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(54) **PYROLYTIC CARBON IMPLANTS WITH POROUS FIXATION COMPONENT AND METHODS OF MAKING THE SAME**

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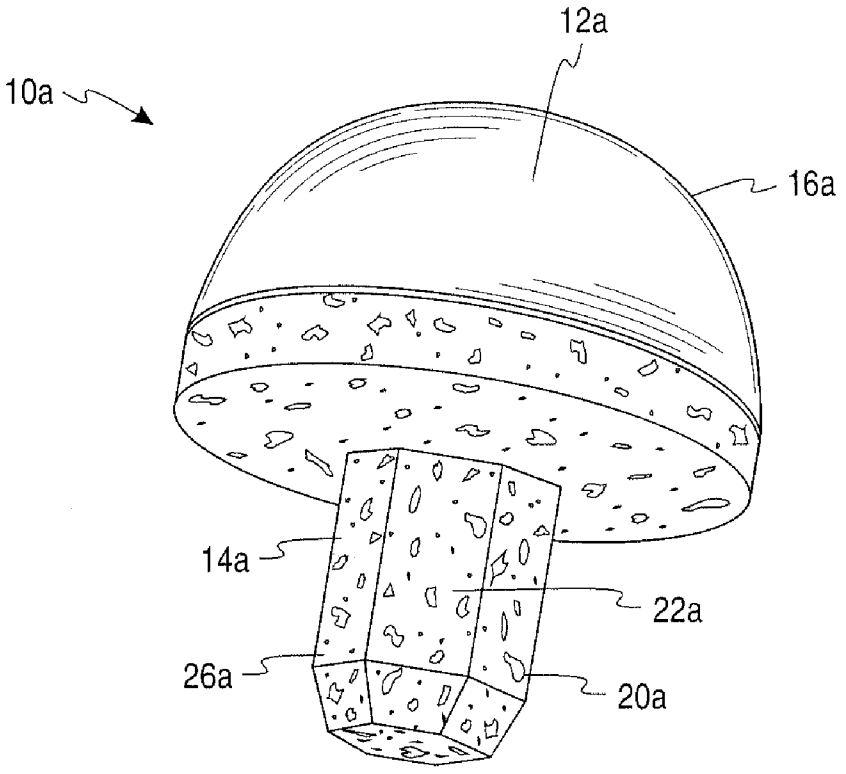
(57) **ABSTRACT**

An orthopedic implant including an articulation portion having a pyrolytic carbon bearing surface and a porous bone on- or in-growth structure, and methods of making the same.



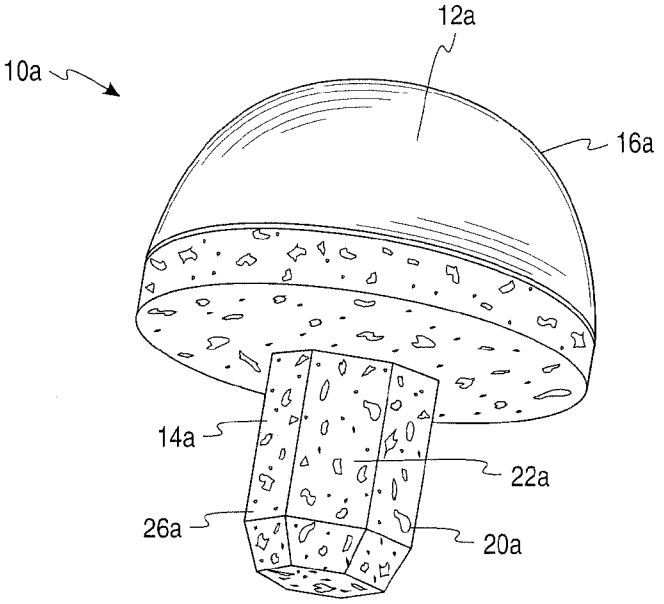

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Fig. 1

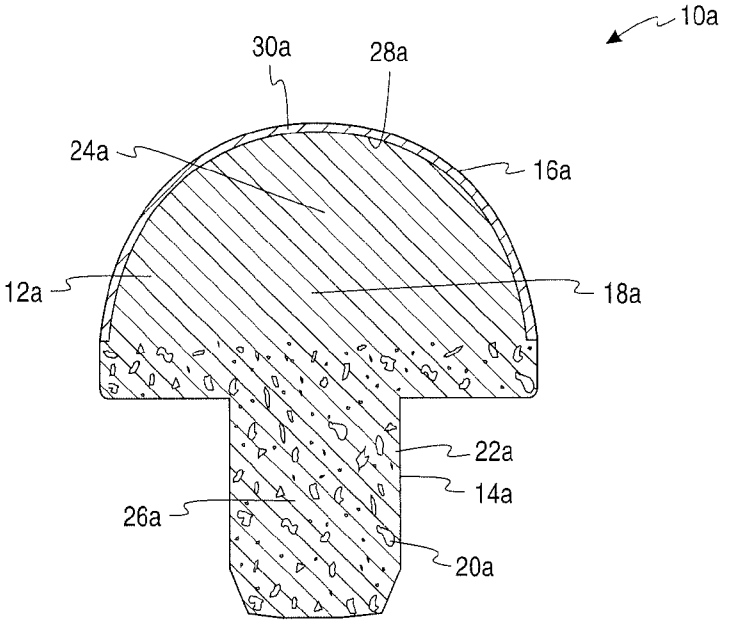
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Fig. 2

