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(54) **COMPOSITE ORTHOPEDIC IMPLANT HAVING A LOW FRICTION MATERIAL SUBSTRATE WITH PRIMARY FRICTIONAL FEATURES AND SECONDARY FRICTIONAL FEATURES**

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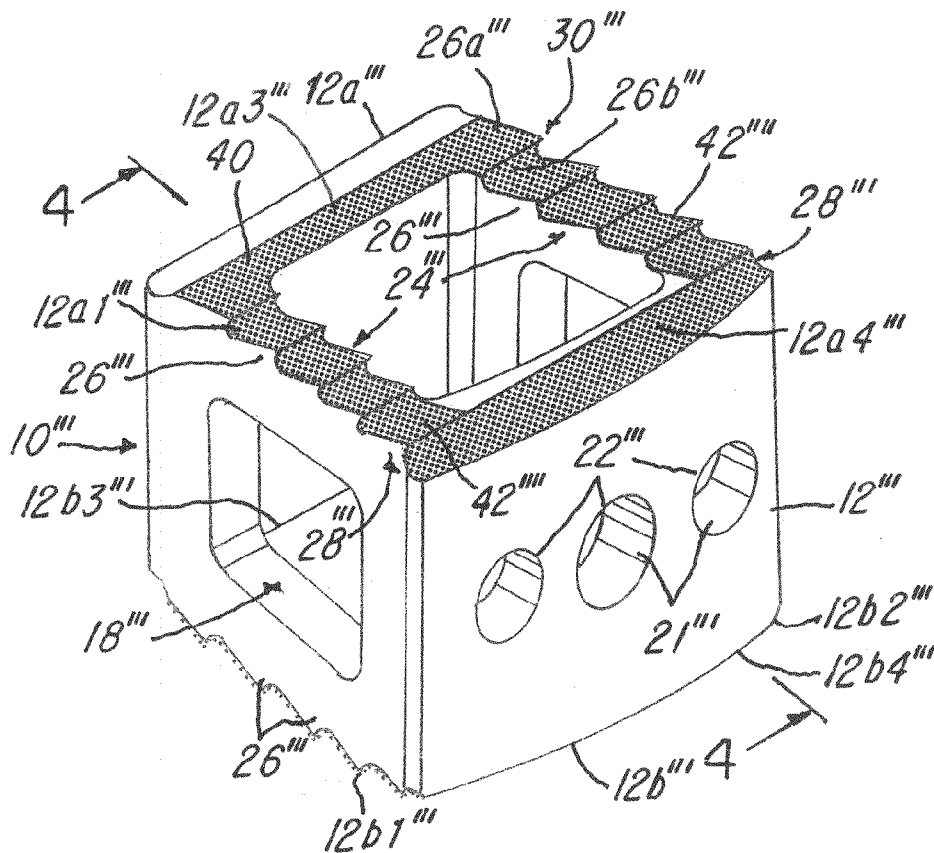
Related U.S. Application Data

(63) Continuation of application No. 14/154,577, filed on Jan. 14, 2014, now Pat. No. 8,979,934, which is a continuation of application No. 13/184,856, filed on Jul. 18, 2011, now abandoned.

(60) Provisional application No. 61/365,912, filed on Jul. 20, 2010.

(57) **ABSTRACT**

An orthopedic implant comprising a substrate material adapted to provide the orthopedic implant. The implant has a primary friction area located on or integral with the substrate material. The primary friction area defining an engagement surface having a primary frictional feature. A secondary friction area is located on or integral with the engagement surface and defining a second frictional feature. The primary friction area and the secondary friction area defining a friction interface zone between the orthopedic implant and at least one bone. The secondary friction area increases a friction of the engagement surface and modulus of elasticity to enhance the frictional engagement between the engagement surface and the at least one bone.



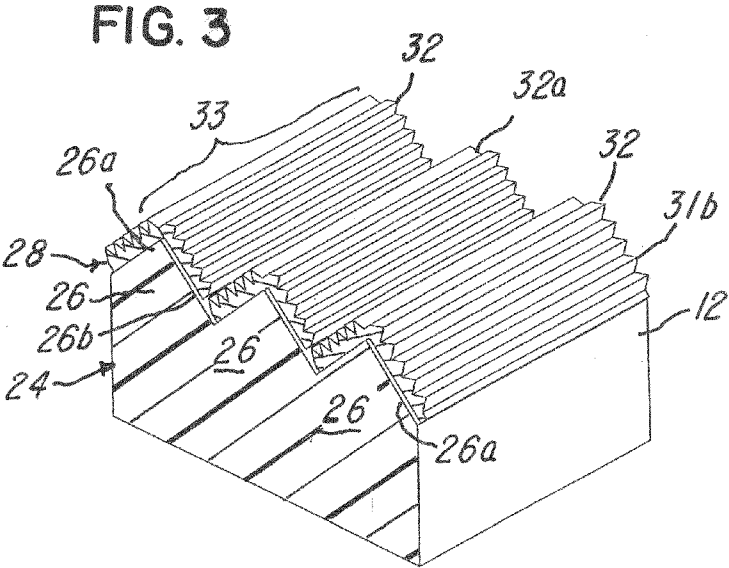
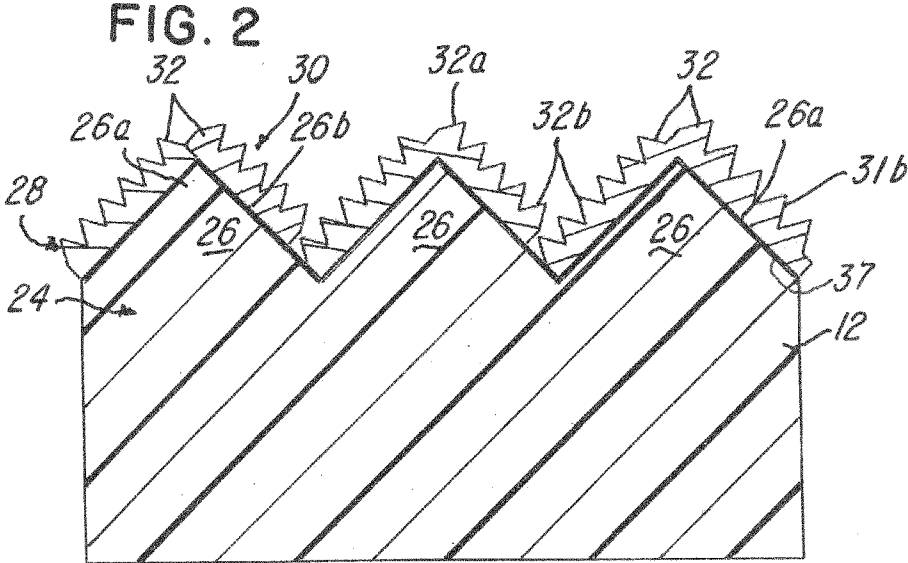


