



(51) International Patent Classification:

A61F 2/74 (2006.01) A61F 2/66 (2006.01)

(21) International Application Number:

PCT/US2024/036038

(22) International Filing Date:

28 June 2024 (28.06.2024)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

63/511,303 30 June 2023 (30.06.2023) US

(71) Applicant: **OTTO BOCK HEALTHCARE LP** [US/US];
11809 Domain Drive, Unit 400, Austin, TX 78758 (US).

(72) Inventor: **JACOBS, Gregory**; 3820 W. Great Lakes Drive,
Salt Lake City, UT 84120 (US).

(74) Agent: **WHITHAM, Michael, E.** et al.; 11491 Sunset Hills
Road, Suite 340, Reston, VA 20190 (US).

(81) Designated States (unless otherwise indicated, for every
kind of national protection available): AE, AG, AL, AM,
AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ,
CA, CH, CL, CN, CO, CR, CU, CV, CZ, DE, DJ, DK, DM,
DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT,

HN, HR, HU, ID, IL, IN, IQ, IR, IS, IT, JM, JO, JP, KE, KG,
KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY,
MA, MD, MG, MK, MN, MU, MW, MX, MY, MZ, NA,
NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO,
RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, ST, SV, SY, TH,
TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, WS,
ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every
kind of regional protection available): ARIPO (BW, CV,
GH, GM, KE, LR, LS, MW, MZ, NA, RW, SC, SD, SL, ST,
SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ,
RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ,
DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT,
LU, LV, MC, ME, MK, MT, NL, NO, PL, PT, RO, RS, SE,
SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN,
GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— with international search report (Art. 21(3))

(54) Title: SYSTEMS AND METHODS FOR AN ARTICULATING PROSTHETIC JOINT

(57) Abstract: Prosthetic joints are disclosed such as an ankle-foot prosthesis. An extendable link of a prosthetic device may lengthen or shorten to bring about flexion and extension. The extendable link may include a hydraulic cylinder configured to provide a flexion damping resistance and an extension damping resistance. The extendable link may further include a spring arranged in parallel with the hydraulic cylinder. The spring biases the rotation of the joint. The spring may be a gas spring. The spring may be inside of a piston assembly of the hydraulic cylinder and act directly on hydraulic fluid. In the context of an ankle-foot prosthesis, the spring may be configured to overcome hydraulic resistance to dorsiflexion rotation.

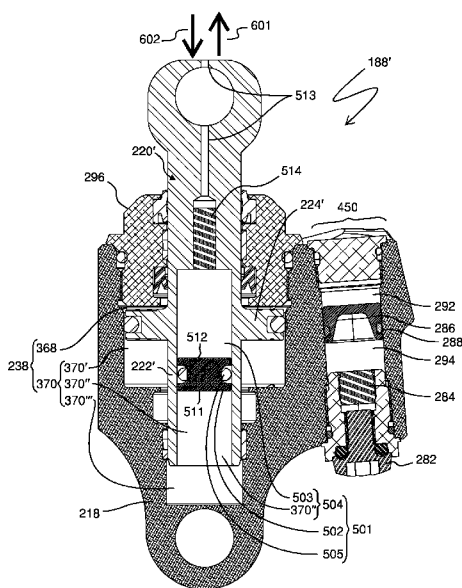


FIG. 15



SYSTEMS AND METHODS FOR AN ARTICULATING PROSTHETIC JOINT

TECHNICAL FIELD

5 The present disclosure relates generally to prosthetic devices, and, more particularly, prosthetic devices such as but not limited to prosthetic ankles and other prosthetic joints.

BACKGROUND

10 Amputees are typically fitted with prosthetic devices that meet specific criteria for that particular amputee. For example, the size, shape, stiffness, and other properties of a prosthetic device are selected and tuned to match the size, shape, strength, and other physical properties and functionality of the given amputee. Changes in these properties of a given amputee may influence whether or not a particular prosthetic device will perform properly and according to
15 expectations for the amputee. It is common for an amputee to change his/her prosthetic device when, for example, the amputee grows in height, weight, strength, or balance capability. Opportunities exist for providing prosthetic devices for amputees that account for changes in the amputee's body and capabilities.

 There are available to amputees three general categories of prosthetic ankle-foot
20 prosthesis designs which articulate during stance phase. One category is known as a single axis foot. This type of design has an ankle rotation axis and ankle rotation is resisted by elastomer bumpers. Elastomers exhibit creep over time, and therefore the ankle behavior is not consistent over time. The second category is hydraulic ankles. Hydraulic ankles, like single axis feet, are passive prosthetics. Hydraulic ankles suffer the drawback of energy dissipation during the gait
25 cycle. In fact, energy loss is widely considered the largest design deficiency in hydraulic ankles on the market to date. The third category is powered ankles, such as the Ottobock® Empower. Unfortunately, powered ankles are very expensive, complex, and heavy. The various drawbacks to each of these categories create an ongoing need for new alternatives for prosthetic articulating ankles and other prosthetic joints.

30

SUMMARY

An aspect of the present disclosure involves prostheses and their components which provide articulation similar to the substituted biological joint without the energy losses associated with hydraulic-only joints. In the context of ankle-foot prostheses, exemplary embodiments provide ankle articulation similar to a human ankle without the energy loss associated with hydraulic ankles. Energy is stored and then returned by one or more springs as the gait cycle progresses. In some embodiments, an exemplary spring for this purpose is an air spring. The air spring may be arranged to exert a force directly on the hydraulic fluid belonging to a dampening subsystem. Return of energy from the air spring may provide propulsion which is adjustable to the individual user. The propulsion effect is exhibited during the stance phase, in particular during dorsiflexion rotation that occurs during the stance phase. Even more particularly, the propulsion effect may be most notable during the mid-stance phase. Exemplary embodiments also permit adjustment of the hydraulic resistance. Accordingly, exemplary prostheses with such features are able to provide whatever resistance and/or propulsion a user desires using only passive (non-powered) components. Relatively high hydraulic resistance settings permit an exemplary prosthesis assembly to act much like a traditional hydraulic ankle. Utilizing relatively lower hydraulic resistance results in the ankle returning energy absorbed during heel strike and increasing the rate of tibial progression compared to a hydraulic-only ankle by creating a joint moment large enough to counteract a user's applied body weight.

According to an aspect of some embodiments, an articulating prosthetic foot is included which collects much of the heel impact energy (e.g., during initial contact and loading response subphases of the stance phase of the gait cycle) and returns it back to the user during tibial progression via a charged spring, e.g., a charged gas spring. Such configuration minimizes the otherwise significant energy loss associated with hydraulic-only fully mechanical articulating prosthetic feet. The spring may be charged by using hydraulic fluid (e.g., oil) displacement which occurs when the hydraulic piston is displaced in a closed hydraulic chamber.

A further aspect of the present disclosure relates to an ankle assembly. The ankle assembly includes a base configured to be attached to a foot spring or foot spring assembly, an extendable link rotatably attached to the base and configured to control rotation of the ankle assembly, and a prosthetic adapter portion rotatably attached to the base and the extendable link

and configured to be attached to a prosthetic worn by the user. The base, the extendable link, and the prosthetic adapter portion define a force triangle that defines an axis of rotation of the ankle assembly. The axis of rotation is positioned below and in line with the center of mass of the user when the ankle assembly is attached to the user.

5 Another aspect of the present disclosure relates to an ankle assembly including a prosthetic adapter portion, an extendable link rotatably attached to the prosthetic adapter portion to define a first pivot point, a base attached to the prosthetic adapter portion to define a second pivot point, and a third pivot point defined by a rotational attachment between the extendable link and the base. The extendable link has a translational axis of extension and compression
10 which allows the extendable link to change length. The extendable link may be comprised of a hydraulic cylinder. The hydraulic cylinder is configured to dampen rotation of the ankle assembly. The first pivot point and the second pivot point define a first pivot distance; the second pivot point and the third pivot point define a second pivot distance; and the first pivot point and the third pivot point define a third pivot distance. The first pivot distance is greater than 30
15 millimeters (mm), the second pivot distance is greater than 30 mm, and the third pivot distance is greater than 25 mm. The third pivot distance defines a moment arm of the hydraulic cylinder about the second pivot.

A further aspect of the present disclosure relates to a prosthetic foot system which includes a spring assembly having a toe end portion and a heel end portion and an ankle
20 assembly attached to the spring assembly. The ankle assembly includes a base attached to a spring assembly, a hydraulic cylinder rotatably attached to the base and configured to dampen rotation of the ankle assembly, and a prosthetic adapter portion rotatably attached to the base and the hydraulic cylinder and configured to be attached to a prosthetic worn by the user. The base, the hydraulic cylinder, and the prosthetic adapter portion define a force triangle that defines an
25 axis of rotation of the spring assembly and base about the prosthetic adapter portion. The axis of rotation is positioned below and in line with the center of mass of the user when the user is in a standing position. The location of the axis of rotation minimizes the force exerted on the hydraulic cylinder when the user is standing, which increases standing stability. A straight hydraulic cylinder may be used. The three pivot points or axes may be arranged to eliminate
30 transverse loads on the shaft of the hydraulic cylinder.

Exemplary ankle assemblies according to this disclosure may include, or may omit, a valve locking system which, when activated, allows hydraulic fluid to circulate until the device reaches its maximum dorsiflexion position, at which point the ankle assembly becomes locked in this maximum dorsiflexion position. Plantarflexion is prevented when the lock is activated. The ankle assembly remains locked until the valve is manually opened, allowing the piston to move in the hydraulic cylinder. The normal operating position for the ankle assembly is in the unlocked position such that the foot has a full range of motion without restriction from the lock. The hydraulic lock helps amputees while driving by preventing plantarflexion which prevents the foot from unexpectedly interfering with the pedals.

Some exemplary hydraulic systems of this disclosure include one or more volume compensator or accumulators. The terms volume compensator and accumulator are used interchangeably throughout this disclosure. Other exemplary hydraulic systems of this disclosure exclude any volume compensator or accumulators, or at least any element for which such functionality is the sole purpose. Lack of fluid compensation can greatly hinder the function of a hydraulic joint. In extreme conditions, the hydraulic fluid will either contract or expand, and fluid expansion results in high pressures and leakage. Lip seals are designed for pressure on one side of the seal, and fluid contraction results in pressure on the wrong side of the seal such that air may enter the hydraulic system. Under certain operating conditions the hydraulic fluid on one side of a hydraulic piston may experience absolute pressures below 1 atmosphere, which may result in air leaking past a seal and mixing with hydraulic fluid. Because air is comprised of smaller molecules than hydraulic fluid, it is more difficult to prevent air from moving past a seal in comparison to hydraulic fluid. Air entrained in hydraulic fluid negatively affects the performance of the fluid causing noise, corrosion, chemical degradation of the fluid, and changing the resistance of a hydraulic cylinder. The constant pressure provided by a volume compensator inhibits cavitation of the hydraulic fluid. Cavitation creates heat and changes the viscosity of the hydraulic fluid, which affects hydraulic performance. The thermal expansion or contraction of the fluid volume can create numerous issues with a hydraulic ankle system. For instance, air pockets may form in the fluid which hinder responsiveness. The system can over-pressurize causing seals to leak. In addition, the hydraulic fluid acts as a lubricant for the shaft and seals and hence there is a very slow but consistent loss of fluid during use which can eventually result in hydraulic malfunction if the lost fluid is not replenished.

According to another aspect of the present disclosure, some prosthetic devices may achieve particularly effective minimization of volume and weight requirements by the arrangement of particular energy storage elements within dampening elements. Some exemplary embodiments entail a combination of at least one spring for storing and then returning energy at various stages of the use of a prosthetic joint and a hydraulic system (e.g., at least one hydraulic cylinder) for dampening motion of the joint as it changes angle. Despite these separate and distinct functions, an exemplary arrangement of these elements in some embodiments involves the spring being positioned partly, or indeed entirely, inside the hydraulic cylinder. In particular, the spring may be positioned entirely within a piston assembly of the hydraulic cylinder. The term piston assembly is used in this disclosure to refer to the combination of at least one shaft and at least one piston, where the piston generally separates an internal cavity of the hydraulic cylinder into at least two cavities. The shaft is responsible for transferring an external force to the piston to cause displacement of the piston within the cylinder's cavity. The shaft is also responsible for transferring force from the piston to an external connection when the piston is displaced within the cylinder's cavity, e.g., by a pressure differential across the piston. The shaft may extend from each side of the piston, which is a configuration known as a double rod-end cylinder. The portions of shaft to either side of the piston may be interchangeably referred to as parts/portions of a shaft (singular) or as respective shafts (plural). Embodiments according to this disclosure which employ a double rod-end cylinder may be configured so that the shafts on both sides of the piston have the same diameter, or in the alternative, different diameters from one another. If the shafts on each side of the piston have the same diameter as one another, a double rod-end cylinder has equal cross-sectional areas (pressure areas) on each side of the piston, which allows piston movement without requiring hydraulic fluid volume compensation to account for different fluid chamber volumes due to different shaft diameters on each side of the piston. A spring positioned inside or within a piston and shaft assembly may mean the spring is positioned entirely within the shaft, entirely within the piston, or partly within each of the shaft and piston. In any of these cases, the arrangement of the spring inside the piston assembly results in a highly efficient use of space and therefore a very compact size for the overall assembly of the prosthetic device. This in turn can allow for a lighter prosthetic. Overall weight of a prosthetic can significantly impact user experience, comfort, and conformance with optimal kinematics for musculoskeletal health and endurance.

According to an aspect of this disclosure, the spring referred to in the preceding paragraph may preferably be configured as a gas spring which includes a gas containing (e.g., gas-filled) cavity the gas or gases within which may be further compressed to store energy or permitted to expand to release stored energy. The arrangement of the gas cavity of the spring inside the piston assembly is for some embodiments advantageous over alternative spring types such as mechanical springs and arrangements which place the spring in a space apart from the piston assembly. A gas spring may be tuned, as by the addition or removal of gas molecules, without necessarily making any change to the maximum volume required by the cavity during operation of the prosthetic device. A gas cavity of a given volume may simply have gas added for a corresponding increase in pressure or gas removed for a corresponding decrease in pressure, such pressure influencing or controlling the minimum magnitude of force contributed by the gas spring during operation of the prosthetic device. A gas spring is also comparatively lighter than mechanical springs, such as coil springs. Moreover, a gas spring is not susceptible to the fatigue over time evident in mechanical springs. A gas spring also does not exhibit the creep in property attributes of various types of mechanical springs.

Air springs, also known as pneumatic or gas or air springs, have design variables which are not available for metal springs. Air springs obey Boyle's law, known mathematically as $P_1V_1=P_2V_2$. By altering the initial air volume V_1 (the maximum volume) and/or the final air volume (the compressed air volume) a vast array of spring rates can be achieved, from near linear to highly non-linear. In addition, both initial and final air volumes can be determined or adjusted by utilizing lightweight volumetric spacers or moving bulkheads or cylinder ends which are adjustable by a screw or threads. A moving bulkhead utilizes a seal and resembles a piston with the screw resembling a shaft, however the moving bulkhead only moves when adjusting the air spring volume and tuning the air spring to achieve a desired spring rate.

For some embodiments, a mechanical spring such as a metal spring may be employed instead of a gas spring. A metal spring may be, for example, a coil spring or a disk spring or a stack of disk springs. Such springs do not bear all the advantages of gas springs discussed above but have certain benefits of their own, the most significant benefit being that mechanical springs will not change performance due to gas leakage.

The provision of a spring's cavity entirely inside a piston assembly also has particular advantages in some embodiments. According to this arrangement, the unique contribution of the

gas spring to the overall volume of the total device (e.g., the prosthetic device) may be zero. One hundred percent of the volume required for the gas spring and all its components may simply occupy a volume required in any case for the provision of the hydraulic cylinder.