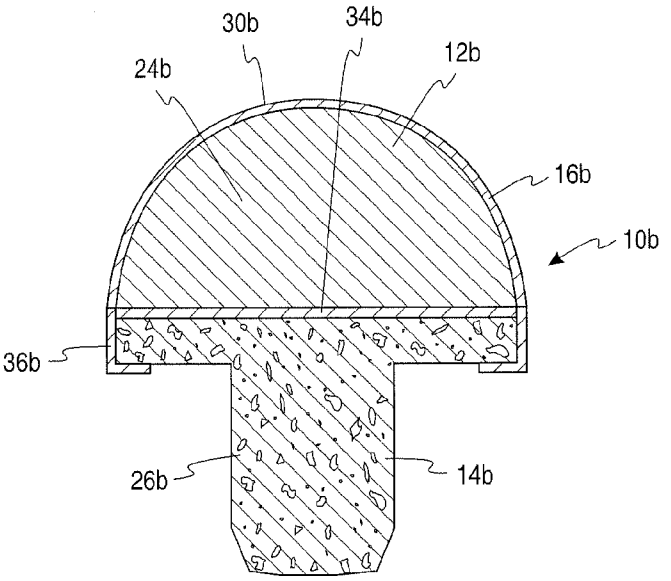


Fig. 3

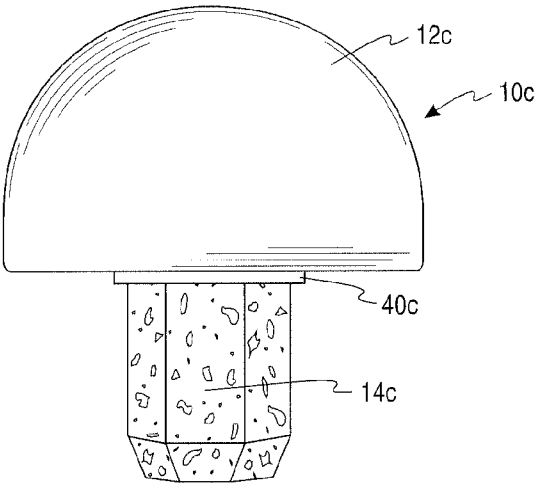


Fig. 4

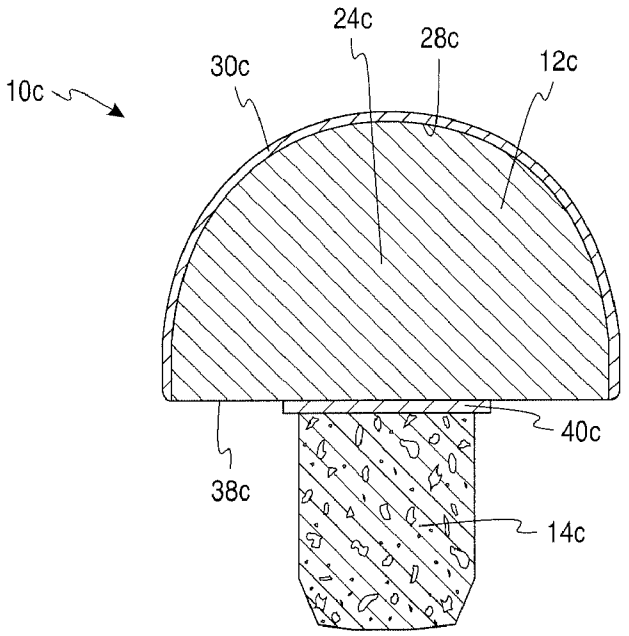


Fig. 5

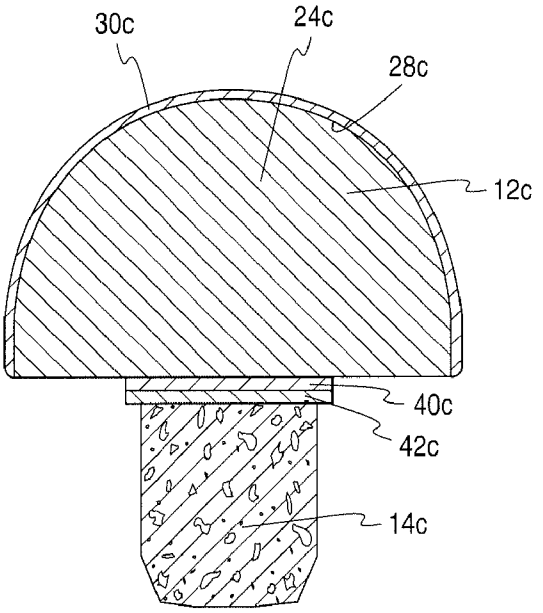
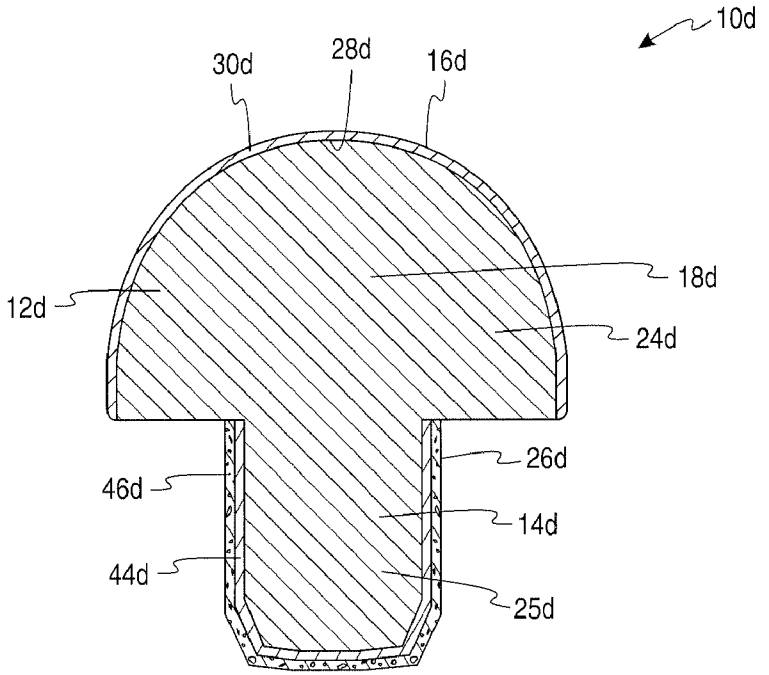


Fig. 6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14d
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Fig. 7

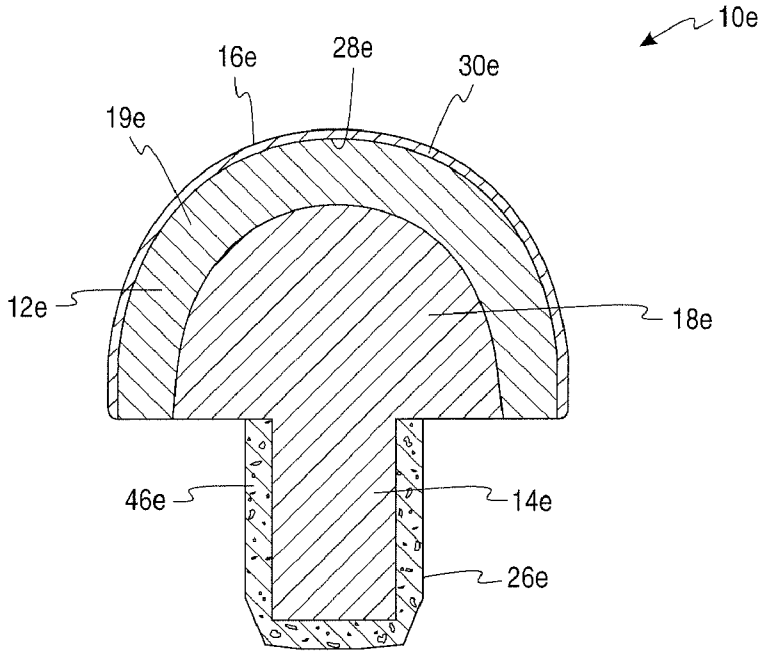
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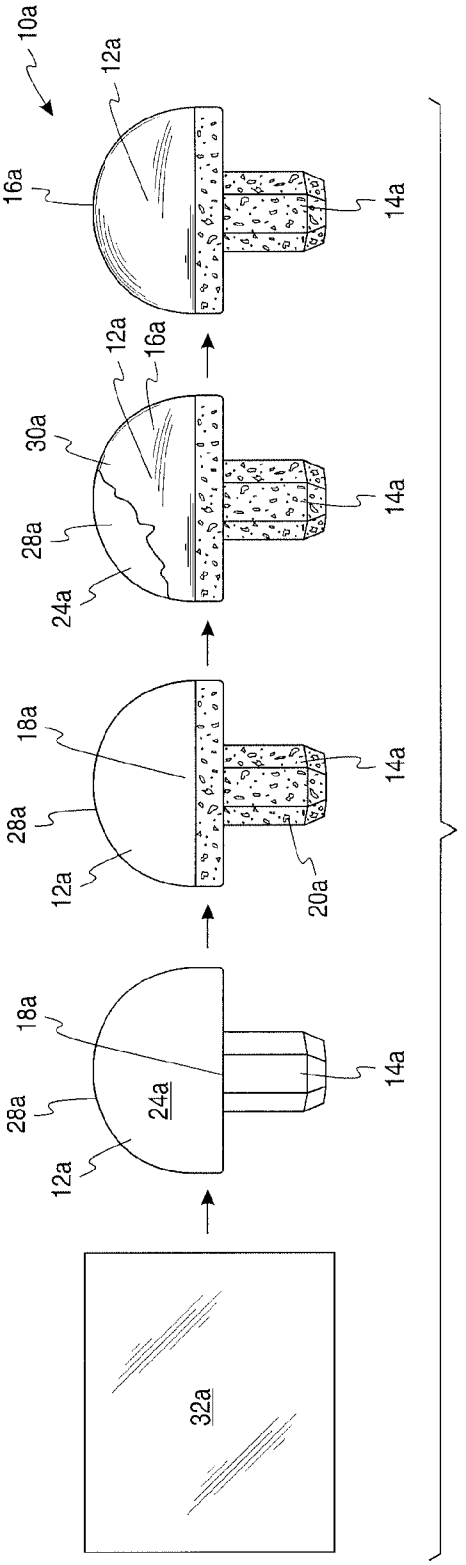
Fig. 8


