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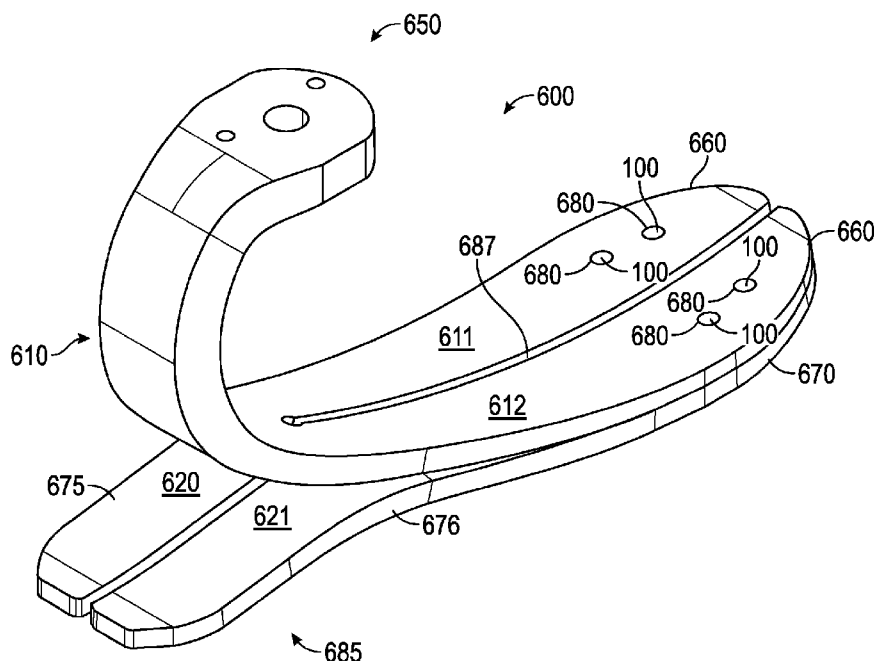


FIG. 6

(57) Abstract: Composite materials with certain functional or securement parameters are provided herein. Layered composite prosthetic with spring layers and composite rivets are provided. Fiber reinforced layers are grouped into keel, sole plate or other component and these components are configured to provide a spring action for the prosthetic alone or in combination. One or more composite rivets are installed to secure components together.



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Prosthetic/Orthosis Spring Layer(s) with Composite Rivet(s)

RELATED APPLICATIONS

[0001] This application claims priority to U.S. provisional application 63/471,046, which was filed on June 5, 2023 and is entitled Prosthetic/Orthosis Spring Layer(s) with Composite Rivet(s). The '046 application is incorporated by reference in its entirety herein.

TECHNICAL FIELD

[0002] Composite materials with certain functional or securement parameters are provided. Layered composite prosthetic with spring layers and composite rivets are provided.

BACKGROUND

[0003] Limb loss is an ongoing problem in the U.S. and around the world. For example, patients who undergo amputation of a lower limb need a prosthetic foot that will allow them to regain their mobility and independence. Patients with lower extremity limb loss or limb difference (LL/LD) are commonly referred to as amputees.

[0004] Prosthetics may have various configurations and attachment designs. Prosthetic feet may be manufactured with composite materials including carbon, glass, and/or aramid fiber. These composite elements may be combined with metal components of steel, titanium, and/or aluminum, and/or other materials such as elastomers and plastics. The configuration and placement of these materials, as well as the material's inherent properties, may affect the performance of a prosthetic.

[0005] Orthoses may have various configurations as well. They may be employed to provide support of upper or lower limbs during walking, standing, running, holding, etc. Orthoses may be manufactured with composite materials including carbon, glass, and/or aramid fiber. These composite elements may be combined with metal components of steel, titanium, and/or aluminum, and/or other materials such as elastomers and

plastics. The configuration and placement of these materials, as well as the materials' inherent properties, may affect the performance of an orthosis.

[0006] Embodiments may comprise composite prosthetics or orthoses, configured to perform and provide stability, flexibility, and/or a proper level of energy return. Embodiments may enable patients with limb loss or limb malfunction to ambulate at various speeds throughout their day. Embodiments may employ composite rivets to secure components of various devices together.

FIGURES

- [0007] Figure 1A shows a side-sectional view of exemplary composite rivet configurations positioned to secure layers of material together, as may be employed in some embodiments.
- [0008] Figure 1B shows a side-sectional view of an exemplary composite rivet positioned to secure layers of material together, as may be employed in some embodiments.
- [0009] Figure 2A shows top, bottom, and side-sectional view of passage or hole configurations that may be employed to receive a composite rivet, as may be employed in some embodiments.
- [0010] Figure 2B shows a side-sectional view of an exemplary composite rivet passage or hole to secure spring layers of material together, as may be employed in some embodiments.
- [0011] Figures 3A-3C show cross-sectional pictures of composite rivets securing layers of a prosthetic together as may be employed in some embodiments.
- [0012] Figure 4 shows a side view of an L-shaped keel and sole plate, either or both acting as a spring layer, and each secured to the other with composite rivets, as may be employed in some embodiments.
- [0013] Figure 5 shows a side view of a low-profile embodiment with composite layers, one or more acting as a spring layer, and all secured to each the other with a composite rivet, as may be employed in some embodiments.
- [0014] Figure 6 shows a rear perspective view of a prosthetic foot with split J-shaped keel, multiple sole plates, and composite rivet passages, as may be employed in some embodiments.
- [0015] Figure 7 shows a top-down view of the prosthetic foot of Figure 6 with split J-shaped keel, multiple sole plates, and composite rivet passages, as may be employed in some embodiments.
- [0016] Figure 8 shows a rear top-down view of the prosthetic of Figure 6, as may be employed in some embodiments.

- [0017] Figure 9 shows a front upright view, of the prosthetic foot of Figure 6 with J-shaped keel, passages for composite rivets, and sole plates, as may be employed in some embodiments.
- [0018] Figure 10 shows a rear upright view of the prosthetic foot of Figure 6, with J-shaped keel, and split sole plate, as may be employed in some embodiments.
- [0019] Figure 11 shows a rear perspective view of a prosthetic foot without split keel and sole plate as may be employed in some embodiments.
- [0020] Figure 12 shows a rear perspective view of a prosthetic foot with partial split keel and sole plate, each providing spring plate functionality, as may be employed in some embodiments.
- [0021] Figure 13 shows a side, upright view, of the prosthetic foot of Figure 13 with split J-shaped keel, sole plate, and prosthetic cover as may be employed in some embodiments.
- [0022] Figure 14 shows a side, upright view of the prosthetic foot of Figure 13 with split J-shaped keel, sole plate, composite rivets, and metallic pyramid coupler, as may be employed in some embodiments.
- [0023] Figure 15 shows an exemplary flexibility / rigidity profile for a prosthetic foot with J-shaped keel, as may be employed in some embodiments.
- [0024] Figure 16 shows an exemplary flexibility / rigidity profile for a prosthetic foot with J-shaped keel, as may be employed in some embodiments.
- [0025] Figure 17 shows exemplary measurement points corresponding with Table 1 for a certain size prosthetic foot with split j-shaped keel, sole plate, and composite rivets, as may be employed in some embodiments.
- [0026] Figures 18A-18D show forces that may be present or developed around composite rivets and components secured by a composite rivet as may be employed in some embodiments.
- [0027] Figure 19 shows a keel layup as may be employed in some embodiments.
- [0028] Figure 20 shows a sole plate layup as may be employed in some embodiments.

DETAILED DESCRIPTION

[0029] Prosthetics can be employed as limb replacements for various limbs of the human body. The function and durability of the prosthetic may vary with specific limb replacement and with anticipated uses, as well as with amputation level. For example, prosthetic feet may be tailored to accommodate highly active individuals in some designs and low activity individuals in other designs. Prosthetic feet may fail to provide a desired level of flexibility, stability and energy return due to increased stiffness in key areas of the prosthetic foot. Stiffness of a prosthetic foot may be increased to improve durability and overcome inherent weaknesses of a particular prosthetic foot design. A prosthetic foot of embodiments may be created by different springs. The bottom spring may be called a sole plate or simply a heel, upper springs may be called keels. The numbers and geometry of a sole plate and a keel of embodiments may vary from design to design. Prosthetic foot designs may attach the sole plate to the keel with bolts, windings, and/or glue. However, doing so adds thickness in the toe, which decreases dorsiflexion, and may make such foot designs less stable in late stance and toe off.

[0030] Embodiments may comprise prosthetics or orthoses comprising various composite material components. These various composite components may comprise one or more composite rivets to join components of a prosthetic or orthosis. These components being secured may be springs and may comprise single or multiple layers of fiber, some layers may be bidirectional, while other layers may be unidirectional. The fiber may comprise one or more of carbon, aramid, or glass.

[0031] In embodiments, composite rivets may be employed to secure components of a prosthetic or orthosis as well as components of other devices. For example, composite rivets may be positioned and sized in prosthetic foot embodiments to allow both the heel and keel of a prosthetic foot to extend to

the toe in a continuous flow/motion while minimizing the overall thickness of the prosthetic foot in the forefoot area. This minimizing of thickness may be in comparison designs employing different connection techniques. In some embodiments, springs may be secured to each other with composite rivets. The springs may be layers or other components having spring-like qualities such that they have extended and protracted positions and a propensity to return to a normal, neutral, or unloaded position when not being under a loading condition. Composite rivets may comprise unidirectional or bidirectional fiber layers as well as both.

[0032] Embodiments may have other applications in prosthetics and orthoses and other devices as well. For example, composite rivets of embodiments may be employed to join composite prosthetic and/or orthotic static components with a very strong yet small and lightweight fastener. In other words, rigid components, which are intended or designed to remain rigid, thereby, providing support, may be secured to each other with composite rivets in embodiments. Composite rivets may also be employed in other devices as well.

[0033] In embodiments, fiber reinforced layers may be grouped into keel, sole plate or other component and these components may be configured to provide a spring action for the prosthetic alone or in combination. One or more composite rivets may be installed to secure components together.

[0034] Embodiments may advantageously have a single or primary material composition, for example, carbon fiber laminates. By using a single material composition with different positions, sizes, shapes, etc., performance inequalities derived from designs employing numerous materials, e.g., steel, aluminum, and carbon fiber, may be reduced or eliminated. Multi-material designs can be affected unequally by outside environmental factors as the different materials of the design react differently to outside forces. This variance in material properties and material behaviors can result in different

portions of a multi-material prosthetic behaving differently. For example, reactive forces applied to a single-material prosthetic may be less likely to create disproportional reactions when compared to a multi-material prosthetic comprising numerous materials, with each material having different inherent material properties.

[0035] Embodiments may employ carbon pre-preg, meaning pre-impregnated carbon fibers. This pre-preg may be employed in various layers of the prosthetics or orthoses or other devices as well as in some or all of the connectors, including the composite rivets described herein. Resins may be employed as the impregnating material of a pre-preg. These resins may be considered an Epoxy and may comprise a thermoset resin.

[0036] As used herein, a composite is considered a mix of two or more substances. One of these substances can be fibers that serve as reinforcement. The reinforcement may comprise carbon, glass, and Kevlar, hemp, flax, peek or another type of material that provides reinforcement for another material the reinforcement is paired with. Composite may comprise one or more binding materials. Generally, these binding materials may comprise thermoset resin, thermoplastic resin, lactate or even concrete. A thermoplastic resin is fluid or moldable until it cools down. In a thermoset resin heat will change the molecules or bonding and when the resin has cured it cannot go back to previous stage. Often, thermoplastics are thought of as inferior to thermoset resins but this comparison can depend upon the application and the quality of the thermoplastic. A thermoplastic resin can be re-heated and potentially re-shaped.

[0037] Embodiments may employ thermoset resins with carbon fiber reinforcement used in unidirectional or multi-directional orientations. Other binding materials and reinforcing materials may be employed in certain embodiments as well.

[0038] As noted above, embodiments may employ one or more composite rivet(s), the rivets comprising fiber reinforced materials, for example carbon fiber reinforcements. The composite rivet or rivets may be configured and positioned in a prosthetic or orthotic device or other device. When positioned in a prosthetic or orthotic or other device the rivet may serve to provide suitable or even enhanced binding characteristics to secured sub-components of the prosthetic or orthotic or other device when compared to alternative binding solutions. Composite rivets of embodiments may also provide suitable or enhanced strength for prosthetics or orthotics. These strength characteristics may result in heightened durability of a prosthetic or orthotic or other device in some embodiments. Composite rivets may be employed in various fiber reinforced prosthetics including prosthetics for upper and lower extremities of the human body as well as various upper and lower extremity orthoses. The rivets may be sized to fit within penetrations of the components to be secured together.