Further various advantages of embodiments of this disclosure may include but are not limited to the following: less fatigue during normal gait; faster walking speed, mimics an anatomical ankle joint; encouragement of more athletic ambulation from an articulating foot including running and jumping; reduced moment loads in the socket caused by dorsiflexion hydraulic resistance; less heat generation within the prosthesis; lower dynamic pressures throughout the hydraulic pathways; sprung heel reduces impact and peak forces within a socket without utilizing vertical length displacement (i.e., leg shortening) which is a disadvantage of vertical shock absorbers that displace axially along a shin axis and take up a significant amount of the limited space between the end of a user's amputated limb and the ground; easy control of the relative amount of hydraulic resistance vs spring propulsion to accommodate any individual user; and energy return in the form of torque rather than force which propels the user forward rather than up as with a vertical shock absorber.

Some exemplary embodiments may include an ankle-foot prosthesis comprising (i) an ankle assembly comprising a prosthetic adapter, an extendable link rotatably attached to the prosthetic adapter to define a first pivot point, and a base rotatably attached to the prosthetic adapter to define a second pivot point and rotatably attached to the extendable link to define a third pivot point; and (ii) a foot spring or foot spring assembly attached to the base and configured to work in series with the ankle assembly. The extendable link comprises (i) a hydraulic cylinder configured to provide a dorsiflexion damping resistance and a plantarflexion damping resistance and (ii) a spring arranged in parallel with the hydraulic cylinder; the spring is a biasing gas spring.

The spring of an ankle-foot prosthesis may be configured to release sufficient energy during any dorsiflexion rotation of the ankle assembly to equal or exceed energy loss from the dorsiflexion damping resistance. While the foot spring assembly is subject to a ground reaction force and the ankle assembly rotates in a dorsiflexion direction, the spring may be configured to release sufficient energy to equal or exceed energy loss from the dorsiflexion damping resistance. The prosthetic adapter, the hydraulic cylinder, and the base may define a force triangle that defines an axis of rotation of the foot spring assembly about the prosthetic adapter; the spring

may create a dorsiflexion biasing moment about the axis of rotation. The dorsiflexion biasing moment from the spring may be at least 3 Nm throughout any period of use. The spring may comprise a gas cavity containing one or more gases at a minimum pressure of 250-1000 psi. The dorsiflexion biasing moment from the spring at a standing position may be 0.05-0.20 Nm/kg body weight. The dorsiflexion biasing moment at 12° of plantarflexion may be 0.15-0.28 Nm/kg body weight. The prosthetic adapter, the hydraulic cylinder, and the base may define a force triangle that defines an axis of rotation of the spring assembly and base about the prosthetic adapter, wherein the axis of rotation is positioned below and in line with a center of mass of a user when the user is in a standing position. The base may define a foot pivot axis; the hydraulic cylinder may define a hydraulic cylinder axis between the first pivot point and the third pivot point; a moment arm distance between the hydraulic cylinder axis and the foot pivot axis may be greater than 25 millimeters (mm). The spring may be arranged to be compressed by hydraulic fluid of the hydraulic cylinder during plantarflexion. Piston displacement of the spring may be different than piston displacement of the hydraulic cylinder. The hydraulic cylinder may comprise a first piston assembly, and the spring may be positioned inside the first piston assembly. The first piston assembly may include a first piston and first piston shaft, and the spring may be positioned at least partly inside the first piston shaft. The ankle-foot prosthesis may further comprise a dorsiflexion stop, and the dorsiflexion stop may be engaged at a standing ankle position.

Some exemplary embodiments may include an assembly comprising a first link; a second link which is an extendable link rotatably attached to the first link to define a first pivot point; and a third link rotatably attached to the first link to define a second pivot point and rotatably attached to the extendable link to define a third pivot point. The extendable link comprises (i) a hydraulic cylinder configured to provide at least a first way of damping resistance and (ii) a spring arranged in parallel with the hydraulic cylinder; the spring is a biasing spring.

The first link of an assembly may be a prosthetic adapter, and the third link may be a base. The extendable link may provide a second way damping resistance. The first way of damping resistance may be resistance to flexion or extension, and the second way of damping resistance may be resistance to extension or flexion.

Some exemplary embodiments may include an extendable link for a prosthesis or orthotic. The extendable link comprises a hydraulic cylinder configured to provide damping

resistance and a spring arranged in parallel with the hydraulic cylinder; the spring is a biasing spring. The spring may be a biasing air spring, and the damping resistance may be resistance to flexion and/or extension.

Exemplary embodiments are advantageously well suited not only for forward ambulation but also for backward ambulation and side stepping. A relatively rapid rate of dorsiflexion return (a relatively rapid rate of toe lift) after heel lift and prior to next contact with the ground helps minimize the risk of the amputee catching the toe on the ground by mistake and stumbling or falling as a result.

The foregoing has outlined rather broadly the features and technical advantages of examples according to the disclosure in order that the detailed description that follows may be better understood. Additional features and advantages will be described hereinafter. The conception and specific examples disclosed may be readily utilized as a basis for modifying or designing other structures for carrying out the same purposes of the present disclosure. Such equivalent constructions do not depart from the spirit and scope of the appended claims. Features which are believed to be characteristic of the concepts disclosed herein, both as to their organization and method of operation, together with associated advantages will be better understood from the following description when considered in connection with the accompanying figures. Each of the figures is provided for the purpose of illustration and description only, and not as a definition of the limits of the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

A further understanding of the nature and advantages of the embodiments may be realized by reference to the following drawings. In the appended figures, similar components or features may have the same reference label.

FIG. 1 is a chart and graph illustrating aspects of a typical gait cycle.

FIG. 2 is a human walking phase diagram further illustrating a typical gait cycle.

FIG. 3 is a perspective view of an exemplary prosthetic foot system including a footshell and a prosthetic foot in accordance with the present disclosure.

FIG. 4 is a perspective view of the prosthetic foot including a foot spring assembly and an ankle assembly.

FIG. 5 is another perspective view of the prosthetic foot of **FIG. 4**.

FIG. 6 is another perspective view of the prosthetic foot of **FIG. 4**.

FIG. 7 is a perspective view of the prosthetic foot of **FIG. 4** with an exploded view of the ankle assembly.

5 **FIG. 8** is a perspective view of an exemplary extendable link.

FIG. 9 is another perspective view of the exemplary extendable link.

FIG. 10 is a top view of the exemplary extendable link.

FIG. 11 is a side view of the exemplary extendable link.

10 **FIG. 12** is an exploded view of an extendable link separating out elements of a hydraulic cylinder and an accumulator or spring.

FIG. 13 is a cross-sectional view of an extendible link with a hydraulic cylinder but without any springs for storing and returning energy during a gait cycle.

FIG. 14 is a hydraulic diagram of the extendible link of **FIG. 13**.

15 **FIG. 15** is a cross-sectional view of an exemplary extendible link with a hydraulic cylinder in parallel with a spring for storing and returning energy during a gait cycle.

FIG. 16 is a schematic hydraulic diagram of the extendible link assembly shown in **FIG. 15**.

FIG. 17 is a cross-sectional view of a further exemplary extendible link with a hydraulic cylinder in parallel with a spring for storing and returning energy during a gait cycle.

20 **FIG. 18** is a cross-sectional view of yet a further exemplary extendible link with a hydraulic cylinder in parallel with a spring for storing and returning energy during a gait cycle.

FIG. 19 is a schematic hydraulic diagram representative of the extendible link assemblies of both **FIG. 17** and **FIG. 18**.

25 **FIG. 20** is an exploded view of an extendable link separating out elements of a plantarflexion adjustment valve, a dorsiflexion adjustment valve, and a plantarflexion lock spool valve.

FIG. 21 is a cross-sectional view of the extendible link shown in **FIG. 10**, taken along cross-section indicators B—B.

30 **FIG. 22** is a cross-sectional view of the extendible link shown in **FIG. 10**, taken along cross-section indicators C—C.

FIG. 23 is a further cross-sectional view of the extendible link shown in **FIG. 10**.

FIG. 24 is yet a further cross-sectional view of the extendible link shown in **FIG. 10**.

FIGS. 25, 26, and 27 show an extendible link with an optional locking valve feature.

FIG. 28 is an exemplary prosthetic foot system in a neutral stance.

5 **FIG. 29** is the prosthetic foot system at maximum plantarflexion such that the pyramid angle of the pyramid connector is zero degrees.

FIG. 30 is the prosthetic foot system positioned with the pyramid angle of the pyramid connector at two degrees.

FIG. 31 is the prosthetic foot system at maximum dorsiflexion such that the pyramid angle of the pyramid connector is zero degrees.

10 **FIG. 32** is a graph of spring force relative to extendable link displacement for an exemplary embodiment.

FIG. 33 is a graph of ankle moment relative to ankle angle for an exemplary embodiment.

15 **FIG. 34** is a graph comparing the response of hydraulic-only ankle to a hydraulic ankle incorporating a gas spring. Both embodiments are utilized by the same amputee.

FIG. 35 is a graph of ankle angle excursion (AAE) (deg) and moment for a trans-tibial amputee walking backward while wearing a prosthetic ankle having hydraulic damping and an air spring in parallel with the damper, consistent with the extendible link of **FIG. 15**.

FIG. 36 is an experimental setup for mechanically testing prosthetic ankle assemblies.

20 **FIG. 37** is sample data characterizing and contrasting the performance of a hydraulic only ankle assembly with the performance of an ankle assembly with a hydraulic damping subsystem in parallel with an air spring.

FIG. 38 is metabolic activity data for a first trans-tibial amputee using three different prostheses.

25 **FIG. 39** is metabolic activity data for a second trans-tibial amputee using three different prostheses.

30 While the embodiments described herein are susceptible to various modifications and alternative forms, specific embodiments have been shown by way of example in the drawings and will be described in detail herein. However, the exemplary embodiments described herein are not intended to be limited to the particular forms disclosed. Rather, the instant disclosure

covers all modifications, equivalents, and alternatives falling within the scope of the appended claims.

DETAILED DESCRIPTION

5

Exemplary embodiments relate variously to prosthetic joints, which may include but are not limited to prosthetic ankles, feet, knees, hips, elbows, shoulders, and wrists. Exemplary assemblies discussed in this disclosure may be particularly configured for application in prosthetic ankles or ankle-foot assemblies. However, those of ordinary skill in the art will appreciate that certain features and components may be employed in a variety of contexts. For instance, exemplary hydraulic cylinders are described which may be arranged in different joints. Generally, some exemplary hydraulic cylinders are employed to influence extension and/or flexion of a joint. Such exemplary hydraulic cylinders may contain, or be arranged in an assembly with, additional components such as springs, e.g., air springs, which modify the effects of the hydraulic cylinder.

For specific illustration, several embodiments are described below in the context of a prosthetic foot system. As shorthand “foot” or “ankle” may sometimes be used in this disclosure in reference to what may technically be an “ankle-foot” prosthesis. The context of such terms will make clear to those of ordinary skill in the art the extent of the anatomy of a full person for which any given embodiment may be a prosthetic substitution. It should also be appreciated that the terms “prosthetic device”, “prosthetic” employed as a noun, “and “prosthesis” are generally used interchangeably in this disclosure. The same is true of the plural tense of any of these nouns.

In the context of prosthetic feet, it is helpful to briefly summarize the conventional understanding of the human gait cycle. **FIGS. 1 and 2** are general representations of the gait cycle. **FIG. 1** includes details of when an ankle may generally be expected to plantarflex or dorsiflex, and through what ranges of angles. In the figure lowercase “n” refers to the neutral position of the ankle. The standing position may sometimes be regarded as the neutral position. Ankle angles may also referred to as positions in this disclosure. Ankle angles which are plantarflexed positions are identified with a lower case “p”. Ankle angles which are dorsiflexed positions are identified with a lowercase “d”. Accordingly, as a few examples, “8p” is a

shorthand for 8 degrees of plantarflexion. By contrast, “10d” is a shorthand for 10 degrees of dorsiflexion. The specific angle measures provided in **FIG. 1** are fairly representative of desired ankle angles for what may be regarded a healthy adult gait cycle. However, all individuals differ to some degree from one another, and it should be understood that the angles indicated in **FIG. 1** are selected in particular merely for illustrative purposes.

The human gait cycle is separated into two primary phases described with respect to a single foot: (1) stance phase when the foot is in contact with the ground, and (2) swing phase when the foot is in the air. Generally, when the left foot is in stance phase, the right foot is in the swing phase. Likewise, when the left foot is in the swing phase, the right foot is in the stance phase. There are five sub-phases to stance phase and three sub-phases to swing phase. The sub-phases belong to stance phase are shaded in **FIG. 1**. Though the knee and hip joints are also implicated in the gait cycle, the following brief discussion of gait cycle will focus on the motion of an intact, healthy human foot and ankle at the foot-ankle complex during the gait cycle.

The first sub-phase of stance phase is initial contact (abbreviated in **FIG. 1** as “IN. CT”). Initial contact occurs when the heel first contacts the ground and is the first 3% of stance phase. It is also referred to as heel strike in some literature; heel strike or initial contact may also be used to describe the moment at which the stance phase begins. Loading response follows initial contact and ends as the foot comes flat to the ground. The foot coming flat to ground typically corresponds with the opposite foot’s toe-off event. During initial contact and loading response, the ankle plantarflexes approximately 8° (to 8p) from the neutral position (n), and the foot comes completely in contact with the ground (also known as foot flat). Neutral position may in some embodiments be interchangeably referred to as standing position. Midstance is next and the ankle articulates from 8° of plantarflexion (8p) to a position of 5° of dorsiflexion (5d). Terminal stance follows and begins as the heel lifts off the ground (“heel off”) and progresses until 10° of dorsiflexion (10d) is achieved. The final sub-phase of stance phase is pre-swing, during which the foot is preparing to leave the ground. During pre-swing the foot plantarflexes from 10° of dorsiflexion (10d) to 20° of plantarflexion (20p). Pre-swing concludes with the foot leaving the ground, also known as “toe-off”.

Swing phase is when the foot is in the air. It immediately follows pre-swing and ends with the next initial contact. The first sub-phase of swing phase is initial swing. During initial swing the foot leaves the ground and travels upwards as the knee flexes. The ankle returns from

the plantarflexed position (20p) achieved during pre-swing to a roughly neutral position (n). Initial swing ends when the knee stops flexing, which is to say the knee has reached its maximum flexed position. It is typically for the left foot and right foot to be approximately adjacent to one another in the coronal plane, meaning neither foot is appreciably more forward of the other, at the end of initial swing. Mid swing occurs next. It begins as the knee starts to extend and ends when the tibia is approximately vertical to the ground. The ankle slightly dorsiflexes (approximately 2°, from n to 2d) during mid swing to help the toes clear the ground. The final sub-phase of swing phase is terminal swing. During terminal swing the knee extends to nearly full extension, and the foot returns to a neutral position (n) to prepare for the next initial contact.

FIG. 3 illustrates a perspective view of an example of a prosthetic foot system 100 including a footshell 102 and a prosthetic foot 104. The prosthetic foot 104 is configured to support the user of the prosthetic foot system 100. The footshell 102 is configured to house and protect the prosthetic foot 104 and to have an aesthetic design. The footshell 102 provides an aesthetic covering for the prosthetic foot 104 to give the appearance of an actual foot. The prosthetic foot 104 may be intended to be used inside a shoe in some embodiments. The prosthetic foot system 100 is configured to be mounted to a limb (not shown), such as a residual limb remaining after an amputation. An example of a residual limb may be a residual limb associated with a below-the-knee amputation. In some embodiments, the footshell 102 may be formed as a unitary device without any separate components. In other embodiments, the footshell 102 and the prosthetic foot 104 may be formed as separate components and assembled after the footshell 102 and the prosthetic foot 104 are formed. One or more of the footshell 102 and the prosthetic foot 104, or components thereof, may be formed or manufactured via an additive manufacturing process such as 3D printing, which forms the footshell 102 and/or the prosthetic foot 104 from a three-dimensional lattice network. Some embodiments may omit a footshell 102.

