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(71) Applicant: CARTIVA, INC. [US/US]; 6120 Windward Parkway, Suite 220, Alpharetta, GA 30005 (US).

(72) Inventors: HALES, Richard, Clay; 3371 Serenade Court, Alpharetta, GA 30004 (US). MANSUETI, Stephanie, Marie; 1907 Brookhaven Circle NE, Atlanta, GA 30319 (US).

(74) Agent: KOUH, Won, Joon et al.; Duane Morris LLP, 30 South 17th Street, Philadelphia, PA 19103 (US).

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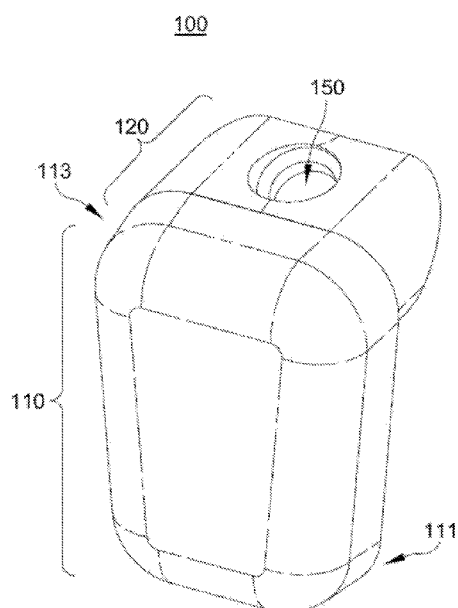


FIG. 1

(57) Abstract: A novel implant for replacing a portion of an articulation surface of a joint is disclosed. The implant includes a bone-engaging surface, a hydrogel portion forming an articulation surface opposite from the first bone-engaging surface, and a bone plate portion configured for securing the implant to a bone that forms the joint.

HYDROGEL IMPLANTS FOR MID-FOOT

FIELD OF DISCLOSURE

[0001] The present disclosure relates generally to orthopedic implants, and more specifically, to hydrogel implants for repairing articulation surfaces in joints in the mid-foot region.

BACKGROUND

[0002] Implants can be used to replace deteriorated or otherwise damaged cartilage within a joint. Such devices can be used to treat osteoarthritis, rheumatoid arthritis, other inflammatory diseases, generalized joint pain, and joint damages.

SUMMARY

[0003] Disclosed herein is an implant for replacing a portion of an articulation surface of a joint, the implant comprising: a main portion configured for inserting into a joint, wherein the main portion comprises: a porous material portion having a first bone-engaging surface; and a hydrogel portion that is bonded to the porous material portion and forming an articulation surface opposite from the first bone-engaging surface; and a bone plate portion configured for securing the implant to a bone that forms the joint; wherein, the main portion having a leading end and a trailing end, wherein the leading end is configured for being inserted into the joint; wherein the bone plate portion is integrally formed with the porous material portion and extends from the trailing end, forming a second bone-engaging surface that is also formed of the porous material and extends from the first bone-engaging surface in a direction opposite from the articulation surface at an angle with respect to the first bone-engaging surface; wherein the bone plate portion comprises a solid metal portion that forms all exterior surfaces of the bone plate portion except for the second bone-engaging surface; and wherein the bone plate portion has at least one screw hole for receiving a bone screw.

[0004] An implant for replacing a portion of an articulation surface of a joint according to another embodiment is disclosed. The implant comprises: a main portion configured for inserting into a joint, wherein the main portion comprises:

a hydrogel portion forming a bone-contacting surface and an articulation surface opposite from the bone-contacting surface;

wherein, the main portion having a leading end and a trailing end, wherein the leading end is configured for being inserted into the joint; and

a bone plate portion configured for securing the implant to a bone that forms the joint;

wherein the bone plate portion comprises:

a first part having a perforated structure that is embedded in the hydrogel portion;

and

a second part that is not embedded in the hydrogel portion and extending from the trailing end in a direction opposite from the articulation surface at an angle $\leq 160^\circ$ but $\geq 80^\circ$ with respect to the bone-contacting surface;

wherein the second part has at least one screw hole for receiving a bone screw.

[0005] An implant for replacing a portion of an articulation surface of a joint according to another embodiment is also disclosed. The implant comprises: a main portion configured for inserting into a joint, wherein the main portion comprises:

a hydrogel portion forming a bone-contacting surface and an articulation surface opposite from the bone-contacting surface;

wherein the bone-contacting surface comprises a protruding part;

wherein, the main portion having a leading end and a trailing end, wherein the leading end is configured for being inserted into the joint; and

a bone plate portion configured for securing the implant to a bone that forms the joint;

wherein the bone plate portion comprises:

a first part having a perforated structure that is embedded in the protruding part of the hydrogel portion; and

a second part that is not embedded in the protruding part of the hydrogel portion and extending from the trailing end in a direction opposite from the articulation surface at an angle $\leq 160^\circ$ but $\geq 80^\circ$ with respect to the bone-contacting surface;

wherein the second part has at least one screw hole for receiving a bone screw.

[0006] An implant for replacing a portion of an articulation surface of a joint according to yet another embodiment is disclosed. The implant comprises: a main portion configured for inserting into a joint and comprising a leading end, a trailing end, an articulation surface and a

bone-contacting surface extending between the leading end and the trailing end, wherein the leading end is configured for being inserted into the joint, wherein the main portion further comprises:

a porous material portion; and

a hydrogel portion forming the articulation surface and the bone-contacting surface opposite from the articulation surface;

wherein the porous material portion is bonded to the hydrogel portion, extending from the trailing end and partially towards the leading end and forms a portion of the bone-contacting surface;

wherein the porous material portion comprises a tapered hole at the trailing end; and

a bone plate configured for securing the implant to a bone that forms the joint;

wherein the bone plate is formed of a solid metal;

wherein the bone plate comprises a tapered stem that is configured to be inserted into the tapered hole in the porous material portion, whereby the tapered stem and the tapered hole cooperate to urge the bone-contacting surface of the implant toward the bone when the implant is inserted into the joint; and

wherein the bone plate has at least one screw hole for receiving a bone screw.

[0007] The novel implants disclosed herein provides hydrogel implants having hybrid structures that allow repair of articular cartilage surfaces in various joint spaces that were not easily repaired and provide robust and durable repaired surfaces utilizing the benefits of utilizing hydrogel material for articulation surfaces.

BRIEF DESCRIPTION OF THE DRAWINGS

[0008] The various embodiments of the inventive hydrogel implant of the present disclosure will be described in more detail in conjunction with the following drawing figures. The structures in the drawing figures are illustrated schematically and are not intended to show actual dimensions.

[0009] FIG. 1 is a perspective view illustration of a hydrogel implant according to a first embodiment of the present disclosure.

[0010] FIG. 2 is an exploded view illustration of the hydrogel implant of FIG. 1.

- [0011] FIG. 3A is a side view illustration of the hydrogel implant of FIG. 1.
- [0012] FIG. 3B is a side view illustration of the hydrogel implant of FIG. 1 in implanted position in a joint.
- [0013] FIG. 4 is a cross-section view illustration of the hydrogel implant of FIG. 1 taken through the section line H-H shown in FIG. 3.
- [0014] FIG. 5 is a top view illustration of the hydrogel implant of FIG. 1 showing only the porous metal foam portion, i.e., the implant without the hydrogel portion and the solid metal portion.
- [0015] FIG. 6 is a cross-section view illustration of the structure shown in FIG. 5 taken through the section line T-T.
- [0016] FIG. 7 is a side view illustration of the hydrogel implant of FIG. 1 showing only the porous metal foam and the solid metal portions, i.e., the implant without the hydrogel portion.
- [0017] FIG. 8 is a cross-section view illustration of the structure shown in FIG. 7 taken through the section line E-E.
- [0018] FIG. 9 is a top view illustration of the structure shown in FIG. 7.
- [0019] FIG. 10 is a top view illustration of the hydrogel implant of FIG. 1.
- [0020] FIG. 11 is a cross-section view illustration of the hydrogel implant taken through the section line M-M shown in FIG. 10.
- [0021] FIG. 12 is a detailed view of the region N identified in the sectional view of FIG. 11.
- [0022] FIG. 13 is a perspective view of a hydrogel implant according to a second embodiment.
- [0023] FIG. 14 is an exploded view illustration of the hydrogel implant of FIG. 13.
- [0024] FIG. 15 is a top view of the bone plate portion of the hydrogel implant of FIG. 13.
- [0025] FIG. 16 is a side view of the bone plate portion shown in FIG. 15.
- [0026] FIG. 17 is a cross-section view of the bone plate portion taken through the section line F-F shown in FIG. 15.
- [0027] FIG. 18 is a detailed view of the region G identified in the sectional view of FIG. 17.

- [0028] FIG. 19 is a detailed view of the region N identified in the sectional view of FIG. 17.
- [0029] FIG. 20 is a perspective view of a hydrogel implant according to a third embodiment.
- [0030] FIG. 21 is an exploded view illustration of the hydrogel implant of FIG. 20.
- [0031] FIG. 22 is a top view of the bone plate portion of the hydrogel implant of FIG. 20.
- [0032] FIG. 23 is a cross-section view of the bone plate portion taken through the section line C-C shown in FIG. 22.
- [0033] FIG. 24 is a detailed view of the region E identified in the sectional view of FIG. 23.
- [0034] FIG. 25 is an illustration of an example of a mold that can be used to form the hydrogel implants of the present disclosure by injection molding.
- [0035] FIG. 26 is a cross-section view of the injection molding set up shown in FIG. 25.
- [0036] FIG. 27 is a perspective view illustration of a hydrogel implant according to a fourth embodiment.
- [0037] FIGs. 28-29 are illustrations showing the hydrogel implant of FIG. 27 implanted into some of the mid-foot joints.
- [0038] FIG. 30 is a perspective view illustration of the main portion of the hydrogel implant of FIG. 27.
- [0039] FIG. 31 is an illustration showing a view of the bone-contacting surface of the main portion shown in FIG. 30.
- [0040] FIG. 32 is a top view illustration of the main portion shown in FIG. 31.
- [0041] FIG. 33 is a side view illustration of the main portion shown in FIG. 31.
- [0042] FIG. 34 is a cross-section view of the main portion shown in FIG. 31 taken through the section line A-A shown in FIG. 32.
- [0043] FIG. 35 is a perspective view of the hydrogel implant of FIG. 27 secured to a bone in its fully implanted configuration.
- [0044] FIG. 36 is a cross-section view of the hydrogel implant shown in FIG. 35 in which the bone plate portion has not yet been seated in its fully implanted configuration.
- [0045] FIG. 37 is a cross-section view of the hydrogel implant shown in FIG. 35 in which the bone plate portion is seated in its fully implanted configuration.

[0046] FIG. 38 is a perspective view illustration of a hydrogel implant according to another embodiment of the present disclosure.

[0047] FIG. 39 is an exploded view illustration of the hydrogel implant of FIG. 38.

[0048] FIG. 40 is a side view illustration of the hydrogel implant of FIG. 38.

[0049] FIG. 41 is a cross-section view illustration of the hydrogel implant of FIG. 38 taken through the section line V-V shown in FIG. 40.

[0050] FIG. 42 is a top view illustration of the hydrogel implant of FIG. 38.

[0051] FIG. 43 is a cross-section view illustration of the hydrogel implant taken through the section line AF-AF shown in FIG. 42.

[0052] FIG. 44 is a detailed view of the region AG identified in the sectional view of FIG. 43.

DETAILED DESCRIPTION

[0053] This description of the exemplary embodiments is intended to be read in connection with the accompanying drawings, which are to be considered part of the entire written description. The drawing figures are not necessarily to scale and certain features may be shown exaggerated in scale or in somewhat schematic form in the interest of clarity and conciseness. In the description, relative terms such as "horizontal," "vertical," "up," "down," "top" and "bottom" as well as derivatives thereof (e.g., "horizontally," "downwardly," "upwardly," etc.) should be construed to refer to the orientation as then described or as shown in the drawing figure under discussion. These relative terms are for convenience of description and normally are not intended to require a particular orientation. Terms including "inwardly" versus "outwardly," "longitudinal" versus "lateral" and the like are to be interpreted relative to one another or relative to an axis of elongation, or an axis or center of rotation, as appropriate. Terms concerning attachments, coupling and the like, such as "connected" and "interconnected," refer to a relationship wherein structures are secured or attached to one another either directly or indirectly through intervening structures, as well as both movable or rigid attachments or relationships, unless expressly described otherwise. When only a single machine is illustrated, the term "machine" shall also be taken to include any collection of machines that individually or jointly execute a set (or multiple sets) of instructions to perform any one or more of the methodologies discussed herein. The term "operatively connected" is such an attachment,

coupling or connection that allows the pertinent structures to operate as intended by virtue of that relationship. In the claims, means-plus-function clauses, if used, are intended to cover the structures described, suggested, or rendered obvious by the written description or drawings for performing the recited function, including not only structural equivalents but also equivalent structures.