[0039] In certain embodiments, blanks for the composite rivets may be cut from a sheet of pre-preg where the length, the width and the shape of the blank may be selected to match the anticipated size of the hole and the thickness of the heel and keel or other component(s), to be joined together. Cut single layer and multilayer blanks may be rolled and twisted and introduced to the hole intended to receive the rivet. This hole may be predrilled into one or more components intended to receive the composite rivet. Rolling and twisting of the blanks before, during, or after the insertion of the blank into the hole may serve to equally spread the fibers of the rivet as well as to equally distribute the fibers of the cured rivet. One or more single layer or multilayer blanks may serve as a rivet in embodiments,

[0040] Once a rivet is inserted, the pre-preg rivets, as well as any components being secured, may be cured by an exothermic reaction. This exothermic reaction may be conducted in an oven under normal atmospheric pressure as

well as pressures above atmospheric pressure and below atmospheric pressure.

[0041] As to prosthetic designs, embodiments may seek to avoid prosthetic foot designs that stop the sole plate or keel short of the toe and/or eliminate the heel completely. In addition, prosthetic embodiments may seek to avoid foot designs that attach the sole plate to the keel with bolts, filament windings, adhesives, and other methods that introduce a wide area of rigidity into the forefoot. Broad areas of rigidity can serve to reduce the flexibility in the prosthetic forefoot and can have a negative impact on the late stages of gait, in that patient's feel less stable, which leads to abnormal and hence inefficient gait, and possible injury to the patient using such prosthetic designs.

[0042] Prosthetic foot embodiments may employ a curved keel. These may include "J" shaped keels, which may have a continuous radius from the attachment point perpendicular to the ground, when in use, and extend to the full-length of the toe. Such "J" shaped keels may also be attached to a sole plate with composite rivets, the rivets being placed where the keel and sole plates meet. This joining region may be flat, curved and combinations thereof.

[0043] Prosthetic foot embodiments may employ a J-shaped keel design to provide a longer spring lever with flexibility that may replicate ankle plantar and dorsi-flexion. Prosthetic foot embodiments may employ a full-length sole plate that may provide a longer lever to better actuate the J-shaped keel. Prosthetic foot embodiments may employ one or more composite rivets to join elements of the prosthetic foot and thereby allow both the sole and keel to extend to the toe of the prosthetic foot without creating a wide area of rigidity in the forefoot. Other configurations and placements of the composite rivets may be employed in various fiber composite prosthetic embodiments.

[0044] Composite rivets of embodiments may employ various constituent materials and various configurations. Unidirectional fiber as well as multi-directional fiber may be employed in composite rivets. These fibers may be

carbon, glass, aramid, and other materials as well. The composite rivets may comprise regions of folded layers of fiber as well as regions of twisted fiber layers. The holes (or sometime called passages herein) in which the composite rivets are placed, may have various configurations as well. The holes may have wider outermost areas and more narrow passages therebetween. The outermost areas, e.g., countersunk recesses, may have various configurations including being funnel shaped, U-shaped, and rectangular. Likewise, the passages therebetween may have various configurations including cylindrical, rectangular, and obround. An angle of countersinking of the outermost areas may have countersinking angles in a range of 120°-35° or more or less. In some embodiments, outermost or wider parts, e.g., countersunk recessed, when filled with fiber and binding/matrix may act as the head of a rivet. The head of the rivet may serve to create a mechanical lock providing additional axial compressive strength so that the strength of the joint may not rely solely on frictional adhesion in the cylindrical part of the hole/rivet interface. The outermost areas may have different configurations above and below the shared passage as well as vary from adjacent or nearby holes as well.

[0045] As noted above, constituent materials of composite rivets may comprise various materials and/or material combinations. These materials may comprise: UD fiber, rolled UD fiber bunches, weaved fiber stockings, UD fiber bunches, twisted UD fiber bunches, twisted fibers, and roped out fibers. In embodiments the fiber direction may coincide with the length axis of the rod. The matrix can be thermoset or thermoplastic in some embodiments.

[0046] Other geometries and positions of the rivet passages and rivets may be employed in embodiments. For example, in embodiments, in addition to or in lieu of composite rivets, looped strands of composite threaded through two adjacent passages may be employed. These strands may reside within a groove between the two passages where the composite strand may lay, thereby giving an overall relatively flat surface and composite strand strength

via the passages and strands passing therethrough. Various passage geometries and configurations are shown in Figure 2A. Other configurations and geometries may also be employed in some embodiments.

[0047] Various configurations of prosthetics and orthotics shape and features may be employed in embodiments. Exemplary shapes and features are taught herein, and some may be seen in the accompanying figures. Certain prosthetic embodiment configurations may be adjusted to accommodate for P-levels (force specifications as described by ISO standard 22675:2016 that are a function of patient weight and activity level). For example, a curve of the surface opposite the build/tooling-surface may be modified to accommodate P-levels, which may result in increasing or decreasing the thickness of the prosthetic composite structure.

[0048] Some embodiments may comprise two springs secured with one or more composite rivets. These features may be employed in orthoses as well as prosthetics of embodiments. Some prosthetic embodiments may comprise one or more of the following features: a metallic pyramid coupler at the top of the prosthesis; a metallic coupler cantilevering over the posterior section of the keel; a metallic coupler cantilevering over the posterior section about 25% to 33% of the total foot length; a split heel with split lateral and medial sides for the entire length of the sole plate and no intervening connecting portions; a J-shaped prosthetic where the keel and the sole plate may be attached in the forward 1/3; a J-shaped prosthetic where sole plate and keel may be attached with any of the following: rivets, flexible adhesive, bolts, screws, and rigid adhesive; a J-shaped prosthetic having the keel and sole plate portion attached in their forward 1/3; a heel section of a J-shaped prosthetic that meets the keel behind in the forward 1/2 of the overall foot length and then returns to neutral position at midstance of a gait cycle; a J-shaped prosthetic where the upright portions of the J have different widths; and a J-shaped prosthetic were

the foot portion and upper cantilevered portion of the J may be approximately horizontal when a wearer is standing.

[0049] Embodiments may provide, during the late stance of the gait cycle, improved stability, and improved loading of the keel. In embodiments, a broader base of support may be provided to the forefoot at or near toe off in the gait cycle. The flexibility within the composite layup and the smooth surface of the soleplate, from the minimization or absence of connectors in the forefoot, may each contribute to this broader base of support and the dynamic gait benefits.

[0050] Exemplary sizing and configurations may be as shown in the accompanying figures. Other sizing and configurations may also be employed in some embodiments.

[0051] Figure 1A shows cross sections of composite rivets 100. The rivets 100 are shown extending through at least two layers of material 110, which may be springs known as keel and sole plate. The material 110 may be various types of composites but may also comprise one or more non-composites. The rivets 100 may provide a mechanical connection between the layers of material 110. Also visible in Figure 1A are that the rivet heads 101 may have various configurations. These may include rounded and flat heads that protrude out of the spring layer or even with the spring layer. Concave, convex, flat, conical, spherical, etc., rivet heads may be employed in some embodiments. In some embodiments, the rivet head 101 may even be recessed from the spring layer or other components being secured. In each of the rivets shown in Figure 1A the rivet has two opposing heads. These heads may act to help retain the layers being joined together. This reaction may be oriented along a lengthwise axis of the rivets. Indeed, in some embodiments, the heads may act to place compressive force inward along its longitudinal axis such that the layers being secured are squeezed together by the rivet. In embodiments, where one or more composite rivet is present without a head on an upper

and/or lower surface, the purpose of the composite rivet may be to secure members from rotation or provide frictional resistance to separation of layers or for both or for other reasons as well.

[0052] As is shown in Figure 1A the rivets 100 may have different head configurations 102, 103, 105, 106 for the same rivet and these head configurations may include chamfered slopes, vertical countersinks, and other passage configurations. In embodiments, the configuration of the rivet may be selected to accommodate the compressive or securement forces needed. The passage's configuration may be selected for the same reason. In some embodiments the shape of the rivet and the shape of the passage may mimic each other. In some embodiments, the passage may be slightly larger than the rivet in its final installed shape while in other embodiments the passage may be slightly narrower than the rivet in its final installed shape. The material layers in Figure 1A and in other embodiments may vary in thickness and other variations to rivet size, shape, position, layer thickness, etc. may also be employed in embodiments.

[0053] Figure 1A also provides information about securement functionality of rivets. Rivets with a head larger than its column, such as rivet head configurations 102, 103, 105, and 106 can provide axial compressive forces or axial resistance to keep layers of material 110 or other components held together. Where counter sunk holes are present, such as in the rivets 105 and 106 of Figure 1A, the presence of the rivet in the countersunk area of the hole may also provide some axial resistance to separation of the layers via the recessed heads of these rivets. Comparatively, a rivet may not employ a head and may occupy a straight passage 208 as is shown in Figure 2A. In these instances, without a countersink passage or rivet with a head, frictional forces between the walls of the passage and the surface of the rivet may provide the sole frictional surface resistance to sheer, separation, rotation or other forces acting on the component rivet connection.

[0054] Figure 1B shows a side-sectional view of an exemplary composite rivet 100 positioned to secure layers of material 110 together, as may be employed in embodiments. Thus, a cross section of a composite rivet extending through several layers of springs is shown and the spring layers may vary in thickness in this and other embodiments. While the passage 680 is shown as a cylinder with top 682 and bottom 681 conical ends various other configurations may be employed in embodiments. The configuration of the top and bottom of the passage may be set so as to provide a constrictive force by the rivet onto the layers being secured together. In other words, if the rivet shrinks in length, this reduction in length may cause a contractive force to be placed by the rivet onto the outermost layers via the conical ends of the passage, which may in turn then also compress the inner layers. Thus, embodiments may employ rivet and passage configurations that serve to apply restrictive forces both through friction at the edges and also through forces developed by rivet contraction or other rivet or passage movement.

[0055] Walls or other surfaces of the passages may be treated by grinding, washing or some type of sizing/primer in embodiments. The passages in embodiments may be drilled through multiple layers at once as well as drilled through layers or other components before the components are brought together for joining by a rivet or rivets. Techniques other than drilling may be employed to create the passages through single and multiple layers.

[0056] Figures 2A and 2B show examples of the passages 201-210 that are made in the layers of material to make room for the composite rivet. Figure 2A shows top 260, bottom 270, and side-sectional view 280 of passage configurations that may be employed to receive a composite rivet, as may be employed in some embodiments. Thus, examples of the passages that are made in the springs to make room for the composite rivet(s) are shown in Figure 2A. As can be seen in Figure 2A, central passages may have various upper and lower opening configurations. These upper and lower openings

may be symmetrical, non-symmetrical, centered on each other and the passage, off centered from each other and/or the passage of which they are a part. The passage may be vertical as well as angled and may have distinct portions along its height. The passage may be straight as well as curved as well. Still other configurations of the passages and the upper and lower openings may be employed in embodiments.

[0057] Figure 2B shows a side-sectional view of an exemplary composite rivet passage 680 to secure layers of material together, as may be employed in some embodiments. In this view, four layers 110 are shown, but other layer numbers may be employed. Also, various passage configurations, like those in Figure 2A or still others may be employed.

[0058] Figures 3A-3C show cross-sectional views of composite rivets 100 as may be employed in embodiments. As can be seen, layers of material 110 are being secured together by rivets 100 located in a passage 680 through the materials. Twists 330 in these composite rivets 100, as may be employed in embodiments, are shown in each of Figures 3A-3C. These twists 330 may have various configurations when employed as can be seen Figures 3A-3C. The twists 330 may comprise a single rotation of the rivet material before insertion as well as a half-turn and multiple turns of the rivet material before insertion in some embodiments. Tight matching between the rivet and the materials to be secured, with little if any spacing therebetween and substantial surface interface between the rivet and the inner surface of the passages, can be seen in Figures 3A-3C.

[0059] Figure 4 shows a side view of an L-shaped keel 440 and sole plate 450, either or both acting as a spring layer, and each secured to the other with composite rivets 100, as may be employed in embodiments. In Figure 4 a view of a basic prosthetic device that may utilize at least one composite rivet for joining springs of composite layers 510 is seen. The keel 440 may employ spring functionality and the sole plate 450 may employ spring functionality

and each may be joined by a composite rivet(s) through a passage as taught herein. The composite rivets 100 may serve to secure the two springs together. The composite rivet(s) may be located at various locations of the device. In this instance, the rivets 100 are located in the toe region of the prosthetic 460. During use, the two springs may come apart from each other and then contact back again during a gait cycle while the portions of the two springs may be securely held by the composite rivet 100. The areas joined by the rivet may not separate from each other (or may marginally separate) during the gait cycle while areas nearby the composite rivet may become somewhat separated from each other due to the spring like functionality of the keel spring and the sole plate spring.