FIG. 6A

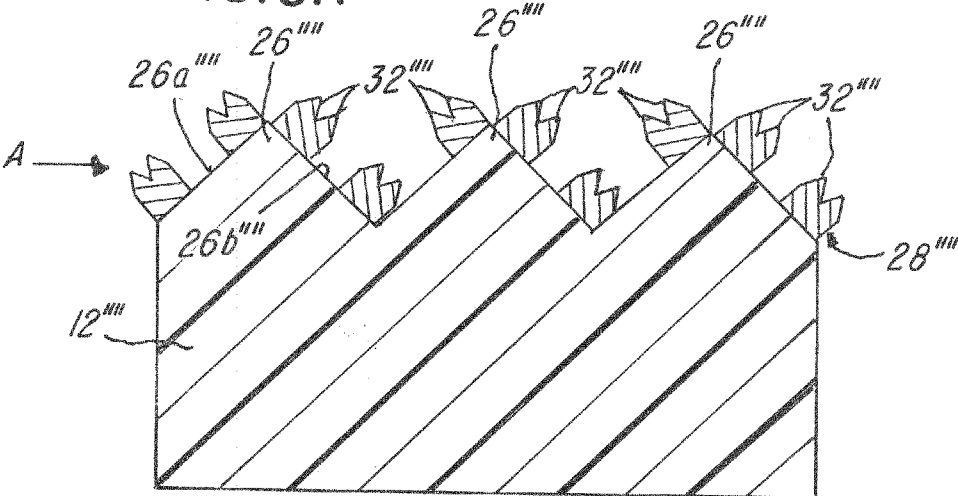


FIG. 6B

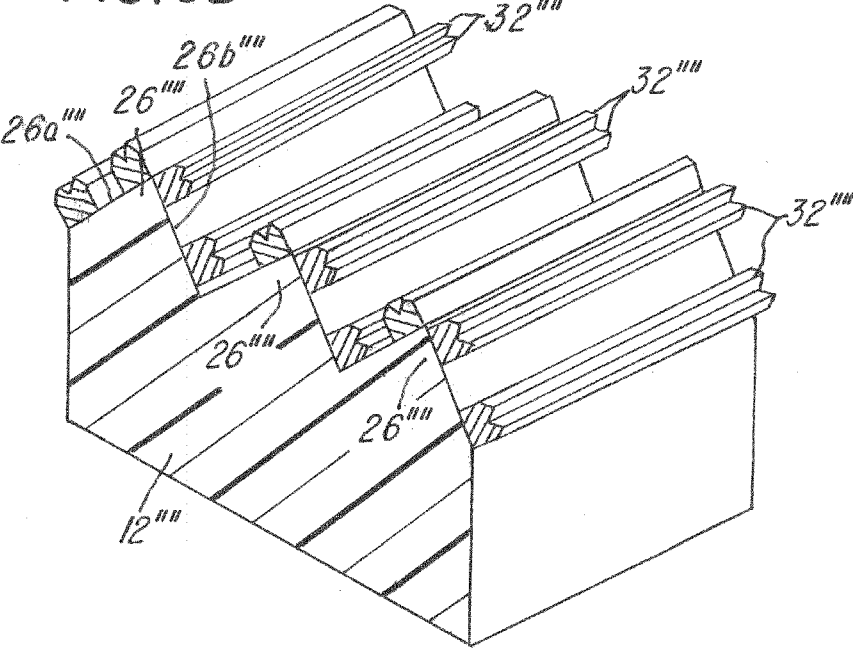


FIG. 7

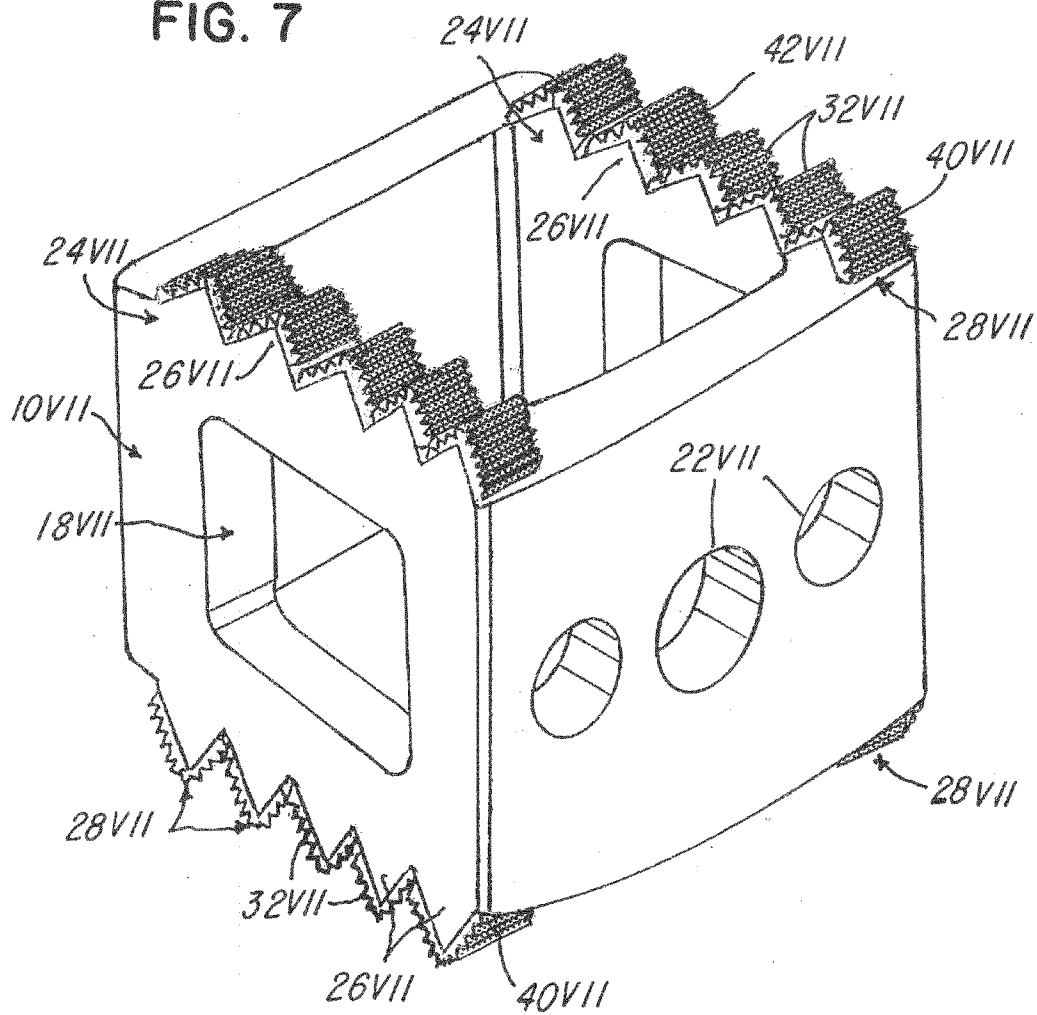


FIG. 8A

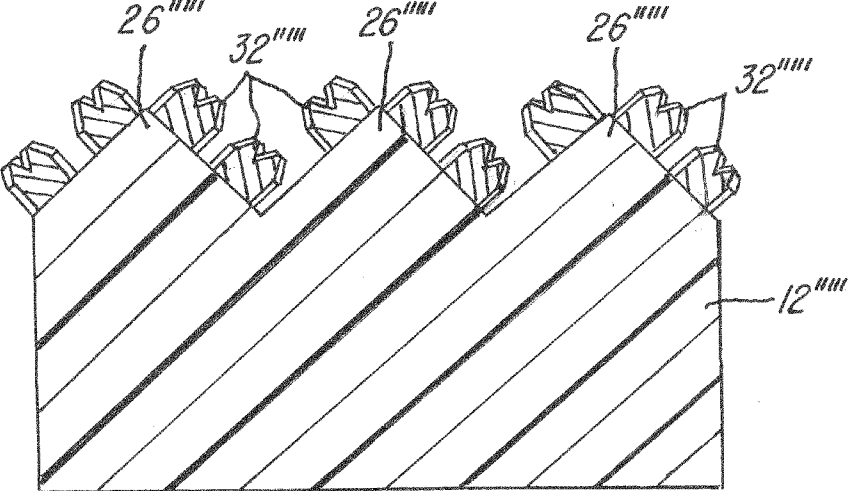


FIG. 8B