FIGS. 4-7 are various views of the prosthetic foot 104. These figures omit illustration of a footshell 102 for a clearer view of components of the prosthetic foot 104. **FIGS. 4-6** are different perspective views, whereas **FIG. 7** is an exploded view. An exemplary prosthetic foot 104 comprises a spring assembly 116 and an ankle assembly 118. An exemplary ankle assembly 118 includes a base 186, an extendable link 188/188'/188"/188''', and a prosthetic adapter portion 190 pivotably attached to each other. The extendable link may be, or at least include, a hydraulic cylinder. The ankle assembly 118 may be or include a passive hydraulic

damping system that provides the ankle joint member damping rotational resistance, with independent and independently adjustable damping resistances in both the plantarflexion and dorsiflexion directions.

Generally, the spring assembly 116 substitutes for a biological foot, and the ankle assembly 118 substitutes for a biological ankle. When in use, these subsystems influence one another such that the behavior and performance of the prosthetic foot 104 derives not from just one or the other subsystem but specifically their combination. That said, the two subsystems may be separable such that the foot spring assembly may be combined with different alternative ankle assemblies, and comparably, the ankle assembly may be combined with different alternative foot assemblies.

The spring assembly 116 includes a base spring 120, a top spring assembly 122, and a heel cushion 124. The spring assembly is rigidly and fixedly attached at a first side 182 of base 186. The top spring assembly 122 is connected to the base spring 120 in a toe end area at a toe end connection 126. The toe end connection 126 may include a bond connection formed by, for example, an adhesive bond. The toe end connection 126 may be formed using an elastic, flexible material that provides at least some relative movement between the base spring 120 and top spring assembly 122 (e.g., rotational movement about a vertical axis, compression, and translational movement in the anterior/posterior and/or medial/lateral direction). The toe end connection 126 may provide the sole connection point between the base spring 120 and top spring assembly 122. Typically, the heel cushion 124 is mounted directly to a top surface of the base spring 120 and arranged to contact a bottom surface of the top spring assembly 122. The heel cushion 124 may be releasably connected to the base spring 120. Alternatively, heel cushion 124 may be releasably connected to the top spring assembly 122. In at least some examples, the heel cushion 124 is connected to the base spring 120 with an interference fit connection using, for example, a retainer 128 that is mounted to the top surface of the base spring 120. The heel cushion 124 may be replaceable with other heel cushions having different properties such as increased or reduced stiffness, compressibility, damping capability, etc. Heel cushions of different sizes and shapes may also be used in place of the heel cushion 124 shown in the figures. In some examples, the prosthetic foot 104 may be operable without any heel cushion 124.

The ankle assembly 118 may be releasably attached to the top spring assembly 122 at its proximal end. In at least one example, the ankle assembly 118 is releasably connected using one

or more fasteners 130a, 130b. A prosthetic adapter portion with different connector features such as a pyramid connector 132 may be used, for example, a female pyramid adapter may replace the male pyramid adapter 132. In at least some examples, the pyramid connector 132 is a replaceable component of the ankle assembly 118. In other embodiments, the pyramid connector 132 is
5 integrally formed with remaining portions of the adapter assembly. Other connector features besides a pyramid connector may be used as part of the adapter assembly for securing the prosthetic foot 104 to another prosthetic member such as a lower leg pylon, a socket, or the like.

The base spring 120 is shown including a toe end 134, a heel end 136, a sandal slot 138, and a balance slot 140. The base spring 120 may also include a top surface 142, a bottom surface
10 144, and the heel cushion retainer 128 positioned at a heel end portion of the base spring 120. The retainer 128 may include a cavity 146 and a rim 148 to help releasably secure the heel cushion 124 to the base spring 120.

The length of the sandal slot 138 is typically in the range of about 0.5 to about 2 inches. The sandal slot 138 is formed in the toe end portion of the base spring 120 and extends posterior
15 from an interior most edge of the base spring 120. The balance slot 140 is also formed at the toe end portion beginning at the anterior most edge of the base spring 120 and extending posteriorly. In at least some embodiments, the balance slot 140 is aligned with a longitudinal center line of the base spring 120. The balance slot 140 may provide enhanced medial/lateral compliance for the prosthetic foot 104, particularly when walking on uneven surfaces.

As shown in at least **FIGS. 4-6**, the base spring 120 has a contoured shape along its
20 length. The side profile of the base spring 120 undulates between concave and convex shapes. In some examples, the distal surface of the base spring 120 is preferably convex in an anterior section, transitions to concave in an arch or mid-section, and may transition back to convex at the posterior end. These contours and the location of the contours, particularly relative to the toe end
25 connection 126 and the heel cushion 124, may provide improved rollover smoothness, enhanced energy feedback to the user, stability, and comfort during use of the prosthetic foot. Providing the lever portion extending posterior of the heel cushion 124 may also provide improved smoothness in the rollover and energy feedback during use.

The top spring assembly 122 is shown including first and second spring members 150,
30 152, a first spacer 154 at the toe end portion of the prosthetic foot, a second spacer 156 positioned at a proximal end of the top spring assembly 122 and a gap G provided between the

first and second spring members 150, 152 along their entire length. The first and second spring members 150, 152 may be referred to as leaf springs. The first and second spring members 150, 152 may extend generally in parallel with each other along their entire lengths. The first spacer 154 may be provided as a bond connection between the first and second spring members 150, 152. In at least some examples, the first spacer 154 comprises the same bond material as used for the toe end connection 126 between the top spring assembly 122 and the base spring 120. In at least some embodiments, the first spacer 154 is positioned generally in alignment with the toe end connection 126 so as to be positioned vertically above the toe end connection 126, or at least partially overlapping the toe end connection 126 in a length dimension of the base spring 120. The first spacer 154 may provide a permanent connection between the first and second spring members 150, 152. The material of first spacer 154 may provide at least some relative movement between the first and second spring members 150, 152 (i.e., rotational movement about a vertical axis, translational movement in an anterior, posterior or medial/lateral direction, compression, etc.). The material of first spacer 154 may be elastic so as to return to its original shape upon removal of a force that is used to compress or deform the first spacer 154.

In other examples, the first spacer may comprise a wear resistant, low friction material that is attached to one of the first and second springs. The first spacer is not attached or connected to the other of the first and second springs. This arrangement supports compression forces between the distal ends of the first and second springs and allows the springs to separate during plantar flexion and also slide against each other at the distal ends of the springs. Such an embodiment may also alter performance of the foot during rollover in comparison to having the first spacer as a bond connection. Tensile and shear forces are not transferred through the spacer, hence the deflection and stress conditions in the upper spring assembly are modified. The first spring is in an unloaded condition during plantarflexion at heel strike and, as the foot rolls over and the user's weight is transferred to the toe, shear displacement between the distal ends of the first and second springs results in increased deflection the foot in the toe region, thereby softening the foot during both the heel strike and terminal stance portions of the gait cycle.

The second spacer 156 may comprise a rigid material that is non-compressible and/or non-elastic. The second spacer 156 may be positioned at a proximal most end of the top spring assembly 122. The second spacer 156 may be aligned with the ankle assembly 118, or at least portions thereof. In the illustrated embodiment, the second spacer 156 includes apertures through

which the fasteners 130a, 130b extend for connection of the ankle assembly 118 to the top spring assembly 122.

The first and second spacers 154, 156 may define the size of the gap G when the prosthetic foot 104 is in a rest state. Typically, the gap G is provided along an entire length of the first and second spring members 150, 152 when the prosthetic foot 104 is in a rest state (i.e., prior to application of a force during use of the prosthetic foot 104). Alternatively, the two upper springs 150, 152 may abut (e.g., directly contact each other) at the connector location. The gap G may vary in size during operation of the prosthetic foot 104. For example, the gap G may reduce in size at the first spacer 154 if the material of the first spacer 154 is compressible during use. In another example, the gap G may reduce or change size at locations between the first and second spacers 154, 156 during use. For example, applying a force from a user during a gait cycle may change the size of gap G at various phases of the gait cycle (e.g., at heel strike, stance phase, and toe off), as the forces are applied and released during use by a wearer, those forces are absorbed and/or fed back through the base spring 120 and heel cushion 124. In at least some embodiments, the first spring member 150 may come into contact with the second spring member 152 during use of the prosthetic foot (i.e., the gap reduces to zero).

The first spring member 150 is shown having an anterior end 158, a proximal end 160, a horizontal portion 162, a slot 164, and fastener apertures 166a, 166b. The second spring member 152 may include an anterior end 168, a proximal end 170, a sloped portion 172, a slot 174, and fastener apertures 176a, 176b. The slot 174 may be aligned with the slot 164 of the first spring member 150 and the balance slot 140 formed in base spring 120. In at least some examples, the slots 140, 164, 174 may extend in a posterior direction to a common location. The slots 140, 164, 174 may terminate at different locations in the anterior direction. The slots 164, 174 may be aligned with a center line of the base spring 120 and top spring assembly 122 so as to provide balanced medial/lateral pronation and compliance during use of the prosthetic foot.

The top spring assembly 122 is mounted to the base spring 120 as shown in at least **FIGS. 4-6**. The heel cushion 124 is arranged to contact a bottom or downward facing side or surface of the top spring assembly 122 (e.g., a bottom surface of first spring member 150 as shown in **FIG. 6**). Although the heel cushion 124 is shown connected to the base spring 120 and not the top spring assembly 122, other embodiments may provide the heel cushion 124 connected to both the base spring 120 and top spring assembly 122, or connected only to the top

spring assembly 122 (e.g., the retainer 128 is mounted to the bottom surface of first spring member 150 for releasable attachment of the heel cushion 124).

The heel cushion 124 may be releasably mounted to the base spring 120 (or top spring assembly 122). Alternatively, the heel cushion 124 may be permanently connected to the base
5 spring 120. The replaceability of heel cushion 124 may provide customization of the amount of heel stiffness, cushioning, energy dampening, and the like provided by heel cushion 124. Heel cushion 124 may be connected with an interference fit connection. Other embodiments may provide for the heel cushion 124 to be secured with a positive connection such as, for example, a fastener, clip, bracket or the like.

10 The heel cushion 124 may include a top surface 178 (see **FIG. 6**), a tapered shape having a variable thickness along its length, a bottom surface 180, a top perimeter rim 182, and a bottom perimeter rim 184. The tapered shape may provide for a smaller thickness at an anterior end as compared to a greater thickness at a posterior end of the heel cushion 124, as shown in **FIG. 6**. The tapered shape of the heel cushion 124 may match the angle and/or curvature of the first
15 spring member 150. As such, the top surface 178 may have a contoured shape rather than a planar shape. Similarly, the bottom surface 180 may have a shape that matches the contour or curvature of the top surface of the base spring 120, as shown in at least **FIG. 6**.

The heel cushion 124 may comprise a shock absorbing, dampening material such as, for example, silicone or urethane elastomers including, for example, silicone or urethane foams. In
20 some embodiments, the heel cushion 124 may include a plurality of different materials, layers of materials, or separate components that are secured together as an assembly to provide the desired cushioning properties. In one example, the heel cushion 124 includes a foam material encapsulated within a protective polymer shell. In another example, the heel cushion 124 includes a gel material or capsule that is encapsulated within a foam material.

25 The base spring 120 and first and second spring members 150, 152 may comprise a fiber reinforced composite material such as, for example, carbon fiber reinforced composite. The first spacer 154 may include an adhesive bond comprising a flexible adhesive such as, for example, a urethane adhesive having a Shore A hardness in the range of about 70 to about 95. During
30 manufacture of the top spring assembly 122, the first and second spring members 150, 152 may be bonded together using a removable gasket between the springs to create a sealed space for the adhesive, and the adhesive is then injected into the space.

The second spring member 152 may be shorter in length than the length for the first spring member 150. This difference in length may allow for a somewhat gradual change in stiffness in the top spring assembly 122. Although two spring members 150, 152 are shown as part of the top spring assembly 122, other embodiments may utilize more than two leaf spring elements, and the leaf spring elements may have the same or different lengths.

The second spacer 156 may comprise a lightweight material such as, for example, aluminum, nylon or fiberglass sheet material (e.g., fiberglass G-10). The top spring assembly 122 may provide a connection between the first and second spring members 150, 152 at opposite ends with a gap G provided there between, thereby providing a number of unexpected structural advantages. These advantages in connection with the type of spacers 154, 156, the toe end connection 126, the heel cushion 124, and/or other features may provide a number of performance advantages as compared to known prosthetic feet. For example, a dual, narrow cantilever beam, one located above the other and with a space in between the upper and lower beams, and with frictionless spacer at the free end to transmit an applied vertical force from the upper beam to the lower beam at the free end, may result in about 15-25% reduction in bending stress and about 30-45% reduction in shear stress as compared to an equivalent stiffness single cantilever beam. If the first spacer is comprised of a low friction material connected to one of the first and second springs, the boundary conditions described are highly accurate.

If the first spacer is a bond connection (e.g., created with a flexible material), the boundary conditions are approximately midway between a frictionless spacer between the distal ends of the first and second spring and a rigid connection at the distal ends of the first and second springs. Because stresses are reduced by using the dual upper spring design, a prosthetic foot utilizing this dual spring design exhibits at least one of improved durability and improved flexibility as compared to single spring designs and dual spring designs which are rigidly connected at the distal end. Furthermore, utilizing a low friction spacer material may provide more flexibility than utilizing a flexible bond connection, thus potentially providing opportunities to achieve different and desirable performance characteristics and multiple design options to achieve the designer's goal. Many of the advantages of the dual cantilever beam designs disclosed herein may be maximized when the two beams (e.g., first and second spring members 150, 152) have substantially equal bending stiffness. If the beams are constructed of unidirectional fiber reinforced composite lamina, the maximum strength/stiffness ratio may be

best achieved when both beams have substantially the same lamina orientation and thickness. As the difference between the bending stiffness of the upper and lower beams increases, the advantages of a dual cantilever spring design typically diminish.

5 The heel cushion 124 may comprise a silicone or urethane elastomer (e.g., an elastomer with the Shore hardness range of about 50A to about 90A). The heel cushion 124 may be retained with retainer 128 in a way that extends around an entire perimeter of the heel cushion 124. Other embodiments may provide for a retainer that extends around only a portion of perimeter of the heel cushion 124. The retainer 128 may be bonded to the top surface 142 of the base spring 120 using, for example, an adhesive. In some embodiments, both the adhesive and
10 the retainer 128 are somewhat flexible to avoid detachment of the retainer 128 from the base spring 120 when the base spring 120 flexes during use. The retainer 128 and adhesive may comprise a plastic material having a Shore hardness in the range of, for example, about 90A to about 50D. Alternatively, the retainer 128 may be cast into the structure of base spring 120 along the top surface 142 thereof, which may eliminate the need for use of an adhesive or other
15 bonding agent.

The retainer 128 may help keep the heel cushion 124 in place by utilizing geometric interlocking features. These interlocking features may include angled (e.g., wedge-shaped) features in the retainer and along an exterior of the heel cushion 124, wherein corresponding surfaces interface to provide a connection. The heel cushion 124 may be deformed or compressed
20 in order to fit into the interior of the retainer 128, and then expanded automatically to its original shape thereby creating an interference fit connection between the features of the retainer 128 and the heel cushion 124. Alternatively, the retainer 128 and the heel cushion utilize a rib that fits into a recess, wherein the rib and recess may be formed on either the retainer 128 or heel cushion 124.

25 Generally, the base spring 120 extends from the toe region to a heel region of the prosthetic foot. The base spring 120 may extend from an interior most point of the prosthetic foot 104 to a posterior most point of the prosthetic foot 104. The top spring assembly 122 may be connected to the base spring 120 at a location spaced posterior of an anterior most edge of the base spring 120. In at least one example, the top spring assembly 122 is positioned posterior of
30 the sandal slot 138 formed at the distal end of the base spring 120. The base spring 120 may

extend in an anterior direction at least as far as an anterior most point along a length of the top spring assembly 122.

As discussed above, the slot or split 140 formed in the base spring 120 from the anterior edge in a posterior direction may be aligned with the slots or slits 164, 174 formed in the top spring assembly 122 from the anterior end of the top spring assembly 122 extending in a posterior direction. These slots or splits may provide for the entire prosthetic foot 104 to be divided into medial and lateral sides at least in the toe and midfoot regions of the prosthetic foot.