[0054] According to an embodiment illustrated in FIGs. 1-12, an implant **100** for replacing a portion of an articulation surface of a joint is disclosed. As shown in FIG. 1, the implant comprises a main portion **110** configured for inserting into a joint and a bone plate portion **120** extending from the main portion **110** at an angle and configured for securing the implant **100** to a bone that forms the joint. As shown in the exploded view of FIG. 2, the main portion **110** comprises a porous material portion **115** having a first bone-engaging surface **130**, and a hydrogel portion **112** that is bonded to the porous material portion **115**.

[0055] Referring to FIGs. 2 and 3A, the hydrogel portion **112** forms an articulation surface **114** located opposite from the first bone-engaging surface **130**. In other words the articulation surface **114** and the first bone-engaging surface **130** face away from each other. The bone plate portion **120** comprises a solid metal portion **122** that forms all exterior surfaces of the bone plate portion **120** except for the second bone-engaging surface **140**. The second bone-engaging surface **140** of the bone plate portion **120** is formed of the same porous material as the porous material portion **115** and is preferably integrally formed with the porous material portion **115** as a unitary structure for ease of manufacturing and producing a more compact structure.

[0056] The bone plate portion **120** comprises at least one screw hole **150** for receiving a bone screw that is used to secure the implant **100** to a bone. There can be more than one screw holes provided in the bone plate portion **120** for implanting into a joint repair site that may require more than one bone screw to secure the implant.

[0057] The main portion **110** of the implant **100** has a leading end **111** and a trailing end **113**, where the leading end is configured for being inserted into the joint. Here, the terms “leading” and “trailing” references generally the implant’s orientation in its implanted position in a joint space and also the orientation as the implant is being inserted into the joint space.

[0058] The bone plate portion **120** is integrally formed with the porous material portion **115** and extends from the trailing end, forming a second bone-engaging surface **140**. Because the

extension piece **117** is formed of the same porous material as the porous material portion **115**, the second bone-engaging surface **140** also promotes the cancellous bone's growth into the second bone-engaging surface **140** and enhance the implant's stability in the repair site.

[0059] As shown by the dashed lines in the side view of the implant **100** in FIG. 3A, the porous material portion **115** has an extension piece **117** that extends from the first bone-engaging surface **130** in a direction opposite from the articulation surface **114** at an angle θ with respect to the first bone-engaging surface **130**. The angle θ between the first and second bone-engaging surfaces **130**, **140** is selected to enable secure attachment of the implant to the bone. In some embodiments, that angle can be substantially 90° . This means that the angle can be $90^\circ \pm 2^\circ$. In some embodiments, the angle is an obtuse angle. In some embodiments, the obtuse angle is $\geq 110^\circ$ and $\leq 160^\circ$. In some embodiments, the obtuse angle is $\geq 130^\circ$ and $\leq 140^\circ$.

[0060] The extension piece **117** is provided to form the second bone-engaging surface **140**. The porous material portion **115** and the extension piece **117** together provide a skeletal base structure on which the hydrogel portion **112** is applied and bonded thereto. This skeletal structure is shown in FIGs. 5 and 6. The solid metal portion **122** fills the space **118** between the extension piece **117** and the porous material portion **115**. In some embodiments, the solid metal portion **122** can be integrally formed with the porous material portion **115** and the extension piece **117**. FIGs. 7-9 show the porous material structures **115**, **117** and the solid metal portion **122** together.

[0061] In FIGs. 5 and 6, because only porous material structures **115** and **117** are shown, without the solid metal portion **122**, the hole **150A** in the extension piece **117** is larger than the bone screw hole **150** which is the final dimension screw hole that is formed by the solid metal portion **122** that overlays on the extension piece **117**.

[0062] In a preferred embodiment, the porous material structures **115**, **117** and the solid metal portion **122** are formed as a unitary structure. For example, the porous material structures and the solid metal portion **122** can be 3-D printed and sintered to form a unitary structure.

[0063] In some embodiments, the bone plate portion **120** and the porous material portions **115** and are formed of surgical grade metal. In a preferred embodiment, the surgical grade metal used is titanium. In more preferred embodiment, the solid metal portion **122** is

formed of titanium metal and the porous material portion **115** and the extension piece **117** are made of porous titanium metal foam.

[0064] The hydrogel portion **112** is bonded to the porous material portion by having some hydrogel material infiltrate into pores of the porous material portion. In preferred embodiments where the porous material is porous titanium metal foam, the hydrogel material infiltrate into pores of the porous titanium metal foam.

[0065] The porous material may comprise an oxide material. The porous material can comprise at least one of surgical grade materials such as aluminum, alumina, zirconia, titanium, titania, stainless steel, PEEK, and steatite that are approved for implantation in humans. The porous material can have a porosity between 45 ppi and 80 ppi. Pores of the porous material can have a dimension between 100 μm and 500 μm . The porous material can be ceramic, metal, or plastic. In some embodiments, the porous material comprises porous ceramic material (e.g., oxide-ceramic), metal (e.g., titanium (e.g., titanium mesh, printed titanium), stainless steel (e.g., stainless steel wool), plastic (e.g., polyaryl ether ketone (PAEK) (e.g., polyether ether ketone (PEEK)), other biocompatible materials, combinations thereof, etc.) In some preferred embodiments, the porous material is porous metal foam material that has open-celled three-dimensional scaffold structure for bone and tissue growth.

[0066] In more preferred embodiments, the porous metal foam material is porous titanium foam. An example of such porous titanium foam material is Wright Medical Technology's BIOFOAM® Cancellous Titanium™ technology. The titanium matrix of BIOFOAM® Cancellous Titanium™ technology has fully interconnected porosity of up to 70% providing an ideal environment for optimum bone ingrowth and incorporation. The titanium matrix of BIOFOAM® Cancellous Titanium™ technology has: compressive strength that is between that of cortical and cancellous bone, thus minimizing deformation under dynamic loading conditions; compressive modulus that is close to that of cancellous bone, allowing the natural transfer of dynamic loads away from the implant to the surrounding bone; and high surface coefficient of friction that provides initial stability in the interface between the implant and the bone, minimizing micro motion and creating a stable environment for rapid ingrowth and fixation. Examples of alternative materials for the porous metal foam is titanium dioxide foam and porous tantalum foam.

[0067] Referring to FIG. 3B, when the implant **100** is implanted in a patient to repair or replace a portion of an articulation surface (e.g., articular cartilage) in a joint, the damaged articulation surface and the adjacent bone region would be prepared to receive the implant **100**. The prepared site would have resected bone surfaces **B1** and **B2** corresponding to the first bone-engaging surface **130** and the second bone-engaging surface **140** of the implant **100**. All or much of the resected bone surfaces **B1** and **B2** would generally be comprised of cancellous bone and because the first and second bone-engaging surfaces **130**, **140** are formed of porous metal foam material that has a mesh-like structure with many pores mimicking the cancellous bone structure, the cancellous bone grows into the porous metal foam structure and further enhances the securement of the implant **100** in the repair site.

[0068] The hydrogel portion **112** can be formed by applying the hydrogel material in a liquid form on the porous material structure **115** in a mold and then allowing the hydrogel material to cross-link by conducting the appropriate processes that are appropriate for the particular type of hydrogel material that is selected for a given application for the implant.

[0069] In some embodiments of the implant **100**, the bond between the hydrogel portion and the porous material portion is enhanced by having some hydrogel material infiltrating into the pores in a portion of the porous material along the surface that comes in contact with the hydrogel material. Thus, in a region in the porous material structure **115** along the hydrogel portion **112**, both the hydrogel material and the porous material co-exist while in the remainder of the porous material structure **115** toward the bone-engaging surface **130**, only the porous material exists without any hydrogel material. That allows the bone-engaging surface **130** to present pores that enable cancellous bone ingrowth.

[0070] The hydrogel material referred to herein refers to a three-dimensional solid resulting from cross-linked hydrophilic polymer chains formed of polyvinyl alcohol (PVA). The hydrogel material can comprise one or more other materials in addition to PVA, such as, for example, other hydrogels, other polymeric materials, additives, and/or the like. In some embodiments, the PVA content of the hydrogel in the implants disclosed herein can be about 40% by weight. The PVA content of the hydrogel can range from about 10% by weight to about 80% by weight, as appropriate for particular application.

[0071] The hydrogel can comprise water, saline, other liquids, combinations thereof, and/or the like. In some embodiments, saline may be preferred over water, because, under certain

circumstances, saline can help maintain osmotic balance with surrounding anatomical tissues following implantation. The exact composition of the hydrogel component in an implant can be selected for optimal performance in a particular application to achieve the desired or required strength, load bearing capacity, compressibility, flexibility, longevity, durability, resilience, coefficient of friction, and/or other properties and characteristics.

[0072] In some embodiments, such hydrogel portions of the implants can be formulated for drug delivery and/or is seeded with growth factors and/or cells. In such embodiments, the hydrogel component can comprise one or more of the following: chondrocytes, growth factors, bone morphogenetic proteins, collagen, hyaluronic acid, nucleic acids, and stem cells. Such factors and/or any other materials included in the implants can help facilitate and/or promote long-term fixation of the implants at the joint site.

[0073] FIG. 10 shows a top view illustration of the hydrogel implant **100**. FIG. 11 is a cross-section view illustration of the hydrogel implant **100** taken through the section line M-M shown in FIG. 10. FIG. 12 is a detailed view of the region N identified in the sectional view of FIG. 11.

[0074] Referring to FIGS. 38-41, an implant **100A** for replacing a portion of an articulation surface of a joint according to another embodiment is disclosed. As shown in FIG. 38, the implant comprises a main portion **110A** configured for inserting into a joint and a bone plate portion **120A** extending from the main portion **110A** at an angle and configured for securing the implant **100A** to a bone that forms the joint. As shown in the exploded view of FIG. 39, the implant **100A** comprises four different components that are bonded together in the following order: a first porous material portion **117A**, a solid metal portion **116A**, a second porous material portion **115A**, and a hydrogel portion **112A**.

[0075] Referring to FIGS. 39 and 40, which is a side view of the implant **100A**, the first porous material portion **117A** has a first bone-engaging surface **130A**, and a second bone-engaging surface **140A**. The top portion **121A** of the first porous material portion **117A** form the second bone-engaging surface **140A** and the remaining portion of the first porous material portion **117A** form the first bone-engaging surface **130A**. On the side opposite of the two bone-engaging surfaces **130A**, **140A**, the solid metal portion **116A** is bonded to the first porous material portion **117A**.

[0076] The solid metal portion **116A** comprises a top portion **122A**, which together with the top portion **121A** of the first porous material portion **117A** form the bone plate portion **120A** of the implant **100A**. Similar to the implant **100** described above, the bone plate portion **120A** of the implant **100A** also comprises at least one screw hole for receiving a bone screw that is used to secure the implant **100A** to a bone. In the illustrated example shown, two screw holes **150A** and **151A** are provided in the bone plate portion **120A** for implanting into a joint repair site that may require more than one bone screw to secure the implant. The top portion **121A** of the first porous material portion **117A** comprises holes **150A'** and **151A'** that correspond to the two screw holes **150A** and **151A**.

[0077] The top portion **122A** of the solid metal portion **116A** forms the exterior surface of the bone plate portion **120A** while the second bone-engaging surface **140A** is formed by the first porous material portion **117A**.

[0078] The second porous material portion **115A** is positioned between and bonded to both the solid metal portion **116A** and the hydrogel portion **112A**. The hydrogel portion **112A** forms an articulation surface **114A** located opposite from the first bone-engaging surface **130A**. In other words, the articulation surface **114A** and the first bone-engaging surface **130A** face away from each other.