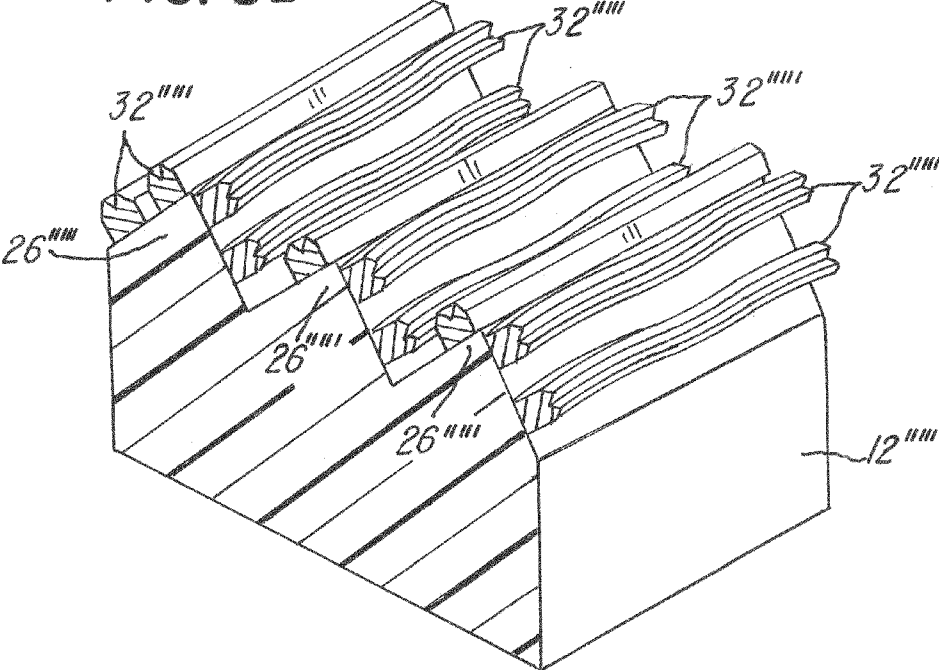


FIG. 9A

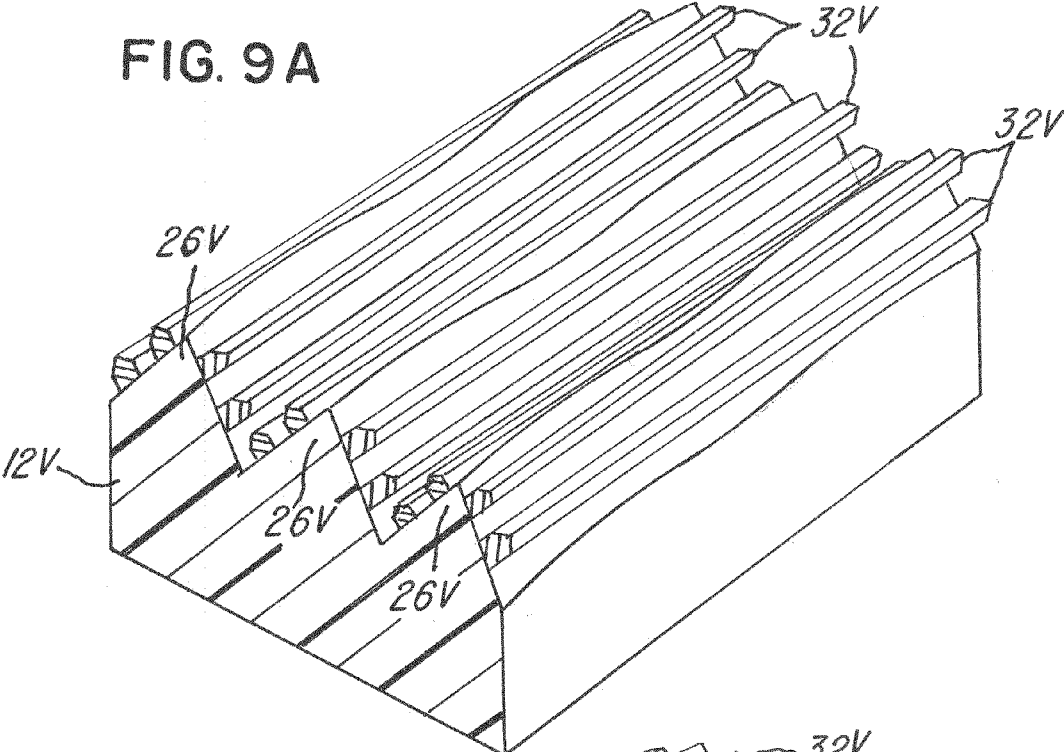
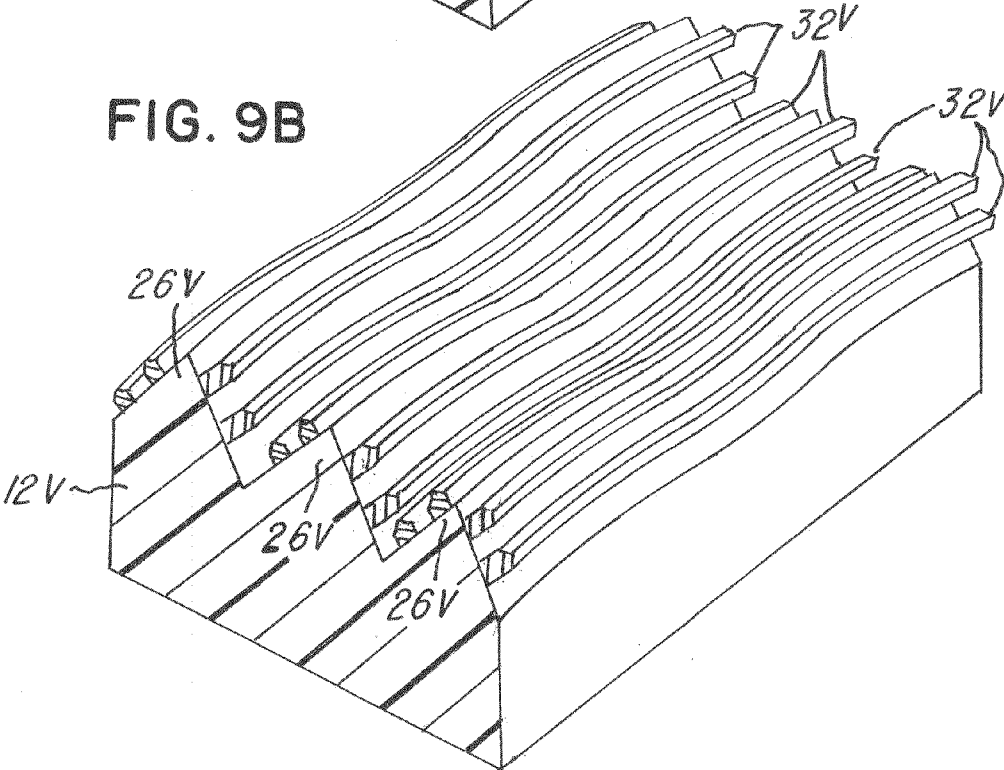


FIG. 9B



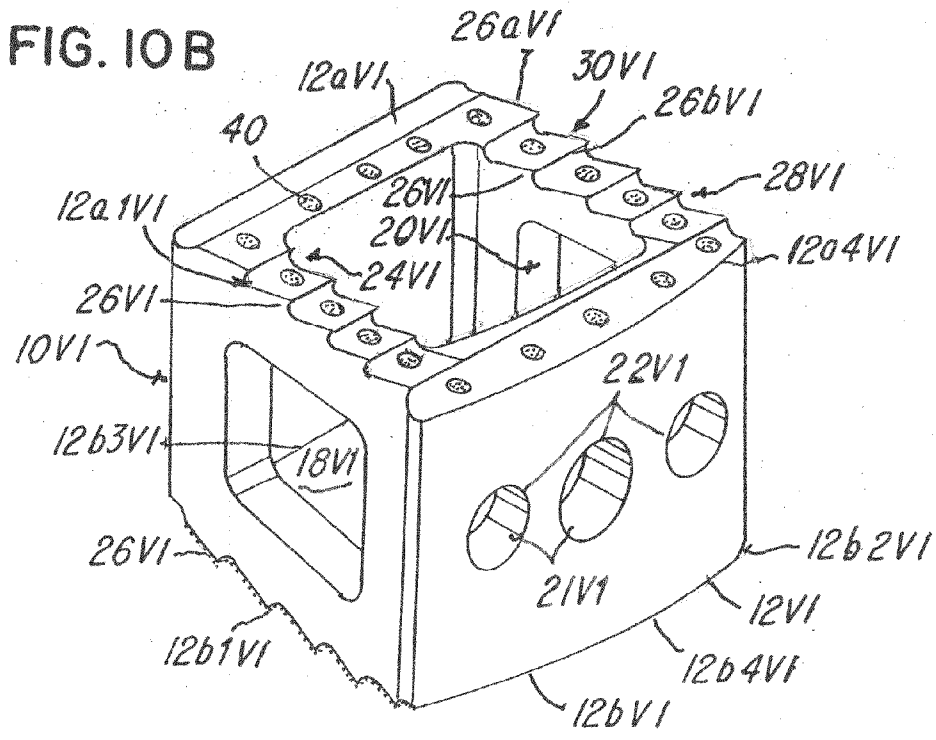
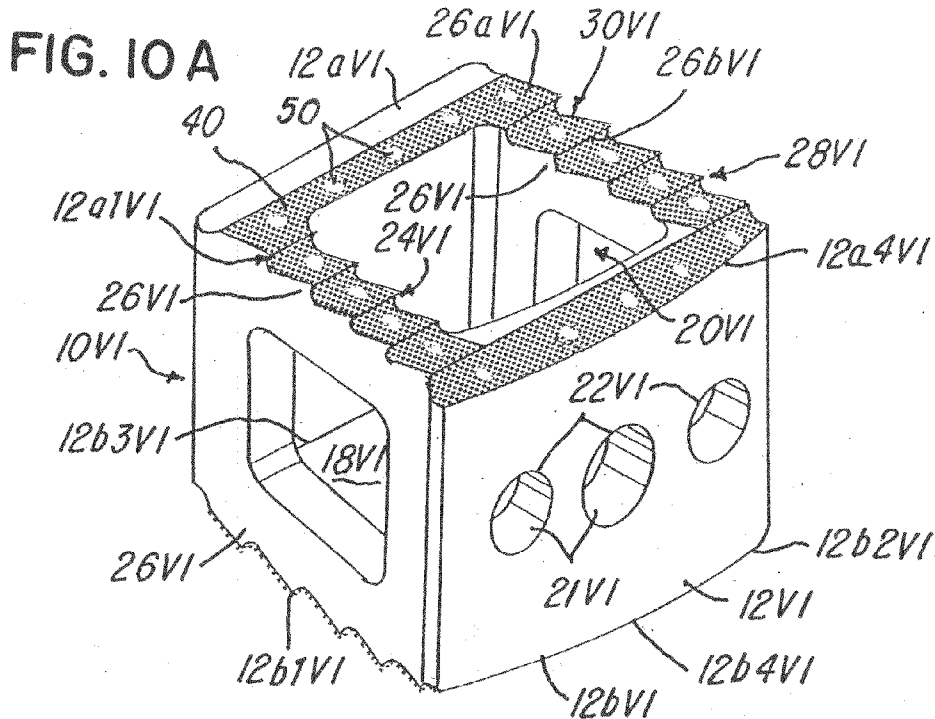