10a
12a
16a
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30a
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18a
20a
32a

Fig. 9a


PROVIDE CARBON BLOCK (32a)
MACHINE CARBON BLOCK (32a) TO FORM CORE (18a)
FORM HOLES TO CREATE PORES (20a) IN BONE FIXATION PORTION (14a)
APPLY PYROLYTIC CARBON TO A SURFACE (28a) OF SUBSTRATE (24a)
APPLY METAL INFILTRATION AND COATING TO BONE FIXATION PORTION (14a)

Fig. 9b

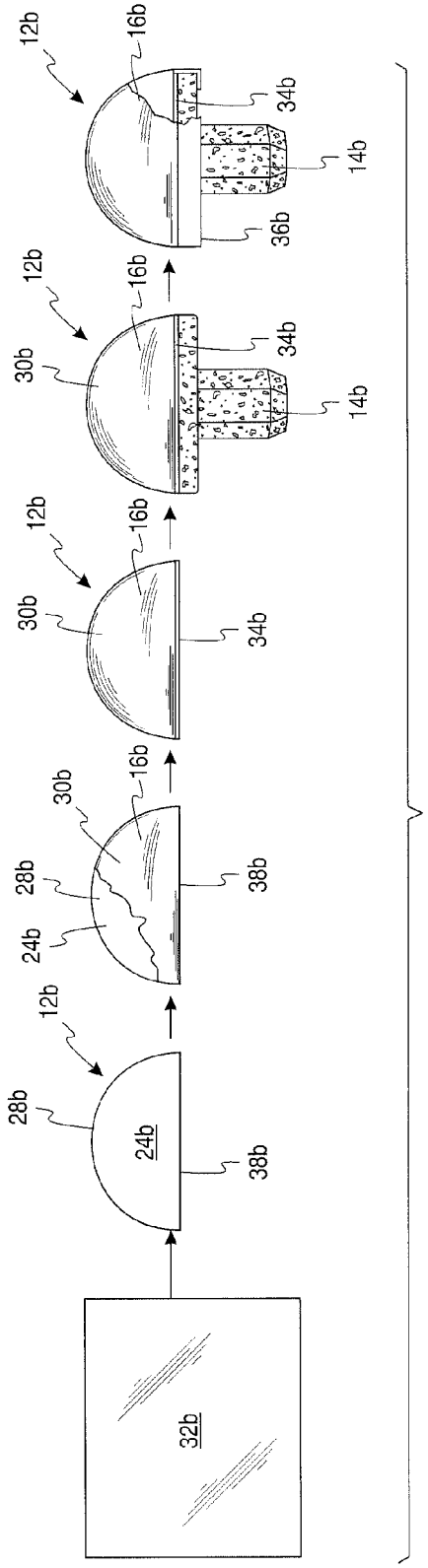

Fig. 10a

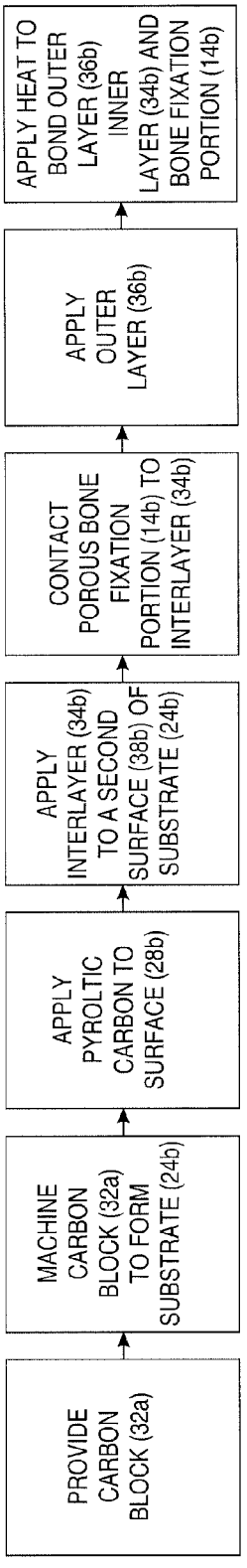

Fig. 10b

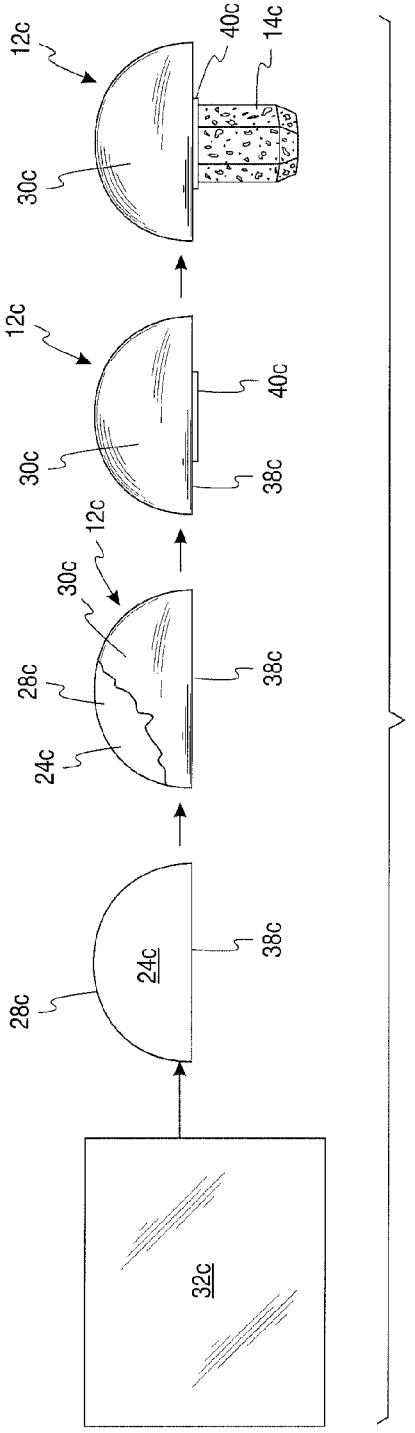

Fig. 11a

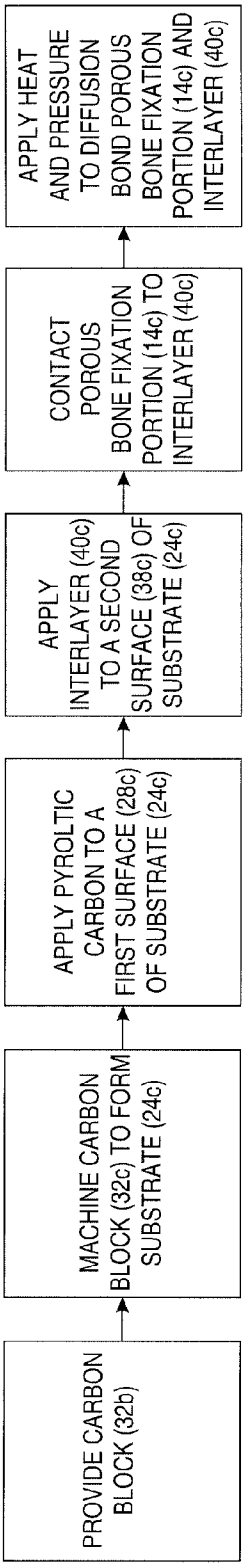

Fig. 11b


PROVIDE CARBON BLOCK (32d)
MACHINE CARBON BLOCK (32d) TO FORM CORE (18d)
APPLY PYROLTIC CARBON TO SURFACE (28a) OF SUBSTRATE (24d)
APPLY INTERMEDIATE LAYER (44d) TO SUBSTRATE (25d)
APPLY POROUS LAYER (46d) TO INTERMEDIATE LAYER (44d)