[0060] Figure 5 shows a side view of composite layers 510, one or more acting as a spring layer, and all secured to each the other with a composite rivet 100, as may be employed in embodiments. In Figure 5, a view of a basic low profile prosthetic device 500 that may utilize at least one composite rivet 100 for joining springs is seen. The upper spring layer may employ spring functionality and the lower spring layer may employ spring functionality and each may be joined by a composite rivet 100 through a passage as taught herein. The composite rivet 100 may serve to secure the two springs 510 together. Composite rivet(s) may be located at various locations of the low-profile device. In this instance the rivet is located in the front third of the device. During use, the two springs 510 may come apart from each other and then contact back again during a loading cycle while the portions of the two springs 510 may be securely held by the composite rivet. The areas joined by the rivet 100 may not separate from each other (or may marginally separate) during the loading cycle while areas nearby the composite rivet may become somewhat separated from each other due to the spring like functionality of the two layers.

[0061] Figure 6 shows a rear perspective view of a prosthetic foot 600 with split J-shaped keel 610 and multiple sole plates 620, 621, as may be employed in embodiments. As can be seen, medial and lateral sole plates 620, 621 are connected to a split J-shaped keel 610 in the prosthetic of Figure 6. The sole plates 620, 621 and J-shaped keel 610 are coupled in the first third of the prosthetic at the keel toe region 660. The attachment may be done with various techniques, including rivets, flexible adhesive, bolts, screws, thread, composite rivets, and rigid adhesive, among other things. Four passages 680 are present in the region 660 of the prosthetic 600 these passages are shown with rivets 100. These passages may have various configurations, including one or more of geometries taught above in Figure 2A. The passages may be uniformly and nonuniformly spaced and may have matching or discordant numbers on either side of the split, e.g., two passages on one side and three passages on the other. A top portion 650 of the J-shaped keel 610 may be cantilevered over other portions of the J-shaped keel as well as cantilevered over portions of one or more sole plates. In Figure 6, two sole plates 620, 621 are shown with each being attached to the J-shaped keel 610 and each running the length of the prosthetic 600. The J-shaped keel 610 is shown with a split 687 running from below the cantilevered upper portion through the keel toe region 660 and between keel portions 611, 612. Thus, embodiments may comprise dual sole plates coupled to a single upper J-shaped keel, the dual sole plates extending for most or all of the length of the prosthetic. These sole plates may mimic each other in shape, functionality, etc. or may be different from each other in embodiments. Adjacent sole plates may have identical or different cross-sections. Adjacent sole plates that mimic each other, e.g., have identical or substantially similar cross-sections and material constructions, may exhibit similar or identical properties during use of the prosthetic. Comparatively, adjacent sole plates having different cross-sections, shapes, length, etc., may exhibit different properties during use of the prosthetic.

Having different properties/ reactions being exhibited during gait or at other times may be helpful to accommodate a patient's needs, for certain other anatomical reasons, or for other reasons as well. Labeled in Figure 6 are upper cantilevered portion 650, keel 610, sole plate 621, heel region 676, sole plate 620, heel region 675, heel 685, keel portions 611, 612, and sole plate 621 toe region 670.

[0062] Figure 7 shows a top-down view of the prosthetic foot 600 of Figure 6 with split J-shaped keel 610 and multiple sole plates 620 and 621 as may be employed in embodiments. A scale is shown near the bottom of Figure 7. This scale has one-half and one-third markers that can be used to understand the relative positions of various features of the prosthetic of Figure 6 and of Figure 7 and of other embodiments being taught herein as well. As can be seen in Figure 7, the passages 680 at the keel toe region 660 of the prosthetic are positioned in the toe third of the prosthetic while the upper cantilevered portion 650 is shown to be positioned in the heel half of the prosthetic 600. The relative positions of passages 680 in a prosthetic are visible in Figure 7. As can be seen passages 680 may not be evenly spaced between each other and corresponding holes on an opposite side of a split of the prosthetic foot 600.

[0063] Figure 8 shows a rear perspective view of a prosthetic foot 600 with split J-shaped keel 610 multiple sole plates (labelled 672 and 673 in Figure 9), and composite rivet passages 680, as may be employed in some embodiments. As can be seen, medial and lateral sole plates 621, 620 are connected to a split J-shaped keel in the prosthetic of Figure 8. The sole plates and J-shaped keel are coupled in the first third of the prosthetic at the toe end, e.g. a sole plate-keel attachment region. The sole plates - keel attachment region is labelled as 890 in Figure 8 and the split heel is labelled as 750. The attachment may be done with various techniques, including rivets, flexible adhesive, bolts, screws, thread, composite rivets, and rigid adhesive, among other things. Four passages are present in the toe region of the prosthetic. These passages may

have various configurations, including one or more of the passage geometries shown in Figure 2A. The passages may be uniformly and nonuniformly spaced and may have matching or discordant numbers on either side of the split, e.g., two holes on one side and three holes on the other. A top portion of the J-shaped keel may be cantilevered over other portions of the J-shaped keel as well as cantilevered over portions of one or more sole plates. In Figure 8, two sole plates are shown with each being attached to the J-shaped keel and each running the length of the prosthetic. The J-shaped keel is shown with a split running from below the cantilevered upper portion through the toe region. Thus, embodiments may comprise dual sole plates coupled to a single upper J-shaped keel, the dual sole plates extending for most or all of the length of the prosthetic. These sole plates may mimic each other or may be different from each other in embodiments. Adjacent sole plates may have identical or different cross-sections. Adjacent sole plates that mimic each other, e.g., have identical or substantially similar cross-sections and material constructions, may exhibit similar or identical properties during use of the prosthetic. Comparatively, adjacent sole plates having different cross-sections, shapes, length, etc., may exhibit different properties during use of the prosthetic. Having different properties/ reactions being exhibited during gait or at other times may be helpful to accommodate a patient's needs, for certain other anatomical reasons, or for other reasons as well. The configuration of the ends of the heel portions 895 of the prosthetic foot as well as the uniform spacing between the sole plates are each visible in this view. While a uniform split spacing is shown, embodiments may have various spacing configurations including even spacings, uneven spacings, tapered spacings, and alternating spacings along the length of the split between sole plates of embodiments.

[0064] Figure 9 shows a front upright view, of the prosthetic foot 600 of Figure 6 with J-shaped keel 610, passages 680 for composite rivets, and sole plates with split between them, as may be employed in some embodiments. Split sole

plate 1 is labelled 672 and split sole plate 2 is labelled 673. The split 687 runs between lateral and medial sides for the entire length of the sole plates without intervening connection points in the prosthetic 600. The location of the underside of the sole plates and the passages 680 of the toe region are visible in this view. Rivets are present in the passages 680 of the prosthetic. As can also be seen, the prosthetic of embodiments may be balanced along a central vertical axis, with symmetry of the prosthetic being present on each side of the vertical axis. The center axis is labelled 965. Symmetry may exist along other reference axes of embodiments as well. For example, symmetry along various reference axes may exist on either side of the split of some embodiments.

[0065] Figure 10 shows a rear upright view of the prosthetic foot of Figure 6, with J-shaped keel 610, passages with composite rivets, and sole plates 672, 673, with split 687 between them as may be employed in some embodiments. The location of the underside of the sole plates and the split heel region 750 are visible in this view. As can be seen in Figure 10 as well, the prosthetic of embodiments may be balanced along a central vertical axis 965, with symmetry of the prosthetic being present on each side of the vertical axis. Figure 10 also provides that embodiments may have prosthetics with split lateral and medial sides for an entire length of the heel or the sole plate, in each case without intervening connection portions (see split 985 without intervening connecting portions between the two sole plates 672 and 673).

[0066] Figure 11 shows a rear perspective view of a prosthetic foot 1100 with J-shaped keel 1210, sole plate 1260, and composite rivet passage 680 with rivet 100 as may be employed in embodiments. The composite rivet passage 680 for a composite rivet to secure spring layers, along with various regions and components are shown in Figure 11. As can be seen in Figure 11 the sole plate 1260 and the keel 1210 are attached in the keel-toe region 660 via a composite rivet 100. The composite rivet 100 is shown between the edges of the sole

plate and keel and in the first third of the prosthetic. A single or multiple composite rivets may be located in other areas of the prosthetic as well. Such composite rivets may be positioned and installed so as to secure a keel to a sole plate or other components of a prosthetic or an orthotic. The size and shape of the passage in which the composite rivet is inserted can add to the strength of the connection created by the composite rivet. The configuration of the composite rivet may add to the strength of the connection created by the composite rivet. Also labelled in Figure 11 are the sole-plate keel attachment region 1290, sole plate toe region 1270, heel 1250, and upper cantilevered portion 1125.

[0067] Figure 12 shows a rear perspective view of a prosthetic foot 1300 with partial split keel 1310 and split sole plate 1360, each providing spring plate functionality, as may be employed in some embodiments. Composite rivets 100 along with various regions and components are labelled in Figure 12. These include sole plate 1360, heel 1350, sole plate toe region 1370, keel-toe region 660, sole plate-keel attachment region 1390, and upper cantilevered portion 1125. As can be seen in Figure 12 the split sole plate and the split J-shaped keel are attached in the keel-toe region 660 via a pair of composite rivets 100. The composite rivets 100 are shown between the edges of the sole plate and the keel and in the first third of the prosthetic. Various composite rivets, composite rivet locations, and composite rivet materials may be employed in this and other embodiments.

[0068] Figure 13 shows a side, upright view, of the prosthetic foot of Figure 12 with split J-shaped keel 1310, split sole plate 1340, and prosthetic cover 1445 as may be employed in embodiments. The prosthetic cover 1445 is shown having a somewhat anatomic foot configuration although other configurations may also be employed in embodiments. Covers may be employed with various features including additional surface friction, sound management, and for

other reasons as well. Keels of embodiments may be a solid plate or be split in the forefoot area in some embodiments.

[0069] Figure 14 shows a side, upright view of the prosthetic foot of Figure 12 with split J-shaped keel 1310, split sole plate 1360, composite rivet passages 680, composite rivet 100, posterior section of keel 1515, and metallic pyramid coupler 1525, as may be employed in some embodiments. Various coupler configurations and placements may be employed in embodiments. In Figure 14, the coupler is shown in a cantilevered region 1125 of the J-shaped keel and in the cross-section of the keel having the greatest thickness. The tapering nature of the cross section of the J-shaped keel is also visible in Figures 14 and 17. A reference scale is provided at the bottom of Figure 14 and reference lines 1570, 1575, show relative position versus the scale provided in Figure 14. Single group of layers or multiple groups of layers may be employed as sole plates in embodiments. Likewise, the keel may be a single group of layers or multiple groups of layers embodiments. Each plate may have a split at least in the toe region of the prosthetic in some embodiments. In some embodiments, as shown above, the bottom may comprise sole plates with a split between them while in others the sole plate and/or keel may not be split. The keel may be split along a majority of its length as well.

[0070] Figure 15 shows an exemplary flexibility/rigidity profile for a prosthetic foot with J-shaped keel, as may be employed in some embodiments. The various sections labelled bend identify lengths along the keel or sole plates or both that may be flexible or flex in a substantially cohesive way. In other words, their relative stiffnesses or flexibility may differ but they may function in a cohesive manner or substantially cohesive manner.

[0071] Annotated Figure 16 shows an exemplary schematic flexibility profile for a prosthetic foot with J-shaped keel as may be employed in embodiments. The various labelled sections identify lengths along the keel or sole plates or both that may be flexible or flex in a substantially cohesive way and with a

relativity scale regarding this flexibility as well. Figure 16 includes a numeric scale to show relative rigidity (or flexibility) between the different portions of the prosthetic of Figures 15 and 16. Other portions of the prosthetic foot may be more or less flexible as well. Flexibility may be adjusted by adding or removing layers of fiber or modifying layers of fiber, for example changing a UD fiber layer to bi-directional fiber layer.

[0072] Figure 17 shows exemplary measurement points corresponding with Table 1 for a certain size prosthetic foot with split J-shaped keel and split sole plate, as may be employed in embodiments. The dimensions of Figure 17 and Table 1 are directed to a certain size and may be modified for other sizes, as well as modified for other reasons in embodiments. Certain dimensional ratios may be held consistently across same-sized embodiments and certain dimensional ratios may vary across same-sized embodiments.

[0073] Figures 18A-18D show forces that may be present or developed around composite rivets and components secured by a composite rivet in some embodiments. Forces may be transferred between the rivet/layer interface 2025 as well as the rivet component interface 2026. These forces may include static and dynamic forces and may be transferred through friction or other transfer mechanisms. Composite rivets may assert inward axial compressive forces to components or layers being secured together and may impose frictional surface forces along a rivet surface interface. These frictional forces and compressive forces may act to hold layers or other components together. These forces may also resist rotation of layers or components being secured by a composite rivet 100. Axial forces are labelled 2050.