[0079] The main portion **110A** of the implant **100A** has a leading end **111A** and a trailing end **113A**, where the leading end **111A** is configured for being inserted into the joint. Here, the terms “leading” and “trailing” references generally the implant’s orientation in its implanted position in a joint space and also the orientation as the implant is being inserted into the joint space.

[0080] Both the first and second porous material portions **117A** and **115A** are preferably made of the same porous material. The first porous material portion **117A** which forms the first and second bone-engaging surfaces, **130A** and **140A**, respectively, promotes the cancellous bone’s growth into the bone-engaging surfaces **130A**, **140A** and enhance the implant’s stability in the repair site.

[0081] As shown in FIG. 40, the first bone-engaging surface **130A** is substantially parallel to the articulation surface **114A** of the hydrogel portion **112A**. The second bone-engaging surface **140A** of the bone plate portion **120A** and the first bone-engaging surface **130A**

form an angle θ with respect to the first bone-engaging surface **130**. The angle θ between the first and second bone-engaging surfaces **130A**, **140A** is selected to enable secure attachment of the implant to the bone. In some embodiments, that angle can be substantially 90° . This means that the angle can be $90^\circ \pm 2^\circ$. In some embodiments, the angle is an obtuse angle. In some embodiments, the obtuse angle is $\geq 110^\circ$ and $\leq 160^\circ$. In some embodiments, the obtuse angle is $\geq 130^\circ$ and $\leq 140^\circ$.

[0082] The first porous material portion **117A**, the solid metal portion **116A**, and the second porous material portion **115A** together provide a skeletal base structure on which the hydrogel portion **112A** is applied and bonded thereto. In some embodiments, the solid metal portion **116A** can be integrally formed with the first and second porous material portions **117A** and **115A** as a unitary structure. For example, the porous material structures and the solid metal portion **116A** can be 3-D printed and sintered to form a unitary structure.

[0083] As in the implant embodiment **100**, the solid metal portion **116A** and the porous material portions **117A**, **115A** can be formed of surgical grade metal such as titanium and/or titanium alloys.

[0084] The hydrogel portion **112A** is bonded to the second porous material portion **115A** by having some hydrogel material infiltrate into pores of the porous material portion. In preferred embodiments where the porous material is porous titanium metal foam, the hydrogel material infiltrate into pores of the porous titanium metal foam. The porous material may comprise of the materials described above in connection with the implant **100**.

[0085] When implanted in a patient, the implant **100A's** arrangement will be similar to the exaple for implant **100** shown in FIG. 3B.

[0086] The hydrogel portion **112A** can be formed by applying the hydrogel material in a liquid form on the porous material structure **115A** in a mold and then allowing the hydrogel material to cross-link by conducting the appropriate processes that are appropriate for the particular type of hydrogel material that is selected for a given application for the implant.

[0087] In some embodiments of the implant, the bond between the hydrogel portion and the porous material portion is enhanced by having some hydrogel material infiltrating into the pores in a portion of the porous material along the surface that comes in contact with the hydrogel material. Thus, in a region in the porous material structure **115A** along the hydrogel

portion **112A**, both the hydrogel material and the porous material co-exist while in the remainder of the porous material structure **115A** toward the bone-engaging surface **130A**, only the porous material exists without any hydrogel material. That allows the bone-engaging surface **130A** to present pores that enable cancellous bone ingrowth.

[0088] FIG. 42 is a top view illustration of the hydrogel implant **100A**. FIG. 43 is a cross-section view illustration of the hydrogel implant **100A** taken through the section line AF-AF shown in FIG. 42. FIG. 44 is a detailed view of the region AG identified in the sectional view of FIG. 43.

[0089] Referring to FIGs. 13-19, an implant **200** for replacing a portion of an articulation surface of a joint according to another embodiment is disclosed. The implant **200** comprises a main portion **210** configured for inserting into a joint. The main portion **210** can comprise a hydrogel portion **212** forming a bone-contacting surface **230** and an articulation surface **214** opposite from the bone-contacting surface **230**. The main portion **210** has a leading end **211** and a trailing end **213**, wherein the leading end is configured for being inserted into the joint. A bone plate portion **220** configured for securing the implant **200** to a bone that forms the joint. The bone plate portion **220** comprises a first part **223** having a perforated structure that is embedded in the hydrogel portion **212**; and a second part **225** that is not embedded in the hydrogel portion and extending from the trailing end **213** in a direction opposite from the articulation surface **214** at an angle $\leq 160^\circ$ but $\geq 80^\circ$ with respect to the bone-contacting surface **230**. The second part **225** has at least one screw hole **250** for receiving a bone screw (not shown). The second part **225** can have generally circular configuration around the screw hole **250** as shown in FIG. 15, but the shape of the second part **225** can be designed to have any appropriate shape to fit into the structure (e.g. contour) of the bones around the particular joint space into which the implant **200** will be implanted.

[0090] In some embodiments of the implant **200**, the second part **225** extends from the trailing end **213** at an angle that is $\leq 110^\circ$ and $\geq 80^\circ$. In some embodiments of the implant **200**, the second part **225** extends from the trailing end **213** at an angle that is substantially 90° (i.e., $90 \pm 2^\circ$). In some embodiments of the implant **200**, the first part **223** of the bone plate portion **220** is embedded in the hydrogel portion **212** and located closer to the bone-contacting surface **230** than the articulation surface **214**. In some embodiments of the implant **200**, the bone-contacting surface **230** is a flat surface. When the bone-contacting surface **230** is a flat surface, the first part

223 of the bone plate portion **220** has substantially flat configuration as shown in FIGs. 13 and 14 to correspond to the flat contour of the bone-contacting surface **230**.

[0091] The implant **200** can be formed by molding the hydrogel material around the first part **223** of the bone plate portion **220** using injection molding or open cavity molding processes known to those in the art. As shown in FIGs. 14 and 19, the first part **223** of the bone plate portion **220**, the part that gets embedded in the hydrogel portion **212**, can be perforated with holes **227** to better enable the hydrogel material to intimately surround and envelope the first part **223** during the molding process so that the resulting implant **200** has the optimal structural integrity.

[0092] The bone plate portion **220** is made of a surgical grade metal, such as stainless steel, cobalt based superalloys, titanium, titanium alloys, etc. In some embodiments, the surgical grade metal is titanium.

[0093] Referring to FIGs. 20-24, an implant **300** according to another embodiment is disclosed. The implant **300** is similar to the implant **200** just described with one of the differences being the provision of a protruding part **316** on the bone-contacting surface **330**.

[0094] The implant **300** for replacing a portion of an articulation surface of a joint comprises a main portion **310** configured for inserting into a joint. The main portion **310** comprises a hydrogel portion **312** forming a bone-contacting surface **330** and an articulation surface **314** opposite from the bone-contacting surface **330**. The bone-contacting surface **330** comprises the protruding part **316** that provides additional structural stability at the interface between the bone and the bone-contacting surface **330** when the implant **300** is implanted in position in a joint space. Preferably, the bone surface that is receiving the implant **300** would be prepared to have a contour that is complementary to the contour of the bone-contacting surface **330** that includes the protruding part **316**.

[0095] Similar to the implant **200**, the main portion **310** of the implant **300** comprises a leading end **311** and a trailing end **313**, where the leading end **311** is configured for being inserted into the joint. The implant **300** further comprises a bone plate portion **320** configured for securing the implant **300** to a bone that forms the joint. The bone plate portion **320** comprises a first part **323** having a perforated structure that is embedded in the protruding part **316** of the hydrogel portion **312**, and a second part **325** that is not embedded in the protruding part of the hydrogel portion. The second part **325** extends from the trailing end **313** in a direction opposite

from the articulation surface **314** at an angle $\leq 160^\circ$ but $\geq 80^\circ$ with respect to the base flat portion of the bone-contacting surface **330** (*i.e.*, the part of the bone-contacting surface **330** excluding the protruding part **316**). The second part has at least one screw hole **350** for receiving a bone screw (not shown). Similar to the implant **200**, the second part **325** can have generally circular configuration around the screw hole **350** as shown in FIG. 21, but the shape of the second part **325** can be designed to have any appropriate shape to fit into the structure (e.g. contour) of the bones around the particular joint space into which the implant **300** will be implanted.

[0096] In some embodiments of the implant **300**, the second part **325** extends from the trailing end **313** at an angle that is $\leq 110^\circ$ and $\geq 80^\circ$. In some embodiments of the implant **300**, the second part **325** extends from the trailing end **313** at an angle that is substantially 90° (*i.e.*, $90 \pm 2^\circ$). In some embodiments, the first part **323** of the bone plate portion is embedded in the hydrogel portion and located closer to the bone-contacting surface **330** than the articulation surface **314**. Preferably, the first part **323** of the bone plate portion **320** has a contour that substantially matches the contour of the protruding part **316** of the hydrogel portion **312**.

[0097] In some embodiments, the protruding part **316** of the bone-contacting surface **330** has a half-cylinder contour and the first part **323** of the bone plate portion has a complementary curved contour. In some embodiments of the implant **300**, the bone plate portion **320** is made of a surgical grade metal, such as stainless steel, cobalt based superalloys, titanium, titanium alloys, etc. In some embodiments, the surgical grade metal is titanium.

[0098] Referring to FIGs. 25 and 26, an example of a molding process for forming the implants **200** and **300** is disclosed. A mold **500** having a plurality of mold cavities **510** is provided. Each of the mold cavity **510** is configured with the outline shape of either the implant **200** or the implant **300**. A bone plate portion **220** or **320** is first placed in each of the mold cavity **510**. Then, a nozzle **550** for dispensing the hydrogel material is positioned into the mold cavity **510** as shown in FIG. 26. Next, the hydrogel material, represented by the arrow **600**, is dispensed into each of the mold cavity **510**. Next, with each of the mold cavities **510** holding a bone plate portion **220** and filled with the hydrogel material, an appropriate post processing is carried out for cross-linking the hydrogel material to form the finished implant product **200**. This process is equally applicable to the implant **300**. The specifics of this post processing would be determined by the particular hydrogel material being used but would be well known to those in the art for the particular formulation of hydrogel.

[0099] Referring to FIGs. 27-37, another embodiment of an implant **400** for replacing a portion of an articulation surface of a joint is disclosed. The implant **400** comprises a main portion **410** configured for inserting into a joint and a bone plate **420** configured for securing the implant **400** to a bone that forms a joint.

[00100] Referring to FIG. 30, the main portion **410** comprises a leading end **411**, a trailing end **413**, an articulation surface **414** and a bone-contacting surface **430** extending between the leading end and the trailing end. The leading end **411** is configured for being inserted into the joint. The main portion **410** further comprises a porous material portion **415** and a hydrogel portion **412** forming the articulation surface **414** and the bone-contacting surface **430** opposite from the articulation surface **414**. The porous material portion **415** is bonded to the hydrogel portion **412** and the porous material portion **415** extends partially from the trailing end **413** towards the leading end **411** and forms a portion of the bone-contacting surface **430**.

[00101] Referring to FIG. 30 and the cross-sectional view in FIG. 34, the porous material portion **415** comprises a tapered hole **460** at the trailing end **413**.

[00102] Referring to the cross-sectional views of FIGs. 36 and 37, in some embodiments, the bone plate **420** is formed of a solid metal and comprises a tapered stem **427** that is configured to be inserted into the tapered hole **460** in the porous material portion **415**. The tapered stem **427** and the tapered hole **460** cooperate to urge the bone-contacting surface **430** of the implant **400** toward the bone when the implant **400** is inserted into the joint. Referring to FIGs. 27, 35-36, the bone plate **420** comprises at least one screw hole **450** for receiving a bone screw S.

[00103] The porous material for the porous material portion **415** can be the same material as the porous material portion **115** of the implant **100** discussed above.

[00104] In some embodiments, the hydrogel portion **412** is bonded to the porous material portion **415** by having some hydrogel material infiltrating into pores in a portion of the porous material portion. The main portion **410** comprising the hydrogel portion **412** and the porous material portion **415** can be formed by an appropriate process such as an injection molding or open cavity molding process as described above in connection with the implant embodiment **100**.