Fig. 12

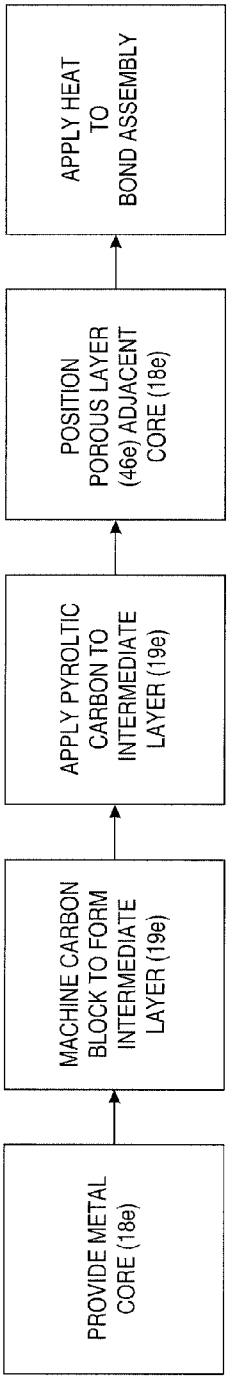
PROVIDE METAL CORE (18e)
MACHINE CARBON BLOCK TO FORM INTERMEDIATE LAYER (19e)
APPLY PYROLTIC CARBON TO INTERMEDIATE LAYER (19e)
POSITION POROUS LAYER (46e) ADJACENT CORE (18e)
APPLY HEAT TO BOND ASSEMBLY

Fig. 13

PYROLYTIC CARBON IMPLANTS WITH POROUS FIXATION COMPONENT AND METHODS OF MAKING THE SAME

CROSS REFERENCE TO RELATED APPLICATION(S)

[0001] This application claims the benefit of U.S. Provisional Application Ser. No. 61/387,678, filed Sep. 29, 2010, which is hereby incorporated by reference in its entirety.

FIELD OF THE DISCLOSURE

[0002] The present disclosure generally relates to prosthetic orthopedic implants, and more particularly to prosthetic orthopedic implants for use in bone joints and methods of making the same. Even more particularly, the present disclosure relates to prosthetic orthopedic implants that include a pyrolytic carbon bearing or articulating surface and a porous bone fixation structure.

BACKGROUND

[0003] Pyrolytic carbon has gained a lot of interest over the past few years as a bearing material in orthopedic applications. The material shows excellent wear characteristics, a modulus of elasticity similar to bone, and high strength. Pyrolytic carbon implants are commonly made by depositing a layer of pyrolytic carbon on a graphite substrate or core. Typically, pyrolytic carbon implants included a solid or non-porous bone fixation portion that is implanted into the bone and relies on a press-fit interference with surrounding bone tissue for fixation of the implant to the bone.

[0004] Bone on-growth or in-growth porous structures, such as porous tantalum and titanium structures, are sometimes used in orthopedic implants as the bone fixation component of the implant. Such porous structures are implanted into the bone and are designed to foster osseointegration. Osseointegration is the integration of living bone tissue within a man-made material. The porous structure and the bone material become intermingled as the bone grows into the pores. This intermingling of the bone tissue with the porous structure can enhance fixation between the orthopedic implant and the bone tissue. Because of the difficulties of bonding porous on-growth and in-growth structures to pyrolytic carbon and graphite surfaces, pyrolytic carbon implants have not included such porous fixation surfaces.

SUMMARY

[0005] In one aspect, the present disclosure is directed to an orthopedic implant including an articulation portion having a pyrolytic carbon bearing surface. The implant also includes a bone fixation portion extending from the articulation portion and having a porous structure configured for bone on-growth or bone in-growth.

[0006] In another aspect, a method of forming an orthopedic implant. The method includes providing a member having a first portion and a porous second portion. A layer of pyrolytic carbon is applied to a surface of the first portion and a metal is applied to the porous second portion.

[0007] In yet a further aspect, a method of forming an orthopedic implant that includes applying a layer of pyrolytic carbon to a first surface of a substrate and placing an interlayer comprising a metal between a second surface of the substrate and a porous metal structure. The porous metal layer, substrate and the interlayer are bonded together.

[0008] In yet another aspect, a method of forming an orthopedic implant including applying a layer of pyrolytic carbon to a first surface of a substrate and applying a metal interlayer to a second surface of the substrate. A porous metal structure is placed in contact with the metal interlayer, and a second outer layer of metal is applied to the substrate, interlayer and porous metal structure to bond the porous metal structure to the substrate.

[0009] In yet a further aspect, a method of forming an orthopedic implant includes applying a layer of pyrolytic carbon to a first surface of a substrate and applying an interlayer comprised of a metal to a second surface of the substrate. A metal sheet is then placed between the interlayer and a porous metal structure, and heat and pressure are applied to bond the metal structure, metal sheet and interlayer together.

BRIEF DESCRIPTION OF THE FIGURES

[0010] In the course of this description, reference will be made to the accompanying drawings, wherein:

[0011] FIG. **1** is a perspective view of one embodiment of an implant of the present disclosure;

[0012] FIG. **2** is a cross-sectional view of the implant of FIG. **1**;

[0013] FIG. **3** is a cross-sectional view of another embodiment of an implant of the present disclosure;

[0014] FIG. **4** is an elevation view of yet another embodiment of an implant of the present disclosure;

[0015] FIG. **5** is a cross-sectional view of the implant of FIG. **4**;

[0016] FIG. **6** is a cross-sectional view of another embodiment of an implant of the present disclosure;

[0017] FIG. **7** is a cross-sectional view of still yet another embodiment of an implant of the present disclosure;

[0018] FIG. **8** is a cross-sectional view of another embodiment of an implant of the present disclosure;

[0019] FIG. **9***a* is a schematic illustration of one embodiment of a method of making an implant of the present disclosure;

[0020] FIG. **9***b* is a flow-chart showing the method illustrated in FIG. **7***a;*

[0021] FIG. **10***a* is a schematic illustration of another embodiment of a method of making an implant of the present disclosure;

[0022] FIG. **10***b* is a flow-chart showing the method illustrated in FIG. **8***a;*

[0023] FIG. **11***a* is a schematic illustration of yet another embodiment of a method of making an implant of the present disclosure;

[0024] FIG. **11***b* is a flow-chart showing the method illustrated in FIG. **9***a;*

[0025] FIG. **12** is a flow-chart of one embodiment of a method of making an implant of the present disclosure; and

[0026] FIG. **13** is a flow-chat of another embodiment of a method of making an implant of the present disclosure.

DETAILED DESCRIPTION

[0027] As required, detailed embodiments of the present invention are disclosed herein; however, it will be understood that the disclosed embodiments are merely exemplary of the invention, which may be embodied in various forms. Therefore, specific details disclosed herein are not to be interpreted as limiting, but merely as a basis for the claims and as a

representative basis for teaching one skilled in the art to variously employ the present invention in virtually any appropriate manner.