[0074] In embodiments, multiple composite rivets may be employed to provide greater resistance to torsion or to provide greater securement forces. The positioning of the composite rivets may also be selected to provide targeted securement forces or movement deterrence. Exemplary shapes of the rivet 100 and the passages 680 for the rivet 100 are present in Figures 18A and 18B and

may be selected to develop different frictional or compressive forces for a particular expected loading. For example, as shown in Figure 18A, a chamfered top and bottom with chamfered edges 2040 of a composite rivet 100 may be employed to develop greater compressive forces than what may be developed by a purely cylindrical rivet without chamfered or other nonvertical sides.

[0075] Figures 18C and 18D show rotational forces 2020 that may be opposed by composite rivets of embodiments. Opposition of these rotational forces may serve to keep layers or other components being secured from rotating differently from each other. In other words, the secured layers 2030 or components 2040 may stay aligned or close to aligned to each other in some embodiments. These rotational forces may be opposed by compressive forces developed by the rivets as well as surface friction between the rivets and the components being secured.

[0076] Figure 19 shows sole plate 2220 layups as may be employed in some embodiments. Sole plates of some embodiments may employ composite fiber fabric, bidirectional layers (carbon fiber, aramid fiber, glass fiber, etc.) e.g., $\pm 45^\circ \pm 30^\circ$, etc., 0° Unidirectional Full Length (carbon fiber, aramid fiber, glass fiber, etc.), 0° Ply drop-off (carbon fiber, aramid fiber, glass fiber, etc.), 90° Unidirectional full length and/or ply drop-off (carbon fiber, aramid fiber, glass fiber, etc.). As described above, the layup layers may have different lengths and may drop off 2230 as is shown in Figure 19. As the layers drop off the flexibility of the sole plate or other component increases and the thickness decreases as fewer layers are present. Some full-length sections 2240 may be present along the entire length of the sole plate 2220 or other component. These full-length sections 2240 may comprise one or more layers and may be positioned at outer surfaces of the sole plate 2220 as well as internal positions of the sole plate 2220 along its length. The direction of the fiber may be 0° and 90° as well as other orientations. A reference axis is shown at Figure 19.

[0077] Figure 20 shows keel 2120 layups as may be employed in embodiments.

Keel 2120 layups of embodiments may employ composite fiber fabric, bidirectional layers (carbon fiber, aramid fiber, glass fiber, etc.) e.g., $\pm 45^\circ \pm 30^\circ$, etc., 0° Unidirectional full length (carbon fiber, aramid fiber, glass fiber, etc.), 0° Unidirectional ply-drop off (carbon fiber, aramid fiber, glass fiber, etc.), 90° Unidirectional full length and/or ply drop-off (carbon fiber, aramid fiber, glass fiber, etc.). The layup layers may have different lengths and may drop off 2170 as is shown in Figure 20. As the layers drop off the flexibility of the keel or other component increases and the thickness decreases as fewer layers are present. Some full-length sections 2180 may be present along the entire length of the keel 2120 or other component. These full-length sections 2180 may comprise one or more layers and may be positioned at outer surfaces of the keel as well as internal positions of the keel 2120 along its length. The direction of the fiber is shown by the 0° and 90° arrows as well as by the reference axis.

[0078] Keel and sole plate lay-ups of embodiments may be adapted for size. For example, an increase or decrease in the number of layers of full-length and/or ply drop-off layers sections may be employed. Layups of embodiments may be adapted for weight or activity level as well. For example, an increase or decrease in the number of layers of full-length and/or ply drop-off layer sections may be employed. Keel and sole plate lay-ups may also employ other fibers such as fiberglass and other composite layered materials.

[0079] Table 1 – Non-Limiting Exemplary Dimensions Corresponding to an Exemplary size 27 P5 foot – as shown in Figure 17. Other dimensions in embodiments may also be employed.

Number	Description	Measurement [mm]
1	Thickness of composite at mount	10.9
2	Thickness of composite at apex of “J” curve	11.3
3	Thickness of sole plate at 20% length from heel	5.4
4	Thickness of composite at toe tip	9.8
5	Inside width of keel	70.6
6	Overall height of foot	111 (excluding pyramid)
7	Length of heel portion of sole plate	67 (measured to the pyramid hole center axis)
8	Sole plate length from apex of posterior curve to apex of toe curve	104
9	Overall length of (foot) soleplate	235
10	The curve may use more than a single radius. The outside curve can be described by an Ellipse with a major radius of 39.5 and a minor radius of 29.3.	Ellipse Major radius 41 Minor radius 29

[0080] While various features, combinations of features, and embodiments are provided herein, other features, combinations of features, and embodiments may also be employed. Features may be combined across embodiments and with different embodiments while remaining within the teachings of the disclosure. For example, split keel and split sole plates as well as intact keels and intact sole plates are shown herein. Other embodiments may include multiple keel elements and/or multiple sole plates. Still further keel and sole plate designs may be employed in embodiments. Composite rivets of carbon, glass, and aramid fibers are mentioned above but still further materials may be employed in composite rivets of embodiments.

WHAT IS CLAIMED IS:

1. A prosthetic foot comprising:
 - a keel spring comprising a cantilevered upper portion and a lower portion, the lower portion having a keel-toe region;
 - a sole plate spring positioned below the keel and coupled to the keel in the keel-toe region;
 - a composite rivet positioned in the keel-toe regions and configured to attach at least one soleplate to at least one keel in the keel-toe region.
2. The prosthetic foot of claim 1 wherein the composite rivet comprises twisted thermoset fiber composites.
3. The prosthetic foot of claim 1 wherein multiple keel and heel components are fixated by at least one composite rivet.
4. The prosthetic foot of claim 1 wherein the composite rivet comprises of carbon fiber.
5. The prosthetic foot of claim 1 wherein the composite rivet is positioned in a first hole, the first hole positioned in the sole plate and the keel in the keel-toe region, the first hole having an opening wider than an inner passage of the first hole.
6. The prosthetic foot of claim 1 wherein the composite rivet is symmetrically formed.
7. The prosthetic foot of claim 1 wherein the composite rivet extends through at least one keel and one sole plate.
8. The prosthetic foot of claim 1 wherein the composite rivet comprises one or more of the following: dry or pre-preg: UD fiber, rolled UD fiber bunches, weaved fiber stockings, UD fiber bunches, twisted UD fiber bunches, twisted fibers, and roped out fibers as well as other materials.
9. The prosthetic foot of claim 1 wherein the keel is formed like a J-shaped, L-shaped or low profile keel.
10. A composite prosthetic comprising:

a first spring layer, the first spring layer comprising a cantilevered upper portion and a lower portion; and
a second spring layer coupled to the first spring layer,
wherein the first spring layer is coupled to the second spring layer with a twisted carbon fiber rivet,
wherein the second spring layer is a soleplate.

11. The prosthetic foot of claim 10 wherein the soleplate is coupled to the first spring layer in an outer third of the soleplate.
12. A prosthetic foot comprising:
a J-shaped keel, the keel comprising a cantilevered upper portion and a split pronged lower portion;
a first sole plate coupled to a first fork of the split pronged lower portion;
a second sole plate coupled to a second prong of the split pronged lower portion,
wherein the first sole plate is spaced apart from the second sole plate along an entire side adjacent to the second sole plate.
13. The prosthetic foot of claim 12 wherein the J-shaped keel and the first and second sole plate comprise one or more layers of carbon fiber.
14. The prosthetic foot of claim 12 wherein the first soleplate is coupled to the first fork of the split pronged lower portion in a first third of the first fork.
15. The prosthetic foot of claim 12 wherein the first soleplate is coupled to the first fork of the split pronged lower portion with a carbon fiber rivet.
16. The prosthetic foot of claim 12 wherein the first soleplate is coupled to the first fork of the split pronged lower portion with a twisted carbon fiber rivet.
17. The prosthetic foot of claim 12 wherein

the first sole plate is coupled to the first fork of the split pronged lower portion
with a twisted carbon fiber rivet.

18. The prosthetic foot of claim 12 wherein the first sole plate is coupled to the first fork of the split pronged lower portion with a twisted pre-preg carbon fiber rivet in an outer third of the first sole plate.

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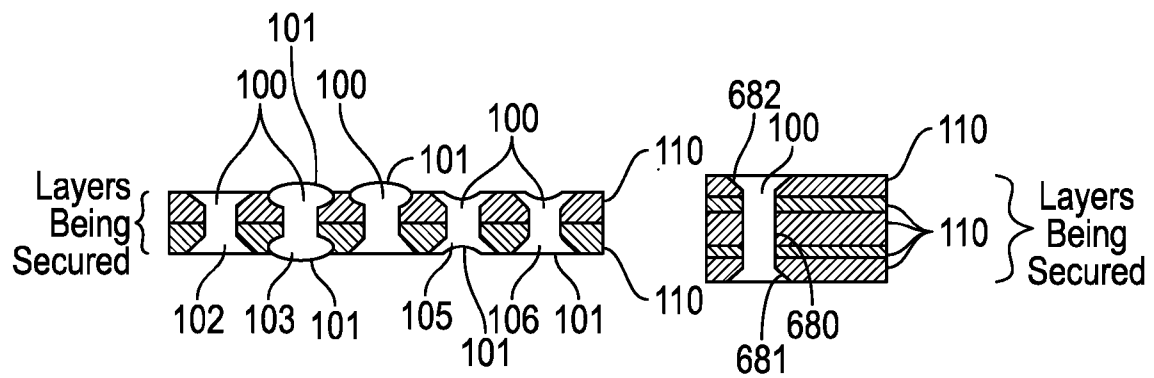