[00105] FIGs. 35-37 are illustrated with the bone of a joint in which the implant **400** is secured. A portion of the bone immediately surrounding the implant **400** is illustrated conceptually as a box-like volume **Bone** for illustration purposes. FIGs. 36 and 37 show how the tapered stem **427** of the bone plate **420** and the tapered hole **460** of the porous material portion

415 engage each other and cooperate to urge the bone-contacting surface **430** of the implant **400** toward the bone when the implant **400** is inserted into the joint. FIG. 36 shows the implant **400** positioned in place in the **Bone**. The bone-contacting surfaces **430** are contacting the prepared bone surface **B3**. The tapered stem **427** of the bone plate **420** is partially inserted into the mating tapered hole **460** in the porous material portion **415** and a bone screw **S** is placed through the screw hole **450** in the bone plate **420** and starting to engage the pre-drilled hole in the **Bone**. FIG. 37 shows the implant **400** where the bone screw **S** is fully screwed into the **Bone** and has secured the bone plate **420** to the Bone. With the bone plate **420** in its fully-seated position, the tapered stem **427** is fully inserted into the tapered hole **460**. The tapered surface of the tapered stem **427** pushes against the sidewall of the tapered hole **460** as the tapered stem **427** reaches its fully-seated position and securely holds the main portion **410** of the implant **400** in place.

[00106] In FIGs. 28 and 29, two examples of the implant **400** are shown implanted in joint spaces between a metatarsal bone and a cuneiform bone. In FIG. 29, a third implant **400** is shown implanted in a subtalar joint space between the talus and the calcaneus.

[00107] Although the devices, kits, systems, and methods have been described in terms of exemplary embodiments, they are not limited thereto. Rather, the appended claims should be construed broadly, to include other variants and embodiments of the devices, kits, systems, and methods, which may be made by those skilled in the art without departing from the scope and range of equivalents of the devices, kits, systems, and methods.

1. An implant for replacing a portion of an articulation surface of a joint, the implant comprising:
 - a main portion configured for inserting into a joint, wherein the main portion comprises:
 - a porous material portion having a first bone-engaging surface; and
 - a hydrogel portion that is bonded to the porous material portion and forming an articulation surface opposite from the first bone-engaging surface; and
 - a bone plate portion configured for securing the implant to a bone that forms the joint; wherein, the main portion having a leading end and a trailing end, wherein the leading end is configured for being inserted into the joint;
 - wherein the bone plate portion is integrally formed with the porous material portion and extends from the trailing end, forming a second bone-engaging surface that is also formed of the porous material and extends from the first bone-engaging surface in a direction opposite from the articulation surface at an angle with respect to the first bone-engaging surface;
 - wherein the bone plate portion comprises a solid metal portion that forms all exterior surfaces of the bone plate portion except for the second bone-engaging surface; and
 - wherein the bone plate portion has at least one screw hole for receiving a bone screw.
2. The implant of claim 1, wherein the porous material is porous metal foam.
3. The implant of claim 1, wherein the porous material is porous titanium foam.
4. The implant of claim 1, wherein the angle between the first and second bone-engaging surfaces is substantially 90°. [In the spec, define what is meant by substantially.]
5. The implant of claim 1, wherein the angle between the first and second bone-engaging surfaces is an obtuse angle.
6. The implant of claim 2, wherein the obtuse angle is $\geq 110^\circ$ and $\leq 160^\circ$.
7. The implant of claim 2, wherein the obtuse angle is $\geq 130^\circ$ and $\leq 140^\circ$.
8. The implant of claim 1, wherein the hydrogel portion is bonded to the porous material portion by having some hydrogel material infiltrate into pores of the porous material portion.
9. The implant of claim 8, wherein the porous material portion is formed of porous titanium metal foam.

10. The implant of claim 1, wherein the bone plate portion and the porous material portion are formed of porous titanium metal foam.

11. An implant for replacing a portion of an articulation surface of a joint, the implant comprising:

a main portion configured for inserting into a joint, wherein the main portion comprises:

a hydrogel portion forming a bone-contacting surface and an articulation surface opposite from the bone-contacting surface;

wherein, the main portion having a leading end and a trailing end, wherein the leading end is configured for being inserted into the joint; and

a bone plate portion configured for securing the implant to a bone that forms the joint; wherein the bone plate portion comprises:

a first part having a perforated structure that is embedded in the hydrogel portion;

and

a second part that is not embedded in the hydrogel portion and extending from the trailing end in a direction opposite from the articulation surface at an angle $\leq 160^\circ$ but $\geq 80^\circ$ with respect to the bone-contacting surface;

wherein the second part has at least one screw hole for receiving a bone screw.

12. The implant of claim 11, wherein the second part extends from the trailing end at an angle that is $\leq 110^\circ$ and $\geq 80^\circ$.

13. The implant of claim 11, wherein the second part extends from the trailing end at an angle that is substantially 90° .

14. The implant of claim 11, wherein the first part of the bone plate portion is embedded in the hydrogel portion and located closer to the bone-contacting surface than the articulation surface.

15. The implant of claim 11, wherein the bone-contacting surface is a flat surface.

16. The implant of claim 11, wherein the bone plate portion is made of a surgical grade metal.

17. The implant of claim 11, wherein the bone plate portion is made of titanium.

18. An implant for replacing a portion of an articulation surface of a joint, the implant comprising:

- a main portion configured for inserting into a joint, wherein the main portion comprises:
 - a hydrogel portion forming a bone-contacting surface and an articulation surface opposite from the bone-contacting surface;

- wherein the bone-contacting surface comprises a protruding part;

- wherein, the main portion having a leading end and a trailing end, wherein the leading end is configured for being inserted into the joint; and

- a bone plate portion configured for securing the implant to a bone that forms the joint; wherein the bone plate portion comprises:

- a first part having a perforated structure that is embedded in the protruding part of the hydrogel portion; and

- a second part that is not embedded in the protruding part of the hydrogel portion and extending from the trailing end in a direction opposite from the articulation surface at an angle $\leq 160^\circ$ but $\geq 80^\circ$ with respect to the bone-contacting surface;

- wherein the second part has at least one screw hole for receiving a bone screw.

19. The implant of claim 18, wherein the second part extends from the trailing end at an angle that is $\leq 110^\circ$ and $\geq 80^\circ$.

20. The implant of claim 18, wherein the second part extends from the trailing end at an angle that is substantially 90° .

21. The implant of claim 18, wherein the first part of the bone plate portion is embedded in the hydrogel portion and located closer to the bone-contacting surface than the articulation surface.

22. The implant of claim 18, wherein the first part of the bone plate portion has a contour that substantially matches the contour of the protruding part of the bone-contacting surface.

23. The implant of claim 22, wherein the protruding part of the bone-contacting surface has a half-cylinder contour.

24. The implant of claim 18, wherein the bone plate portion is made of a surgical grade metal.

25. The implant of claim 18, wherein the bone plate portion is made of titanium.
26. An implant for replacing a portion of an articulation surface of a joint, the implant comprising:
- a main portion configured for inserting into a joint and comprising a leading end, a trailing end, an articulation surface and a bone-contacting surface extending between the leading end and the trailing end, wherein the leading end is configured for being inserted into the joint, wherein the main portion further comprises:
 - a porous material portion; and
 - a hydrogel portion forming the articulation surface and the bone-contacting surface opposite from the articulation surface;
 - wherein the porous material portion is bonded to the hydrogel portion, extending from the trailing end and partially towards the leading end and forms a portion of the bone-contacting surface;
 - wherein the porous material portion comprises a tapered hole at the trailing end;
- and
- a bone plate configured for securing the implant to a bone that forms the joint;
 - wherein the bone plate is formed of a solid metal;
 - wherein the bone plate comprises a tapered stem that is configured to be inserted into the tapered hole in the porous material portion, whereby the tapered stem and the tapered hole cooperate to urge the bone-contacting surface of the implant toward the bone when the implant is inserted into the joint; and
 - wherein the bone plate has at least one screw hole for receiving a bone screw.
27. The implant of claim 26, wherein the porous material is porous metal foam.
28. The implant of claim 26, wherein the porous material is porous titanium foam.
29. The implant of claim 26, wherein the metal is a surgical grade metal.
30. The implant of claim 29, wherein the metal is titanium.
31. The implant of claim 26, wherein the hydrogel portion is bonded to the porous metal foam portion by having some hydrogel material infiltrating into pores in a portion of the porous metal foam portion.