FIG. 11

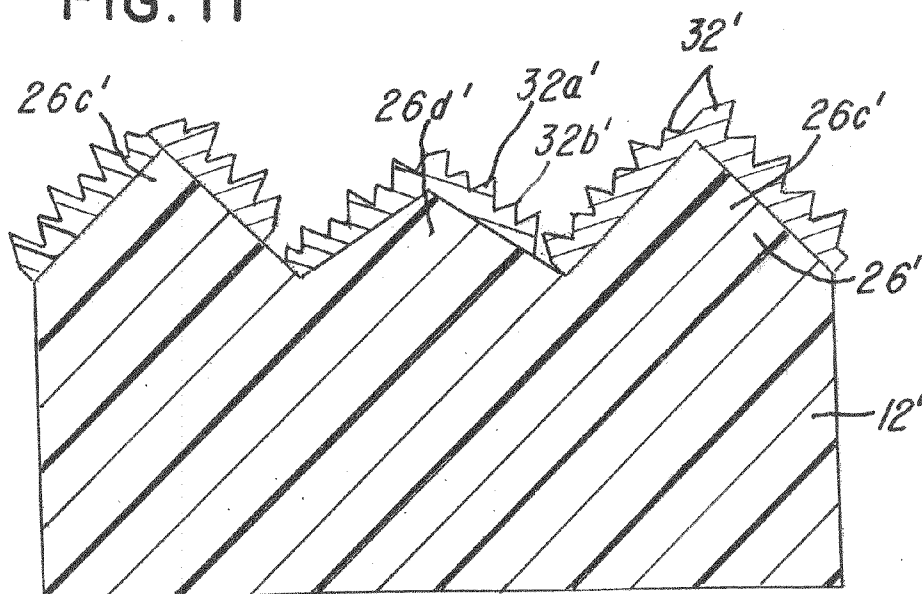


FIG. 12A

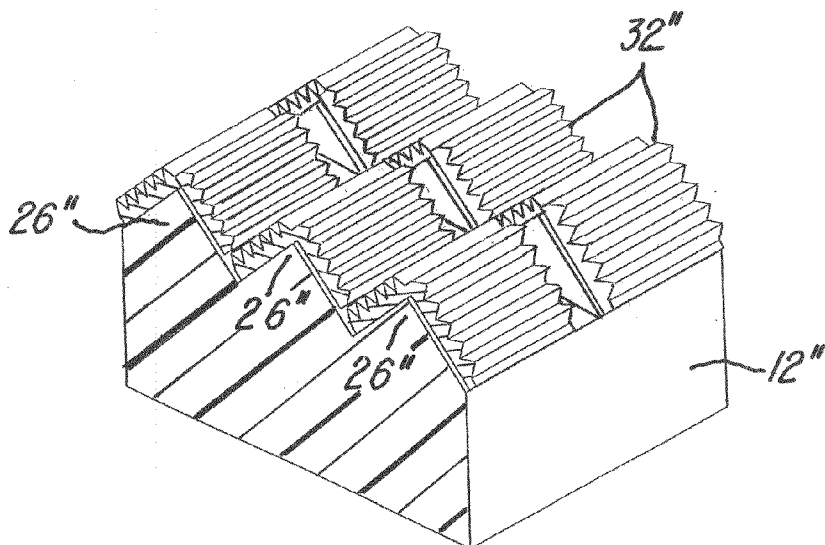
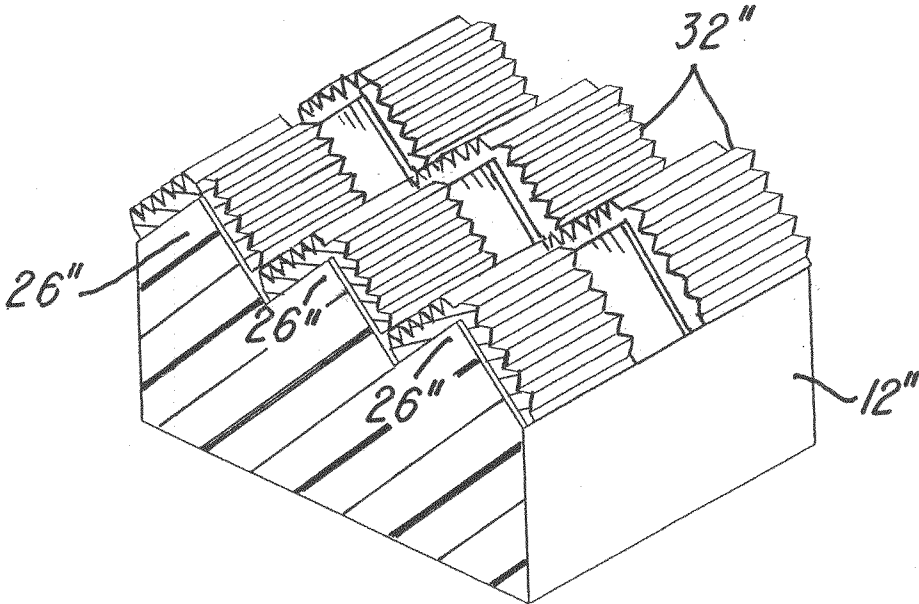


FIG. 12B



**COMPOSITE ORTHOPEDIC IMPLANT
HAVING A LOW FRICTION MATERIAL
SUBSTRATE WITH PRIMARY FRICTIONAL
FEATURES AND SECONDARY FRICTIONAL
FEATURES**

**CROSS-REFERENCE TO RELATED
APPLICATIONS**

[0001] The present application is a continuation of U.S. application Ser. No. 14/154,577 filed Jan. 14, 2014, which is a continuation of U.S. application Ser. No. 13/184,856 filed Jul. 18, 2011, which claims priority to provisional U.S. Application Ser. No. 61/365,912 filed Jul. 20, 2010, to which Applicant claims the benefit of the earlier filing date. These applications are incorporated herein by reference and made a part hereof.

BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention

[0003] This invention relates to a composite orthopedic implant having a low friction material substrate with primary frictional features and secondary frictional features.

[0004] 2. Description of the Related Art

[0005] The placement of spinal implants between vertebrae is a common surgical procedure. A number of such spinal implants, which are generally hollow and box-shaped or cylindrical, have been developed. One risk of such procedures is the post-operative expulsion or dislocation of the implanted device. There is a need to increase the frictional forces between the device and the bone surface.

[0006] The most advantageous material for the manufacture of intervertebral spinal implants is thermoplastic polymer, of which the most commonly used is polyetheretherketone (PEEK). This material has proven biocompatibility with human tissue and is biomechanically strong enough to withstand long-term cyclical loading as occurs within the spine. This type of material has a modulus of elasticity similar to bone, reducing the probability of bone subsidence which can occur with harder metallic implants. A significant problem, however, with the use of such polymeric spinal implants is inherent low levels of bone-device surface interaction. Machined or molded polymeric materials tend to have relatively high levels of lubricity, elasticity, and smoothness which conspire to reduce friction at the bone-device interface. This can result in undesirably low frictional forces between bone and the implanted device. Several parties have attempted to address this issue by adding large frictional features to the polymer implant. These features are typically exemplified by surface teeth of various designs. Although surface teeth increase interface friction somewhat, the underlying challenges of lubricity, smoothness and elasticity remain.

[0007] What is needed, therefore, is a polymer implant that builds upon the current state of the art.

SUMMARY OF THE INVENTION

[0008] One object of an embodiment is to provide simple frictional features that add a metallic surface material which has features of low lubricity, low elasticity and secondary frictional features. Such a design will maintain the desirable biomechanical properties of the polymeric implant itself while addressing frictional shortcomings at the bone-device

interface. Physical properties of the metallic surface can be further optimized using dispersed deposition techniques onto the polymeric substrate.

[0009] A composite bone-device interface used, in its preferred embodiment, in an orthopedic implant for the support of spinal vertebrae. The interface is manufactured from, in its preferred embodiment, a combination of biocompatible materials, which comprise a bone-device interface zone. The interface zone comprises a relatively low friction polymeric substrate material and primary frictional features. The primary frictional features further comprise a high-friction surface material containing secondary frictional features.

[0010] One object of one embodiment is to provide a primary friction feature in combination with a secondary friction feature.

[0011] Another object is to provide an embodiment where the primary friction feature is integral with the body and comprises the same material as the body, such as a polymeric substrate, whereas the secondary friction feature which is integral with, applied to, deposited on or otherwise adhered to the primary friction feature is of a different substrate, such as a metal or a metal alloy.

[0012] Still another object is to provide a surgical implant having improved frictional engagement at the bone-implant engaging interfaces.

[0013] Still another object is to provide an embodiment wherein the secondary frictional features are plasma vapor depositions on the primary frictional features.

[0014] Still another embodiment is to provide an implant having a body with both primary frictional features and secondary frictional features.

[0015] Yet another object of one embodiment is to provide primary and secondary frictional features in the form of teeth or serrations that can be regular or irregular in shape, discontinuous or continuous or otherwise have different or the same shape or configuration with respect to each other.

[0016] Another object of an embodiment is to provide secondary frictional features in the form of elongated teeth that are situated on or integral with the primary frictional features, which in one embodiment are also teeth, and which are either regular and uninterrupted or irregular and interrupted.

[0017] In one aspect, one embodiment comprises an orthopedic implant comprising a substrate material adapted to provide the orthopedic implant, a primary friction area located on or integral with the substrate material, the primary friction area having a primary surface having a primary frictional feature, and a secondary friction area located on or integral with the primary surface and defining a secondary frictional feature, the primary friction area and the secondary friction area defining a friction interface zone, the secondary friction area increasing a friction of the primary surface to enhance the frictional engagement between the primary surface and at least one bone, wherein the primary surface defines a plurality of teeth or serrations, wherein the secondary frictional feature defines a plurality of teeth, points or peaks located on or integral with the primary friction area.

[0018] In another aspect, another embodiment comprises an orthopedic implant comprising a body comprising a composite material, a first friction area situated between the body and bone of a patient when the orthopedic implant is implanted in the patient, the first friction area comprising a plurality of teeth or serrations, and a second friction area associated with the first friction area for directly engaging the bone, wherein the second friction area defines a plurality of

teeth, points or peaks located on or integral with the first friction area, each of the first and second friction areas for improving a frictional engagement between the bone and the orthopedic implant.

[0019] In yet another aspect, another embodiment comprises a method for improving a frictional interface between an implant and bone of a patient, comprising the steps of processing a body to comprise a primary friction feature, and processing the body to comprise a secondary friction feature directly located on or integral with the primary friction feature, wherein the secondary friction feature defines a plurality of teeth, points or peaks that are located on or integral with the primary friction feature.

[0020] This invention, including all embodiments shown and described herein, could be used alone or together and/or in combination with one or more of the features covered by one or more of the claims set forth herein, including but not limited to one or more of the features or steps mentioned in the following bullet list and the claims:

[0021] The orthopedic implant wherein the primary friction area having a primary friction surface that is at least one of machined, molded, extruded, sintered or deposited substrate.

[0022] The orthopedic implant wherein the deposited substrate is a polymeric substrate.