The top spring assembly 122 includes first and second spring members 150, 152 that extend to different anterior positions along the length of the prosthetic foot. At least **FIG. 6** illustrates the first spring member 150 extending further in an anterior direction than the second spring member 152. The first spacer 154 is positioned at the anterior most edge of the second spring member and spaced posterior of the anterior most edge of the first spring member 150.

The top spring assembly 122 extends generally parallel with the base spring 120 in the toe, midfoot, and heel regions of the base spring 120. As described above, other embodiments may provide for the top spring assembly 122 to continue extending in a generally horizontal or slightly angled direction relative to the base spring 120 and/or a horizontal plane through the heel end portion.

Additionally, the gap G may be substantially constant when the prosthetic foot 104 is in a rest or unloaded state. During use of the prosthetic foot 104, portions of the first and second spring members 150, 152 may move toward and/or away from each other to alter the size of gap G at various locations along the length of the top spring assembly 122. In at least some embodiments, portions of the first and second spring members 150, 152 may contact each other.

The fasteners 130a-b may be arranged side-by-side in a medial/lateral direction. In other arrangements, the fasteners 130a-b may be arranged in alignment with a length dimension of the prosthetic foot 104. Although only two fasteners 130a-b are shown in **FIG. 6**, only one or more than two fasteners 130a-b may be used. The fasteners 130a-b may provide a positive connection between the first and second spring members 150, 152, a positive connection between the top spring assembly 122 and the ankle assembly 118, and/or a positive connection between one or both of the first and second spring members 150, 152, and the spacer 156. In some examples, the fasteners 130a-b are connected directly to one or both of the first and second spring members 150, 152 (e.g., to a threaded seat formed in one or both of the first and second spring members

150, 152), or may be connected to a nut (not shown) positioned on an opposite side of the top spring assembly 122.

The prosthetic foot 104 may provide energy feedback, stability, force dampening and the like associated with the use of spaced apart spring members in the top spring assembly 122, the use of a heel cushion 124 arranged in the specific location and having the size and shape shown in **FIG. 6**, the shape and size of the top spring assembly 122 and base spring 120, and the size, shape, and orientation of the ankle assembly 118. Furthermore, the base spring 120 and top spring assembly 122 may include slots (e.g., slot 140 for base spring 120 and slots 164, 174 for first and second spring members 150, 152) that provide medial/lateral pronation and ambulation for the prosthetic foot 104, which may provide improved stability for the user, particularly on uneven ground surfaces.

The prosthetic foot 104 may be a dual or multiple toe spring prosthetic foot. The prosthetic foot 104 may be a single toe spring prosthetic feet. The heel assemblies, adapter assemblies, attachment assemblies, and other features disclosed with reference to any single embodiment disclosed herein may be interchangeable with features of other prosthetic foot embodiments disclosed herein.

In alternative embodiments, the connection between the base spring and the top spring assembly and between the first and second spring members in the anterior region of the foot and may be provided with bolts or other fasteners. A rigid spacer may be provided between the spring members and/or between the top spring assembly and the base spring. The use of bolts or other fasteners in combination with an altered geometry of the first and second spring members may eliminate gaps that may otherwise exist at connection points at the anterior end of the prosthetic foot. In another embodiment, a connection between the first and second spring members may be made by wrapping carbon fiber or glass fiber around the first and second spring members at the connection point between the first and second spring members, and securing the spring members and the fiber by impregnating the fiber with epoxy or similar thermosetting resin. A similar connection may be made between the top spring assembly and the base spring.

In another example, the connection at the proximal end of the top spring assembly may be created by altering a geometry of the first and second spring members such that no gap exists at the connection points between the first and second springs. In this arrangement, a gap may still be provided between the first and second spring members at other locations along their lengths.

In some embodiments, one or more of the first and second spring members may be inserted into a slot formed in the prosthetic connector (e.g., base 186 of ankle assembly 118), and the first and second spring members are secured together and to the prosthetic connector with an adhesive or a fastener.

5 Discussion now turns to the exemplary ankle assembly 118 depicted by **FIGS. 4-7**. As briefly mentioned above, an exemplary ankle assembly 118 includes a base 186, an extendable link 188/188'/188"/188"', and a prosthetic adapter portion 190 pivotably attached to each other. The ankle assembly 118 provides the user a more natural feel during the gait-cycle. An ankle assembly 118 gives the amputee some fluid-like movement during normal use, as opposed to a
10 more rigid feel that is associated with the typical prosthetic foot. Specifically, an exemplary ankle assembly may include one or more (up to all of) the following features: (1) a dorsi flexion stop which limits the dorsiflexion rotation of the ankle assembly, transferring load to the composite spring or springs located in the forefoot area of a foot assembly, allowing the composite springs to provide support and store energy (2) a soft dorsi flexion stop that improves
15 the transition between the hydraulic resistance and spring resistance created by the composite foot spring elements; (3) a manual hydraulic lock which prevent plantarflexion of the ankle such that when the ankle reaches maximum dorsiflexion it will be locked; (4) a volume compensator that maintains the hydraulic system at a preloaded pressure on the fluid and compensates fluid loss; (5) a hydraulic lock that may lock the ankle in any position to enable the user to use
20 different height heels (shoes) with the same prosthetic ankle and foot; (6) an improved hydraulic geometry; and (7) one or more springs configured to store energy during plantarflexion rotation of the ankle assembly and release stored energy during dorsiflexion rotation of the ankle assembly. In some embodiments some of these features may be omitted.

 The improved hydraulic geometry may entail locating the ankle pivot points such that a
25 high percentage of the axial load is supported by the pivot structure when the user is standing. Furthermore, the hydraulic cylinder has improved leverage about the base and foot spring pivot point, reducing the pressure of the hydraulic fluid in the system and reducing the required strength and mass of the hydraulic cylinder. Resulting advantages further include increased cycle life and seal integrity.

30 An exemplary ankle assembly 118 enables both plantarflexion motion and dorsiflexion motion of the prosthetic foot 104. Enabling plantarflexion motion at an ankle joint allows the

metatarsophalangeal (ball of foot) area of the foot to achieve contact with the ground earlier in the gait cycle. The ball of foot/wide part of the foot provides stability during the gait cycle. The ankle assembly 118 also enables a small amount of dorsiflexion, relative to a standing position, which results in reduced and adjustable resistance to tibial progression when the prosthetic shin is vertical or near vertical when compared to a prosthetic foot without an ankle assembly. When an amputees' center of mass is directly above the shin and the shin is vertical, the amputee does not have much leverage over the lever arm created by the forefoot of a prosthetic foot. The ankle assembly 118 mitigates this limitation of prosthetic feet.

As described below, the rotation axis of the foot spring assembly is forward of the pyramid axis of the pyramid connector 132. Therefore, the center of mass (COM) of the amputee is directly above the rotation axis when standing, allowing amputees to stand without significant movement of the ankle assembly 118. This design feature also minimizes impact when the ankle reaches the end of its hydraulic range in the dorsiflexion direction (the dorsiflexion stop).

An ankle assembly 118 may comprise both a dorsiflexion stop and a plantarflexion stop. A dorsiflexion stop is a component, or assembly of components, which establishes a maximum dorsiflexion angle for the ankle assembly 118 and prosthetic foot 104. A plantarflexion stop is a component, or assembly of components, which establishes a maximum plantarflexion angle for the ankle assembly 118 and prosthetic foot 104. An exemplary dorsiflexion stop may comprise, for example, a dorsiflexion stop bumper 274 that reduces or eliminates an impact at the end of the dorsiflexion travel (see **FIG. 12**). As the ankle assembly 118 dorsiflexes, it eventually reaches the end of its hydraulic range-of-motion. At this point the flex of the spring assembly 116 takes over and starts to bend. If this transition were abrupt, it would not be comfortable for the amputee and may result in impact noise. The dorsiflexion stop bumper gradually squeezes as the ankle assembly 118 reaches this transition point, allowing a smooth transition from the hydraulic function to the flexing function of the spring assembly 116. Additionally, the dorsiflexion stop bumper 274 may be low-profile disc springs that would respond in a similar way as the elastomeric stop and provide a smooth transition between the hydraulic function and the composite spring function of the ankle assembly 118 and spring assembly 116. A dorsiflexion stop in any embodiment may alternatively not include any bumper at all. The dorsiflexion stop may be engaged at a zero degree ankle position, or the standing position. This assists an amputee with standing up straight.

A plantarflexion stop may, for example, be established simply by the displacement distance of the hydraulic cylinder's piston within the piston cavity. When the hydraulic piston reaches its maximum position in the cylinder, no further displacement is possible past such maximum position. Once the piston reaches this maximum position (whether in the dorsi flexion or plantar flexion positions) it is still free to move away from this maximum position towards the opposite maximum position and return to another point rest.

The base 186 has a first side 192 and a second side 194. The first side 192 is sized and shaped to correspond to a shape of the first spring member 150 such that the posterior end of the first side 192 is arranged substantially flush with the first spring member 150. The second side 194 is sized and shaped to accommodate three sets of bore holes that attach the base 186 to the first spring member 150, the hydraulic cylinder of the extendable link 188/188'/188''/188''', and the prosthetic adapter 190. Specifically, the base 186 defines a first set of bore holes (with hole axes 196a, 196b), a second set of bore holes 198a, 198b, and a third set of bore holes 200a, 200b. The first set of bore holes with axes 196a, 196b are configured to receive fasteners 130a, 130b that fasten the base 186 to the first spring member 150. The second set of bore holes 198a, 198b are configured to receive a portion of the extendable link 188/188'/188''/188''' to maintain a position of the extendable link 188/188'/188''/188''' while allowing the extendable link 188/188'/188''/188''' to rotating relative to the base 186. Similarly, the third set of bore holes 200a, 200b are configured to receive a portion of the prosthetic adapter 190 to maintain a position of the prosthetic adapter 190 while allowing the prosthetic adapter 190 to rotating relative to the base 186. The base 186 is a monolithic and rigid part which does not function as a spring and exhibits no appreciable deflection or deformation during use and is made of a lightweight metal, for example aluminum, magnesium or titanium.

The prosthetic adapter 190 defines a bore 202 configured to receive the pyramid connector 132, a cavity 204 configured to receive a portion of the extendable link 188/188'/188''/188''', a fourth set of bore holes 206 configured to receive a piston fastener 208, and a base bore 210 configured to receive a base fastener 212. The prosthetic adapter 190 is sized and shaped to accommodate the pyramid connector 132, the cavity 204, the fourth set of bore holes 206, the piston fastener 208, the base bore 210, and the base fastener 212. Specifically, the prosthetic adapter 190 includes a first portion or bulbous portion 214 and a second portion or tapered portion 216. The bulbous portion 214 defines the cavity 204 and is bulbous to enable the

cavity 204 to be voluminous enough to receive a portion of the extendable link 188/188'/188''/188'''. Additionally, the bulbous portion 214 is large enough to define the bore 202 and the fourth set of bore holes 206 to accommodate the pyramid connector 132 and the piston fastener 208. The tapered portion 216 is smaller than the bulbous portion 214 such that the taper portion 216 is received between the third set of bore holes 200a, 200b of the base 186. The base fastener 212 extends between the third set of bore holes 200a, 200b and through the base bore 210 to attach the prosthetic adapter 190 to the base 186.

Several alternative exemplary extendable links are illustrated in the figures and will now be discussed in detail. The alternative extendable links are respectively labeled 188, 188', 188'', and 188'''. As conveyed in **FIGS. 4-11**, alternative extendable links may be configured with substantially the same exterior appearance. As used in this disclosure, a “hydraulic cylinder” may comprise a variety of components implicated in some respect with hydraulics. Generally, the term “hydraulic cylinder” refers to a combination of at least a piston, a shaft, a body/housing which defines a piston cavity housing the piston, and hydraulic fluid acted upon by the piston.

The piston divides the cavity into two hydraulic chambers. Fluid flow between the two chambers provides damping. The term “hydraulic cylinder” may further include any channels and valves through which the hydraulic fluid may flow. The term “hydraulic cylinder” may or may not include further elements. The context of the term as used in this disclosure will make clear to those of ordinary skill in the art the extent to which other elements, if any, may be part of a given hydraulic cylinder. Significant differences among the alternative extendable links 188, 188', 188'', and 188''' are apparent from their internal components for which cross-sectional views are provided.

FIGS. 12, 13, and 14 show a hydraulic-only (HO) extendable link 188. Extendable link 188 does not include any springs capable of storing and releasing significant energy over a gait cycle. The cross-sectional depiction of **FIG. 13** generally corresponds with the cross-section A—A taken in **FIGS. 10 and 11**. The extendable link 188 includes a body 218 and a piston assembly 220 at least partially positioned with the body 218. The piston assembly 220 is configured to slide within the body 218 to resist and/or dampen rotation of the ankle assembly 118. The piston assembly 220 includes a shaft 222 and a piston 224 attached to (or integrally formed with) the shaft 222. The shaft defines a first bore hole 226 and the body defines a second bore hole 228. The first bore hole 226 receives the piston fastener 208 and enables the extendable link 188 and

the prosthetic adapter 190 to rotate relative to each other. The second bore hole 228 receives a piston body fastener 230 and enables the extendable link 188 and the base 186 to rotate relative to each other.

5 The body 218 defines a plurality of body cavities 232 and a plurality of channels 234 that are configured to contain and channel a hydraulic fluid to dampen or prevent rotation of the ankle assembly 118. Specifically, the body 218 defines a pressurization cavity 236, a piston cavity 238, a plantar valve cavity 240, and a dorsi valve cavity 242. In some but not all embodiments, a body 218 may include a plantarflexion lock spool valve cavity. The body 218 further defines a pressurization channel 246, a first piston cavity channel 248, a second piston cavity channel 250, a dorsi flexion adjustment channel 252, and a plantar flexion adjustment channel 254.

The body 218 may further define an accumulator port 256. The accumulator port 256 is designed as a hydraulic resistor which allows the volume compensator 450 to maintain fluid volume in the hydraulic circuit(s) yet minimizes pressure cycling in the volume compensator 450. Cycling of the accumulator with every step results in wear of the accumulator piston seal and creates heat. Changes in fluid temperature result in changes in hydraulic resistance, and high fluid temperatures increase fluid and seal degradation rates. Minimizing heat generation is an important design consideration for a hydraulic ankle.

20 The hydraulic cylinder of the extendable link 188 includes a plurality of wear rings or bushings 260 and seals 262. Specifically, the hydraulic cylinder includes a shaft guide bushing 272 circumscribing the shaft 222 and positioned within the body 218 that protects and guides the shaft 222 within the body 218 and a piston guide bushing 266 and piston seal 276 circumscribing a portion of the piston 224 and positioned within the piston cavity 238 that protects and guides the piston 224 within the piston cavity 238. The hydraulic cylinder of the extendable link 188 also includes a first shaft wiper/seal 300, a second shaft seal 270, and a third shaft seal (not shown in **FIG. 12**) all circumscribing the shaft 222 and configured to prevent hydraulic fluid from leaking out of the hydraulic cylinder.

25 The hydraulic cylinder of the extendable link 188 may further include a dorsiflexion stop bumper 274 within the piston cavity 238 that improves the transition between the hydraulic resistance and spring resistance created by the composite foot spring elements. The dorsiflexion stop bumper 274 is positioned on a surface 278 of the piston 224 and the dorsiflexion stop 274

contacts surface 280 of the piston cavity 238. The dorsiflexion stop 274 may be made of a soft, elastic material that prevents or mitigates the impact of the piston 222 on the surface 280 of the piston cavity 238. Thus, the dorsiflexion stop 274 improves the transition between the hydraulic resistance and spring resistance created by the composite foot spring elements.

5 A volume compensator 450 may be filled with one or more gases (e.g., nitrogen filled) to enable pressurization of the fluid in the hydraulic system. The use of a chamber that is pressurized with an inert gas or gases which contain little or no oxygen reduces the degradation of elastomeric seals. Nitrogen may be considered more desirable than air for some applications because the pressure of nitrogen is not as sensitive to temperature as air.