[0028] Generally, the prosthetic implants disclosed herein include an articulation portion having a pyrolytic carbon bearing or articulating surface and a porous bone in-growth or on-growth fixation structure or portion which is combined or otherwise associated with the articulation portion. Pyrolytic carbon is a brittle material that is biocompatible with bone and cartilage. It has good wear and strength properties and has been found to be a good bearing or articulating material for joint repair and replacement applications. The bearing surface of implants may articulate against, for example, natural body tissues, such as bone, or may articulate against a surface of an adjacent prosthetic component. Such implants are particularly useful in bone joint repair and replacement and may be used to treat or repair defects in, for example, the knee, hip, shoulder, fingers, elbow, toes or ankle. However, it will be appreciated that the use of such implants are not limited to joint repair or in connection with the joints specifically identified.

[0029] Referring to FIGS. **1** and **2**, implant **10***a* includes a first portion or articulation portion **12***a* associated with a second portion or bone fixation portion **14***a*. In the illustrated embodiment, the bone fixation portion **14***a* is shaped to be received into or implanted into a section of bone at the location of a joint and includes a porous bone in-growth or on-growth structure or region. The articulation portion **12***a* further includes a bearing surface **16***a* that is comprised of pyrolytic carbon and that functions as an articulating or bearing surface for the implant **10***a*. In the illustrated embodiment, the bearing surface **16***a* forms an outer layer or cover of the articulation portion **12***a*, and more specifically entirely covers an underlying body or substrate **24***a* (see FIG. **2**). However, it will be appreciated that the bearing surface **16***a* may be sized to only cover a portion or multiple portions of the substrate **24***a* depending on the desired articulation points of the implant. Alternatively, the entire articulation portion **12***a* could be formed of pyrolytic carbon.

[0030] In the embodiment illustrated in FIGS. **1** and **2** and other figures contained herein, the articulation portion **12***a* is hemispherically shaped or ball-shaped. In this configuration, the articulation portion **12***a* may function, for example, as the articulating head or ball of a ball and socket joint commonly found in hip or shoulder. The articulation portion **12***a* of this and other embodiments described herein may be, however, designed for other joint functions, used in other types of joints, or even used for other orthopedic applications. Accordingly, the articulation portion **12***a* may take on any variety of suitable sizes and regular and irregular geometric shapes, depending on the application. For example, the articulation portion may be cubical, cylindrical, cup-shaped, etc. In addition, depending on the desired application, the bearing surface **16***a* may take on any variety of configurations, for example, concave.

[0031] The second or bone fixation portion **14***a* preferably includes a porous structure or region **26***a* in order to allow for bone in-growth or on-growth. In one embodiment, the bone fixation portion **14***a* may be made entirely or partially from a porous material or made to contain pores and more specifically surface pores **20***a*. Further, the bone fixation portion **14***a* includes a projection or stem element **22***a* that is sized and shaped to be implanted into bone. In the illustrated embodiment, the stem element **22***a* has a polygonal cross-section and, more particularly a hexagonal cross-section. In other embodiments, the stem element **22***a* may have other polygonal shapes or may be cylindrical, spherical, conical, or any other suitable configuration. In further embodiments, multiple projections or stem elements **22***a* may be incorporated to assist in limiting implant rotation or to provide different bone fixation arrangements.

[0032] When implanted within bone, the porous structure or region **26***a* of the bone fixation portion **14***a* and in particular the stem element **22***a* is receptive to bone cell and tissue on- and/or in-growth which enhances fixation of the implant **10***a* to the bone. The porous region **26***a* of the bone fixation portion **14***a* and the porous regions of the bone fixation portions of other embodiments described herein may have a pore size, pore interconnectivity, and/or other features that facilitate bone tissue on- and/or in-growth into the pores, as known in the art. Preferably, the bone fixation portion **14***a* is formed entirely from a highly porous material or a material adapted to be porous that may have a porosity as low as about 55, 65, or 75 percent by volume or as high as about 80, 85, or 90 percent by volume. However, it will be appreciated that the bone fixation portion **14***a* may not be entirely constructed of a porous material but includes region(s) comprised of porous materials positioned thereon.

[0033] Referring to FIG. **2**, in this embodiment, the implant **10***a* has a core **18***a* that includes the body or substrate **24***a* of the articulation portion **12***a* and the porous section or region **26***a* of the bone fixation portion **14***a*. In one embodiment, the core **18***a* and consequently the substrate **24***a* and porous region **26***a* may be constructed out of a single material, for example, carbon, and more particularly, a dense, isotropic graphite. As such, the substrate **24***a* and the porous stem element **22***a* may be of a one-piece or unitary body or construction.

[0034] In order to enhance the visibility of the implant or portions thereof under fluoroscopy or x-ray imaging, the carbon may be doped with or otherwise include any suitable radiopacifiers, such as tungsten, zirconia or barium sulphate. In the embodiment illustrated in FIG. **2**, the substrate **24***a* includes an exterior surface **28***a* that has pyrolytic carbon layer **30***a* positioned at least partially thereon. The pyrolytic carbon layer **30***a* helps form the bearing surface **16***a* of articulation portion **12***a*. It shall be appreciated that core **18***a* also may be constructed out of any other suitable material that can have pyrolytic carbon applied thereto and is suitable for use in orthopedic applications.

[0035] The pyrolytic carbon layer **30***a* may be applied to the substrate **18***a* by any suitable method known in the art. For example, the pyrolytic carbon layer **30***a* may be applied by chemical vapor deposition (CVD) or physical vapor deposition (PVD). In the embodiment shown in FIG. **2** and other embodiments described herein, the pyrolytic carbon layer **30***a* has a uniform thickness. The thickness of the pyrolytic carbon layer **30***a*, however, may vary to accommodate particular applications of the implant. Preferably, the pyrolytic carbon layer **30***a has a thickness of at least about* 50 μm. In other embodiments, the pyrolytic carbon layer **30***a* has a thickness of at least about 200 μm, 300 μm, 400 μm or 500 μm. In other embodiments, the pyrolytic carbon layer is between about 500 μm and 1000 μm.

[0036] Referring back to bone fixation portion **14***a*, in this embodiment, the bone fixation portion **14***a* comprises porous region **26***a* of the core **18***a*. As explained in more detail below, porous region **26***a* of core **18***a* may be formed by drilling or

machining holes or pores **20***a* or a matrix of holes or pores into and/or through the porous region **26***a*. The resultant holes or pores **20***a* of porous region **26***a* may then be infiltrated and coated with a coating, such as a metal coating, to promote bone in-growth or on-growth, as described in more detail below. In one embodiment, the pores **20***a* pass through the entire bone fixation portion **14***a*. In other embodiments, the pores **20***a* are created to a porous region that extends between about 500 um and 4000 um and preferably between about 1000 um and 2000 um from the outer surface and into the bone fixation portion **14***a*. Alternatively, as discussed below with respect to FIGS. **7** and **8**, the porous region **26***a* could be constructed out of a material with the desired porosity and attached or applied to the core.