[0023] The orthopedic implant wherein the primary friction surface defines a plurality of teeth or serrations.

[0024] The orthopedic implant wherein the secondary friction area that is at least one of machined, molded, extruded, sintered or deposited substrate.

[0025] The orthopedic implant wherein the secondary friction area comprises at least one of a microscopically or macroscopically rough surface.

[0026] The orthopedic implant wherein the secondary friction area is regular in shape.

[0027] The orthopedic implant wherein the secondary friction area is irregular in shape.

[0028] The orthopedic implant wherein the substrate material is made from a thermoplastic.

[0029] The orthopedic implant wherein the thermoplastic is a polyetheretherketone (PEEK).

[0030] The orthopedic implant wherein a modulus of elasticity of the substrate material is less than or equivalent to bone.

[0031] The orthopedic implant wherein the substrate material has a low coefficient of friction with bone.

[0032] The orthopedic implant wherein at least one of the primary friction area or the secondary friction area being made from a metal or metallic alloy.

[0033] The orthopedic implant wherein at least one of the primary friction area or the secondary friction area having a modulus of elasticity that is the same as or greater than bone.

[0034] The orthopedic implant wherein at least one of the primary friction area or the secondary friction area comprising a higher coefficient of friction with bone.

[0035] The orthopedic implant wherein the primary friction area comprising a higher coefficient of friction with bone and the secondary friction area comprising a higher coefficient of friction than the primary friction area.

[0036] The orthopedic implant wherein the primary friction area having a modulus of elasticity that the same as or greater than bone and the secondary friction area

having a modulus of elasticity that is the same or greater than the primary friction area.

[0037] The orthopedic implant wherein the secondary frictional feature is integral with, welded to, adhered to or otherwise affixed to the primary frictional feature.

[0038] The orthopedic implant wherein the secondary frictional feature is sprayed onto, melted to or applied to the primary friction area.

[0039] The orthopedic implant wherein the secondary frictional feature is defined by particles that are at least one of round, not round or acicular, circular, coarse, acyclic.

[0040] The orthopedic implant wherein the particles are continuous or discontinuous or discrete on at least a portion of the primary frictional feature.

[0041] The orthopedic implant wherein the secondary frictional feature defines a plurality of teeth, points or peaks are located on or integral with the primary friction area.

[0042] The orthopedic implant wherein the plurality of teeth, points or peaks are neither regular nor symmetrical.

[0043] The orthopedic implant wherein the plurality of teeth, points or peaks are regular and symmetrical.

[0044] The orthopedic implant wherein the primary frictional feature and the secondary frictional feature are made from different materials.

[0045] The orthopedic implant wherein the primary frictional feature and the secondary frictional feature are made from the same materials.

[0046] The orthopedic implant wherein the at least one of the primary frictional feature, the secondary frictional feature or the substrate material is made from a different material than the others.

[0047] The orthopedic implant wherein the secondary frictional feature increases a coefficient of friction of the orthopedic implant and bone.

[0048] The orthopedic implant wherein the orthopedic implant is a spinal implant.

[0049] The orthopedic implant wherein the spinal implant is a cage.

[0050] The orthopedic implant wherein the secondary frictional feature is a deposit onto the primary surface.

[0051] The orthopedic implant wherein the deposit is a plasma vapor deposition deposit.

[0052] The orthopedic implant wherein the primary surface defines a plurality of teeth or serrations and the deposit is applied to surfaces of one or more of the plurality of teeth or serrations.

[0053] The orthopedic implant wherein the body and the first friction area comprise have a modulus of elasticity that is lower than a modulus of elasticity of the second friction area.

[0054] The orthopedic implant wherein the second friction area defines a frictional engaging surface that increases a coefficient of friction between the first friction area and the bone.

[0055] The orthopedic implant wherein body is made from a polymeric material, and at least one of the first or second friction areas comprises a metallic or metallic alloy.

[0056] The orthopedic implant wherein the first friction area defines a plurality of teeth or serrations and the second friction area defines a layer or coating thereon.

- [0057] The orthopedic implant wherein the second friction area is uninterrupted.
- [0058] The orthopedic implant wherein the composite material is made from a thermoplastic.
- [0059] The orthopedic implant wherein a modulus of elasticity of the composite material is less than or equivalent to bone.
- [0060] The orthopedic implant wherein a coefficient of friction associated with the composite material and bone is lower than a coefficient of friction between the second friction area and the bone.
- [0061] The orthopedic implant wherein each of the first friction area and the second friction area are made from a metal or metallic alloy and the body is made of a polymer.
- [0062] The orthopedic implant wherein each of the first friction area or the second friction area have a modulus of elasticity that is the same as or greater than bone.
- [0063] The orthopedic implant wherein each of the first friction area and the second friction area comprise a higher coefficient of friction with bone.
- [0064] The orthopedic implant wherein the second friction area is integral with, welded to, adhered to or otherwise affixed to the first friction area.
- [0065] The orthopedic implant wherein the second friction area is sprayed onto, melted to, adhered to or applied to the first friction area.
- [0066] The orthopedic implant wherein the second friction area is defined by particles that are at least one of round, not round, circular, coarse, acyclic.
- [0067] The orthopedic implant wherein the particles are continuous or discontinuous or discrete on at least a portion of the first friction area.
- [0068] The orthopedic implant wherein the second friction area defines a plurality of points or peaks on the first friction area.
- [0069] The orthopedic implant wherein the plurality of points or peaks are neither regular nor symmetrical.
- [0070] The orthopedic implant wherein the plurality of points or peaks are regular and symmetrical.
- [0071] The orthopedic implant wherein the second friction area is a deposit onto the first friction area.
- [0072] The orthopedic implant wherein the first friction area defines a plurality of teeth or serrations and the deposit is applied to surfaces of one or more of the plurality of teeth or serrations.
- [0073] The method wherein the primary friction feature has a primary friction surface that is at least one of machined, molded, extruded, sintered or deposited substrate.
- [0074] The method wherein the least one of machined, molded, extruded, sintered or deposited substrate is a polymeric substrate.
- [0075] The method wherein the primary friction surface defines a plurality of teeth or serrations.
- [0076] The method wherein the secondary friction feature that is at least one of machined, molded, extruded, sintered or deposited substrate.
- [0077] The method wherein the secondary friction feature comprises at least one of a microscopically or macroscopically rough surface.
- [0078] The method wherein the secondary friction feature is regular in shape.
- [0079] The method wherein the secondary friction feature is irregular in shape.
- [0080] The method wherein the least one of machined, molded, extruded, sintered or deposited substrate has a low coefficient of friction with bone.
- [0081] The method wherein at least one of the primary friction surface or the secondary friction feature being a deposit on the primary friction surface of a metal or metallic alloy.
- [0082] The method wherein the secondary friction feature defines a plurality of teeth, points or peaks on the primary friction surface.
- [0083] The method wherein the method comprises the step of depositing the secondary friction feature onto the primary friction feature.
- [0084] The method as wherein the depositing step is performed using plasma vapor deposition.
- [0085] These and other objects and advantages will be apparent from the following description, the accompanying drawings and the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

- [0086] FIG. 1 is a perspective view of one embodiment;
- [0087] FIG. 1A is sectional view taken along the line 1A-1A in FIG. 1;
- [0088] FIG. 2 is an enlarged view of a portion of the implant shown in FIG. 1 showing details of the primary friction feature and secondary friction feature;
- [0089] FIG. 3 is a perspective view of the enlargement shown in FIG. 2;
- [0090] FIG. 4 is a sectional view taken along the line 4-4 in FIG. 5 illustrating the secondary friction feature in the form of a deposit or coating on the primary friction feature;
- [0091] FIG. 5 is a view of another embodiment showing the primary friction feature as teeth and the secondary friction feature as a deposit or coating;
- [0092] FIGS. 6A-6B is a view of another embodiment of the invention showing the elongated teeth that are interrupted or spaced in the direction of arrow A;
- [0093] FIG. 7 is a view of another embodiment of the invention similar to FIG. 5;
- [0094] FIGS. 8A-8B are views of the secondary friction features having a curved or serpentine shape;
- [0095] FIGS. 9A-9B illustrate an embodiment wherein the primary friction features have a curved or serpentine shape while the secondary friction features have a generally linear (FIG. 9A) shape or a curved (FIG. 9B) shape;
- [0096] FIGS. 10A-10B illustrate another embodiment similar to FIGS. 4 and 5 wherein the deposit or coating is selectively placed;
- [0097] FIG. 11 illustrates the primary friction feature and secondary friction feature in the form of teeth having different shapes, pitches, pitch thickness and the like; and
- [0098] FIGS. 12A-12B illustrate embodiments wherein the primary friction feature or secondary friction feature are interrupted (FIG. 12A) along their longitudinal length and wherein the primary friction feature is not interrupted along its longitudinal length, but the secondary friction feature is interrupted (FIG. 12B).

DETAILED DESCRIPTION OF PREFERRED
EMBODIMENTS

[0099] Referring now to FIGS. 1-5, a first embodiment of an orthopedic implant 10 is shown. The orthopedic implant 10 comprises a body 12 that is adapted to provide or define the orthopedic implant 10. In the illustration being described, the orthopedic implant 10 could be a spinal implant, such as a cage, plate or other implant wherein surfaces of the orthopedic implant 10 engage, for example, bone of a patient. In one application, the orthopedic implant 10 is situated between adjacent vertebrae (not shown) of a patient. In the illustration being described, the orthopedic implant 10 comprises the body 12 made from a substrate or composite material, such as a polymeric material. The polymeric material may be a thermoplastic material, such as polyetheretherketone (PEEK). The substrate or composite material has a low coefficient of friction with bone.

