curable liquid that forms the intermediate portion 24A, the cured material may harden in the undercuts adjacent the stem portion 32, between the head portion 34 and the inserts 20A, 22A. The anchors 30 may provide a more secure bond between the intermediate portion 24A and the inserts 20A, 22A.

[0031] Similarly FIG. 7 shows an implant 10B including inserts 20B, 22B, and an intermediate portion 24B. In the illustrated embodiment, the inserts 20B, 22B include a plurality of anchors 36 comprising a recess 38. As above, the injectable resin 112 may harden in the recesses 38. The anchors 36 may provide a more secure bond between the intermediate portion 24B and the inserts 20B, 22B.

[0032] In embodiments described above, the inserts 20, 22 have formed substantially the entire superior 14 and inferior surfaces 16 of the implant 10. However, this is not expressly required. The inserts 20, 22 may extend over some area that is less than the entire bone-contact surface. For instance, FIG. 8 shows an embodiment of an implant 10C in which the osteoconductive inserts 20C, 22C are disposed at the superior 14 and inferior 16 surfaces of the implant 10C. However, the inserts 20C, 22C form less than the entire superior 14 and inferior 16 surfaces, respectively. The intermediate portion 24C forms the remaining portion of the superior 14 and inferior 16 surfaces.

[0033] In addition, there is no express limitation on the number of inserts 20, 22 that are included at the bone contact surfaces of the implant 10. Thus, for example, FIG. 9 shows an implant 10D in which the superior surface 14 includes a plurality of osteoconductive inserts 20D, 120D. In the present embodiment, two inserts 20D, 120D are provided at the superior surface 14, though a larger number of inserts 20D, 120D may be provided. Likewise, the inferior surface 16 includes two osteoconductive inserts 22D, 122D, though a larger number may be included in the implant 10D.

[0034] Embodiments described above have pertained to vertebral implants 10 in which superior and inferior bone contact surfaces are located on the same body. However, this is not expressly required. The curvature of the respective bone contact surfaces may be disposed in separate implants or separate implant members such as the vertebral implant 110 shown in FIG. 10. The vertebral implant 110 represents a spinal arthroplasty device and comprises three main components: a first end plate 112, a second end plate 114, and a nucleus 116. In the orientation shown, the first end plate 112 is a superior end plate while the second end plate 114 is an inferior end plate. Each end plate 112, 114 may include a respective bone interface surface 118, 120 that is placed in contact with a corresponding a vertebral member (not shown). The nucleus 116 is positioned between the end plates 112, 114. The interface between the nucleus 116 and each end plate 112, 114 is a sliding interface that allows for sliding motion of the nucleus 116 relative to the end plates 112, 114. The arrows labeled A and B in FIG. 10 illustrates this sliding motion. In the illustrated embodiment, each end plate 112,

114 is constructed with an osteoconductive insert 130, 132 that is formed onto a resin substrate 134, 136, respectively.

[0035] The vertebral implant 110 shown in FIG. 10 is configured to restore motion between vertebral bodies. In other procedures, such as vertebrectomies or corpectomies, one or more vertebral bodies are removed and an implant is inserted in the space left by the removed vertebrae. These types of devices include multiple components similar to the implant 110. For example, FIG. 11 illustrates an exemplary corpectomy device 210 in which an expandable cage 216 is disposed between end plates 212, 214. Other types of devices may include spacers, rods, or other fixed or expandable members spanning a distance between first and second end plates 212, 214. As illustrated, osteoconductive inserts 230, 232 may be incorporated onto a non-osteoconductive resin substrate 234, 236 to promote bone growth at respective bone-contact surfaces.