[0037] A schematic illustration and flowchart of one embodiment of a method of making the implant **10***a* illustrated in FIGS. **1** and **2** are shown in FIGS. **9***a* and **9***b*, respectively. It is understood that the steps of the method may be carried out in any suitable order which results in an implant fit for its desired orthopedic use. In one step, a block of carbon **32***a*, preferably a dense, isotropic graphite, is machined or otherwise processed into a desired shape to form the core **18***a* of implant **10***a*. In the embodiment shown, the block **32***a* is machined into a core **18***a* having a substrate **24***a* and a bone fixation portion **14***a*. The substrate **24***a* at least partially forms the articulation portion **12***a*. Holes or pores **20***a* or a matrix of holes or pores are then created in the bone fixation portion **14***a* of the core **18***a*, resulting in a porous region **26***a* of bone fixation portion **14***a*. In one embodiment, the bone fixation portion **14***a* is drilled or otherwise machined to create holes **20***a* in porous region **26***a*.

[0038] In another step, the bone fixation portion **14***a* is masked or otherwise protected or covered leaving substrate **24***a* of core **18***a* exposed and a pyrolytic carbon layer **30***a* is applied to the outer surface **28***a* of substrate **24***a*. The pyrolytic carbon layer **30***a* may be applied by any suitable process. In one embodiment, the pyrolytic carbon layer **30***a* is applied by CVD. In yet another step, the articulation portion **12***a*/substrate **24***a* is masked or otherwise protected and covered leaving the bone fixation portion **14***a* and more particularly the porous region **26***a* exposed and a coating is applied to at least a portion of the porous region **26***a* so that the coating infiltrates the holes **20***a* and coats the porous regions **26***a* of second portion **14***a*. In one embodiment, the coating is a metal such as but not limited to, tantalum, titanium, niobium, alloys of the same or any other suitable metal or alloy. Further, the metal may be applied to the porous regions **26***a* by, for example, CVD, PVD or any other suitable process. Other examples of coatings include bone on-growth or in-growth coatings such as hydroxyapatite or forms of calcium phosphate.

[0039] The resulting implant **10***a* includes a articulation or first portion **12***a* including a pyrolytic carbon bearing surface **16***a* and second or bone fixation portion **14***a* having a porous structure or region **26***a* that is suitable for bone cell and tissue on- and/or in-growth.

[0040] FIG. **3** illustrates another embodiment of an implant **10***b* of the present disclosure which includes an articulation or first portion **12***b* and a second or bone fixation portion **14***b* with a porous region **26***b*. Similar to the previous embodiment, the articulation portion **12***b* includes a body or substrate **24***b* having a pyrolytic carbon layer **30***b* thereon that forms the bearing surface **16***b*. The substrate **24***b* may be made of any material or combination of materials suitable for having pyrolytic carbon applied thereto and in one embodiment the substrate **24***b* is carbon, preferably a dense, isotropic graphite. Additionally, in order to enhance the visibility of the implant or portions thereof under fluoroscopy or x-ray imaging, the carbon may be doped with or otherwise include any suitable radiopacifiers, such as tungsten, zirconia and barium sulphate.

[0041] In this embodiment, the bone fixation portion **14***b* comprises a porous structure preferably constructed out of metal. The bone fixation portion **14***b* is separately formed and is not unitary with the substrate **24***b*. The bone fixation portion **14***b* may be made of any suitable porous bone on-or in-growth metal structure known in the art. For example, the bone fixation portion **14***b* may be made of Trabecular Metal®, generally available from Zimmer, Inc. of Warsaw, Ind. Such material may be formed from a reticulated vitreous carbon foam substrate which is infiltrated and coated with a metal, such as tantalum, titanium, niobium, alloys of the same or any other suitable metal or alloy, by a CVD process in the manner disclosed in U.S. Pat. No. 5,282,861. The porous metal structure may have a pore size, pore interconnectivity, and/or other features that facilitate bone tissue on-and/or in growth.

[0042] As described in more detail below, the bone fixation portion **14***b* is bonded or otherwise attached to the substrate **24***b* of the articulation portion **12***b* by a metal interlayer **34***b* and/or a metal outer layer **36***b*. The metal interlayer **34***b* may be a layer of metal deposited or otherwise placed on a surface of substrate **24***b* or may be a sheet or foil positioned between substrate **24***b* and bone fixation portion **14***b*. Preferably, metal interlayer **34***b* and metal outer layer **36***b* are constructed out of the same metal or alloy as that of the bone fixation portion **14**. It should be noted that the thicknesses of metal interlayer **34***b* and metal outer layer **36***b* are not drawn to scale in the figures, but have been exaggerated for illustrative purposes. Such interlayer **34***b* may have a thickness of between about 100 um and about 1 mm, and more preferably between about 400 um and about 600 um. The outer layer **36***b* may have a thickness of between about 50 um and about 400 um, and more preferably between about 150 um and about 250 um. However, it will be appreciated that the thicknesses may be altered in order to obtain the desired implant properties.

[0043] A schematic illustration and flowchart showing one embodiment of a method of making implant **10***b* are shown in FIGS. **10***a* and **10***b*, respectively. It is understood that the steps of the method may be performed in any order that produces an implant suitable for use in orthopedic applications. A block of carbon **32***b*, preferably a dense, isotropic or fiber reinforced graphite, is machined or otherwise processed to form the substrate **24***b* of articulation portion **12***b* of the implant **10***b*. In order to form bearing surface **16***b*, a pyrolytic carbon layer **30***b* is applied to an outer surface **28***b* of substrate **24***b* by any suitable method known in the art. For example, the pyrolytic carbon layer may be applied by CVD.

[0044] An interlayer **34***b*, preferably metallic and more specifically, a tantalum or titanium interlayer, is applied to outer surface **38***b* of the substrate **24***b*. The metal interlayer **34***b* may be applied by any suitable method known in the art, such as CVD or PVD. Further, the metal interlayer **34***b* may be formed of a metal foil or sheet. Undercuts, holes and/or other surface deviations may be located or formed in substrate **24***b*, and particularly in outer surface **38***b*, so that when the metal interlayer **34***b* is applied to outer surface **38***b*, the metal

enters and engages the undercuts, holes, etc. to form a mechanical interlock between the interlayer **34***b* and substrate **24***b*.

[0045] The bone fixation portion **14***b*, which is comprised of a porous metal structure and preferably a porous tantalum structure, is placed against the metal interlayer **34***b*. A metal outer layer **36***b*, preferably a tantalum metal outer layer, is applied to the bone fixation portion **14***b*, the metal interlayer **34***b*, and substrate **24***b*/articulation portion **12***b*. Again, the substrate **24***b* may include undercuts, holes or other deviation so that when outer layer **36***b* is applied, the metal may engage and enter such undercuts, holes or other deviations in the surface to create a mechanical interlock. Preferably, but not necessarily, the interlayer **34***b*, outer layer **36***b* and bone fixation portion **14***b* are all constructed of the same metal. After the outer layer **36***b* has been applied, the metal interlayer **34***b*, metal outer layer **36***b* and bone fixation portion **14***b* are subjected to elevated temperatures to bond the bone fixation portion **14***b* to substrate **24***b* and form the implant **10***b*.

[0046] FIGS. **4** and **5** illustrate another embodiment of an implant **10***c* of the present disclosure. Similar to the other embodiments, the implant **10***c* includes a articulation or first portion **12***c* and a bone fixation or second portion **14***c*. Referring to FIG. **5**, the articulation portion **12***c* includes a body or substrate **24***c*. The substrate **24***c* includes a surface **28***c* having a pyrolytic carbon layer **30***c* positioned thereon. The substrate **24***c* may be made of any material or combination of materials suitable for having pyrolytic carbon applied thereto and in one embodiment the substrate **24***c* is carbon, preferably a dense, isotropic or fiber reinforced graphite. Additionally, in order to enhance the visibility of the implant or portions thereof under fluoroscopy or x-ray imaging, the carbon may be doped with or otherwise include any suitable radiopacifiers, such as tungsten, zirconia or barium sulphate.