32. The implant of claim 26, wherein the bone plate portion and the porous metal foam portion are formed of titanium.

33. The implant of claim 26, wherein the porous metal foam portion is porous titanium metal foam.

1/21

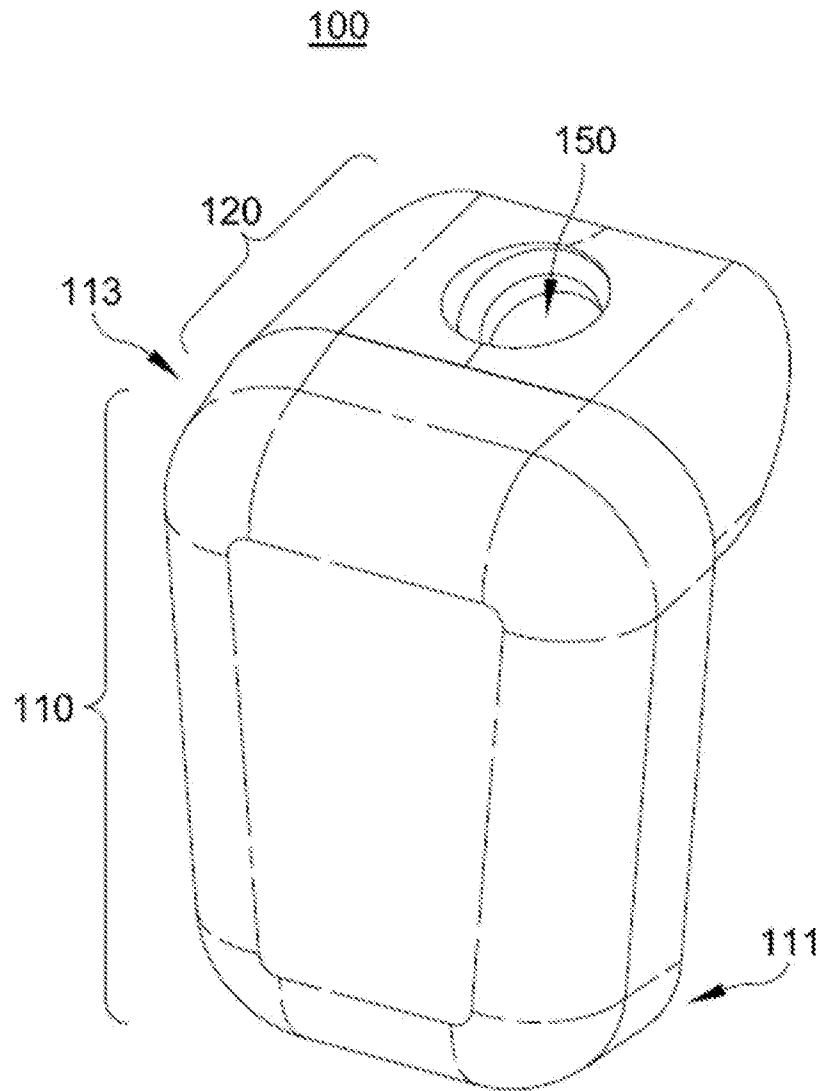


FIG. 1

2/21

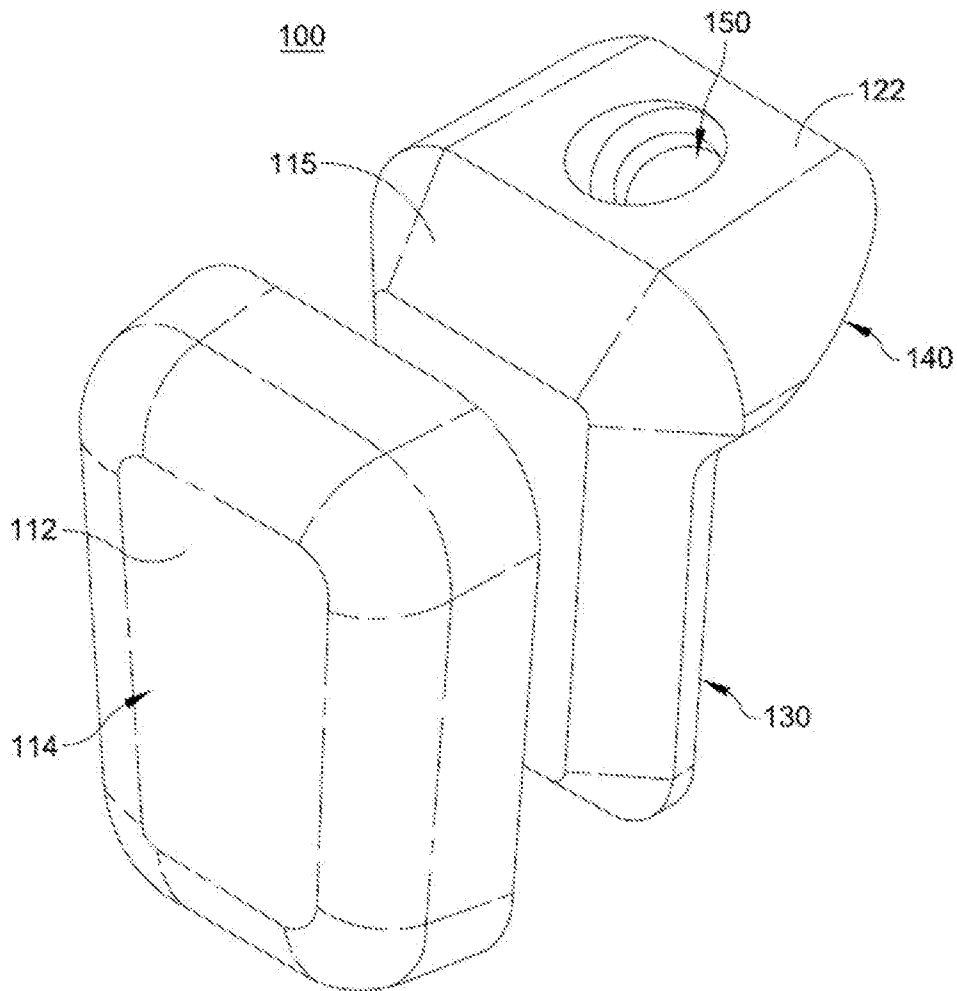


FIG. 2

3/21

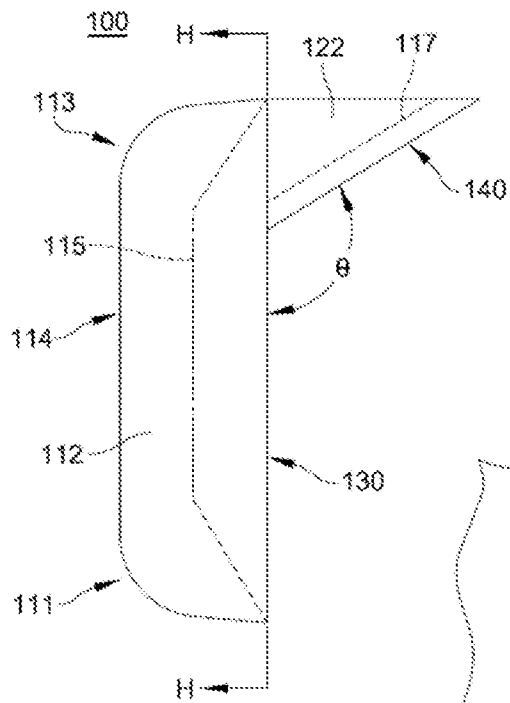


FIG. 3A

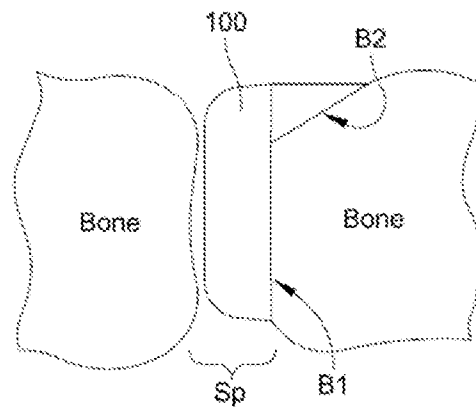


FIG. 3B

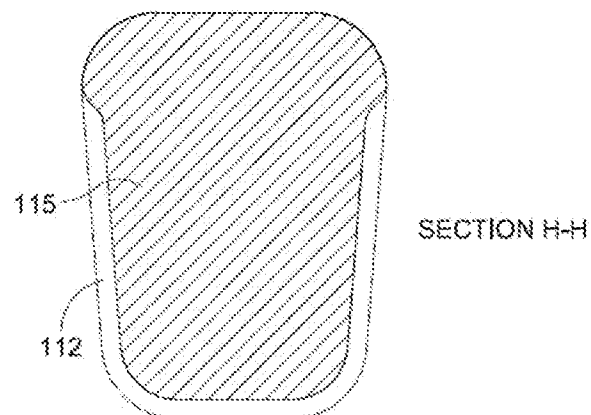


FIG. 4

4/21

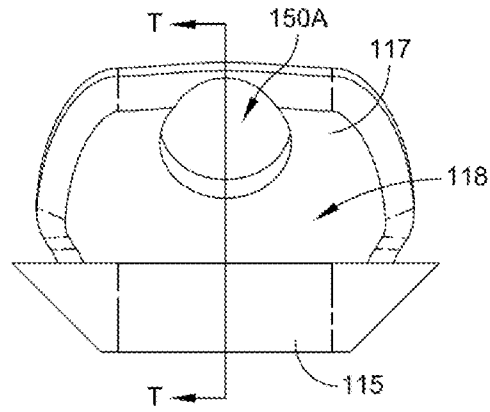


FIG. 5

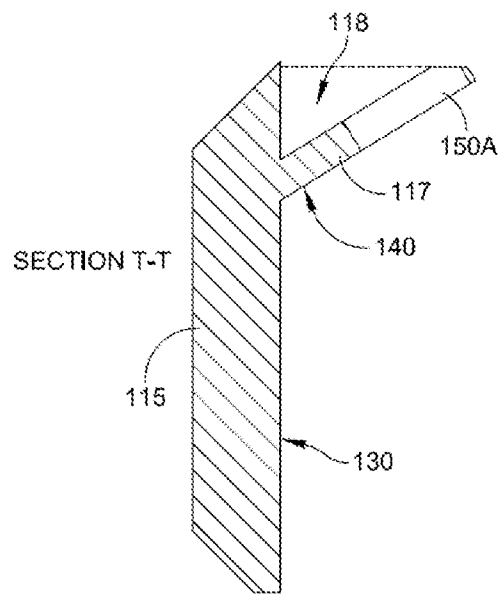


FIG. 6

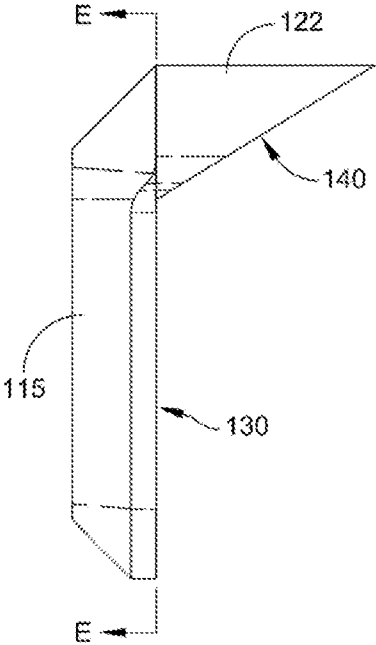


FIG. 7

SECTION E-E

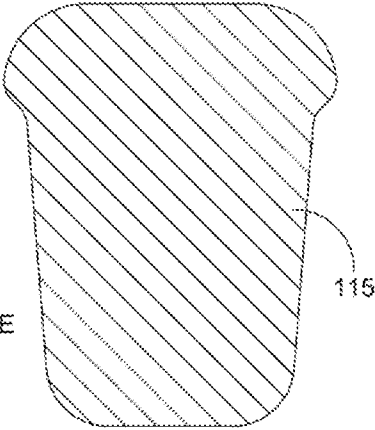


FIG. 8

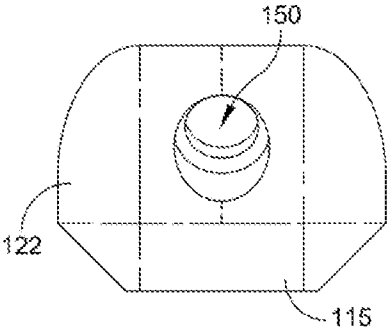


FIG. 9

6/21

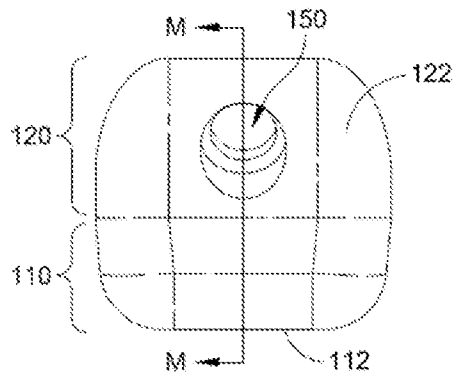
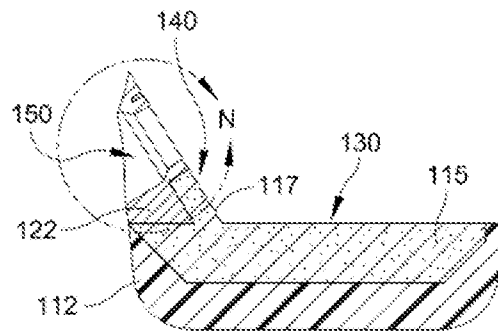
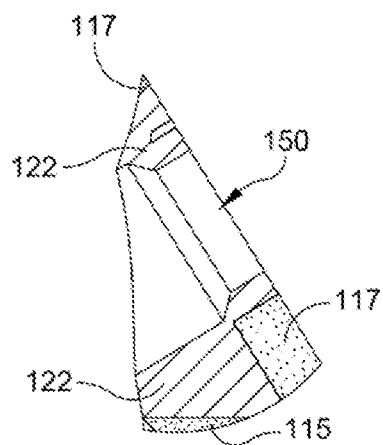