FIG. 1A

FIG. 1B

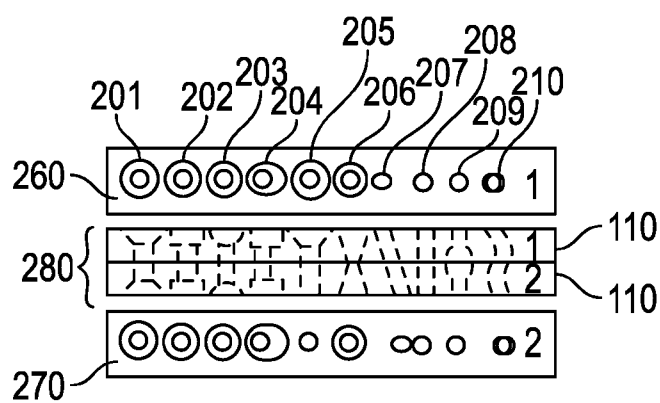


FIG. 2A

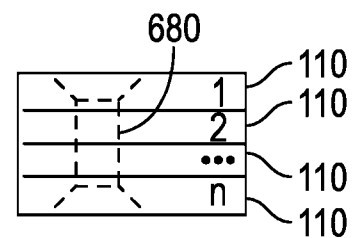


FIG. 2B

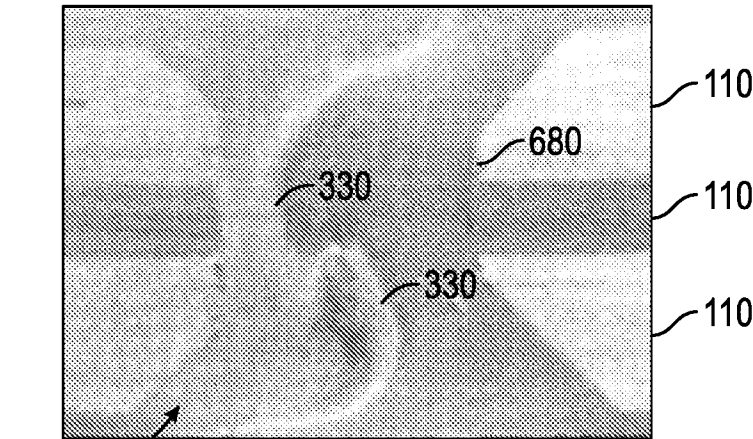


FIG. 3A

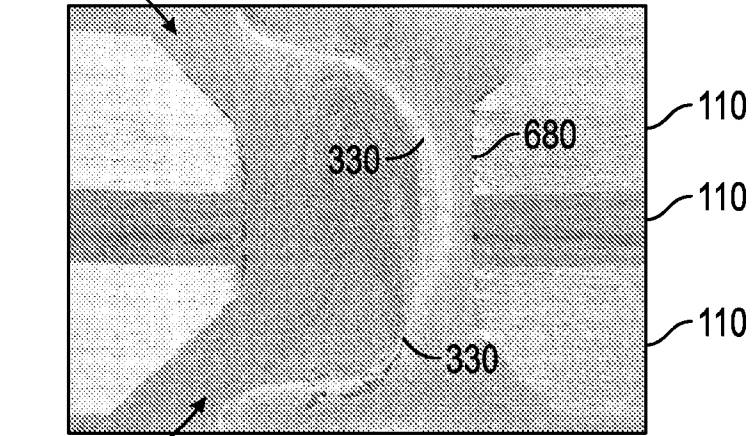


FIG. 3B

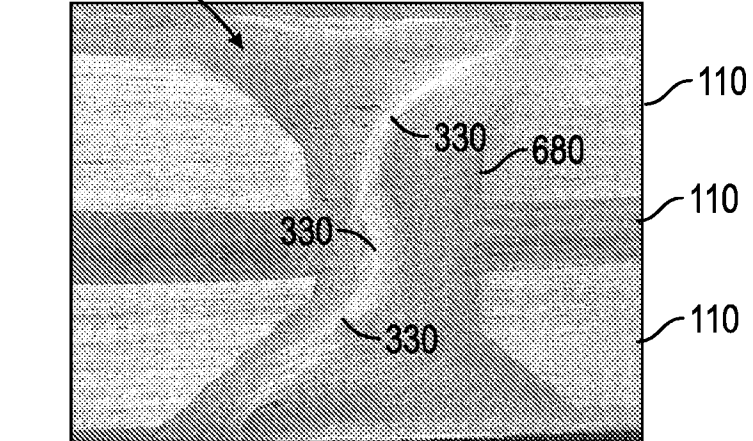


FIG. 3C

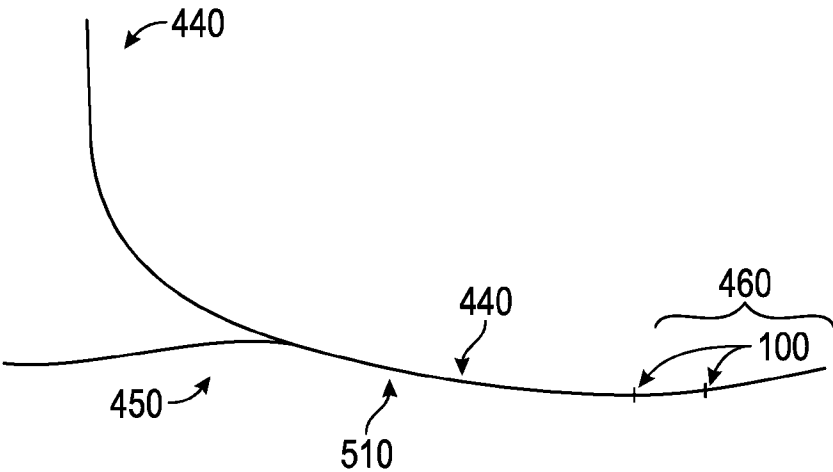


FIG. 4

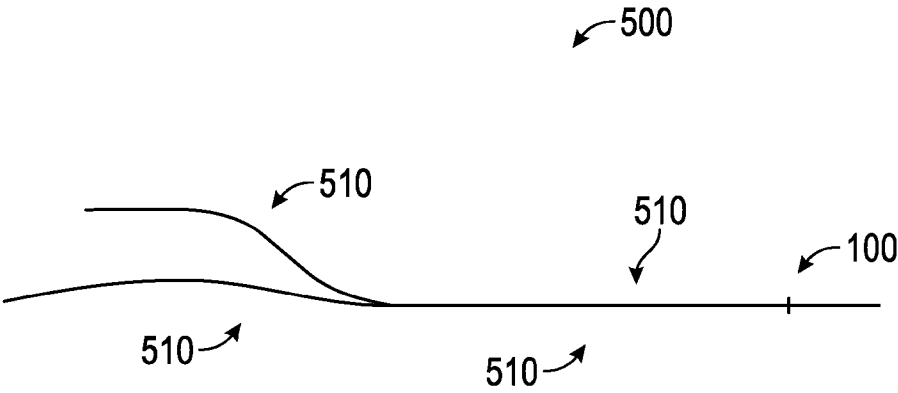


FIG. 5

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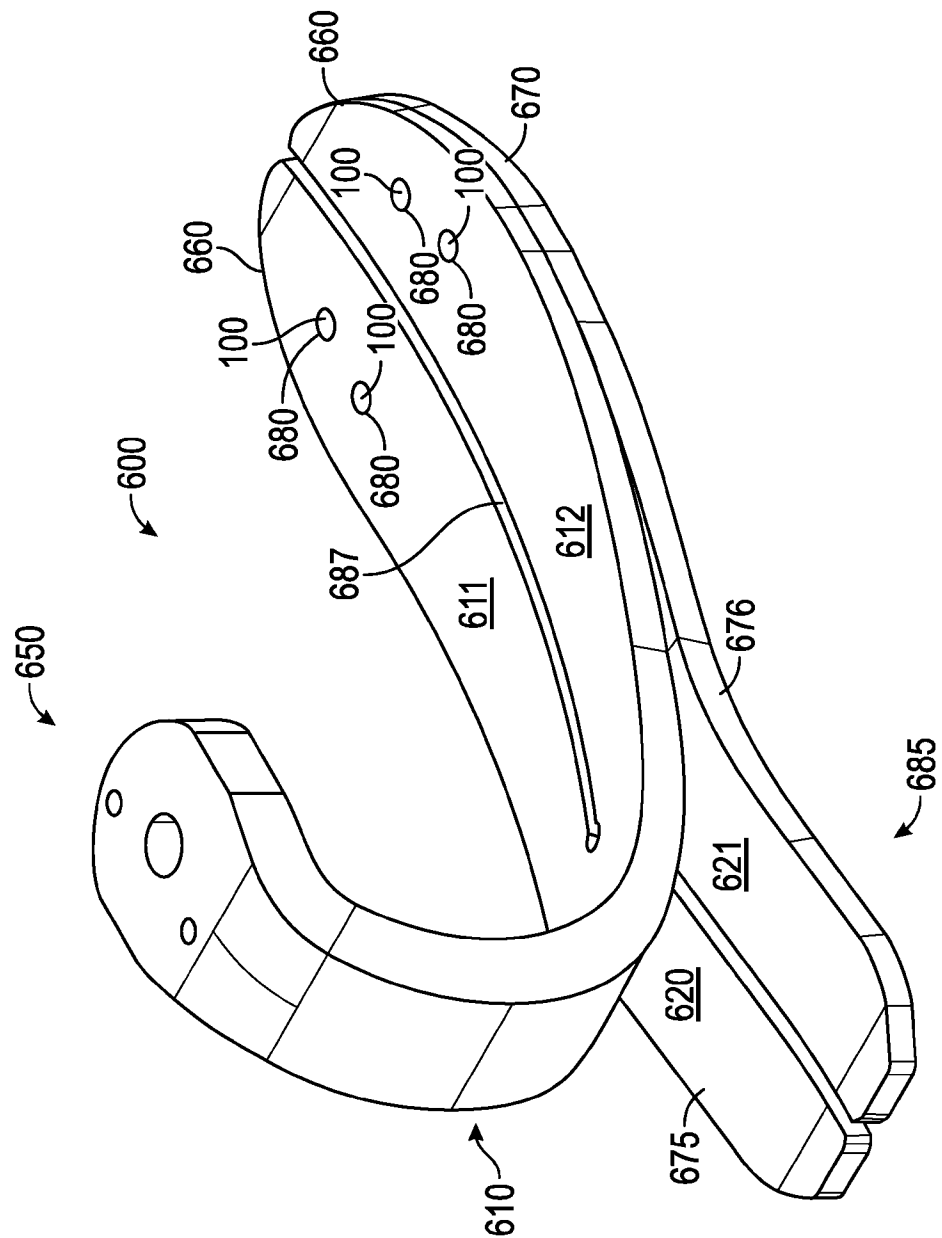