10 The volume compensator 450 includes the pressurization cavity 236, a cap 282, a plug 284, a pressurization piston 286, and a piston seal 288 circumscribing the pressurization piston 286. The volume compensator 450 maintains the hydraulic system at a preloaded pressure on the fluid and compensates fluid loss. The pressurization cavity 236 defines an opening 290 and the cap 282 is removably positioned within the opening 290 and the plug 284 may be permanently
15 positioned within the opening 290. The pressurization piston 286 separates the pressurization cavity 236 into a hydraulic fluid portion 292 and an inert gas portion 294. The hydraulic fluid portion 292 contains hydraulic fluid and is in fluid communication with the piston cavity 238, the plantar valve cavity 240, the dorsi valve cavity 242, and the plantarflexion lock spool valve cavity. The plug 284 is formed of an elastic material such as, but not limited to, rubber. The inert
20 gas portion 294 contains an inert gas such as, but not limited to, nitrogen. The inert gas portion 294 is configured to pressurize the hydraulic fluid. Specifically, a user inserts a needle (not shown) of a syringe (not shown) through the plug 284 and injects the inert gas into the inert gas portion 294, increasing the pressure of the inert gas portion 294. The increased pressure of the inert gas portion 294 presses on the pressurization piston 286 which increases the pressure of the
25 hydraulic fluid within the hydraulic cylinder of extendable link 188. The pressurization channel 246 transmits the increased pressure to hydraulic fluid in the channels 234 and the body cavities 232. The pressurization channel 246 or another component connecting volume compensator 450 with a remainder of the hydraulic system includes accumulator port 256. The accumulator port 256 is a relatively small orifice that substantially restricts fluid flow to or from the volume
30 compensator 450. The accumulator port 256 behaves as a hydraulic resistor which allows the volume compensator 450 to maintain fluid volume in the hydraulic circuit(s) yet minimizes

pressure cycling in the volume compensator 450. In short, the accumulator port 256 eliminates or minimizes to negligibility any spring qualities of the volume compensator 450.

The hydraulic cylinder of extendable link 188 further includes a cap 296 including threading 268, a cap seal 264 circumscribing a portion of the threading 298. The shaft 222 includes a first portion 302 screwed into a second portion 304. The hydraulic cylinder of extendable link 188 is assembled by positioning the wear rings 260 and the seals 262 within the hydraulic cylinder of extendable link 188 as shown in **FIG. 12**. The first portion 302 is inserted into a bore 306 of the cap 296 and the second portion 304 is screwed into the first portion 302. The cap 296 is then screwed into the body 218 such that the piston assembly 220 is positioned within the hydraulic cylinder of extendable link 188.

FIG. 14 illustrates a flow diagram bearing on the body cavities, channels, and valves described above. The patient actuates the hydraulic cylinder of extendable link 188 by walking such that the piston assembly 220 is shifted toward a first end 364 of the piston cavity 238 or a second end 366 of the piston cavity 238. The piston 224 divides the piston cavity 238 into a first cavity 368 and a second cavity 370. As the piston 224 moves through the piston cavity 238, hydraulic fluid is channeled from one of the first cavity 368 and the second cavity 370 through the channels 234.

An independent adjustability of dorsiflexion damping resistance may be achieved by at least one adjustable control valve 451 arranged in a flow path 453 of hydraulic fluid during dorsiflexion. Comparably, an independent adjustability of plantarflexion damping resistance may be achieved by at least one adjustable control valve 452 arranged in a flow path 454 of hydraulic fluid during plantarflexion. Referring to both **FIG. 14** and **FIG. 20**, dorsiflexion adjustment valve 310 comprises both the check valve 340 and adjustable control valve 451. Plantarflexion adjustment valve 308 comprises both the check valve 342 and adjustable control valve 452.

During dorsiflexion, the piston 224 shifts up toward the first end 364 of the piston cavity 238 such that a volume of the first cavity 368 is reduced and the hydraulic fluid within the first cavity 368 is displaced through the channels 234 into the second cavity 370. More specifically, in the illustrated embodiment, the hydraulic fluid within the first cavity 368 is channeled through the first piston cavity channel 248, the dorsi flexion adjustment channel 252, and the second piston cavity channel 250 and into the second cavity 370. The dorsiflexion adjustment valve 310 is rotated to increase or decrease the pressure drop through the dorsiflexion adjustment valve 310

to control the dampening effect of the hydraulic cylinder of extendable link 188 on the dorsiflex movement. The second check valve 342 prevents the hydraulic fluid from flowing through the plantar flexion adjustment channel 254.

During plantarflexion, the piston 224 shifts down toward the second end 366 of the piston cavity 238 such that a volume of the second cavity 370 is reduced and the hydraulic fluid within the second cavity 370 is displaced through the channels 234 into the first cavity 368. More specifically, in the illustrated embodiment, the hydraulic fluid within the second cavity 370 is channeled through the second piston cavity channel 250, the plantar flexion adjustment channel 254, and the first piston cavity channel 248 and into the first cavity 368. The plantarflexion adjustment valve 308 is rotated to increase or decrease the pressure drop through the plantarflexion adjustment valve 308 to control the damping effect of the hydraulic cylinder on the plantarflexion movement. The first check valve 340 prevents the hydraulic fluid from flowing through the dorsi flexion adjustment channel 252.

FIGS. 15 and 16 depict an extendable link 188' which is an alternative from the extendable link 188 described above. Generally, the extendable link 188' may be physically substituted for the extendable link 188 in any of the assemblies of this disclosure, but the alternative extendable links have distinctly different behaviors and result in significantly different experiences when in use by an amputee. The cross-sectional depiction of **FIG. 15** generally corresponds with the cross-section A—A taken in **FIGS. 10 and 11**. A comparison with **FIG. 13** is useful to identify features which substantially correspond with those in the embodiment of **FIG. 13**. **FIG. 15** employs identical numerical identifiers to those in **FIG. 13** for substantially identical components which have already been described above. It will be understood to those of skill in the art that the descriptions above with respect to extendable link 188 are also applicable to extendable link 188' to the extent components and subassemblies match or correspond between the two alternative embodiments. However, extendable link 188' has some features and resulting performance differences from extendable link 188, as will be discussed.

The piston 224' of extendable link 188' (analogous to piston 224 in extendable link 188) generally may travel in either direction 601 or 602, provided it has not reached either the flexion stop or the extension stop. Piston travel in direction 601 (relative to body 218) elongates the extendable link 188'. When arranged with a base 186 and prosthetic adapter 190 according to an

ankle assembly 118 of this disclosure, elongation of the hydraulic cylinder rotates the prosthetic joint assembly about a pivot point in a flexion direction (e.g., dorsiflexion). Piston travel in direction 602 shortens the extendable link 188'. In the context of an ankle assembly 118, shortening of the hydraulic cylinder rotates the prosthetic joint assembly about the pivot point in an extension direction (e.g., plantarflexion). It should be appreciated that in other joint assemblies, the extendable link may be arranged such that elongation results in extension, and shortening results in flexion. This is true, for example, in an elbow prosthetic in which an extendable link according to this disclosure is arranged to substitute for the work performed by the natural bicep muscle.

The extendable link 188' of **FIG. 15** differs most notably from extendable link 188 of **FIG. 13** by its accommodation of a biasing spring 501. The biasing spring 501 works in parallel with the hydraulic cylinder, although both elements have functionally different effects on the behavior of the piston assembly 220' and, more broadly speaking, the prosthetic joint assembly as a whole. In particular, the hydraulic cylinder is configured to provide damping resistance to rotation of the joint assembly. This may take the form of, for example, a damping resistance to the base 186 rotating in either direction about the third pivot point 384 (see, e.g., **FIG. 7**). The damping resistance may additionally (or alternatively) refer more generally to resistance of the entire joint assembly rotating about an axis of rotation defined by the force triangle created by the combination of a prosthetic adapter (e.g., 190), base (e.g., 186), and extendable link. In contrast to the hydraulic cylinder, the biasing spring 501, as its name implies, provides a non-zero biasing force. The biasing force may bias the piston assembly 220' to move in either direction 601 or direction 602, but not both directions. In the context of an exemplary ankle-foot prosthesis according to exemplary assemblies described above, the biasing spring 501 may be arranged to provide dorsiflexion assistance by providing a biasing force that biases the piston assembly 220' in the direction 601 (thereby supplying a force to lengthen the extendable link 188').

Recall from description above and **FIG. 13**, for example, that the piston 224 is arranged inside a piston cavity 238. The piston cavity 238 is split by the piston 224 into a first cavity 368 and second cavity 370. A simplified depiction of this arrangement is provided by **FIG. 14**. In **FIG. 15**, the spring 501 introduces a third cavity 503. The cavity 503 is fluidically isolated from both the first cavity 368 and second cavity 370. Whereas the first cavity 368 and second cavity

370 are filled with hydraulic fluid which may pass between the cavities through previously described channels (see, e.g., **FIG. 14** and accompanying description), the third cavity 503 may be filled primarily or entirely with one or more gases, in particular, one or more gases under pressure. Moreover third cavity 503 is not in any way fluidically connected with the cavities containing hydraulic fluid. It should be appreciated that the characterization of the third cavity 503 being filled primarily or entirely with one or more gases does not preclude the inclusion of minor amounts of non-gases such as lubricants and/or anti-corrosion agents.

In addition to the gas cavity 503, spring 501 further comprises a piston 502 and dynamic seal 505 on the piston. Piston 502 may be described in this disclosure as the “second” piston 502 to distinguish it from the “first” piston 224' belonging to the extendable link 188'. Piston 502 may also be described as the spring piston 502 to distinguish it from the hydraulic piston 224'.

The piston 502, at least within the exemplary configuration portrayed by **FIG. 15**, separates gas in the third cavity 503 from hydraulic fluid of the extendable link 188'. The piston 502 is arranged to be acted upon by a first force supplied by the one or more compressed gases in the third cavity 503 and a second force supplied by the hydraulic fluid. In particular, the second force is supplied by the hydraulic fluid in cavity 370, with the result that the spring 501 supplies a bias force that urges the piston assembly 220' to move in direction 601, which in the broader prosthetic ankle-foot joint assembly translates to a dorsiflexion assist force (and ankle moment).

As illustrated, the arrangement in **FIG. 15** is such that spring 501 only supplies a bias force to the piston assembly 220' which urges the extendable link 188' to elongate. This is accomplished in part by the unrestricted fluidic access between second cavity 370 and the side 511 of piston 502. The opposite side 512 of piston 502 faces into the gas cavity 503. Owing to the limitations of cross-sectional views, the extent of second cavity 370 may not be immediately appreciated from **FIG. 15**. Second cavity 370 includes subspaces 370', 370'', and 370'''. In comparison to **Fig. 13**, the lower shaft seal has been eliminated, which allows hydraulic fluid to flow into subspaces 370'' and 370''', expanding the volume of cavity 370 without any change required in the volume of space occupied by body 218. Hydraulic fluid in any one of these three subspaces is substantially at the same pressure as any hydraulic fluid in either of the other two subspaces at any given time. Subspace 370' is immediately adjacent to a side of piston 224'. Subspace 370''' accommodates displacement of an end of the piston shaft 222'. Subspace 370'' is a hollowed out interior portion of piston shaft 222'. Together, the gas cavity 503 and subspace

370" constitute a piston cavity 504 which is sized and shaped to accommodate piston 502 and limit piston 502 to a single degree of freedom, namely displacement along a single linear axis corresponding with directions 601 and 602.

5 The magnitude range of the force suppliable by the spring 501 during use of the prosthesis may be set prior to use based on the gas pressure inside cavity 503. In some exemplary embodiments, the minimum pressure may be set in the range 200-1000 pounds per square inch (psi). In some embodiments, the minimum pressure may be set in the range 375-750 psi. In some embodiments the minimum pressure may be set in the range 400-600 psi. The magnitude range of the force supplied to side 512 of piston 502 of spring 501 by the one or more gases in cavity 10 503 may be adjusted and calibrated by adding or removing gas molecules to the cavity 503. To this end, the extendable link 188' may include one or more channels 513 and a filling port seal 514 through which a needle or comparable instrument may be temporarily inserted to gain temporary access to cavity 503. Additional gas may be supplied to cavity 503 through the needle (not illustrated), or gas already in cavity 503 may be withdrawn out through the needle. The seal 15 514, in the configuration illustrated by **FIG. 15**, prevents egress of gas or liquid from cavity 503. However, the seal 514 is configured to permit passage of a needle or similar instrument and then reseal itself again after the needle is removed. Rubbers, polymers, and rubber-polymer composites are exemplary materials for seal 514 to achieve this functionality.

The assembly of **FIG. 15** includes an accumulator 450, which may also be referred to as 20 a volume compensator, which maintains the hydraulic system at a preloaded pressure on the fluid and compensates fluid loss. Generally, when the prosthesis is in equilibrium (as when resting for a reasonable duration of time), the pressure of the hydraulic fluid substantially matches the minimum pressure of the gas in cavity 503. Ideally, an accumulator supplies a fixed load to the hydraulic fluid which does not vary during use of the prosthesis. In practice, however, the load 25 from the accumulator may vary by small but generally negligible amounts during use. For purposes of this disclosure, an accumulator is distinguished from a spring like spring 501. Spring 501 provides deliberate non-zero forces (and corresponding loads and moments) which vary substantially over the course of use of the prosthesis. That is to say, in the context of an ankle-foot prosthesis, the magnitude of the mechanical effects of spring 501 changes substantially 30 depending on the subphase of the gait cycle and/or the angular position of the foot spring components 116 relative to the prosthetic adapter 190 position, which is defined as the prosthetic

ankle angle. The changing force (or load or moment) from a spring 501 means the spring contributes a greater impact to certain subphases of the gait cycle than to other subphases of the gait cycle. By contrast, an accumulator like accumulator 450 is specifically configured to provide an effect to the overall system which is substantially constant and unchanging for the entire gait cycle. The purpose of accumulator 450 is to ensure the hydraulic circuit remains filled with fluid and air does not ingress into the hydraulic fluid throughout the lifecycle of the ankle device by pressurizing the fluid in the entire hydraulic circuit (i.e., on both sides of the piston). Accumulator 450 as shown in FIG. 15 does not bias piston 224' towards either extension or compression of the extendable link.

FIG. 15 presents an exemplary arrangement by which the spring 501 is inside the piston assembly 220' of the hydraulic cylinder of extendable link 188'. Alternatively, spring 501 may be positioned somewhere other than inside the piston assembly of the hydraulic cylinder (see, e.g., positioning of spring 501' in **FIG. 17**, discussed in greater detail below). However, the arrangement of spring 501 inside the piston assembly 220' bears certain advantages such as but not limited to highly efficient use of space and therefore a very compact size for the overall assembly. This in turn can allow for a lighter prosthesis; the overall weight of a prosthesis can significantly impact user experience, comfort, and conformance with optimal kinematics for musculoskeletal health and endurance. The size of an ankle assembly is an important design consideration, and an ankle assembly which is equal to size or smaller than a human ankle is highly desirable for aesthetic reasons.

FIG. 16 depicts fluid flow directions among the cavities already discussed and depicted by **FIG. 15** from a schematic perspective. For schematic purposes, the spring 501 is not literally depicted inside the shaft 222' or piston 224'. From the schematic it can be appreciated that fluid flow between subspace 370''' and subspace 370'' is unrestricted. From a hydraulics perspective, the subspaces 370''' and 370'' are substantially always at the same pressure as one another. In contrast, the accumulator 450, in particular its fluid portion 292, does not bear this relationship with any subspace of cavity 370 of the hydraulic cylinder of extendable link 188'.

FIG. 17 is an extendable link 188'' which is an exemplary alternative to extendable link 188' of **FIG. 15**. The cross-sectional depiction of **FIG. 17** generally corresponds with the cross-section A—A taken in **FIGS. 10 and 11**. In **FIG. 17** a spring 501' is included which corresponds in functionality to spring 501. However, spring 501' is positioned alongside, not inside, the

hydraulic cylinder of extendable link 188'. Furthermore, an accumulator is omitted entirely. A channel 610 permits hydraulic fluid to move freely between subspace 370''' and cavity 611 such that the pressure in subspace 370''' and cavity 611 are substantially the same. Though arranged differently, the components of spring 501' generally bear the same functionalities as components in spring 501. Namely, gas cavity 503' corresponds with gas cavity 503; piston cavity 504' corresponds with piston cavity 504; piston 502' corresponds with piston 502; dynamic seal 505' corresponds with dynamic seal 505; piston side 511' corresponds with piston side 511; piston side 512' corresponds with piston side 512; and filling port seal 514' corresponds with seal 514.