FIG. 10



SECTION M-M

FIG. 11



DETAIL N

FIG. 12

7/21

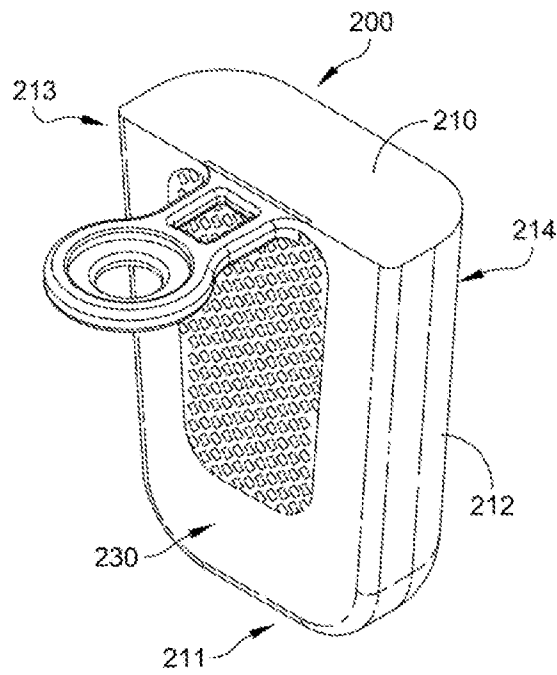


FIG. 13

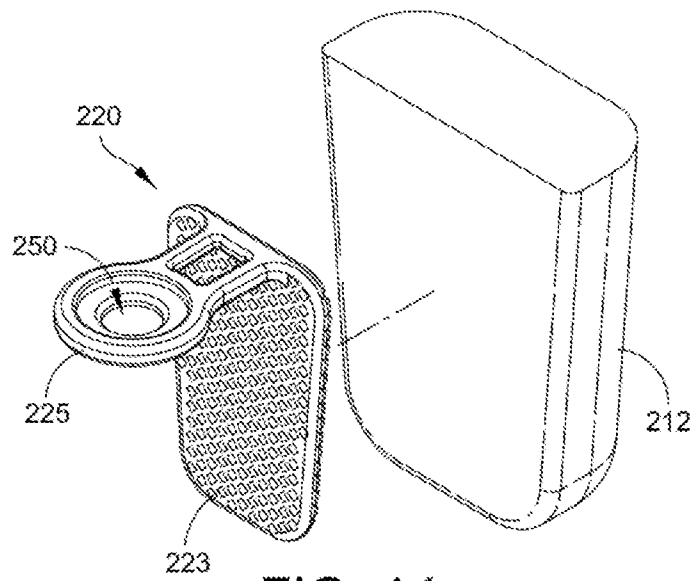


FIG. 14

8/21

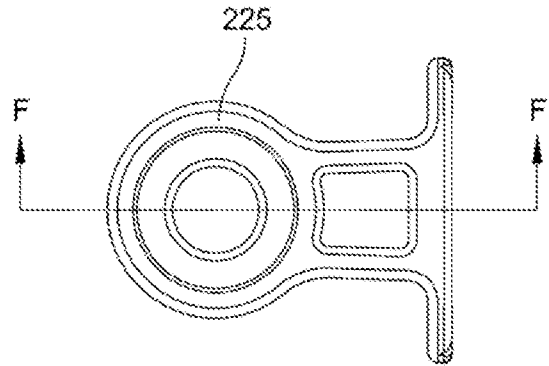


FIG. 15

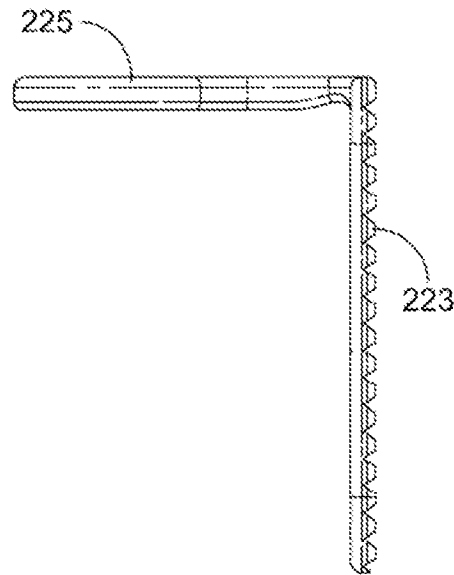
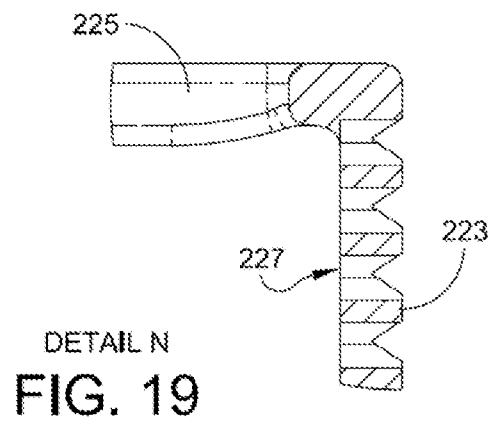
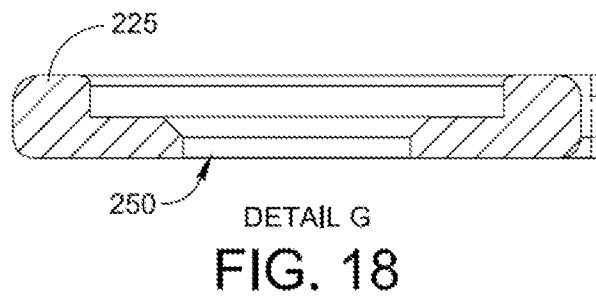
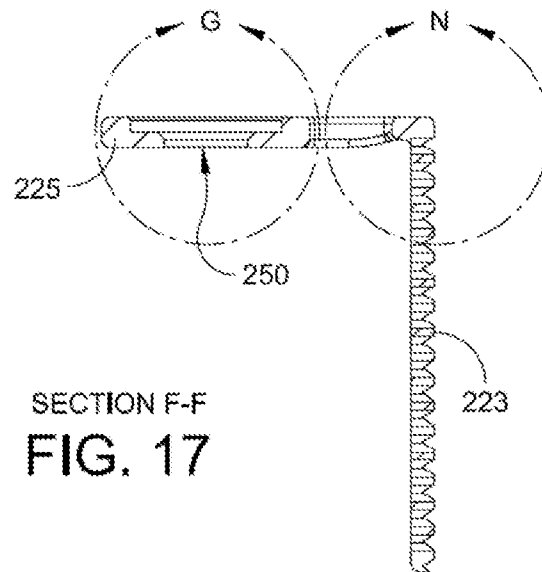


FIG. 16

9/21



10/21

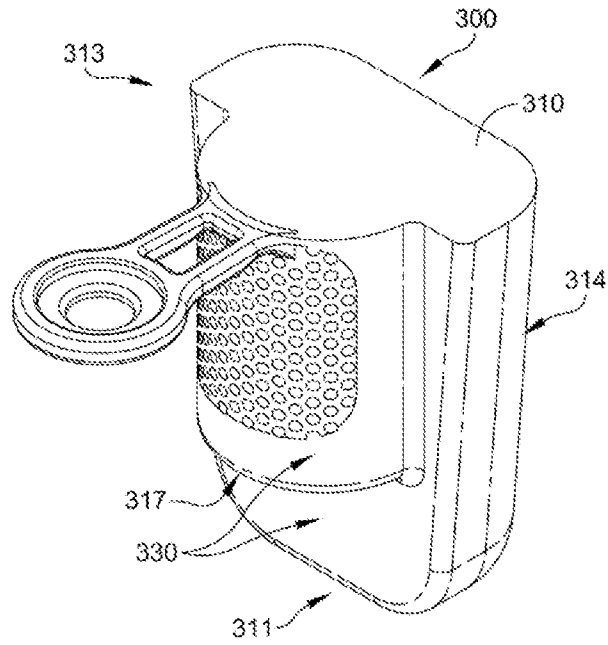


FIG. 20

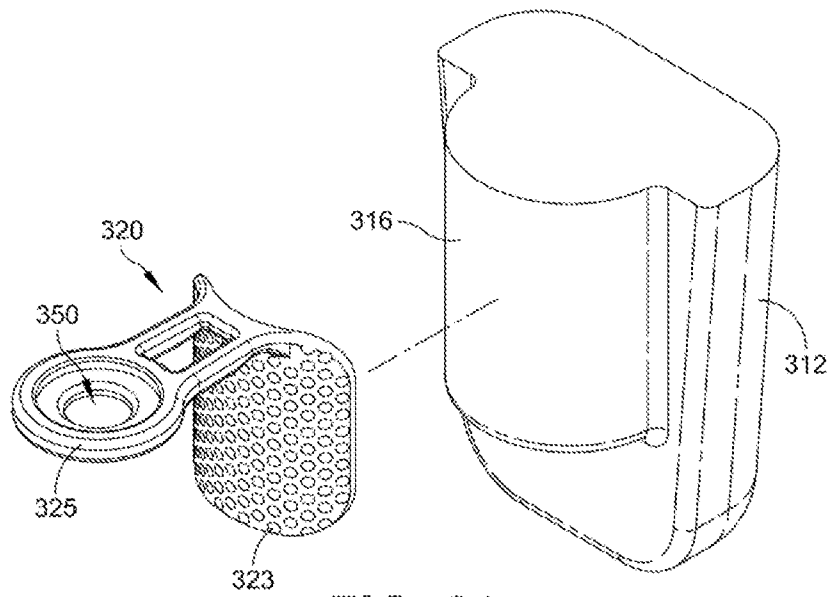


FIG. 21

11/21

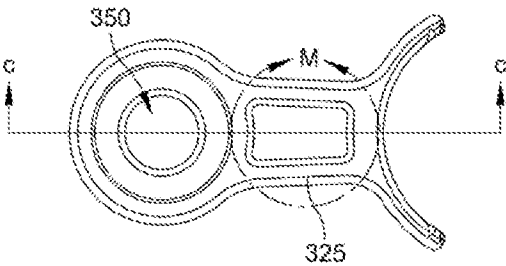
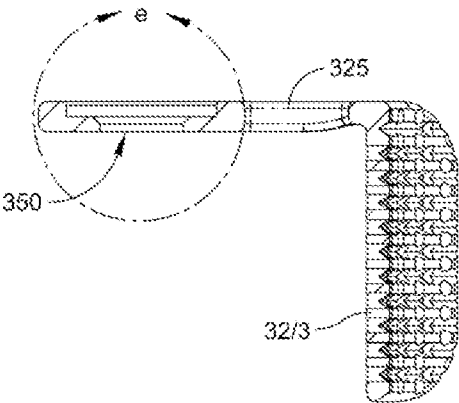
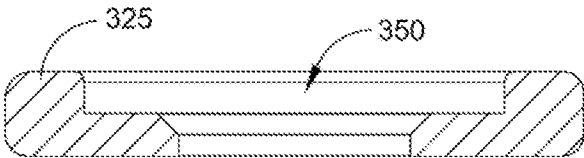