FIG. 6

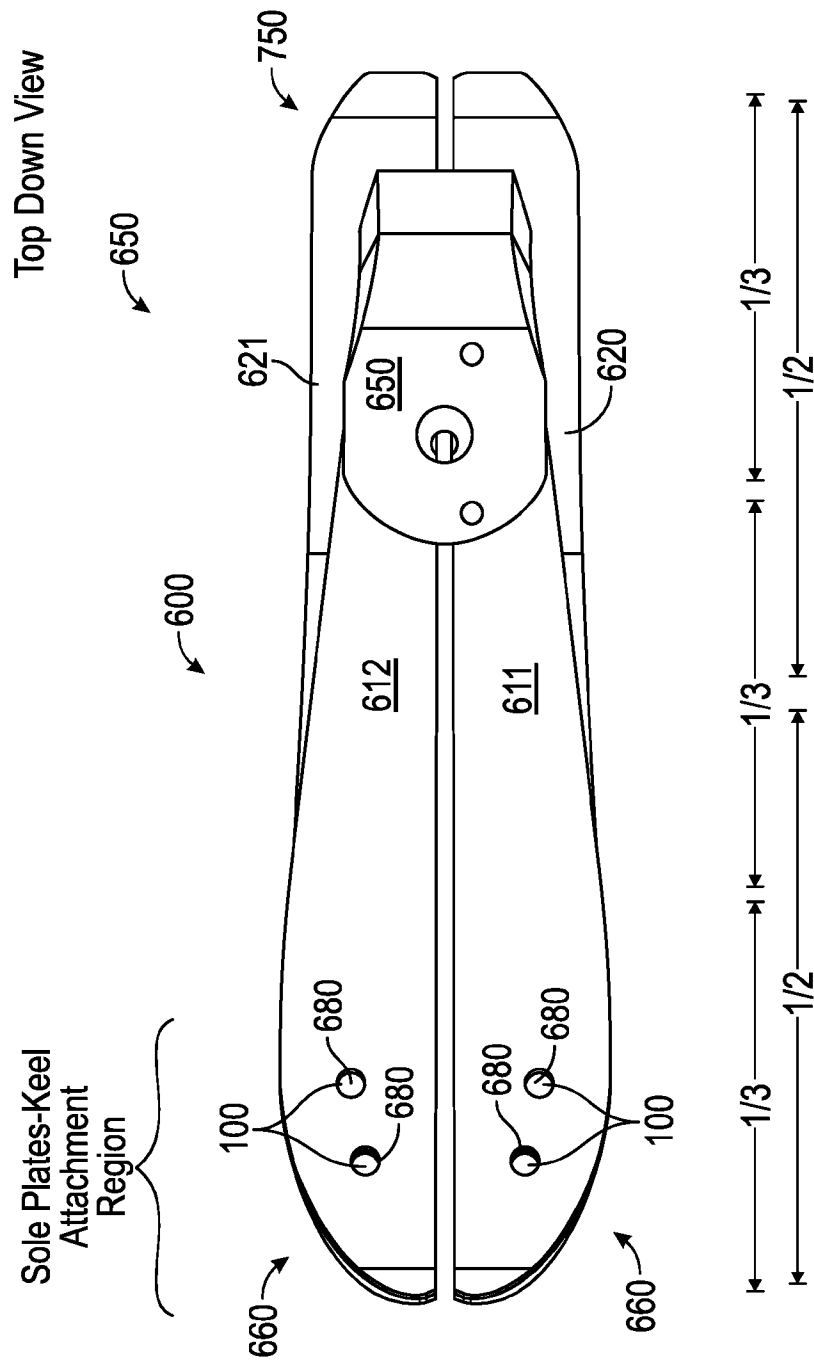


FIG. 7

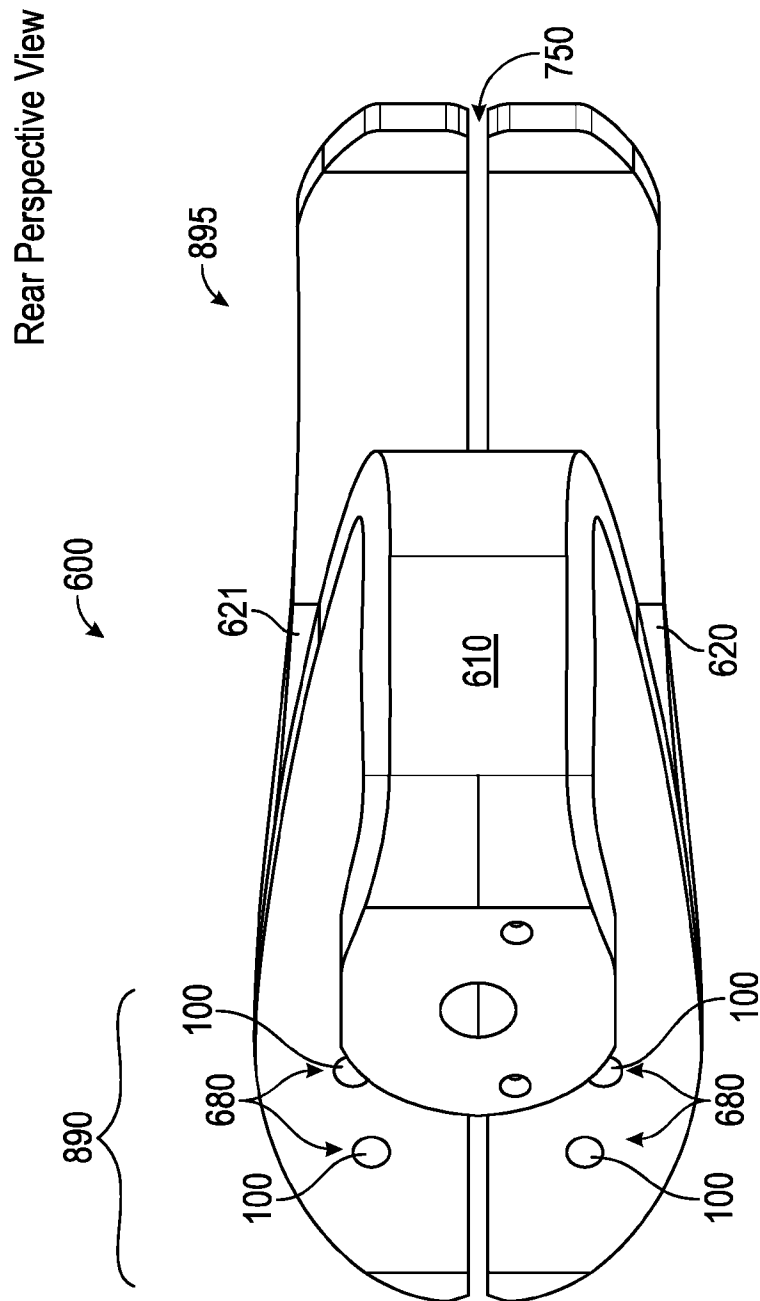


FIG. 8

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Front Upright View

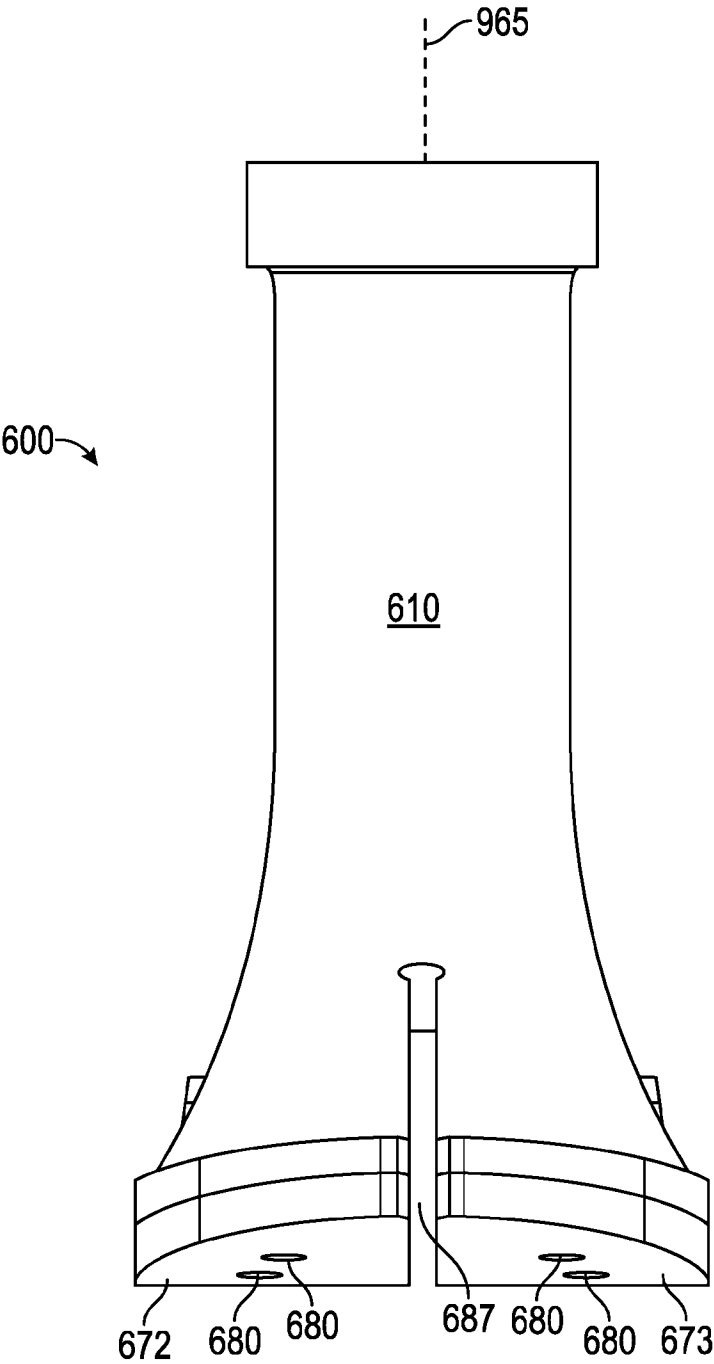


FIG. 9

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Rear Upright View

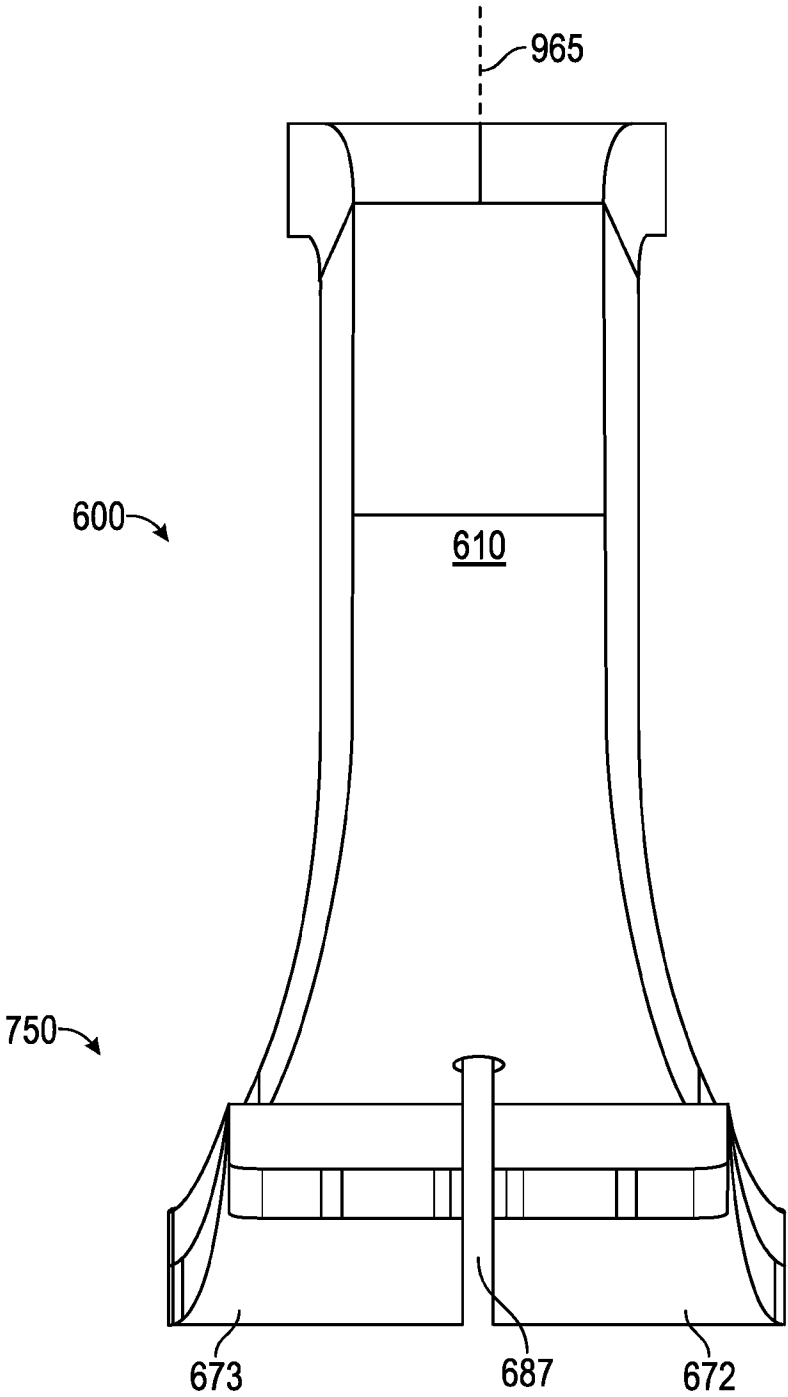


FIG. 10