[0100] The orthopedic implant 10 defines an orthopedic cage 11 in this illustration having a plurality of walls 14a, 14b, 14c and 14d. The walls 14a and 14c have windows 18 and 20 as shown. The orthopedic implant 10 has a plurality of walls 21 that define tool apertures 22 for receiving a tool (not shown) for placement of the orthopedic implant 10, for example, between adjacent vertebrae (not shown) in the patient.

[0101] The orthopedic implant 10 further has a first end 12a and a second end 12b. As best illustrated in FIGS. 2-5, note that the orthopedic implant 10 comprises a first or primary friction area, layer or feature 24 applied to, adhered to or integrally formed on each ends 12a and 12b. In the illustration, the body 12 defines a cage 11 that has four bone-engaging areas or surfaces 12a1, 12a2, 12b1 and 12b2.

[0102] In the illustration being described, the first or primary friction area, layer or feature 24 comprises or is adapted to define a first plurality of teeth or serrations 26 which are integrally formed in the surfaces 12a1, 12a2, 12b1 and 12b2 as shown. The body 12 is machined, molded, extruded, centered, cast or has a deposited substrate that is applied to the body 12 to provide or define the first or primary friction area, layer or feature 24. Although not shown, it should be appreciated that the first or primary friction area, layer or feature 24 may be separate from and non-integral with the body 12, for example, but that is secured thereto by a weld, bond adhesive or other type of fixation. In the illustration being described relative to FIGS. 1-3, the first or primary friction area, layer or feature 24 comprises the first plurality of teeth or serrations 26 that are integral with the body 12 and both are made of the same polymeric substrate, such as polyetheretherketone (PEEK). Alternatively, the body 12 could be made from a polymeric substrate while the first or primary friction area, layer or feature 24 may comprise a metallic or metallic alloy that is applied or, adhered to or otherwise affixed or secured to the body 12. After the orthopedic implant 10 is implanted into the patient, the first or primary friction area, layer or feature 24 becomes situated between the body 12 and the bone of the patient, such as the adjacent vertebra (not shown).

[0103] As mentioned earlier, the first or primary friction area, layer or feature 24 comprises the first plurality of teeth or serrations 26 that are integral with both ends 12a and 12b of the body 12, and each of the areas or surfaces 12a1, 12a2, 12b1 and 12b2 have the first plurality of teeth or serrations 26. For ease of illustration, portions of the first plurality of teeth or serrations 26 on the surface 12a2 are shown fragmentarily and enlarged in FIGS. 2 and 3, but it should be understood that

the first plurality of teeth or serrations 26 of the first or primary friction area, layer or feature 24 on the other portions of surface 12a2 and on the other surfaces 12a1, 12b1 and 12b2 are substantially the same in this embodiment.

[0104] The orthopedic implant 10 further comprises a second or secondary friction area, layer or feature 28 associated with the first or primary friction area, layer or feature 24. In the illustration being described, the second or secondary friction area, layer or feature 28 is applied to, deposited on, adhered to, bonded, located on or integral with the first or primary friction area, layer or feature 24 as shown. In the illustration being shown in FIGS. 1-3, the first or primary friction area, layer or feature 24 and the second or secondary friction area, layer or feature 28 cooperate to define a plurality of friction interface zones 30 (FIGS. 1-1A).

[0105] The second or secondary friction area, layer or feature 28 is applied to, deposited on, adhered to, located on or adhered to teeth surfaces, such as surfaces 26a and 26b (FIG. 2) of each of the first plurality of teeth or serrations 26 on the surfaces 12a1, 12a2, 12b1 and 12b2 where the orthopedic implant 10 engages bone and increases a friction between each of the first plurality of teeth or serrations 26 and the bone of the patient. It has been found that the enhanced frictional engagement facilitates maintaining the position of the orthopedic implant 10 in the patient. For example, it is desirable that the cage 11 illustrated in FIGS. 1 to 5 not move after it is implanted in the patient, and the second or secondary friction area, layer or feature 28 enhances the frictional engagement between the first or primary friction area, layer or feature 24 and the bone of the patient to prevent or minimize such movement.

[0106] The first or primary friction area, layer or feature 24 comprises a first or primary friction feature in the form of the first plurality of teeth or serrations 26, and the second or secondary friction area, layer or feature 28 comprises a second or secondary friction feature that enhances the orthopedic implant's 10 friction interface zone 30. In the embodiment of FIGS. 1-3, 6A-6B, 7, 8A-8B, 9A-9B, 11 and 12A-12B, the second or secondary friction area, layer or feature 28 comprises a second plurality of teeth or serrations 32 integral with, deposited on, adhered to or otherwise applied to one or more of the first plurality of teeth or serrations 26 as shown. The body 12, the first or primary friction area, layer or feature 24 and the second or secondary friction area, layer or feature 28 is manufactured from, in its preferred embodiment, a combination of bio-compatible materials, including but not limited to, at the friction interface zone 30.

[0107] In the illustration being described, the second or secondary friction area, layer or feature 28 may comprise a microscopically and/or macroscopically rough or porous surface, which enhances the frictional engagement between the first or primary friction area, layer or feature 24 and the bone of the patient. The rough surface may be provided by, for example, sand blasting, coating, plasma spraying, vapor deposition, adhering a frictional layer, peening or even laser shock peening.

[0108] The secondary friction features may comprise a machined, molded, extruded, sintered or deposited surface material. In the illustration of FIGS. 4-5, 10A and 10B, the deposited surface material may comprise a coating or deposition that is sprayed onto, melted to or otherwise applied or adhered to the primary surface 26a of the first or primary friction area, layer or feature 24. In the embodiment shown in FIGS. 4, 5, 7 and 10A-10B, the coating or deposition is a

plasma vapor deposition applied using a conventional plasma vapor deposition process. Thus, it should be understood that the second or secondary friction area, layer or feature **28** may be integral with, welded to, machined into, adhered to, deposited on or otherwise affixed, processed or applied to the first or primary friction area, layer or feature **24**.

[0109] In the illustrations being described, the body **12**, the first or primary friction area, layer or feature **24** and the second or secondary friction area, layer or feature **28** may be made from the same bio-compatible material or one or more of them can comprise or be made from different bio-compatible materials. In one embodiment, each of the body **12** and the first or primary friction area, layer or feature **24** are made of a bio-compatible polymeric substrate, such as polyetheretherketone (PEEK), while the second or secondary friction area, layer or feature **28** is comprised of a metal or metallic alloy. In the embodiments of FIGS. 1-5, the body **12** and the first or primary friction area, layer or feature **24** are integral and monolithically formed and are made from the same PEEK material, while the second or secondary friction area, layer or feature **28** is a metallic material, metal, or metallic alloy, such as titanium, cobalt or associated alloys. It should be understood that the body **12**, first or primary friction area, layer or feature **24** and the second or secondary friction area, layer or feature **28** could be the same material, such as a polymer, a metal or metal alloy or different materials.

[0110] The body **12** and the first or primary friction area, layer or feature **24** comprise the polymeric substrate have a relatively low modulus of elasticity and/or a modulus of elasticity equivalent to bone while the second or secondary friction area, layer or feature **28** has a higher modulus elasticity and has a modulus of elasticity that is higher than bone. It should be understood, however, that both of the first or primary friction area, layer or feature **24** and/or the second or secondary friction area, layer or feature **28** could comprise a relatively high modulus of elasticity or a modulus of elasticity that is higher than bone if desired.

[0111] Thus, at least one or both of the first or primary friction area, layer or feature **24** or the second or secondary friction area, layer or feature **28** may comprise a relatively high coefficient of friction with bone, while the underlying substrate or body **12** and the first or primary friction area, layer or feature **24** may comprise a relatively low modulus of elasticity and low coefficient of friction relative to bone. In the embodiment of FIGS. 1-5, the second or secondary friction area, layer or feature **28** comprises a higher coefficient of friction and higher modulus of elasticity compared to the first or primary friction area, layer or feature **24** and body **12** which facilitate the frictional engagement and locking of the orthopedic implant **10** in the patient, such as between the patient's vertebra.

[0112] Thus, it should be understood that while the body **12** and the first or primary friction area, layer or feature **24** and the second or secondary friction area, layer or feature **28** may be made from the same materials having the same coefficient of friction and modulus of elasticity, they could comprise different materials which have either the same or different coefficients of friction and/or the same or different moduli of elasticity. Also, the first or primary friction area, layer or feature **24** and the second or secondary friction area, layer or feature **28** could be different materials and their respective modulus of elasticity and coefficients of friction relative to bone may be different as mentioned earlier.

[0113] Again, it should be understood that one advantage of the embodiments being described is that they enhance the frictional engagement of the orthopedic implant **10** when it is implanted in the patient. Thus, the orthopedic implant **10** having the first or primary friction area, layer or feature **24** comprising the second or secondary friction area, layer or feature **28** will comprise a higher modulus of elasticity and higher coefficient of friction compared to bone.

[0114] Advantageously, the polymers or polymeric materials used in the past may be utilized in manufacturing the body **12** and the shortcomings of such materials can be used to provide the orthopedic implant **10** having the body **12** that has relatively high levels of lubricity, elasticity and smoothness, but which have been adapted, machined or processed as provided herein to provide relatively high modulus of elasticity and high coefficients of friction at the orthopedic implant **10**-bone interface by providing the first or primary friction area, layer or feature **24** with the second or secondary friction area, layer or feature **28** as described herein.