FIG. 22



SECTION C-C

FIG. 23



DETAIL E

FIG. 24

12/21

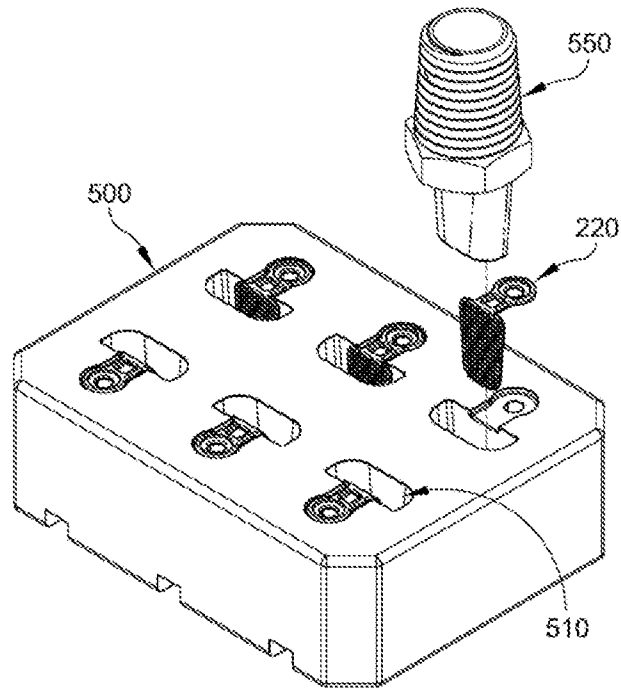


FIG. 25

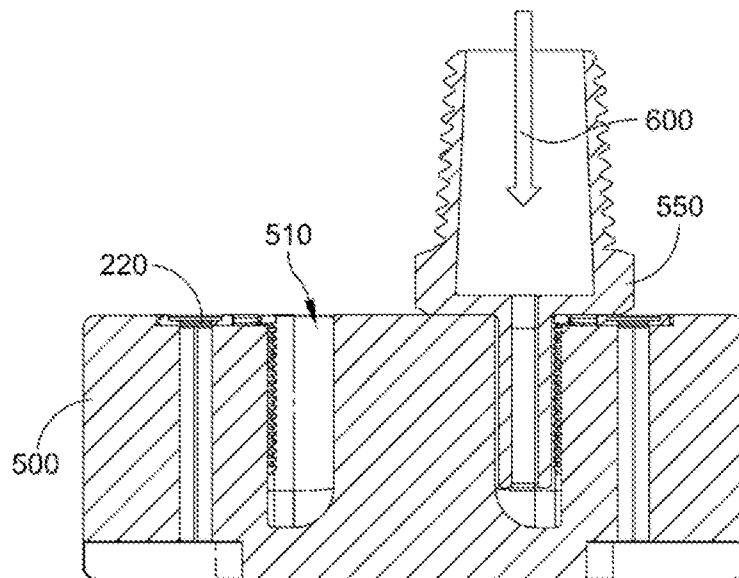


FIG. 26

13/21

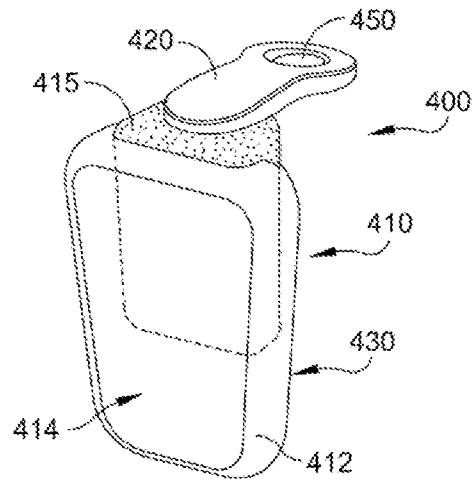


FIG. 27

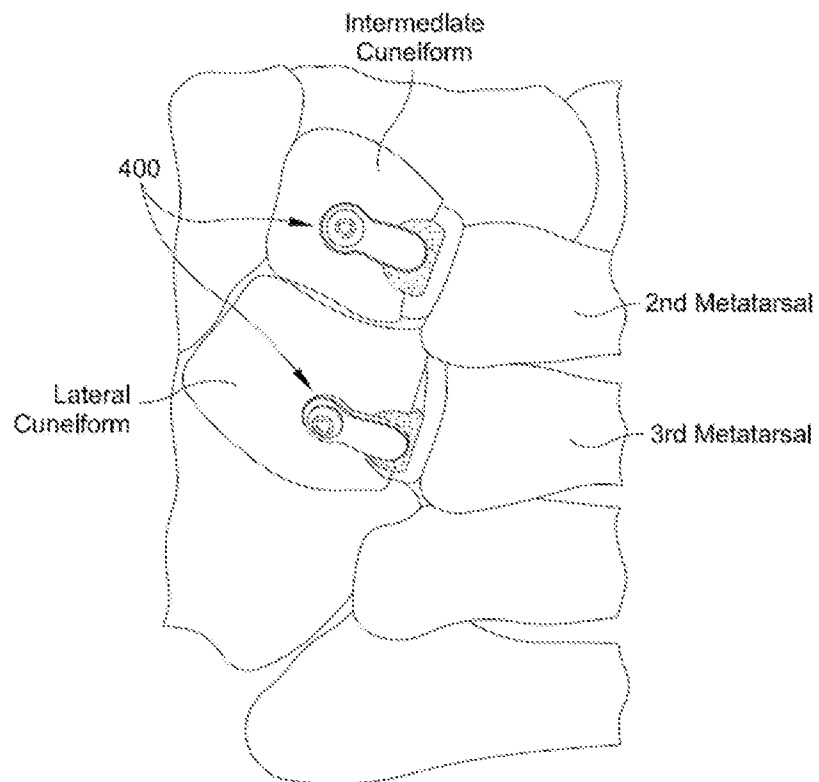


FIG. 28

14/21

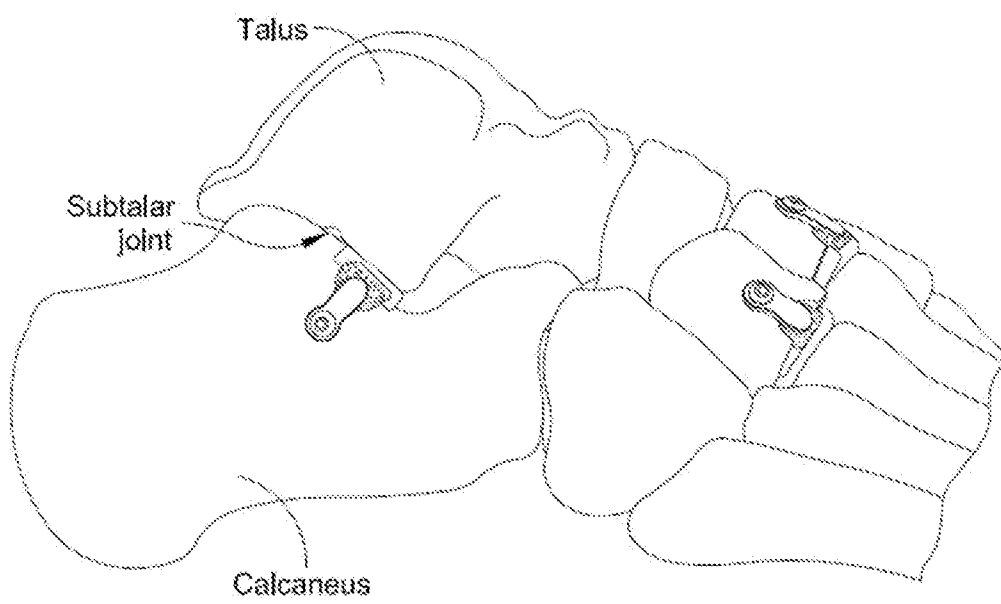


FIG. 29

15/21

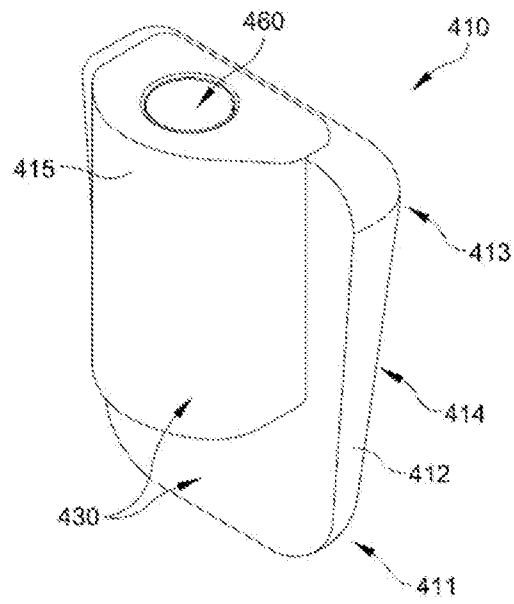


FIG. 30

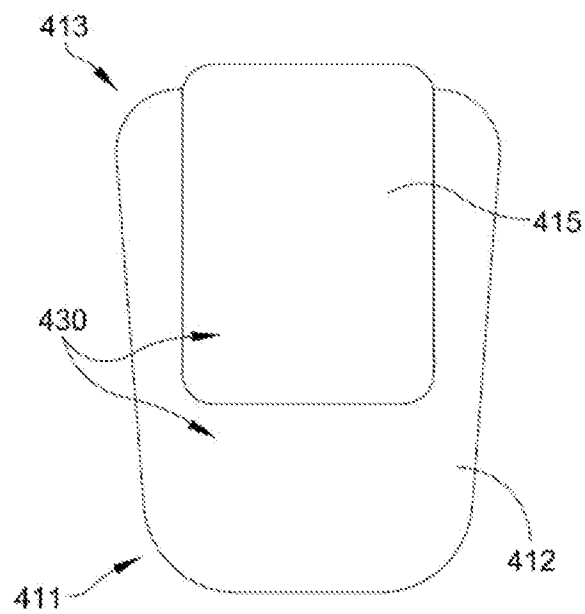


FIG. 31

16/21

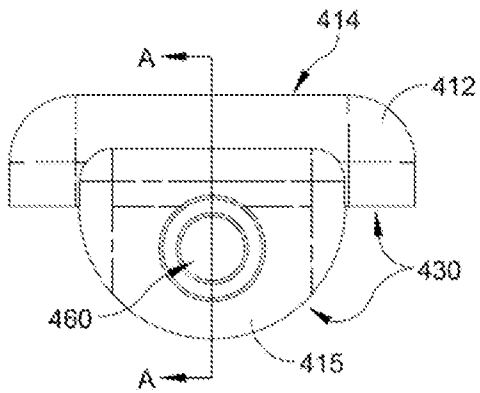


FIG. 32

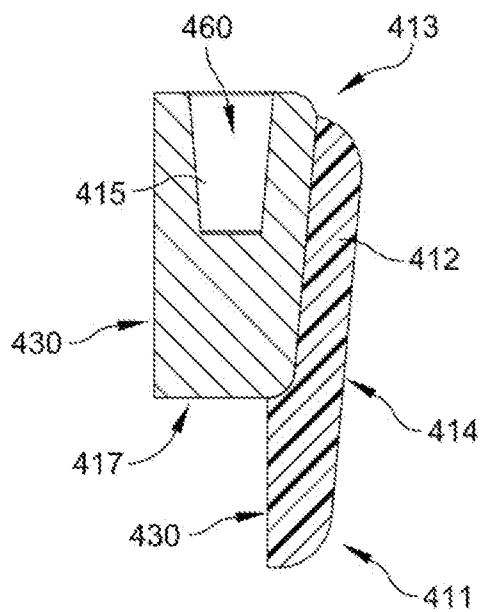


FIG. 34

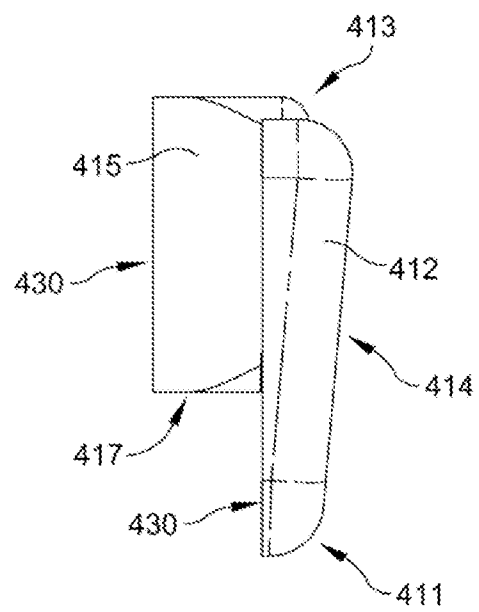


FIG. 33

17/21

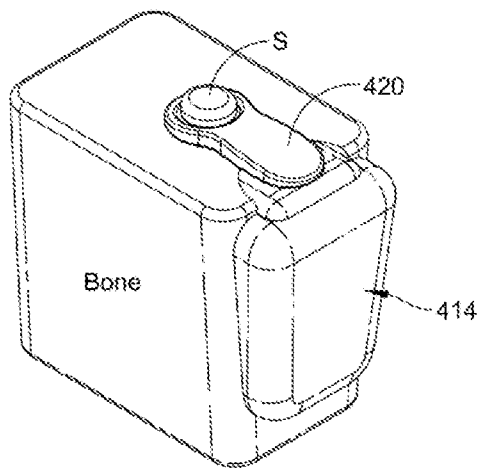


FIG. 35

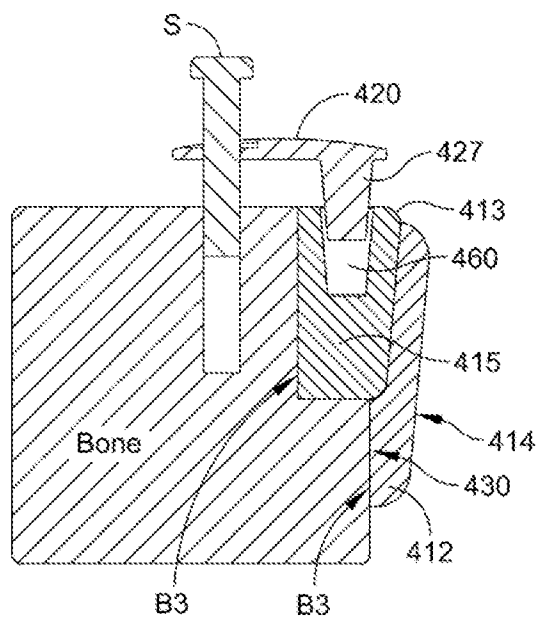


FIG. 36

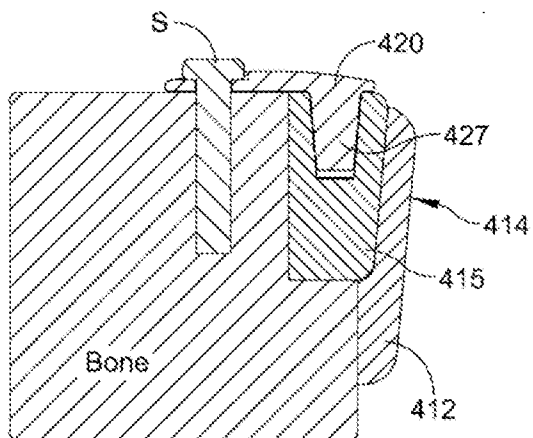


FIG. 37

18/21

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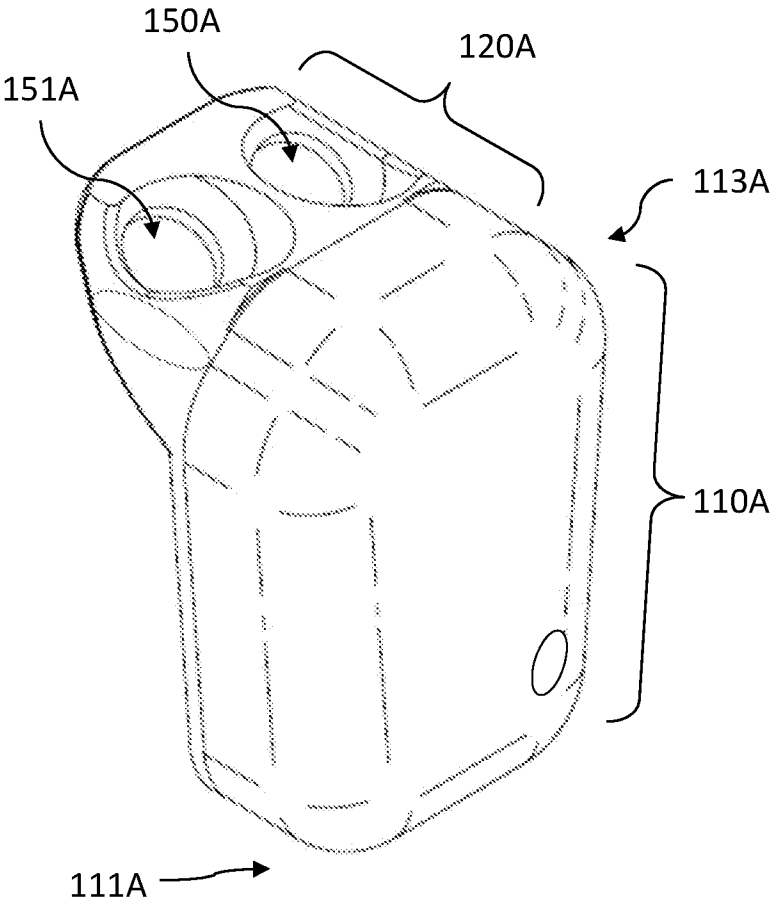


FIG. 38

19/21

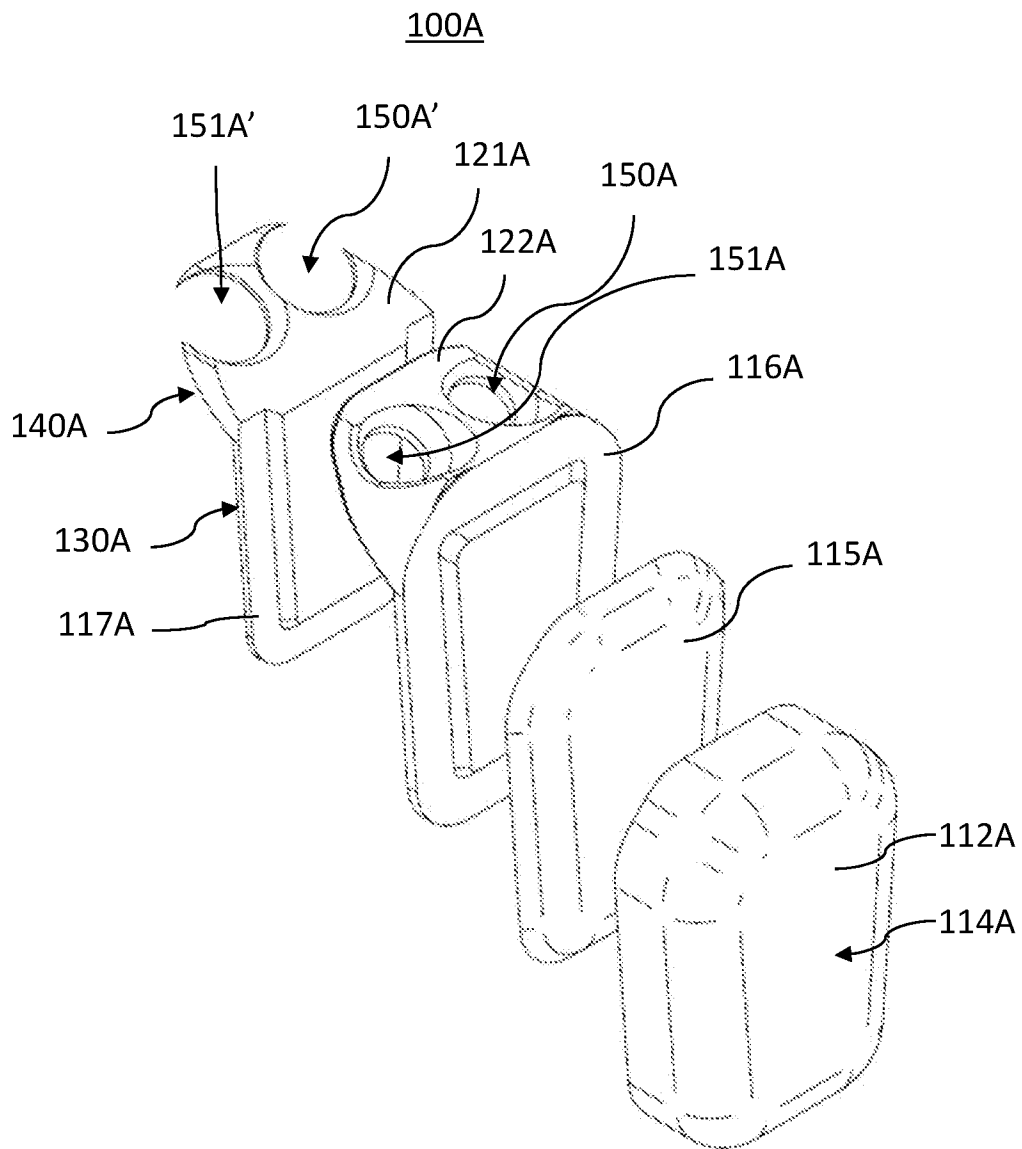


FIG. 39

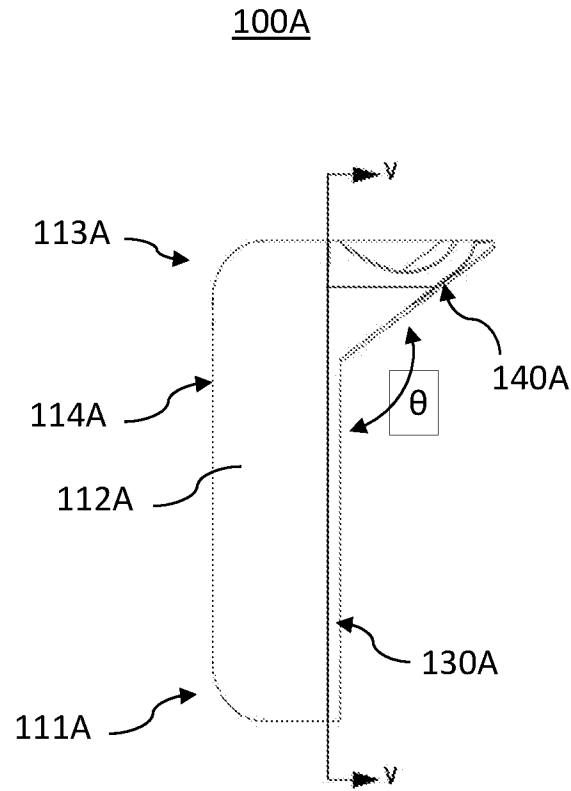


FIG. 40

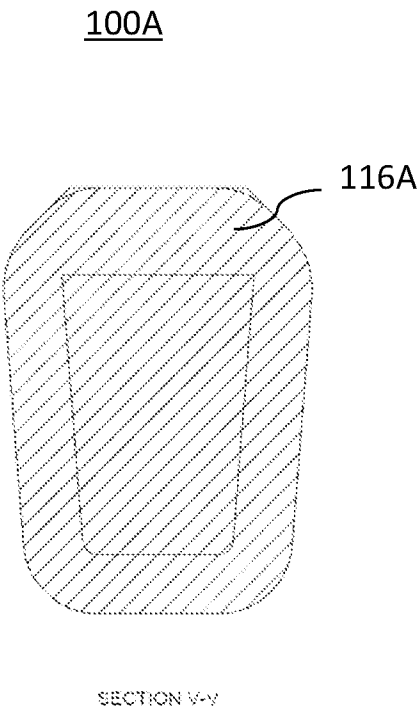


FIG. 41

21/21

100

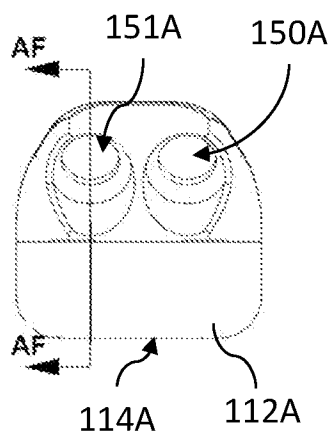


FIG. 42

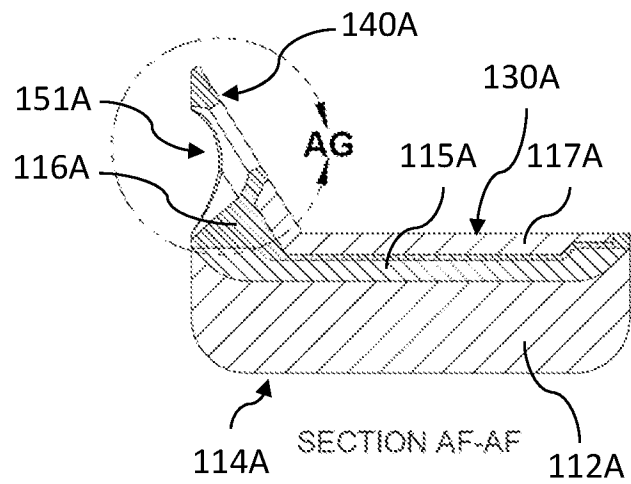
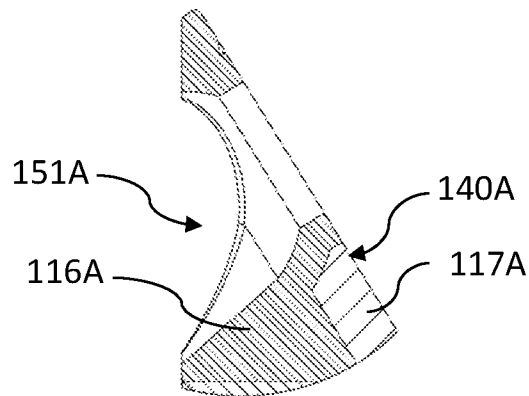


FIG. 43



Detail AG

FIG. 44

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 20/25724

A. CLASSIFICATION OF SUBJECT MATTER

IPC - A61F 2/30 (2020.01)

CPC - A61F 2/30749, A61F 2002/30751, A61F 2002/4238, A61F 2/30756, A61F 2002/30757, A61F 2002/30761