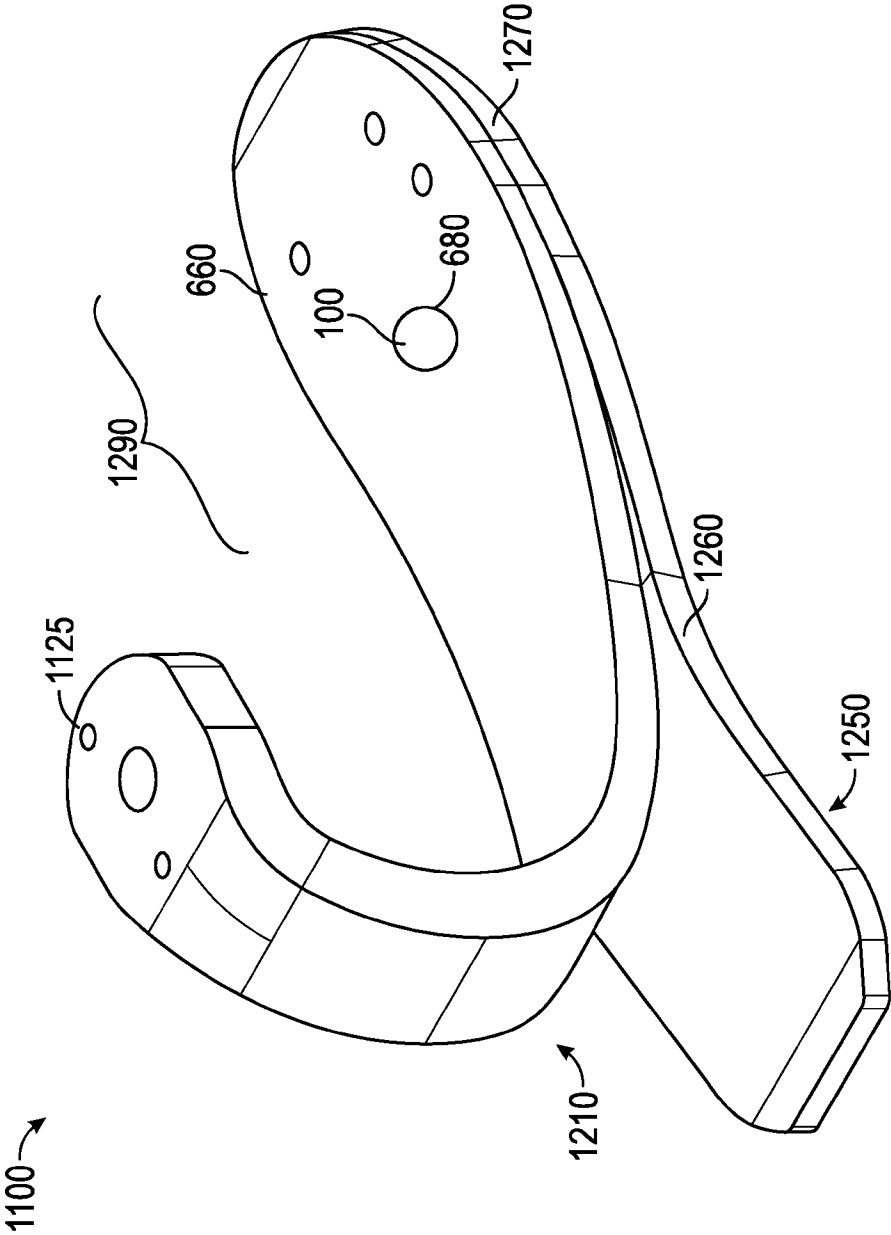


FIG. 11

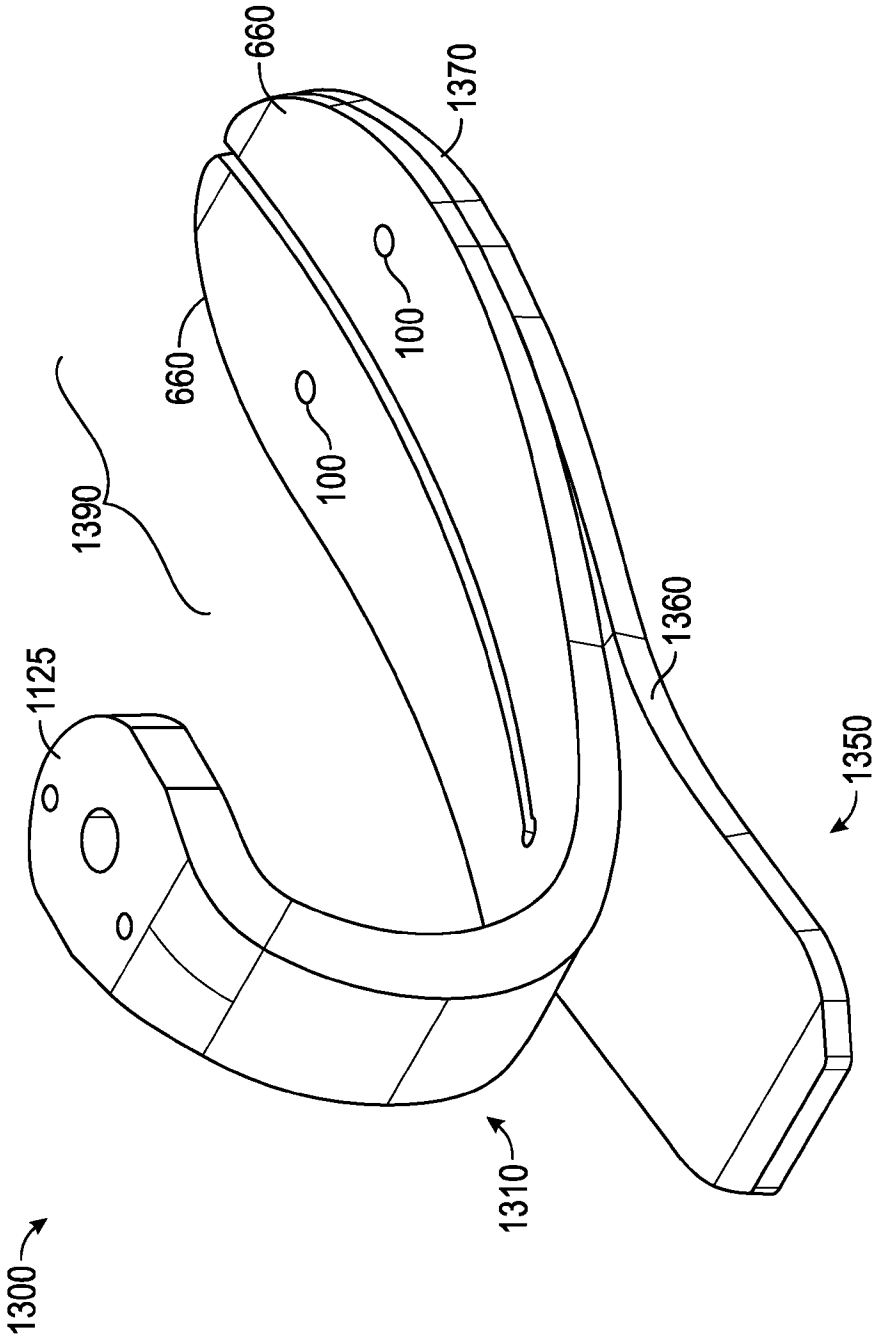


FIG. 12

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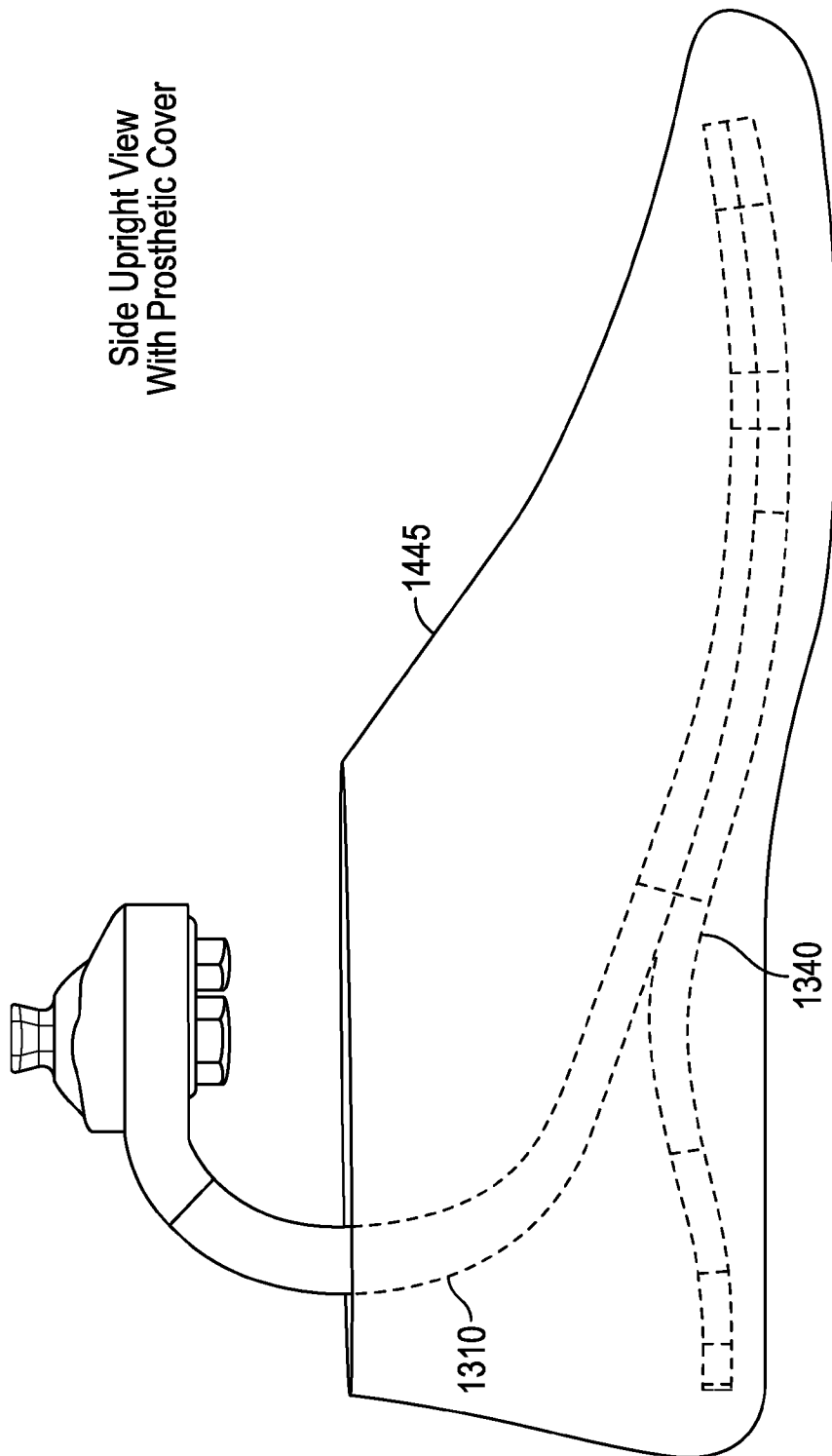


FIG. 13

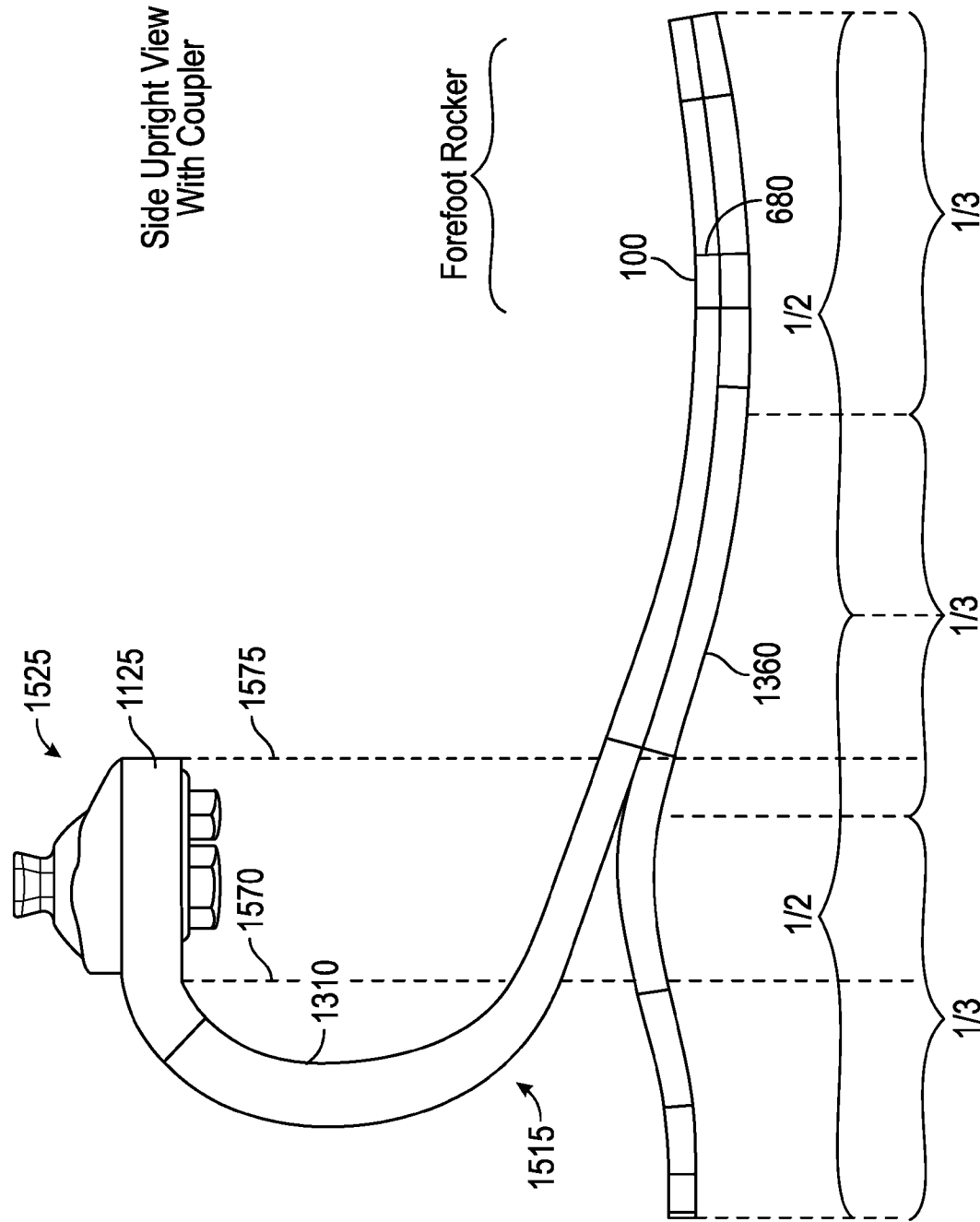


FIG. 14

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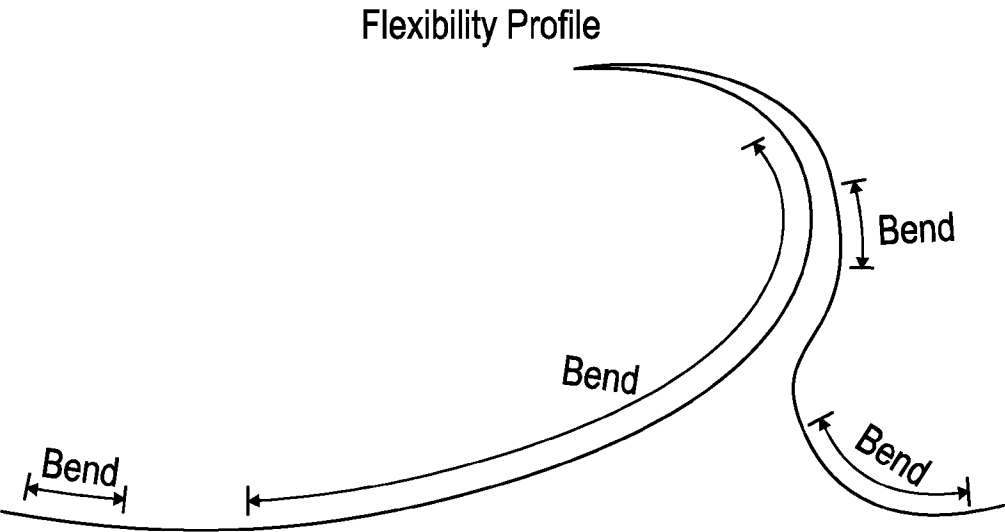