FIG. 18 is a further extendable link 188''' which is an exemplary alternative to the extendable links 188' (**FIGS. 15-16**) and 188'' (**FIG. 17**). Here the arrangement of the hydraulic cylinder of extendable link 188''' and spring 501 corresponds with the hydraulic cylinder and spring of extendable link 188' disclosed and described in connection with **FIG. 15**. However, an accumulator is omitted entirely. Spring 501 mitigates the need for an accumulator, since under most operating conditions the entire hydraulic circuit will be pressurized by the air spring. However, referencing **FIG. 19**, if fluid flow from cavity 370''' to cavity 368 is sufficiently restricted by valve 452, and a sufficient compressive load is applied to the extendable link, the majority of fluid will flow into spring 501 and a vacuum condition may be created in cavity 368, potentially allowing air to ingress the upper shaft seal(s) over an extended period of use. Hence, depending on operating conditions, including both accumulator 450 and spring 501 into the design of the extendable link (as shown in extendable link 188' of **FIGS. 15-16**) may be advantageous.

FIG. 19 is a schematic depicting fluid flow directions and valves corresponding with the configuration of extendable link 188'' of **FIG. 17** as well as the configuration of extendable link 188''' of **FIG. 18**.

Dorsiflexion stops and/or plantarflexion stops in extendable links 188', 188'', and 188''' may be substantially the same as the stops described above for extendable link 188. The dorsiflexion stop may be engaged at a zero degree ankle position, or the standing position. This assists an amputee with standing up straight.

All of the extendable links 188, 188', 188'', and 188''' include a passive hydraulic damping system that provides the ankle joint member damping rotational resistance, with independent and independently adjustable damping resistances in both the plantarflexion and

dorsiflexion directions. Exemplary hydraulic subsystem elements for providing rotational damping resistance were introduced in the flow schematics of **FIGS. 14, 16, and 19**.

FIG. 20 provides an exploded assembly view which depicts exemplary hydraulic subsystem components as they may appear inside extendable links 188, 188', 188'', and 188'''.

5 Note that elements 358, 360, and 362 are optional elements for an optional locking valve feature discussed in greater detail below in connection with **FIGS. 25-27**. A locking valve feature may be included or excluded from extendable links 188, 188', 188'', and 188'''. In general, most depictions of extendable links 188', 188'', and 188''' in this disclosure omit a locking valve feature. **FIGS. 21 and 22** are cross-sections taken from **FIG. 10** at B—B and C—C to assist in
10 the showing of the exemplary hydraulic subsystem components.

Referring to **FIGS. 20, 21, and 22**, (see also **FIGS. 9 and 10**), a plantarflexion adjustment valve 308 is positioned in the plantarflexion valve cavity 240 and a dorsiflexion adjustment valve 310 is positioned in the dorsi valve cavity 242. The plantarflexion adjustment valve 308 and the dorsiflexion adjustment valve 310 each include a valve body 312, at least one
15 seal 314, a ball stock 316, a ball stock retention pin 318, and a valve retention pin 320. The valve body 312 define valve fluid path 322, an internal cavity 324, a screw head 326, a first side slot 328, and a second side slot 330. The valve body 312 is positioned in the plantar valve cavity 240 or the dorsi valve cavity 242 such that the screw head 326 faces out of the plantar valve cavity 240 or the dorsi valve cavity 242. In the illustrated embodiment, the screw head 326 includes a
20 hexagonal recess. In alternative embodiments, the screw head 326 may include any type of screw head that enables the plantarflexion adjustment valve 308 or the dorsiflexion adjustment valve 310 to operate as described herein. Additionally, the valve body 312 is positioned in the plantar valve cavity 240 or the dorsi valve cavity 242 such that the valve fluid path 322 is positioned within and in flow communication with the plantar flexion adjustment channel 254 and the dorsi
25 flexion adjustment channel 252.

Additionally, the valve retention pin 320 is inserted into the body 218 such that the valve retention pin 320 is partially positioned in the plantar valve cavity 240 or the dorsi valve cavity 242 and within the first side slot 328 such that the valve body 312 is rotatably maintained in the plantar valve cavity 240 or the dorsi valve cavity 242, and the first side slot in combination with
30 pin 320, limits the rotational range of valves 308 and 310. The at least one seal 314 includes a first seal 332 positioned in the second side slot 330 and a second seal 334 positioned at an end of

the valve body 312. The ball stock retention pin 318 is positioned within the internal cavity 324 and the ball stock 316 is positioned on either side of the ball stock retention pin 318 such that the ball stock 316 defines a check valve. Specifically, the ball stock 316 is positioned on a first side 336 of the ball stock retention pin 318 to define a first check valve 340 and the ball stock 316 is positioned on a second side 338 of the ball stock retention pin 318 and within the internal cavity 324 to define a second check valve 342. The valve body 312 is rotated to increase or decrease the length of the valve fluid path 322 the hydraulic fluid flows through to increase or decrease the pressure drop through the plantarflexion adjustment valve 308 and the dorsiflexion adjustment valve 310. The valve fluid path 322 has a variable depth and the pressure drop is adjusted by both increasing the flow path distance and altering the cross-sectional area of the flow path.

FIGS. 25-27 provide illustration to a locking valve feature which is present in some embodiments of this disclosure and omitted from other embodiments of this disclosure. It should be understood that this feature is optional, being included or excluded as desired, based on the needs and preferences of the intended end user of a given prosthesis configured in accordance with this disclosure. The following description of the optional locking valve feature may refer to elements illustrated by and labeled within one or more of **FIGS. 14 and 20** in addition to **FIGS. 25-27**.

An ankle assembly may incorporate a plantarflexion lock spool valve 344 that, when activated, allows hydraulic fluid to circulate until the device reaches its maximum dorsiflexion position, at which it becomes locked in this maximum position. Plantarflexion is prevented when the plantarflexion lock spool valve 344 is activated. The ankle assembly 118 remains locked until the plantarflexion lock spool valve 344 is manually opened allowing the piston to move in the hydraulic cylinder. The normal operating position for the ankle assembly 118 is in the unlocked position such that the foot has a full range of motion without restriction. The plantarflexion lock spool valve 344 helps amputees while driving by preventing plantarflexion which prevents the foot from unexpectedly interfering with the pedals. The plantarflexion lock spool valve 344 provides added safety for driving and unique tasks such as steadying oneself in awkward footing situations, and provides a repeatable locked position. The plantarflexion lock disclosed allows a user to activate the lock while standing and then move the foot to the maximum dorsiflexion position, which prevents movement of the ankle until the locking mechanism is de-activated.

The plantarflexion lock spool valve 344 includes a valve body 358, at least one seal 360, and at least one end 362. The valve body 358 is positioned within the body 218 such that the valve body 358 is positioned within at least one of the channels 234 to prevent flow of the hydraulic fluid through the channels 234. Specifically, in the illustrated embodiment, the valve body 358 is positioned within the second piston cavity channel 250. The seals 360 circumscribe the valve body 358 and the ends 362 either include or are attached to the lever 346, the rotatable knob 350, and the push button 354.

A plantarflexion lock spool valve 344 is positioned in the plantarflexion lock spool valve cavity 244 and is configured to prevent plantarflexion of the ankle such that when the ankle reaches maximum dorsiflexion it will be locked in the maximum dorsiflexion position. In the illustrated embodiment, the plantarflexion lock spool valve 344 is a manual hydraulic lock including at least one of a push button spool valve, rotatable knob spool valve, and a lever spool valve. Specifically, as shown in **FIGS. 25-27**, the plantarflexion lock spool valve 344 may include a lever 346 that actuates a lever spool valve 348, a rotatable knob 350 that actuates a rotatable knob spool valve 352, and/or at least one push button 354 that actuates a push button spool valve 356. In alternative embodiments, a lock such as plantarflexion lock spool valve 344 and its respective cavity 244 may be omitted, depending on the needs and desires of intended users.

FIG. 28 illustrates the prosthetic foot system 100 positioned on a flat, horizontal ground surface 372 in a neutral stance such that a pyramid angle 374 between the top surface of the pyramid connector 132 is 0°. As shown in **FIG. 28**, the pyramid connector 132 defines a pyramid connector axis 376 through a middle of the pyramid connector 132 which is oriented vertically. The piston assembly 220 defines a piston axis 378 through a middle of the shaft 222.

The piston fastener 208 defines a first pivot point 380 extending through a middle of the piston fastener 208, the base fastener 212 defines a second pivot point 382 extending through a middle of the base fastener 212, and the piston body fastener 230 defines a third pivot point 384 extending through a middle of the piston body fastener 230. A first pivot distance 386 is defined as the distance between the first pivot point 380 and the second pivot point 382. A second pivot distance 388 is defined as the distance between the second pivot point 382 and the third pivot point 384. A third pivot distance 390 is defined as the distance between the first pivot point 380 and the third pivot point 384.

Additionally, a moment arm 392 is defined as the distance between the second pivot point 382 and the piston axis 378. A pyramid axis distance 394 is defined as the distance between the second pivot point 382 and the pyramid connector axis 376. An axis angle 396 is defined as the angle between the pyramid connector axis 376 and the piston axis 378. A top spring angle 398 is defined as the angle between the flat surface 372 and the first spring member 150. A heel distance 400 is defined as the distance between the flat surface 372 and a heel portion of the footshell 102 and a forefoot distance 402 is defined as the distance between the flat surface 372 and a forefoot portion of the footshell 102.

The pyramid axis of a prosthetic foot is typically located at between 25% to 35% of the foot length measured from the heel end of the footshell. The center of mass is located between 65 and 100 mm anterior to the posterior most end of the foot shell depending on foot size, or at $1/3$ of the foot length ± 10 mm. Some adjustment to the location of a prosthetic foot based on the effective spring stiffness of the prosthetic foot may be made by a prosthetist.

Moreover, the geometry of an ankle assembly described herein may include a greater distance between the pivot axes 382 and 384 on the base 186 compared to other hydraulic ankle/feet. Increased pivot distance increases the distance between the cylinder axis and the foot pivot point (the moment arm 392), which reduces the forces on the hydraulic cylinder and results in reduced stresses and strains in the hydraulic cylinder assembly and also allows for either decreased hydraulic pressure or a smaller cylinder and piston diameter at equivalent pressure.

Reducing forces and maximum hydraulic pressures increases reliability and reduces weight.

In the illustrated embodiment, the first pivot distance 386, the second pivot distance 388, and the third pivot distance 390 define a force triangle that distributes the weight of the user and defines an axis of rotation of the ankle assembly 118. In the illustrated embodiment, the axis of rotation of the ankle assembly 118, more specifically the axis of rotation of the base and foot spring assembly is positioned forward of the pyramid connector 132 and below and in line with the center of mass of the user. The rotation axis of the foot is forward of the pyramid axis. Therefore, the center of mass of the user is directly above the rotation axis when standing, allowing users to stand without significant movement of the ankle assembly 118. Thus, the above-described geometry of the ankle assembly 118 also minimizes impact when the ankle reaches the end of its hydraulic range in the dorsiflexion direction (the dorsiflexion stop) because when the user's center of mass is directly above rotation axis 382 there is no moment acting on

ankle assembly 118 and hence no force on hydraulic cylinder 188. If the dorsiflexion stop engages at or within a few degrees of the standing position, for a brief moment in time during the gait cycle there is very little, or no, driving force to create an impact.

In the embodiment illustrated in **FIG. 28**, the first pivot distance 386 is about 50 millimeters (mm) to about 60 mm or about 58.8 mm, the second pivot distance 388 is about 25 mm to about 40 mm or about 33.0 mm, the third pivot distance 390 is about 50 mm to about 60 mm or about 58.6 mm, the moment arm 392 is about 25 mm to about 40 mm or about 31.7 mm, the pyramid axis distance 394 is about 19 mm to about 26 mm or about 23.0 mm, the axis angle 396 is about 15° to about 20° or about 17.1°, the top spring angle is about 15° to about 20° or about 18.2°, and the heel distance 400 and the forefoot distance 402 are both about 0 mm, indicating the foot, including the footshell, is flat on a horizontal ground surface.

FIG. 29 illustrates the prosthetic foot system 100 positioned on the flat surface 372 at maximum plantarflexion such that the pyramid angle 374 of the pyramid connector 132 is 0°. In the embodiment illustrated in **FIG. 29**, the first pivot distance 386 is about 50 millimeters (mm) to about 60 mm or about 58.8 mm, the second pivot distance 388 is about 25 mm to about 40 mm or about 33.0 mm, the third pivot distance 390 is about 50 mm to about 60 mm or about 52.5 mm, the moment arm 392 is about 25 mm to about 40 mm or about 32.8 mm, the pyramid axis distance 394 is about 19 mm to about 26 mm or about 23.0 mm, the axis angle 396 is about 15° to about 20° or about 18.3°, the top spring angle is about 20° to about 30° or about 29.1°, and the heel distance 400 is about 30 mm to about 40 mm or about 30.23 mm.

FIG. 30 illustrates the prosthetic foot system 100 positioned on the flat surface 372 when the prosthetic foot system 100 is arranged in a shoe (not shown) such that the pyramid angle 374 of the pyramid connector 132 is 2°. The heel distance 400 is a typical shoe height of about 5 mm to about 20 mm or about 10 mm. In the embodiment illustrated in **FIG. 30**, the first pivot distance 386 is about 50 millimeters (mm) to about 60 mm or about 58.8 mm, the second pivot distance 388 is about 25 mm to about 40 mm or about 33.0 mm, the third pivot distance 390 is about 50 mm to about 60 mm or about 57.5 mm, the moment arm 392 is about 25 mm to about 40 mm or about 32.0 mm, the pyramid axis distance 394 is about 19 mm to about 26 mm or about 23.0 mm, the axis angle 396 is about 15° to about 20° or about 17.4°, and the top spring angle is about 20° to about 30° or about 22.3°.

FIG. 31 illustrates the prosthetic foot system 100 positioned on the flat surface 372 at maximum dorsiflexion such that the pyramid angle 374 of the pyramid connector 132 is 0°. In the embodiment illustrated in **FIG. 31**, the first pivot distance 386 is about 50 millimeters (mm) to about 60 mm or about 58.8 mm, the second pivot distance 388 is about 25 mm to about 40 mm or about 33.0 mm, the third pivot distance 390 is about 50 mm to about 60 mm or about 58.6 mm, the moment arm 392 is about 25 mm to about 40 mm or about 31.7 mm, the pyramid axis distance 394 is about 19 mm to about 26 mm or about 23.0 mm, the axis angle 396 is about 15° to about 20° or about 17.1°, the top spring angle is about 10° to about 20° or about 18.2°, the heel distance 400 is about 0 mm, and the forefoot distance 402 is about 0 mm to about 10 mm or about 1.13 mm.

The above-described geometry of the ankle assembly 118 enables plantarflexion motion at an ankle joint, which allows the metatarsophalangeal (i.e., ball of foot) area of the foot to achieve contact with the ground earlier in the gait cycle. The ball of foot/wide part of the foot provides stability during the gait cycle. The above-described geometry of the ankle assembly 118 also enables a small amount of dorsiflexion, relative to a standing position, which results in reduced and adjustable hydraulically controlled resistance to tibial progression during the portion of the gait cycle between foot flat and midstance when the rotational range of the ankle assembly reaches a dorsiflexion limit. When an amputees' center of mass is directly above the shin and the shin is vertical, the amputee does not have much leverage over the lever arm created by the forefoot of a prosthetic foot. The above-described geometry of the ankle assembly 118 further enables clearance during swing phase which reduces stumbling and falling. Because the rotation around the ankle assembly 118 is dampened by hydraulic resistance, the foot portion stays in a dorsiflexed position during swing phase until the heel makes contact with the ground and plantarflexion begins.