[0036] An exemplary process for making the vertebral implants may include steps of providing an osteoconductive insert comprising a bone contact surface and a substrate interface, orienting a matrix of fibers to extend outward from the interface surface, and forming a body constructed at least partially from a biocompatible polymer into the substrate interface and around the matrix of fibers. Forming the body in this manner may include extending the matrix of fibers into the body between about one and two millimeters. Furthermore, it may be appropriate to orienting the matrix of fibers substantially transverse to the substrate interface. The osteoconductive insert may be positioned to cover substantially the entire bone contact surface of the vertebral implant. The matrix of fibers may comprise carbon fibers or metal fibers.

[0037] Another exemplary process for making the vertebral implants may include steps of preforming an osteoconductive insert, inserting the osteoconductive insert into a mold, introducing a biocompatible polymer into the mold and forcing the biocompatible polymer into contact with the insert, and causing the polymer to cure within the insert so that the insert forms a bone contact surface of the vertebral implant. These process steps may further include positioning the osteoconductive insert to form substantially all of the bone contact surface of the vertebral implant. The preforming process may include exemplary processes such as molding osteoconductive material to form the osteoconductive insert and forming a porous matrix of fibers into the osteoconductive insert. Furthermore, the step of forcing the polymer into contact with the insert further may cause the polymer to cure around a matrix of fibers that extend outward from an outer surface of the osteoconductive insert.

[0038] The osteoconductive inserts are not limited to vertebral implants. For example, osteoconductive inserts may be incorporated into other orthopedic implants formed from a non-osteoconductive resin such as tibial and femoral knee components, hip stems, and acetabular cups 300 such as that shown in FIG. 12. The illustrated cup 300 includes a substrate portion 302 that is sized and shaped to accept a femoral stem 310. An osteoconductive insert 304 is formed onto the substrate 302. The acetabular cup 300 may be molded using the process steps similar to that depicted in FIGS. 5A-5D.

[0039] Furthermore, embodiments disclosed above have not included any particular surface geometry, coating, or porosity as are found in conventionally known vertebral implants. Surface features such as these are used to promote bone growth and adhesion at the interface between an implant and a vertebral end plate. Examples of features used for this

purpose include, for example, teeth, scales, keels, knurls, and roughened surfaces. Some of these features may be applied through post-processing techniques such as blasting, chemical etching, and coating, such as with hydroxyapatite. The bone interface surfaces, including the osteoconductive inserts, may also include growth-promoting additives such as bone morphogenetic proteins. Alternatively, pores, cavities, or other recesses into which bone may grow may be incorporated via a molding process. Other types of coatings or surface preparation may be used to improve bone growth into or through the bone-contact surfaces. However, the inserts that include these types of features may still be formed and characterized by the aspects disclosed herein.

[0040] Spatially relative terms such as “under”, “below”, “lower”, “over”, “upper”, and the like, are used for ease of description to explain the positioning of one element relative to a second element. These terms are intended to encompass different orientations of the device in addition to different orientations than those depicted in the figures. Further, terms such as “first”, “second”, and the like, are also used to describe various elements, regions, sections, etc and are also not intended to be limiting. Like terms refer to like elements throughout the description.

[0041] As used herein, the terms “having”, “containing”, “including”, “comprising” and the like are open ended terms that indicate the presence of stated elements or features, but do not preclude additional elements or features. The articles “a”, “an” and “the” are intended to include the plural as well as the singular, unless the context clearly indicates otherwise.

[0042] The present invention may be carried out in other specific ways than those herein set forth without departing from the scope and essential characteristics of the invention. For instance, the implant **10** depicted in FIGS. **2-9** may be described as an ALIF device, implantable from an anterior approach. However, the osteoconductive inserts may be incorporated in other types of vertebral implants, including but not limited to TLIF or PLIF devices. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive, and all changes coming within the meaning and equivalency range of the appended claims are intended to be embraced therein.