[0047] Bone fixation portion **14***c* may be made of any suitable porous bone on-or in-growth metal structure described herein or known in the art. Alternatively, the bone fixation portion could be constructed of a material that could be made porous through any method known in the art. The porous bone fixation portion **14***c* is bonded to the substrate **24***c* using interlayer **40***c*. Interlayer **40***c* is preferably a metal that is readily soluble with the metal of the porous stem **14***c*. As explained in more detail below, interlayer **40***c* may be applied to surface **38***c* of the substrate **24***c* by any suitable deposition process, such as CVD or PVD. Undercuts, holes and/or other surface deviations may be located in substrate **24***b*, and particularly in surface **38***c*, so that when the metal interlayer **40***c* is applied to surface **38***c*, the metal enters and engages the undercuts, holes, etc. to form a mechanical interlock between the metal interlayer **40***c* and substrate **24***c*. In another embodiment, the interlayer **40***c* may be a metal sheet or foil.

[0048] In a further embodiment, as shown in FIG. **6**, the implant **10***c* may include both a deposited interlayer **40***c* and a thin interlayer such as a metal foil or sheet **42***c* located between bone fixation portion **14***c* and substrate **24***c* to assist in the bonding process. It should be noted that the thicknesses of metal interlayer **40***c* and metal foil **42***c* are not drawn to scale in the figures, but have been exaggerated for illustrative purposes. The interlayer **40***c* may have a thickness of between about 100 um and about 1000 um, and more preferably between about 400 um and about 600 um. The foil sheet **42***c* may have a thickness of between about 100 um and about 1000 um, and more preferably between about 400 um and about 600 um.

[0049] A schematic illustration and flowchart showing one embodiment of a method of making the implants **10***c* illustrated in FIGS. **5** and **6** are shown in FIGS. **11***a* and **11***b*, respectively. The steps of the method described herein may be performed in any order that produces an implant suitable for use in orthopedic applications. A block of carbon **32***c*, preferably a dense, isotropic graphite, is machined or otherwise processed to form the substrate **24***c* of articulation portion **12***c* of the implant. A pyrolytic carbon layer **30***c* is applied to an outer surface **28***c* of the substrate **24***c*. A metal interlayer **40***c*, preferably comprised of a metal that is readily soluble with the metal of the porous metal second portion **14***c*, is applied to surface **38***c* of substrate **24***c*. In one embodiment, the metal interlayer is comprised of titanium. The metal interlayer **40***c* may be applied by any suitable process know in the art, such as CVD. Undercuts, holes or other surface deviations may be located in the substrate **24***c*, and in particular surface **38***c*, so that when the metal interlayer **40***c* is applied to the substrate **24***c*, the metal enters and engages the undercuts, holes, etc. to form a mechanical interlock between the metal interlayer **40***c* and substrate **24***c*. In another embodiment, interlayer **40***c* is a metal foil or sheet.

[0050] A bone fixation portion **14***c* comprised of a porous metal structure, such as any of the porous metal structures described herein or known in the art, is placed against the metal interlayer **40***c* to form an assembly. In one embodiment, one of the porous bone fixation portion **14***c* and the interlayer **40***c* is comprised of tantalum and the other one is comprised of titanium. Optionally, an interlayer such as a metal foil or sheet (not shown) may be placed between the porous metal bone fixation portion **14***c* and a deposited metal interlayer **34***c* so that the implant includes both a deposited metal interlayer **40***c* and a metal foil or sheet. In one embodiment the metal foil or sheet is constructed out of the same metal as the interlayer **34***c*.

[0051] Heat and pressure are applied to the assembly for a period of time sufficient to induce solid state diffusion between the interlayer **40***c* and porous metal bone fixation portion **14***c*, and, if used, the metal foil or sheet. As is known to those skilled in the art, solid-state diffusion is the movement and transport of atoms in solid phases. Solid-state diffusion bonding forms a joint through the formation of bonds at an atomic level due to transport of atoms between two or more metal surfaces. Heat and pressure may be supplied to the assembly by a variety of methods known in the art. For example, the assembly may be heated electrically, radiantly, optically, by induction, by combustion, by microwave, or any other suitable means known in the art. Pressure may be applied mechanically by clamping the assembly together prior to insertion of the assembly into a furnace, or pressure may be applied via a hot pressing system capable of applying pressure once the assembly reaches a target temperature, as is known in the art. Furthermore, hot pressing may include hot isostatic pressing, also known in the art. In one embodiment, the assembly is clamped and heated to at least about 940° C. for 4 hours in a vacuum or in another sub-atmospheric pressure of an inert atmosphere.

[0052] Preferably, the clamped assembly is heated to less than the melting temperature of the components. The time required to achieve bonding may be as little as less than 1 hour and as long as about 48 hours, and will depend on the metals involved, the temperatures, atmosphere and the pressures applied. After the diffusion process has been completed, the implant is formed.

[0053] Yet another embodiment of an implant **10***d* of the present disclosure is illustrated in FIG. **7**. Implant **10***d* includes a core **18***d* that defines a substrate **24***d* for an articulation portion **12***d* and a substrate **25***d* for a bone fixation portion **14***d*. Similar to other embodiments disclosed herein, the substrate **24***d* of the articulation portion **12***d* has a pyrolytic carbon layer **30***d* thereon that forms the bearing surface **16***d*. The core **18***d* may be made of any material or combination of materials suitable for having pyrolytic carbon applied thereto and in one embodiment the substrate **24***d* is carbon, preferably a dense, isotropic graphite. Additionally, in order to enhance the visibility of the implant or portions thereof under fluoroscopy or x-ray imaging, the carbon may be doped with or otherwise include any suitable radiopacifiers, such as tungsten.

[0054] The bone fixation portion **14***d* further includes a porous exterior layer **46***d* overlaying at least a portion of substrate **25***d* of core **18***d* to form porous region **26***d*. The exterior layer **46***d* may be made of any suitable porous bone on- or in-growth material known in the art. For example, the exterior layer **46***d* may be made of metal structure such as but not limited to titanium or tantalum. However, it will be appreciated that other materials may be used depending upon the desired characteristics of the implant. The porous region **26***d* may have a thickness, pore size, a pore interconnectivity, and/or other features that facilitate bone tissue on-and/or in growth. In one embodiment, the exterior layer **46***d*/porous region **26***d* may have a thickness of between about 5 μm and about 300 μm. In order to facilitate the bonding of the exterior layer **46***d* to the substrate **24***d*, the bone fixation portion **14***d* may include an intermediate layer **44***d*. In the embodiment illustrated in FIG. **7**, the intermediate layer **44***d* is formed from a metal such as titanium that is applied via CVD or PVD onto the substrate **25***d* of core **18***d*. The intermediate layer **44***d* may have a thickness of up to about 1 mm.

[0055] FIG. **12** is a flowchart showing one embodiment of a method of making the implant **10***d* illustrated in FIG. **7**. The steps of the method described herein may be performed in any order that produces an implant illustrated in FIG. **7**. In one step, a block of carbon, preferably a dense, isotropic graphite, is machined or otherwise processed to form core **18***d* with substrate **24***d* and substrate **25***d*. In another step, a pyrolytic carbon layer **30***d* is applied to the outer surface **28***d* of substrate **24***d* of the articulation portion **12***d*. An intermediate layer **44***d*, preferably comprised of a metal that can adhere to the graphite substrate **24***e* is applied, preferably via CVD or PVD, to an outer surface of the substrate **25***d* of the bone fixation portion **14***d*. The exterior porous layer **46***d* is applied to the intermediate layer **44***d*, preferably via plasma spraying. However, it will be appreciated that any other suitable method of attaching the exterior layer **46***d* to the intermediate layer **44***d* or directly to the substrate **25***d* if the intermediate layer is omitted may be used. The bearing surface **16***d* of the pyrolytic carbon layer **30***d* may be polished or otherwise treated or conditioned in order to obtain a generally smooth articulating surface.