For example, the rotation axis of the foot is forward of the pyramid axis. Therefore, the center of mass (COM) of the amputee is directly above the rotation axis when standing, allowing amputees to stand without significant movement of the ankle assembly 118. Thus, the above-described geometry of the ankle assembly 118 also minimizes impact when the ankle reaches the end of its hydraulic range in the dorsiflexion direction (the dorsiflexion stop).

As mentioned above, in an ankle-foot prosthesis the spring 501 or spring 501' may be configured to provide a dorsiflexion biasing force/moment. It is generally desirable that the gas

cavity 503/503' be configured with a minimum pressure of at least 200psi, 300psi, 400psi, or 500psi, or greater. Such minimum pressure exists when the ankle is at a maximum dorsiflexion position. This position corresponds with the extendable link 188'/188"/188''' being at a maximum length in the force triangle configuration depicted in **FIGS. 4-7**, for example. Exemplary

5 moment arms within this force triangle are already described above. Selecting by way of illustration the exemplary value for the moment arm of the hydraulic cylinder of 32 mm, and an exemplary minimum gas cavity pressure of 500 psi, the resultant minimum force exerted by the gas spring 501/501' is approximately 368 N and a minimum moment of 12.0 Nm. For an 80 kg person this results in a minimum spring force at full extension of the extendable link of 4.6N/kg
10 of body weight, and the moment from this force is approximately 0.15 Nm/kg of body weight. . Generally, for some embodiments, the dorsiflexion biasing moment from the spring 501/501' is always at least 3 Nm. Such minimum force supplied at any given moment by the gas spring on hydraulic fluid of the hydraulic cylinder in cavity 370 may be regarded as a preload force with respect to operation of the prosthetic. In general, for some embodiments, the dorsiflexion
15 biasing moment from the spring at a standing position may be 0.05-0.20 Nm/kg body weight of the user (the wearer of the prosthesis). The dorsiflexion biasing moment at 12° of plantarflexion may be 0.15-0.28 Nm/kg body weight of the user. The spring rate of the gas spring may be from 0.2 N/(mm·kg) of body weight to 1.0 N/(mm·kg) based on spring forces and linear deflections at 0° and 12° of ankle angle. The spring rate may be linear or non-linear between these points. The
20 angular spring rate may be 0.0036 Nm/(deg·kg) to 0.018 Nm/(deg·kg) of body weight based on moments and angular displacements at 0° and 12° of ankle angle. The angular spring rate may be linear or non-linear between these points.

For an entire gait cycle, an exemplary ankle-foot prosthesis still dissipates a non-zero quantity of energy. The hydraulic cylinder dissipates energy both during plantarflexion rotation
25 of the joint and dorsiflexion rotation of the joint. Because some of the energy input to the system is stored and then returned, however, the net energy demand of the system on the user is reduced in embodiments involving a spring 501/501' compared to embodiments which omit such a spring. The spring and the hydraulic cylinder may be configured such that an exemplary ankle assembly dissipates less than 4 Joules of energy, or less than 3 Joules of energy, for every step (a
30 full gait cycle). The spring and hydraulic cylinder may be configured such that an exemplary

ankle assembly dissipates less than 0.05J/kg of body weight, or less than .038 J/kg of body weight.

Both the spring and the hydraulic cylinder are compressed during any plantarflexion rotation of the prosthetic ankle. However, the spring piston displacement is different than the hydraulic piston displacement. Due to the areas of the hydraulic and gas pistons being different, more/less displacement is needed to accommodate for the change in area but keeping the displaced volume equal. Travel of the hydraulic cylinder's piston displaces hydraulic fluid which in turn compresses the gas spring via the gas spring's piston. At any point, resistance to further compression of the gas spring is provided by both the spring (for which the resistance is position dependent) and the hydraulic cylinder (for which the resistance is rate dependent). Energy stored in the spring during plantarflexion rotation is returned during dorsiflexion rotation of the joint. It is advantageous in some embodiments that the spring be configured to release sufficient energy during any dorsiflexion rotation of the ankle assembly to equal or exceed energy loss from the dorsiflexion damping resistance caused by the hydraulic cylinder. In particular, it is advantageous in some embodiments that when the foot spring assembly is subject to a ground reaction force (e.g., as occurs during stance phase) and the ankle assembly rotates in a dorsiflexion direction (e.g., as occurs during mid-stance), the spring is configured to release sufficient energy to equal or exceed energy loss from the dorsiflexion damping resistance. To the user's experience, the prosthesis appears to have no dorsiflexion resistance under these conditions. To the user's experience, the prosthesis may actually exhibit perceptible dorsiflexion assistance, giving the feel of propelling the user forward during dorsiflexion rotation, midstance, and tibial progression. The energy/force/moment provided by the spring 501/501' from one moment in time to the next is controlled/mitigated by the hydraulic resistance, which is adjustable. Whether the combination of the gas spring and the hydraulic cylinder is providing a net positive or net negative ankle moment (resistance or propulsion), depends on both ankle position and the angular rate of motion and is adjustable to the user's preference.

During swing phase, an ankle-foot prosthesis is not subject to any ground reaction force. However, it is still desirable in some embodiments that the extendable link be configured such that it extends in an absence of external forces up to the dorsiflexion stop. This causes the toe of the foot spring assembly to lift up (with respect to the ground) making it less likely the user will accidentally contact the toe with the ground and trip as a result. When a user stops mid-step and

turns around, walks backward, or when the user is side stepping (e.g., as when cooking in the kitchen) passive hydraulic feet do not toe lift at a rate that is desired and can often lead to trips due to catching the toe on the ground. Exemplary embodiments may be configured to rotate in a dorsiflexion direction in an absence of external forces at a rate above a predetermined minimum threshold set to minimize or avoid these inconveniences.

Lower limb prosthetic components may benefit from adjustability and are typically connected using an industry standard prosthetic pyramid connection. A prosthetic pyramid connection typically consists of a male pyramid connector/adaptor and a complementary female pyramid connector/adaptor connected to each other. The combination of the male and female adaptors may provide for angular adjustment between two prosthetic components. The male portion may include two primary features: a pyramid protrusion and a contoured (e.g., spherical) surface. The pyramid protrusion may have four planar surfaces that are oriented in posterior, anterior, medial, and lateral directions. These surfaces may be angled with respect to a pyramid axis, wherein the pyramid axis extends along a longitudinal axis of the shin or thigh of the limb. The pyramid surfaces typically are angled in the range of about 10 degrees to about 30 degrees, and more particularly about 15 degrees. Due to the angles of the four pyramid surfaces, the protrusion necks down in a distal direction. The necked down end transitions to the contoured (e.g., spherical) surface. The contoured portion may be part of a separate base component with the pyramid protrusion fixedly and rigidly attached to the base component. Alternatively, the base component may be integrated to the spherical feature where the two features are combined into a single monolithic block of material.

The pyramid protrusion may be threaded into the base component with the threads glued or otherwise fixed to prevent unthreading. Alternate methods of fixedly attaching a pyramid protrusion to a base component including a spherical surface are possible such as, for example, creating a stud on the narrow end of the pyramid protrusion and molding the stud into a fiber reinforced moldable base material, or by deforming the stud such that the stud creates a strong interference fit between the pyramid protrusion and the base component. A male pyramid adaptor may be monolithic meaning it is formed or composed of a single, continuous material without joints or seams. However, as discussed herein, the male pyramid adaptor may comprise a plurality of components, such as one or more components that adjust an effective length of the pyramid adaptor.

A female pyramid adapter may include a predominantly hollow cylinder with a spherical surface formed on one end and four threaded fasteners. The inner surface of the cylinder may not be round or cylindrical as recesses are commonly formed on this surface to allow increased articulation of the male protrusion within the cylinder while adjusting the angle between the components. The spherical surfaces of both the male and female components have a near identical spherical radius to allow mating with each other. Fasteners (e.g., two or more fasteners) may be threaded into the cylinder at an angle relative to the cylinder axis (e.g., 15 degree angle), and the fasteners may engage one or more of the four planar surfaces of the male pyramid protrusion to releasably secure the position of the pyramid connection. By adjusting the depth of the fasteners in the female component, the angle between the male and female pyramid components can be changed and the angle between two prosthetic components can be adjusted. A female pyramid component may be referred to as a pyramid receiver. A female pyramid adapter may be monolithic. The threaded fasteners typically are separate components in a monolithic female pyramid adapter.

A male or female pyramid adapter component may be machined or formed directly onto a prosthetic device, for example, a prosthetic knee. For the purposes of this disclosure, a pyramid adapter may be either the male or female component of a pyramid connection and include either a pyramid protrusion and a spherical mating surface in the case of a male pyramid adapter or a spherical mating surface with multiple (e.g., four) threaded fasteners to engage and lock a pyramid protrusion in the case of a female adapter. A pyramid adapter may be fabricated separately from other components and include design features allowing the adapter to be attached to other prosthetic components in addition to connecting the complementary opposite component of a pyramid connection.

EXAMPLES

FIGS. 32, 33, and 34 depict sample data collected for a prototypical ankle-foot prosthesis that included an extendable link configured in accordance with extendable link 188' of **FIG. 15** assembled with a prosthetic adapter 190, base 186, and foot spring assembly 116 consistent with **FIGS. 4-7**. **FIG. 34** further includes sample comparative data for a prototypical ankle-foot prosthesis that included an extendable link configured in accordance with extendable link 188 depicted in **FIG. 13**, for example, assembled with a prosthetic adapter 190, base 186, and foot spring assembly 116 consistent with **FIGS. 4-7**. As shorthand, the prototype with an

extendable link 188' is referred to as a H+AS ankle, in reference to it having a hydraulic subsystem and air spring. By contrast, the prototype with an extendable link 188 is referred to as a HO ankle, in reference to it having a hydraulic subsystem only (no biasing springs).

As generally indicated by **FIGS. 32 and 33**, a nearly linear relationship may exist between air spring force (and moment) and hydraulic shaft displacement in an H+AS ankle. Comparably, a nearly linear relationship may exist between air spring force (and moment) and ankle angle. Alternatively, non-linear relationships which exploit the design variables of a gas spring may exist to optimize prosthetic ankle behavior.

FIG. 34 presents ankle angle and ankle moment as a function of time and demonstrates the difference between an ankle which only has hydraulic damping (HO) and an ankle which has both hydraulic damping and an air spring in parallel with the damper (H+AS). Both prototype ankles utilized the same composite foot and basic ankle designs. 0° of ankle angle represents the standing position and a negative ankle angle represents plantarflexion positions of the foot about the ankle joint. The data has been aligned so toe-off occurs at the same time for both ankles. The H+AS ankle included an air spring in addition to adjusting the dorsiflexion stop position from a 2° dorsiflexed position used for the HO ankle to a 0° position for the H+AS ankle relative to the standing position. The two ankles were used by the same 80 kg trans tibial amputee. Both ankles were adjusted to the user's preferred hydraulic settings and the air spring chamber was pressurized to 500 psi when the ankle was in the maximum dorsiflexion position.

The peak heel moment of the HO ankle is 68% larger than the peak heel moment of H+AS ankle (29.3 vs 17.4 Nm). The Stance Phase is 10% longer for the HO ankle (775 vs 700 ms) and the Plantarflexion phase of the HO ankle is 75% longer than the H+AS ankle (300 vs 525 ms). The angular displacement of the HO ankle is approximately twice the displacement of the H+AS ankle (6.48° vs 3.21°). The self-selected walking speed of the H+AS ankle is 6.4% faster than the HO ankle (1100 vs 1175 ms).

FIG. 35 is a graph of ankle angle excursion (AAE) (deg) and moment for a trans-tibial amputee walking backward while wearing a prosthetic ankle having hydraulic damping and an air spring in parallel with the damper, consistent with the embodiment depicted by **FIGS. 15 and 16**. The data demonstrates that the exemplary ankle performs exceptionally well even during backward ambulation. The maximum moment (93.77 Nm) coincides with toe strike. The minimum moment (-16.89 Nm) coincides with heel lift followed by a return toward neutral.

Following heel lift, the ankle prosthetic exhibits an inherent dorsiflexion return, lifting the toe of the prosthetic on its own prior to next toe strike. Desirably, the rate of dorsiflexion return (or the rate of toe lift) is at least as fast as rate of the user lifting the heel. Exemplary embodiments may have a rate of dorsiflexion return of at least 10 degrees/second after heel lift. In an ankle with only hydraulic damping and no spring, little to no angle change may be expected after heel lift until the amputee brings the prosthetic back into contact with the ground.

FIG. 36 is an image of an experimental setup in which a machine moves an ankle assembly 3600 through the range of motion expected of the ankle assembly when such assembly is part of a prosthetic ankle-foot assembly (e.g., prosthetic foot 104 in **FIGS. 3-7**) in use by an amputee moving through a regular gait cycle. The machine was operated in displacement control to create 12.5 mm of sinusoidal displacement of the test machine actuator, which is connected to the ankle assembly by two moment arms.

FIG. 37 is a graph characterizing two different ankle assemblies operated in the test arrangement shown in **FIG. 36**. The dashed line is data collected from a hydraulic only (HO) ankle assembly, which is to say an ankle assembly in which the extendible link corresponds with link 188 of **FIGS. 13 and 14**. The solid line, on the other hand, is data collected from an ankle assembly in which the extendible link had a hydraulic cylinder and air spring (H+AS) in parallel with one another, consistent with link 188' of **FIGS. 15 and 16**. Each of the two ankle assemblies was acted upon in the experimental setup of **FIG. 36** to simulate one complete dorsiflexion and plantarflexion cycle. The dorsiflexion (DF) and plantarflexion (PF) valves were at the minimum hydraulic resistance setting.

The HO ankle assembly demonstrates largely symmetric behavior about two axes: a vertical axis at the mid stroke position (6.25 mm displacement) and a horizontal axis located at zero load. The sinusoidal displacement velocity is maximum at 6.25 mm, and hence the maximum hydraulic resistance is expected at maximum velocity. The minimum velocity occurs at both zero and 12.5 mm of displacement, where minimum or zero force occurs. The dashed line representing the HO ankle does not demonstrate complete symmetry about the two axes, and this is explained by manufacturing tolerances and wear. The HO ankle assembly used in this test had been utilized for other test procedures.

Comparing data from the H+AS ankle assembly (solid line) against the HO ankle assembly (dashed line) when their respective hydraulic damping valves were set to the minimum

level of hydraulic resistance, **FIG. 37** shows a consistent reduction in the force which the machine must supply during the dorsiflexion phase of the cycle and an increase in force required during the plantarflexion phase of the cycle when using the H+AS ankle assembly. The reduction is attributable to the air spring in the H+AS ankle assembly supplying energy that assists the machine in bringing about the dorsiflexion rotation. The machine had to supply more force during the plantarflexion cycle when using the H+AS ankle assembly. The increase is attributable to the air spring in the H+AS ankle assembly resisting the plantarflexion motion; the air spring is being charged (further to a minimum preload charge) during this phase. An upside of the charge is that at the start of dorsiflexion, the air spring's release of stored energy results in the machine needing to do little to no work for multiple millimeters of displacement. This is evident in the relative plateau in area 3700 of the graph. The latter feature means users can customize the amount of displacement over which they prefer the air spring to significantly assist during initial dorsiflexion rotation.

One advantage of prostheses which include H+AS ankle assemblies over alternative passive prostheses is a comparatively lighter energy demand placed on an amputee during use. Metabolic testing was performed with two trans-tibial amputees each of whom was recorded walking while wearing a "pure" carbon spring prosthesis, while wearing a HO ankle assembly foot system, and while wearing a H+AS ankle assembly foot system. The carbon spring prosthesis included no hydraulic damping subsystem nor any air spring. The HO foot system included a hydraulic only (HO) ankle assembly, which is to say an ankle assembly in which the extendible link corresponds with link 188 of **FIGS. 13 and 14**. The H+AS foot system included an ankle assembly in which the extendible link had a hydraulic cylinder and air spring (H+AS) in parallel with one another, consistent with link 188' of **FIGS. 15 and 16**.