FIG. 15

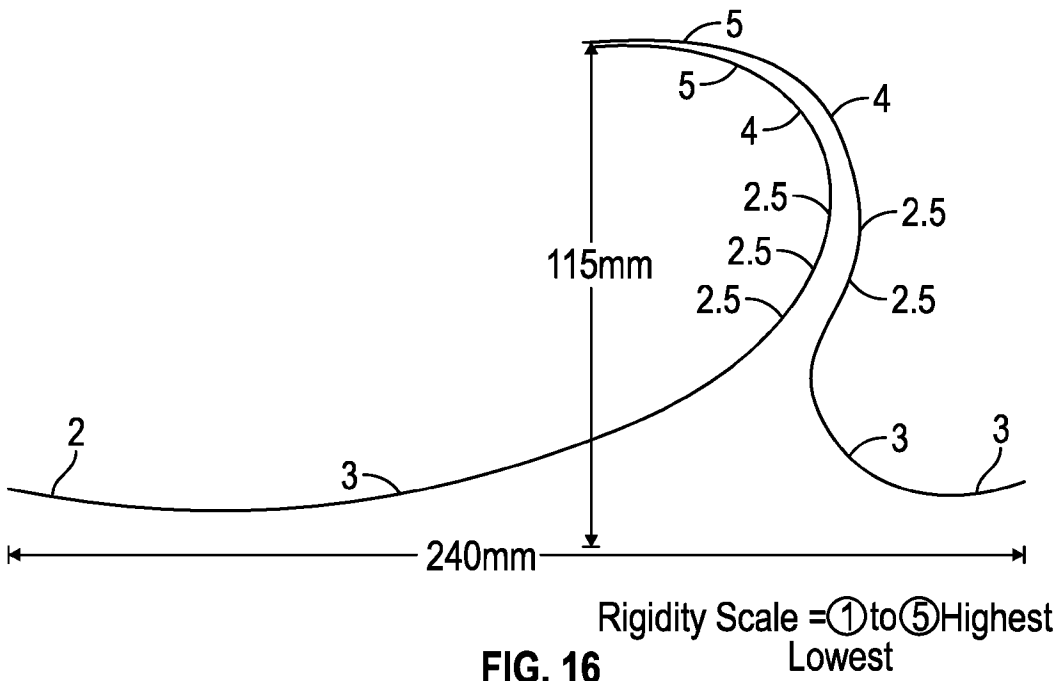


FIG. 16

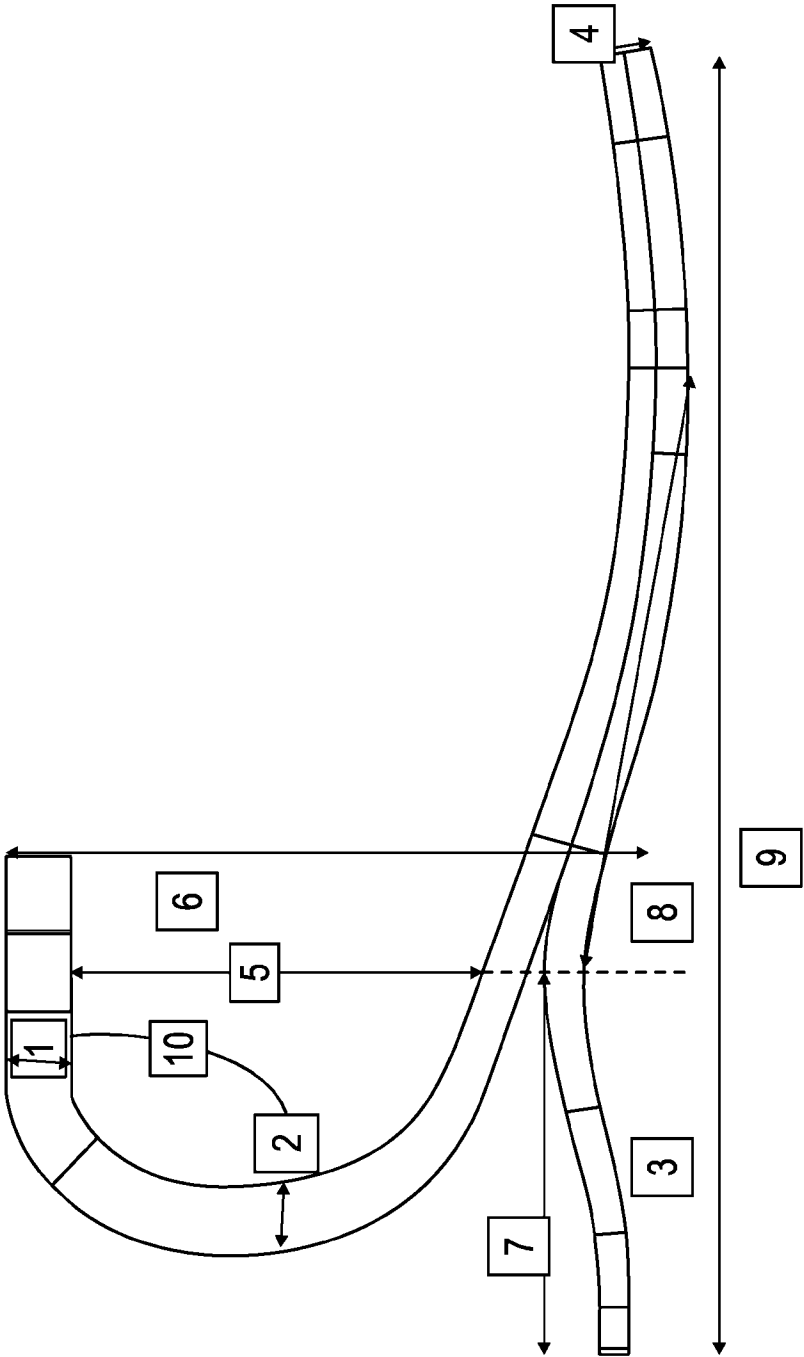


FIG. 17

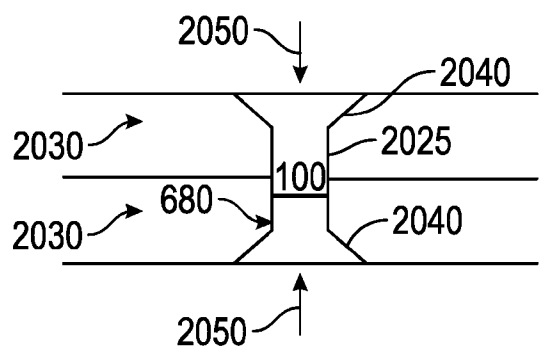


FIG. 18A

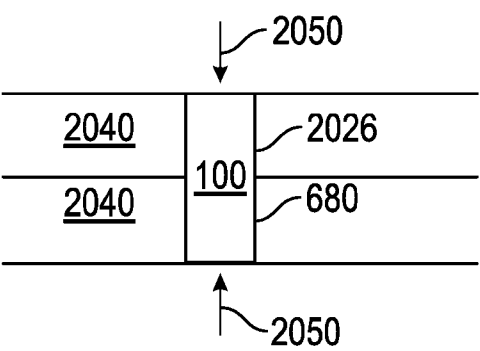


FIG. 18B

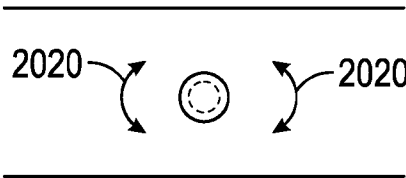


FIG. 18C

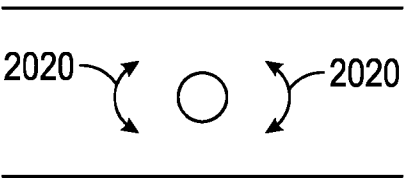


FIG. 18D

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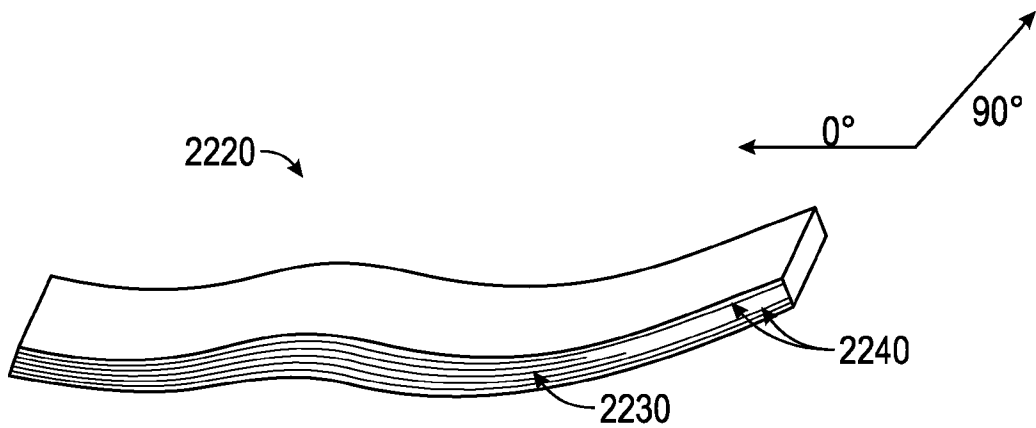


FIG. 19

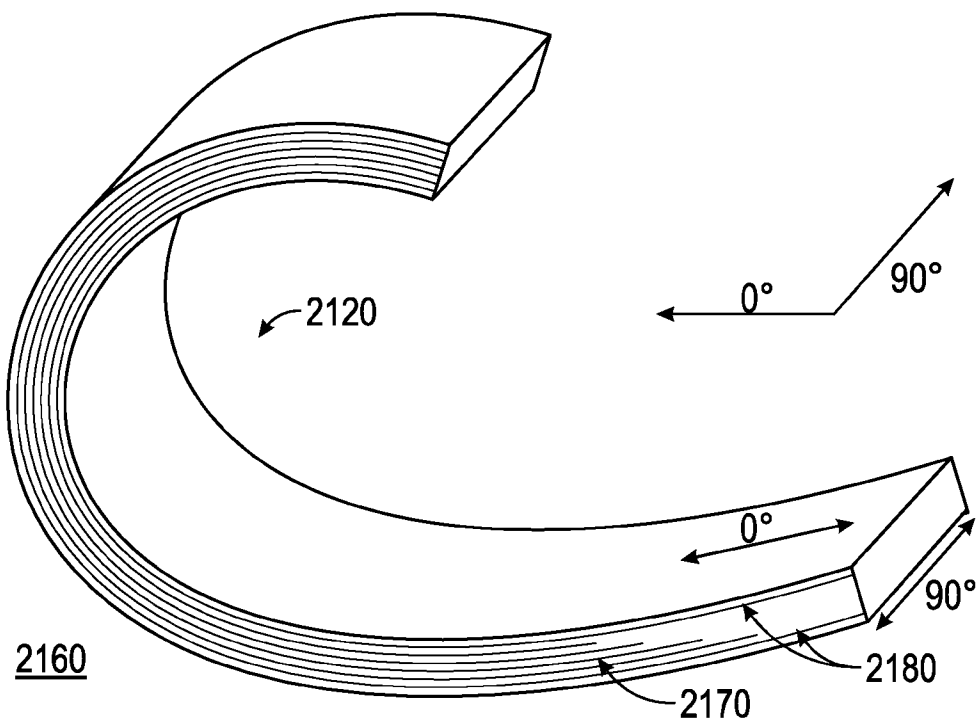


FIG. 20

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2024/030784

A. CLASSIFICATION OF SUBJECT MATTER A61F 2/60(2006.01)i; A61F 2/50(2006.01)i; A61F 2/66(2006.01)i; A61F 2/78(2006.01)i; A61F 2/30(2006.01)i 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) A61F 2/60(2006.01); A61F 2/66(2006.01); A61F 2/72(2006.01); A61N 2/00(2006.01); A61N 2/02(2006.01); F16B 13/04(2006.01) Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Korean utility models and applications for utility models Japanese utility models and applications for utility models Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) eKOMPASS(KIPO internal) & Keywords: prosthetic foot, keel, sole plate, composite rivet, cantilevered upper portion, split pronged lower portion, hole		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2003-0191541 A1 (PHILLIPS, V. L.) 09 October 2003 (2003-10-09) paragraphs [0010]-[0051]; figures 1-6	12-14
Y		1-11,15-18
Y	US 4478544 A (STRAND, N. S.) 23 October 1984 (1984-10-23) column 1, line 64 - column 6, line 2; claim 1; figures 1-9	1-11,15-18
A	US 2019-0070426 A1 (ALAM, I. K.) 07 March 2019 (2019-03-07) paragraph [0045]	1-18
A	US 2023-0064710 A1 (ÖSSUR ICELAND EHF) 02 March 2023 (2023-03-02) paragraphs [0004]-[0019]	1-18
A	US 2015-0088270 A1 (THE OHIO WILLOW WOOD COMPANY) 26 March 2015 (2015-03-26) paragraphs [0007]-[0012]	1-18
☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.		
* Special categories of cited documents: “A” document defining the general state of the art which is not considered to be of particular relevance “D” document cited by the applicant in the international application “E” earlier application or patent but published on or after the international filing date “L” document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) “O” document referring to an oral disclosure, use, exhibition or other means “P” document published prior to the international filing date but later than the priority date claimed “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 “X” document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone “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 11 September 2024		Date of mailing of the international search report 13 September 2024
Name and mailing address of the ISA/KR Korean Intellectual Property Office 189 Cheongsa-ro, Seo-gu, Daejeon 35208, Republic of Korea Facsimile No. +82-42-481-8578		Authorized officer HEO, Joo Hyung Telephone No. +82-42-481-5373

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.

PCT/US2024/030784

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				US	7060104	B2	13 June 2006
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