[0056] Turning to FIG. **8**, implant **10***e* is another embodiment of an orthopedic device of the present disclosure and is similar to the other implants disclosed herein. Implant **10***e* includes a metallic core **18***d*, such as but not limited to titanium or tungsten, that partially defines an articulation portion **12***e* and bone fixation portion **14***e*. The articulation portion **12***e* has a pyrolytic carbon layer **30***e* thereon that forms the bearing surface **16***e*. An intermediate layer **19***e* is positioned between the pyrolytic carbon layer **30***e* and the core **18**. The intermediate layer **19***e* is preferably constructed out of a material, such as carbon, preferably a dense, isotropic graphite, that can bond or otherwise adhere to the metal core **18***e* and pyrolytic carbon layer **30***e*. The core **18***e* also forms the interior portion of the bone fixation portion **14***e* and is at least partially surrounded by a porous exterior layer **46***e* that forms the porous region **26***e*. In the illustrated embodiment, the exterior layer **46***e* is made of a metal such as but not limited to porous titanium or tantalum metal structures. In one embodiment, the exterior layer **46***e* is Trabecular Metal®, generally available from Zimmer, Inc. of Warsaw, Ind. It will be appreciated, however, that other materials for the exterior layer **46***e* may be used depending upon the desired characteristics of the implant. The exterior layer **46***e*/porous region **26***e* preferably have a thickness, pore size, a pore continuity, and/or other features that facilitate bone tissue on-and/or in growth.

[0057] FIG. **13** is a flowchart showing one embodiment of a method of making the implant **10***e* illustrated in FIG. **8**. The steps of the method described herein may be performed in any order that produces an implant illustrated in FIG. **8**. In one step, the metallic core is formed to the desired shape using a metal such as but not limited to titanium or tungsten. In another step, a block of carbon, preferably a dense, isotropic graphite, is machined or otherwise processed to form the intermediate layer **19***e*. The core **18***e* and intermediate layer **19***e* are positioned adjacent one another. Heat and pressure are applied to the assembly for a period of time sufficient to induce solid state diffusion between the core **18***e* and intermediate layer **19***e*. In another step, a pyrolytic carbon layer **30***e* is applied to the outer surface **28***e* of the intermediate layer **19***e*. The bearing surface **16***e* of the pyrolytic carbon layer **30***e* may be polished or otherwise treated or conditioned in order to obtain a generally smooth articulating surface. An exterior layer **46***e* is applied to the core **18***e* of the bone fixation portion **14***e* to form the porous region **26***e*. The exterior layer **46***e* is preferably comprised of a metal that can adhere to the material of the core **18***e*. in one embodiment, the exterior layer **46***e* comprised of a metal such as titanium is applied to the core **18***e*, preferably via plasma spaying. Alternatively, the exterior layer **46***e* may be comprised of a porous tantalum metal structure such as Trabecular Metal®, generally available from Zimmer, Inc. of Warsaw, Ind. In this embodiment, the metal exterior layer **46***e* may be positioned adjacent the core **18***e*. Heat and pressure are applied to the assembly for a period of time sufficient to induce solid state diffusion between the metal exterior layer **46***e* and the core **18***e*. It will be appreciated that bonding of the core **18***e* and intermediate layer **19***e* to one another and the exterior layer **46***e* to the core **18***e* could be formed in either a single step or two step process.

[0058] It will be understood that the methods, compositions, devices and embodiments described above are illustrative of the applications of the principles of the subject matter disclosed herein. It will also be understood that certain modifications may be made by those skilled in the art without departing from the spirit and scope of the subject mater disclosed and/or claimed herein. Thus, the scope of the invention is not limited to the above description, but is set forth in the following claims and/or any future claims made in any application that claims the benefit of this application.

What is claimed is:

1. An orthopedic implant, comprising:

an articulation portion having a pyrolytic carbon bearing surface; and

a bone-fixation portion extending from the articulation portion and having a porous structure configured for bone on-growth or bone in-growth.

2. The implant of claim **1** wherein the articulation portion further includes a substrate and the bone-fixation portion is bonded to the substrate.

3. The implant of claim **2** further including a metal interlayer positioned at least partially between the bone-fixation portion and the substrate.

4. The implant of claim **3** wherein the metal interlayer and the bone-fixation portion are comprised of the same metal material.

5. The implant of claim **3** wherein the interlayer is comprised of a first metal and the bone fixation portion is comprised of a second metal, and the first metal is soluble with the second metal.

6. The implant of claim **3** further including a metal outer layer at least partially covering the bone fixation portion and the interlayer, wherein the interlayer and metal outer layer bond the bone fixation portion to the substrate.

7. The implant of claim **1** wherein the bone fixation portion is comprised of porous tantalum.

8. The implant of claim **2** wherein the substrate is comprised of isotropic graphite.

9. A method of forming an orthopedic implant, comprising:

providing a carbon member having an articulation portion and a bone fixation portion with a porous region;

applying a layer of pyrolytic carbon on an outer surface of the articulation portion;

applying a metal coating to the porous region of the bone fixation portion.

10. The method of claim **9** in which the metal coating is selected from the group consisting of tantalum, titanium, niobium or alloys or combinations thereof.

11. The method of claim **9** wherein the pyrolytic carbon is applied by chemical vapor deposition.

12. A method of forming an orthopedic implant, comprising:

providing a substrate having a first surface and a second surface;

applying a layer of pyrolytic carbon to the first surface of the substrate;

placing an interlayer comprising a metal between the second surface of the substrate and a porous metal structure; and

bonding the porous metal structure and the substrate together to form the orthopedic implant.

13. The method of claim **12** wherein the bonding comprises applying heat and pressure to the substrate, interlayer and porous metal structure for sufficient time to achieve solid-state diffusion between the interlayer and the porous metal structure.

14. The method of claim **12** wherein one of the porous metal structure and the interlayer is comprised of tantalum and the other is comprised of titanium.

15. The method of claim **12** wherein the interlayer is applied to the second surface of the substrate by chemical vapor deposition.

16. The method of claim **12** wherein the pyrolytic carbon is applied by chemical vapor deposition.

17. A method of forming an orthopedic implant, comprising:

applying a layer of pyrolytic carbon to a first surface of a substrate;

applying a metal interlayer to a second surface of the substrate;

contacting a porous metal structure with the metal interlayer; and

applying a second outer layer of metal to the substrate, interlayer and porous metal structure.

18. The method of claim **17** in which the metal interlayer, metal outer layer and porous metal structure all comprise the same metal.

19. The method of claim **18** in which the metal is selected from the group consisting of titanium, tantalum, niobium or alloys or combination of the same.

20. The method of claim **17** in which the pyrolytic carbon is applied to the substrate by chemical vapor deposition.

21. The method of claim **17** in which the metal interlayer is applied to the substrate by chemical vapor deposition.

22. The method of claim **17** in which the metal outer layer is applied by chemical vapor deposition.

23. A method of forming an orthopedic implant, comprising:

applying a layer of pyrolytic carbon to a first surface of a substrate;

applying an interlayer comprised of a metal to a second surface of the substrate;

providing a porous metal structure;

placing a metal foil between the interlayer and the porous metal structure; and

diffusion bonding the porous metal structure, the metal foil and the interlayer.

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