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

See Search History document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

See Search History document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y -- A	US 4,502,161 A (WALL) 05 March 1985 (05.03.1985) Entire document, especially Abstract, col 3, ln 30- col 4, ln 38 and FIGS. 1-2, 6.	1-25 ----- 26-33
Y -- A	US 2002/0022884 A1 (MANSMANN) 21 February 2002 (21.02.2002) Entire document, especially Abstract, para[0072], [0085].	1-25 ----- 26-33
Y	US 2008/0195211 A1 (LIN et al.) 14 August 2008 (14.08.2008) Entire document, especially Abstract, para[0072], [0080]-[0081] and FIG. 10.	23
A	US 6,468,314 B2 (SCHWARTZ et al.) 22 October 2002 (22.10.2002) Entire document.	1-33
A	US 7,037,342 B2 (NILSSON et al.) 02 May 2006 (02.05.2006) Entire document.	1-33
A	US 7,713,306 B2 (GIBBS) 11 May 2010 (11.05.2010) Entire document.	1-33

☐ Further documents are listed in the continuation of Box C.☐ See patent family annex.

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"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

28 May 2020

Date of mailing of the international search report

15 JUL 2020

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Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450

Facsimile No. 571-273-8300

Authorized officer

Lee Young

Telephone No. PCT Helpdesk: 571-272-4300