[0115] As mentioned earlier, the first or primary friction area, layer or feature **24** may be machined, molded, integral extruded, sintered or deposited onto the body **12**. The first or primary friction area, layer or feature **24** may be separate from or integral with the body **12** as mentioned earlier. Likewise, the second or secondary friction area, layer or feature **28** may be machined, molded, extruded, sintered or deposited directly on the first or primary friction area, layer or feature **24** and may also be separate from or integral with it. For example, the second or secondary friction area, layer or feature **28** may be sprayed onto, deposited on, melted to, or otherwise applied to or adhered to the first plurality of teeth or serrations **26** surfaces, such as surfaces **26a** and **26b** of each of the first plurality of teeth or serrations **26**, and/or on each surface **12a1**, **12a2**, **12b1** and **12b2** having the first or primary friction area, layer or feature **24**, thereby enhancing the frictional engagement between the orthopedic implant **10** and the bone. As mentioned earlier, the second or secondary friction area, layer or feature **28** may be deposited on these surfaces using a plasma vapor deposition process.

[0116] Returning to the embodiment of FIGS. 1-3, the first or primary friction area, layer or feature **24** comprises the first plurality of teeth or serrations **26** that have peaks and valleys in cross section and are elongated, with each tooth or serration being generally the same in shape and dimension. Likewise, the second or secondary friction area, layer or feature **28** is defined by the second plurality of teeth or serrations **32** that are machined into, integral with, adhered to or applied directly to the surfaces **26a** and **26b** of the first plurality of teeth or serrations **26** as illustrated in FIGS. 1-3. In the illustration being described, the plurality of teeth **32** are thermally bonded, adhered, impregnated, embedded on or in into the teeth **26**. For ease of illustration, FIG. 2 shows bonding of the teeth or serrations **32** to teeth or serrations **26** with an adhesive **37**, but it should be understood that the teeth may be adhered by other means. As with the first plurality of teeth or serrations **26**, the second plurality of teeth or serrations **32**, such as teeth **32a** and **32b** in FIG. 2, may each comprise generally the same shape and be elongated along the longitudinal axis and continuous as shown in FIG. 3. In other words, the first and second pluralities of teeth or serrations **26** and **32** may be regular in shape.

[0117] Note that the first plurality of teeth or serrations **26** are elongated and comprise surfaces **26a** and **26b** comprising the rows or strips **33** of the second plurality of teeth or serra-

tions 32. The rows or strips 33 are made of metal or a metal alloy, such as titanium or other biocompatible substance capable of providing a high-friction layer, in the illustration and adhered to or overmolded with the body 12.

[0118] In the illustration, the orthopedic implant 10 is inserted into the patient and the first or primary friction area, layer or feature 24 and the second or secondary friction area, layer or feature 28 on surfaces 12a1, 12a2, 12b1 and 12b2 frictionally engage bone to secure the orthopedic implant 10 in the patient.

[0119] FIGS. 6-9B and 11-12B illustrate other embodiments with like parts being identified with the same part numbers except that one or more legends or prime marks ("''") have been added to distinguish the various embodiments of these figures.

[0120] Note that the first plurality of teeth or serrations 26' in FIG. 11 comprises different cross-sectional shapes and sizes. Thus, the first and second pluralities of teeth or serrations 26' and 32' may be adapted to be irregular in shape, and the first plurality of teeth or serrations 26' in FIG. 11 could comprise different cross-sectional shapes and sizes. For example, note that tooth 26c' has a different shape and size compared to tooth 26d'.

[0121] Likewise, the shape or size of each individual tooth, such as teeth 32a' and 32b' (FIG. 11) of the second plurality of teeth or serrations 32' may be different. Thus, the individual teeth in each of the first and second plurality of teeth or serrations 26' and 32' could be the same or have different shapes, and they could have different pitches, depths, widths and the like and will be described later herein.

[0122] As mentioned, while the embodiment in FIGS. 1-3 illustrate that each of the first plurality of teeth or serrations 26 and the second plurality of teeth or serrations 32 are generally regular and uninterrupted as shown, but it should be understood that either at least one of both of the first and second pluralities of teeth or serrations 26 and 32 may be non-elongated and interrupted. For example, FIG. 12A illustrates that both the first plurality of teeth or serrations 26" and the second plurality of teeth or serrations 32" that are situated on or integral with each of the first plurality of teeth or serrations 26' are not continuous and are interrupted along their longitudinal axis. FIG. 12B illustrates an embodiment where only the second plurality of teeth or serrations 32" is interrupted, but not the first plurality of teeth or serrations 26". Alternatively, while the embodiments shown in FIGS. 12A and 12B illustrates first and second pluralities of teeth or serrations 26" and 32" being interrupted along their longitudinal axis, it should be understood that there may be a mixture of interrupted and uninterrupted teeth if desired.

[0123] FIGS. 6A-6B illustrate still another embodiment wherein the second plurality of teeth or serrations 32'''' are spaced or interrupted in the direction of arrow A in FIG. 6A-6B as shown. In this regard, it should be appreciated that one or both surfaces of each tooth, such as surfaces 26a'''' and 26b'''' in FIGS. 6A-6B, are shown as having at least one or a plurality of the second plurality of teeth or serrations 32'''' mounted thereon or integral therewith. They are separately shown, but it should be understood that either one or both surfaces of the plurality of teeth or serrations 26'''' , such as surfaces 26a'''' and 26b'''' , may either have or not have less teeth or one or more of the second plurality of teeth or serrations 32'''' .

[0124] Still other embodiments are shown in FIGS. 8A-8B and 9A-9B wherein the second plurality of teeth or serrations

32'''' are shown in a curved or serpentine and non-linear shape. It should be understood that the first plurality of teeth or serrations 26'''' could also be provided in a serpentine or curved shape, with the second plurality of teeth or serrations 32'''' as shown. Although not shown, the first plurality of teeth or serrations 26'''' could be generally serpentine or curved (FIGS. 9A-9B) with the second plurality of teeth or serrations 32'''' also having a serpentine or curved shape. FIGS. 8A-8B illustrate the first teeth or serrations 26 being generally linear with the second teeth or serrations 32 being curved or serpentine.

[0125] Although not shown, it should be appreciated that the embodiments shown in FIGS. 6, 7, 8A-8B, 9A-9B and 11 could be provided such that they are continuous and uninterrupted or discontinuous and interrupted. Likewise, the teeth illustrated in the figures could be provided such that the first and second pluralities of teeth or serrations 26 and 32 in the embodiments are not of the same cross-sectional dimension or shape. As mentioned earlier relative to FIG. 11, it should be understood that the individual tooth 26 and 32 could be adapted or provided so that they are neither regular nor symmetrical when viewed in one or more of the directions in arrow B, arrow C or arrow D in FIGS. 1-1A. Thus, individual teeth of both the first plurality of teeth or serrations 26 and the second plurality of teeth or serrations 32 could have different pitches, depths, widths and the like.

[0126] Referring now to the embodiment shown in FIGS. 4, 5, 10A and 10B, the second or secondary area, layer or feature 28 may be provided in the form of a deposit or coating 40. As with prior embodiments, those parts that are the same or similar to the parts shown in FIGS. 1-1A are identified with the same part number except that prime marks ("''") has been added to the part numbers in FIGS. 4 and 5 and a mark ("VI") has been added to those parts in the embodiment of FIGS. 10A and 10B. As mentioned earlier, the second or secondary friction area, layer or feature 28'''' coating or deposit 40'''' could be deposited onto, sprayed onto, melted onto or otherwise applied to the first or primary area, layer or feature 24'''' . In the illustration being described relative to FIGS. 4 and 5, the coating 40'''' comprises a plurality of particles 42'''' that are deposited onto, adhered to or otherwise applied to surfaces 12a1'''' , 12a2'''' , 12b1'''' and 12b2'''' . In this embodiment, the coating 40'''' is applied using a plasma layer deposition

[0127] In this regard, the body 12'''' defines the orthopedic implant 10'''' for implanting into the patient. The first or primary area, layer or feature 24'''' in this embodiment is similar to the embodiment in FIGS. 1-1A in that each surface 12a1'''' , 12a2'''' , 12b1'''' and 12b2'''' has or defines a plurality of teeth or serrations 26'''' . In the illustration being described, each of the plurality of teeth or serrations 26'''' comprises a first surface 26e'''' (FIG. 4) and the second surface 26f'''' as shown having the coating or deposit 40'''' of particles 42'''' . Note also that areas or surfaces 12a3'''' , 12a4'''' , 12b3'''' and 12b4'''' (FIG. 5) also have the coating or deposit 40'''' of particles 42'''' . In the illustration being described, the coating or deposit 40'''' is titanium, cobalt or associated alloys. As previously mentioned, the teeth or serrations 26 may be asymmetrical to enhance frictional engagement.

[0128] Thus, each of the ends 12a'''' and 12b'''' in the illustration being described comprise the coating or deposit 40'''' of particles 42'''' . In the illustration shown in FIGS. 4 and 5, note that the layer or coating 46'''' is continuous over the first or primary area, layer or feature 24'''' and on ends 12a'''' and 12b'''' , but it should be understood that the ends 12a'''' and

12b^m could be spot coated, and less than the entire first or primary area, layer or feature 24^m may have no deposit or coating thereon. This is illustrated in FIGS. 10A-10B where some of the areas of the first teeth or serrations 26, such as the areas 50, may not comprise the deposit or coating as shown. Stated another way, the coating 40^{vt} or deposit 40^m may be selectively provided or applied to those surfaces of the orthopedic implant 10^m that engage bone.