What is claimed is:

1. A vertebral implant device for insertion between vertebral bodies in a patient, the implant comprising:
 - an insert comprising a first bone contact surface and an opposing second surface, the insert constructed from an osteoconductive material with fibers with some of the fibers including a first section positioned in the insert and a second section that extends outward from the second surface, the insert also including an anchor that extends outward from the second surface a greater distance than the second sections of the fibers; and
 - a non-osteoconductive body attached to the second surface of the insert and being formed from a different material than the insert;
 - the second sections of the fibers and the anchor being positioned in the body;
 - the insert and the anchor having a unitary construction formed from the osteoconductive material.
2. The vertebral implant of claim 1, wherein the fibers include carbon fibers.
3. The vertebral implant of claim 1, wherein the fibers include metallic filaments.

4. The vertebral implant device of claim 1, wherein the fibers that extend outward from the second surface are aligned approximately perpendicular to an interface between the insert and the body.

5. The vertebral implant device of claim 1, wherein the anchor includes a stem that extends outward from the second surface of the insert and an enlarged head spaced away from the second surface of the insert, the enlarged head including a greater width than the stem.

6. The vertebral implant device of claim 5, wherein the head includes a major axis that is approximately perpendicular to the stem.

7. The vertebral implant device of claim 1, wherein the insert includes a smaller thickness than the body.

8. The vertebral implant device of claim 1, wherein an additional number of the fibers are completely embedded within the insert.

9. A vertebral implant device for insertion between first and second vertebral bodies in a patient, the implant comprising:
 - a body constructed from a first material and having a first side and an opposing second side;

- an insert attached to the first side of the body and being constructed from a second material having a plurality of fibers;

- an anchor that extends outward from the insert into the body, the anchor including a stem adjacent to the insert and a head spaced away from the insert and positioned at an end of the stem, the stem including a smaller width than the head; and

- the anchor and a portion of the plurality of fibers extending outward from the insert and into the body to improve adhesion between the body and the insert.

10. The vertebral implant device of claim 9, wherein the plurality of fibers are aligned approximately perpendicular to an interface between the body and the insert.

11. The vertebral implant of claim 9, wherein the plurality of fibers includes one of carbon fibers and metallic filaments.

12. The vertebral implant device of claim 9, wherein the insert extends completely across the first side of the body and includes a smaller thickness than the body.

13. The vertebral implant device of claim 9, wherein a second portion of the plurality of fibers are completely embedded within the insert.

14. A vertebral implant device for insertion between first and second vertebral bodies in a patient, the implant comprising:
 - an intermediate portion constructed of a first material and including a first side and a second side;

- a first insert attached to the first side of the intermediate portion and including a first contact surface configured to contact against the first vertebral body when the vertebral implant device is inserted in the patient;

- a second insert attached to the second side of the intermediate portion including a second contact surface configured to contact against the second vertebral body when the vertebral implant device is inserted in the patient;

- each of the inserts being constructed from a second material with a plurality of fibers, a portion of the plurality of fibers of each of the first and second inserts extending into the intermediate portion;

- a plurality of anchors that extend outward from the first and second inserts and into the intermediate portion, each of the plurality of anchors including a stem adjacent to the insert and a head spaced away from the insert and positioned at an end of the stem.

15. The vertebral implant device of claim **14**, wherein the first insert and at least one of the plurality of anchors are integrally formed from the second material and have a one-piece construction.

16. The vertebral implant device of claim **15**, wherein the second insert and at least another one of the plurality of anchors are integrally formed from the second material and have a one-piece construction.

17. The vertebral implant device of claim **14**, wherein the portion of the plurality of fibers that extend outward from the first insert are aligned approximately perpendicular to an interface between the intermediate portion and the first insert.

18. The vertebral implant device of claim **17**, wherein the portion of the plurality of fibers that extend outward from the second insert are aligned approximately perpendicular to an interface between the intermediate portion and the second insert.

19. The vertebral implant of claim **16**, wherein the plurality of fibers include one of carbon fibers and metallic filaments.

20. The vertebral implant device of claim **15**, wherein each of the first and second inserts include a smaller thickness than the intermediate portion.

* * * * *