[0129] In the embodiment of FIG. 7, the surfaces, such as surfaces 32b^{vii} and 32c^{vii} of each of the second plurality of teeth or serrations 32^{vii} comprises a deposit or coating or deposit 40^{vii} of particles 42^{vii} similar to that shown in FIG. 5. Thus, it should be understood that the embodiment shown in FIGS. 4 and 5 illustrates the second or secondary area, layer or feature 28^m comprising the deposit or coating as shown, whereas the embodiment illustrated in FIG. 7 shows the first or primary area, layer or feature 24^{vii} having the first plurality of teeth or serrations 26^{vii} having the second or secondary area, layer or feature 28^{vii} in the form of the second plurality of teeth or serrations 32^{vii} which themselves have the coating or deposit 40^{vii} of particles 42^{vii}.

[0130] In the illustrations being described, any particles 42^{vii} that are applied, sprayed, adhered, coated, deposited or melted onto at least one of the first or primary area, layer or feature 24^{vii} or the second or secondary area, layer or feature 28^{vii} may be round, not round or circular or non-circular, coarse, acyclic, and may form a continuous layer or discontinuous or discreet layer on all or only a portion of the first or primary area, layer or feature 24^{vii} or the second or secondary area, layer or feature 28^{vii}. As mentioned earlier, the first or primary area, layer or feature 24^{vii} and the second or secondary area, layer or feature 28^{vii} may be comprised of the same substance or material or they could comprise different materials, such as a metallic or metallic alloy as mentioned earlier herein, or a thermal plastic such as PEEK. In the illustration of FIGS. 4, 5, 7 and 10A-10B, the layer or coating 46^m is a metallic coating of titanium, cobalt or associated alloys deposited on the first plurality of teeth or serrations 26^m using plasma vapor deposition.

[0131] Advantageously, the second or secondary area, layer or feature in all embodiments augments at least a portion or all of the external first or primary area, layer or feature, such as the surfaces 26a, 26b of the one or more of the first plurality of teeth or serrations 26 in the embodiment of FIGS. 1-3 in order to enhance or add high friction to the engagement surfaces of the orthopedic implant 10. While traditional implants have engagement surfaces that engage bone, the embodiments described herein improve the frictional engagement between the bone and the orthopedic implant 10 by adding the second or secondary area, layer or feature 28 which provides improved frictional engagement between the frictional surfaces of the orthopedic implant 10 and bone.

[0132] Advantageously, one advantage of the orthopedic implant 10 as described herein is that it improves the inherently low levels of bone-orthopedic implant 10 interface and surface interaction. The primary frictional features described herein add a surface material, such as a metallic surface material, to the first or primary friction area, layer or feature 24 which provides low lubricity, low elasticity and the secondary frictional features defined by the second or secondary friction area, layer or feature 28. The embodiments described provide or comprise a design that will maintain the biomechanical properties of the orthopedic implant 10 while

addressing frictional shortcomings of the orthopedic implant 10 and the interfaces between the bone and the implants of the past.

[0133] This invention, including all embodiments shown and described herein, could be used alone or together and/or in combination with one or more of the features covered by one or more of the claims set forth herein, including but not limited to one or more of the features or steps mentioned in the Summary of the Invention and the claims.

[0134] While the system, apparatus and method herein described constitute preferred embodiments of this invention, it is to be understood that the invention is not limited to this precise system, apparatus and method, and that changes may be made therein without departing from the scope of the invention which is defined in the appended claims.

What is claimed is:

1. An orthopedic implant comprising:
 - a substrate material adapted to provide the orthopedic implant;
 - a primary friction area located on or integral with said substrate material, said primary friction area having a primary surface having a primary frictional feature; and
 - a secondary friction area located on or integral with said primary surface and defining a secondary frictional feature;
 - said primary friction area and said secondary friction area defining a friction interface zone, said secondary friction area increasing a friction of said primary surface to enhance the frictional engagement between said primary surface and at least one bone;
 - wherein said primary surface defines a plurality of teeth or serrations;
 - wherein said secondary frictional feature defines a plurality of teeth, points or peaks located on or integral with said primary friction area.
2. The orthopedic implant as recited in claim 1 wherein said primary friction area having a primary friction surface that is at least one of machined, molded, extruded, sintered or deposited substrate.
3. The orthopedic implant as recited in claim 2 wherein said deposited substrate is a polymeric substrate.
4. The orthopedic implant as recited in claim 2 wherein said primary friction surface defines a plurality of teeth or serrations.
5. The orthopedic implant as recited in claim 4 wherein said secondary friction area that is at least one of machined, molded, extruded, sintered or deposited substrate.
6. The orthopedic implant as recited in claim 4 wherein said secondary friction area comprises at least one of a microscopically or macroscopically rough surface.
7. The orthopedic implant as recited in claim 1 wherein said secondary friction area is regular in shape.
8. The orthopedic implant as recited in claim 1 wherein said secondary friction area is irregular in shape.
9. The orthopedic implant as recited in claim 1 wherein said substrate material is made from a thermoplastic.
10. The orthopedic implant as recited in claim 9 wherein said thermoplastic is a polyetheretherketone (PEEK).
11. The orthopedic implant as recited in claim 1 wherein a modulus of elasticity of said substrate material is less than or equivalent to bone.
12. The orthopedic implant as recited in claim 11 wherein said substrate material has a low coefficient of friction with bone.

13. The orthopedic implant as recited in claim 1 wherein at least one of said primary friction area or said secondary friction area being made from a metal or metallic alloy.

14. The orthopedic implant as recited in claim 1 wherein at least one of said primary friction area or said secondary friction area having a modulus of elasticity that is the same as or greater than bone.

15. The orthopedic implant as recited in claim 11 wherein said at least one of said primary friction area or said secondary friction area having a modulus of elasticity that the same as or greater than bone.

16. The orthopedic implant as recited in claim 1 wherein at least one of said primary friction area or said secondary friction area comprising a higher coefficient of friction with bone.

17. The orthopedic implant as recited in claim 16 wherein at least one of said primary friction area or said secondary friction area having a modulus of elasticity that the same as or greater than bone.

18. The orthopedic implant as recited in claim 1 wherein said primary friction area comprising a higher coefficient of friction with bone and said secondary friction area comprising a higher coefficient of friction than said primary friction area.

19. The orthopedic implant as recited in claim 1 wherein said primary friction area having a modulus of elasticity that the same as or greater than bone and said secondary friction area having a modulus of elasticity that is the same or greater than said primary friction area.

20. The orthopedic implant as recited in claim 1 wherein said secondary frictional feature is integral with, welded to, adhered to or otherwise affixed to said primary frictional feature.

21. The orthopedic implant as recited in claim 1 wherein said secondary frictional feature is sprayed onto, melted to or applied to said primary friction area.

22. The orthopedic implant as recited in claim 21 wherein said secondary frictional feature is defined by particles that are at least one of round, not round or acicular, circular, coarse, acyclic.

23. The orthopedic implant as recited in claim 22 wherein said particles are continuous or discontinuous or discrete on at least a portion of said primary frictional feature.

24. The orthopedic implant as recited in claim 1 wherein said secondary frictional feature defines a plurality of teeth, points or peaks are located on or integral with said primary friction area.

25. The orthopedic implant as recited in claim 24 wherein said plurality of teeth, points or peaks are neither regular nor symmetrical.

26. The orthopedic implant as recited in claim 24 wherein said plurality of teeth, points or peaks are regular and symmetrical.

27. The orthopedic implant as recited in claim 1 wherein said primary frictional feature and said secondary frictional feature are made from different materials.

28. The orthopedic implant as recited in claim 1 wherein said primary frictional feature and said secondary frictional feature are made from the same materials.

29. The orthopedic implant as recited in claim 1 wherein said at least one of said primary frictional feature, said secondary frictional feature or said substrate material is made from a different material than the others.

30. The orthopedic implant as recited in claim 1 wherein said secondary frictional feature increases a coefficient of friction of said orthopedic implant and bone.

31. The orthopedic implant as recited in claim 1 wherein said orthopedic implant is a spinal implant.

32. The orthopedic implant as recited in claim 31 wherein said spinal implant is a cage.

33. The orthopedic implant as recited in claim 1 wherein said secondary frictional feature is a deposit onto said primary surface.

34. The orthopedic implant as recited in claim 33 wherein said deposit is a plasma vapor deposition deposit.

35. The orthopedic implant as recited in claim 33 wherein said primary surface defines a plurality of teeth or serrations and said deposit is applied to surfaces of one or more of said plurality of teeth or serrations.

36. An orthopedic implant comprising:
a body comprising a composite material;

a first friction area situated between the body and bone of a patient when the orthopedic implant is implanted in the patient, said first friction area comprising a plurality of teeth or serrations; and

a second friction area associated with said first friction area for directly engaging said bone;

wherein said second friction area defines a plurality of teeth, points or peaks located on or integral with said first friction area;

each of said first and second friction areas for improving a frictional engagement between said bone and said orthopedic implant.

37. A method for improving a frictional interface between an implant and bone of a patient, comprising the steps of:

processing a body to comprise a primary friction feature; and

processing said body to comprise a secondary friction feature directly located on or integral with said primary friction feature;

wherein said secondary friction feature defines a plurality of teeth, points or peaks that are located on or integral with said primary friction feature.

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