FIG. 38 shows the metabolic activity (W/kg) of the first test subject. **FIG. 39** shows the metabolic activity (W/kg) of the second test subject. Three six-minute walk tests performed by each test subject were averaged together, and the final two minutes for each test subject are shown in **FIGS. 38 and 39**. The first test subject exerted 8.8% more energy expenditure using the HO ankle compared to utilizing the H+AS ankle. The second test subject exerted 3.7% more energy using the HO ankle compared to utilizing the H+AS ankle. These results demonstrate a significant advancement in the field of prosthetics. The H+AS design provides ankle articulation without the energy loss associated with hydraulic ankles. Energy loss is the largest performance

deficiency in hydraulic ankles available in the market. The energy return of the H+AS design provides increased propulsion in both the Plantarflexion and Toe Loading phases in comparison to the HO ankle/foot. The design also allows a user to adjust the hydraulic resistance to provide whatever proportion of resistance or propulsion they desire. With high hydraulic resistance the ankle performance is similar to a common hydraulic ankle, while at low hydraulic resistance settings the H+AS ankle provides both energy return and shock absorption, resulting in an increased rate of tibial progression and a faster walking speed in comparison to an ankle with only hydraulic resistance.

The foregoing description, for purpose of explanation, has been described with reference to specific embodiments. However, the illustrative discussions above are not intended to be exhaustive or to limit the invention to the precise forms disclosed. Many modifications and variations are possible in view of the above teachings. The embodiments were chosen and described in order to best explain the principles of the present systems and methods and their practical applications, to thereby enable others skilled in the art to best utilize the present systems and methods and various embodiments with various modifications as may be suited to the particular use contemplated.

Where a range of values is provided in this disclosure, it is understood that each intervening value, to the tenth of the unit of the lower limit unless the context clearly dictates otherwise, between the upper and lower limit of that range and any other stated or intervening value in that stated range, is encompassed within the invention. The upper and lower limits of these smaller ranges may independently be included in the smaller ranges and are also encompassed within the invention, subject to any specifically excluded limit in the stated range. Where the stated range includes one or both of the limits, ranges excluding either or both of those included limits are also included in the invention.

Unless otherwise noted, the terms “a” or “an,” as used in the specification and claims, are to be construed as meaning “at least one of.” In addition, this statement is intended to serve as antecedent basis for use of such exclusive terminology as “solely”, “only”, and the like in connection with the recitation of claim elements, or use of a “negative” limitation. In addition, for ease of use, the words “including” and “having,” as used in the specification and claims, are interchangeable with and have the same meaning as the word “comprising.” In addition, the term

“based on” as used in the specification and the claims is to be construed as meaning “based at least upon.”

CLAIMS

What is claimed is:

1. An ankle-foot prosthesis, comprising
 an ankle assembly comprising
 a prosthetic adapter,
 an extendable link rotatably attached to the prosthetic adapter to define a first pivot point, and
 a base rotatably attached to the prosthetic adapter to define a second pivot point and rotatably attached to the extendable link to define a third pivot point; and
 a foot spring or foot spring assembly attached to the base and configured to work in series with the ankle assembly,
 wherein the extendable link comprises
 a hydraulic cylinder configured to provide a dorsiflexion damping resistance and a plantarflexion damping resistance, and
 a spring arranged in parallel with the hydraulic cylinder, wherein the spring is a biasing gas spring.
2. The ankle-foot prosthesis of claim 1, wherein the spring is configured to release sufficient energy during any dorsiflexion rotation of the ankle assembly to equal or exceed energy loss from the dorsiflexion damping resistance.
3. The ankle-foot prosthesis of claim 1, wherein while the foot spring or foot spring assembly is subject to a ground reaction force and the ankle assembly rotates in a dorsiflexion direction, the spring is configured to release sufficient energy to equal or exceed energy loss from the dorsiflexion damping resistance.
4. The ankle-foot prosthesis of claim 1, wherein the prosthetic adapter, the hydraulic cylinder, and the base define a force triangle that defines an axis of rotation of the foot spring or foot

spring assembly about the prosthetic adapter, wherein the spring creates a dorsiflexion biasing moment about the axis of rotation.

5. The ankle-foot prosthesis of claim 4, wherein the dorsiflexion biasing moment from the spring is always at least 3 Nm.

6. The ankle-foot prosthesis of claim 1, wherein the spring comprises a gas cavity containing one or more gases at a minimum pressure of 200-1000 psi.

7. The ankle-foot prosthesis of claim 1, wherein the dorsiflexion biasing moment from the spring at a standing position is 0.05-0.20 Nm/kg body weight.

8. The ankle-foot prosthesis of claim 1, wherein the dorsiflexion biasing moment at 12° of plantarflexion is 0.15-0.28 Nm/kg body weight.

9. The ankle-foot prosthesis of claim 1, wherein the prosthetic adapter, the hydraulic cylinder, and the base define a force triangle that defines an axis of rotation of the spring assembly and base about the prosthetic adapter, wherein the axis of rotation is positioned below and in line with a center of mass of a user when the user is in a standing position.

10. The ankle-foot prosthesis of claim 1, wherein the base defines a foot pivot axis, wherein the hydraulic cylinder defines a hydraulic cylinder axis between the first pivot point and the third pivot point, wherein a moment arm distance between the hydraulic cylinder axis and the foot pivot axis is greater than 25 millimeters (mm).

11. The ankle-foot prosthesis of claim 1, wherein the spring is arranged to be compressed by hydraulic fluid of the hydraulic cylinder during plantarflexion.

12. The ankle-foot prosthesis of claim 1, wherein piston displacement of the spring is different than piston displacement of the hydraulic cylinder.

13. The ankle-foot prosthesis of claim 1, further comprising a dorsiflexion stop, wherein the dorsiflexion stop is engaged at a standing ankle position.
14. The ankle-foot prosthesis of claim 1, wherein the hydraulic cylinder comprises a first piston assembly, and wherein the spring is positioned inside the first piston assembly.
15. The ankle-foot prosthesis of claim 14, wherein the first piston assembly includes a first piston and first piston shaft, wherein the spring is positioned at least partly inside the first piston shaft.
16. The ankle-foot prosthesis of claim 2, wherein while the foot spring or foot spring assembly is subject to a ground reaction force and the ankle assembly rotates in a dorsiflexion direction, the spring is configured to release sufficient energy to equal or exceed energy loss from the dorsiflexion damping resistance.
17. The ankle-foot prosthesis of claim 16, wherein the prosthetic adapter, the hydraulic cylinder, and the base define a force triangle that defines an axis of rotation of the foot spring or foot spring assembly about the prosthetic adapter, wherein the spring creates a dorsiflexion biasing moment about the axis of rotation.
18. The ankle-foot prosthesis of claim 17, wherein the dorsiflexion biasing moment from the spring is always at least 3 Nm.
19. The ankle-foot prosthesis of claim 18, wherein the spring comprises a gas cavity containing one or more gases at a minimum pressure of 200-1000 psi.
20. The ankle-foot prosthesis of claim 19, wherein the dorsiflexion biasing moment from the spring at a standing position is 0.05-0.20 Nm/kg body weight.
21. The ankle-foot prosthesis of claim 20, wherein the dorsiflexion biasing moment at 12° of plantarflexion is 0.15-0.28 Nm/kg body weight.

22. The ankle-foot prosthesis of claim 21, wherein the prosthetic adapter, the hydraulic cylinder, and the base define a force triangle that defines an axis of rotation of the spring assembly and base about the prosthetic adapter, wherein the axis of rotation is positioned below and in line with a center of mass of a user when the user is in a standing position.

23. The ankle-foot prosthesis of claim 22, wherein the base defines a foot pivot axis, wherein the hydraulic cylinder defines a hydraulic cylinder axis between the first pivot point and the third pivot point, wherein a moment arm distance between the hydraulic cylinder axis and the foot pivot axis is greater than 25 millimeters (mm).

24. The ankle-foot prosthesis of claim 23, wherein the spring is arranged to be compressed by hydraulic fluid of the hydraulic cylinder during plantarflexion.

25. The ankle-foot prosthesis of claim 24, wherein piston displacement of the spring is different than piston displacement of the hydraulic cylinder.

26. The ankle-foot prosthesis of claim 25, further comprising a dorsiflexion stop, wherein the dorsiflexion stop is engaged at a standing ankle position.

27. The ankle-foot prosthesis of claim 26, wherein the hydraulic cylinder comprises a first piston assembly, and wherein the spring is positioned inside the first piston assembly.

28. The ankle-foot prosthesis of claim 27, wherein the first piston assembly includes a first piston and first piston shaft, wherein the spring is positioned at least partly inside the first piston shaft.

29. The ankle-foot prosthesis of claim 14, wherein the first piston assembly includes a first piston and first piston shaft, wherein the spring is positioned at least partly inside the first piston shaft.

30. The ankle-foot prosthesis of claim 29, further comprising a dorsiflexion stop, wherein the dorsiflexion stop is engaged at a standing ankle position.

31. The ankle-foot prosthesis of claim 30, wherein piston displacement of the spring is different than piston displacement of the hydraulic cylinder.

32. The ankle-foot prosthesis of claim 31, wherein the spring is arranged to be compressed by hydraulic fluid of the hydraulic cylinder during plantarflexion.

33. The ankle-foot prosthesis of claim 32, wherein the base defines a foot pivot axis, wherein the hydraulic cylinder defines a hydraulic cylinder axis between the first pivot point and the third pivot point, wherein a moment arm distance between the hydraulic cylinder axis and the foot pivot axis is greater than 25 millimeters (mm).

34. The ankle-foot prosthesis of claim 33, wherein the prosthetic adapter, the hydraulic cylinder, and the base define a force triangle that defines an axis of rotation of the spring assembly and base about the prosthetic adapter, wherein the axis of rotation is positioned below and in line with a center of mass of a user when the user is in a standing position.

35. The ankle-foot prosthesis of claim 34, wherein the dorsiflexion biasing moment at 12° of plantarflexion is 0.15-0.28 Nm/kg body weight.

36. The ankle-foot prosthesis of claim 35, wherein the dorsiflexion biasing moment from the spring at a standing position is 0.05-0.20 Nm/kg body weight.

37. The ankle-foot prosthesis of claim 36, wherein the spring comprises a gas cavity containing one or more gases at a minimum pressure of 200-1000 psi.

38. The ankle-foot prosthesis of claim 37, wherein the prosthetic adapter, the hydraulic cylinder, and the base define a force triangle that defines an axis of rotation of the foot spring or foot

spring assembly about the prosthetic adapter, wherein the spring creates a dorsiflexion biasing moment about the axis of rotation.

39. The ankle-foot prosthesis of claim 38, wherein the dorsiflexion biasing moment from the spring is always at least 3 Nm.

40. The ankle-foot prosthesis of claim 39, wherein while the foot spring or foot spring assembly is subject to a ground reaction force and the ankle assembly rotates in a dorsiflexion direction, the spring is configured to release sufficient energy to equal or exceed energy loss from the dorsiflexion damping resistance.

41. The ankle-foot prosthesis of claim 40, wherein the spring is configured to release sufficient energy during any dorsiflexion rotation of the ankle assembly to equal or exceed energy loss from the dorsiflexion damping resistance.

42. An assembly, comprising

a first link;

a second link which is an extendable link rotatably attached to the first link to define a first pivot point; and

a third link rotatably attached to the first link to define a second pivot point and rotatably attached to the extendable link to define a third pivot point,

wherein the extendable link comprises

a hydraulic cylinder configured to provide at least a first way of damping resistance, and

a spring arranged in parallel with the hydraulic cylinder, wherein the spring is a biasing spring.

43. The assembly of claim 42, wherein the first link is a prosthetic adapter and the third link is a base.

44. The assembly of claim 42, wherein the extendable link provides a second way damping resistance.

45. The assembly of claim 44, wherein the first way of damping resistance is resistance to flexion or extension, and wherein the second way of damping resistance is resistance to extension or flexion.

46. An extendable link for a prosthesis or orthotic, comprising
a hydraulic cylinder configured to provide damping resistance, and
a spring arranged in parallel with the hydraulic cylinder, wherein the spring is a biasing spring.

47. The extendable link of claim 46, wherein the spring is a biasing air spring, and wherein the damping resistance is resistance to flexion and/or extension.

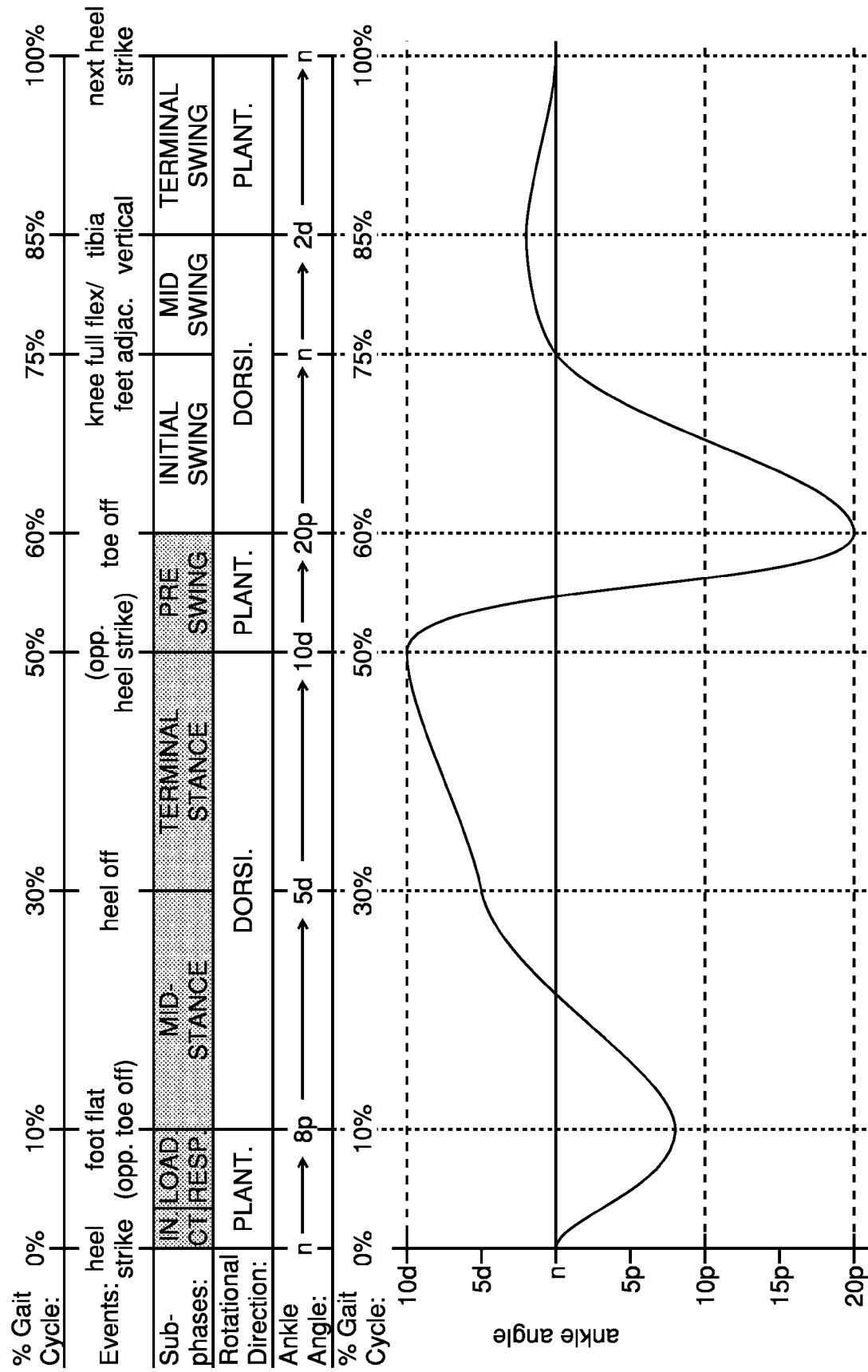


FIG. 1

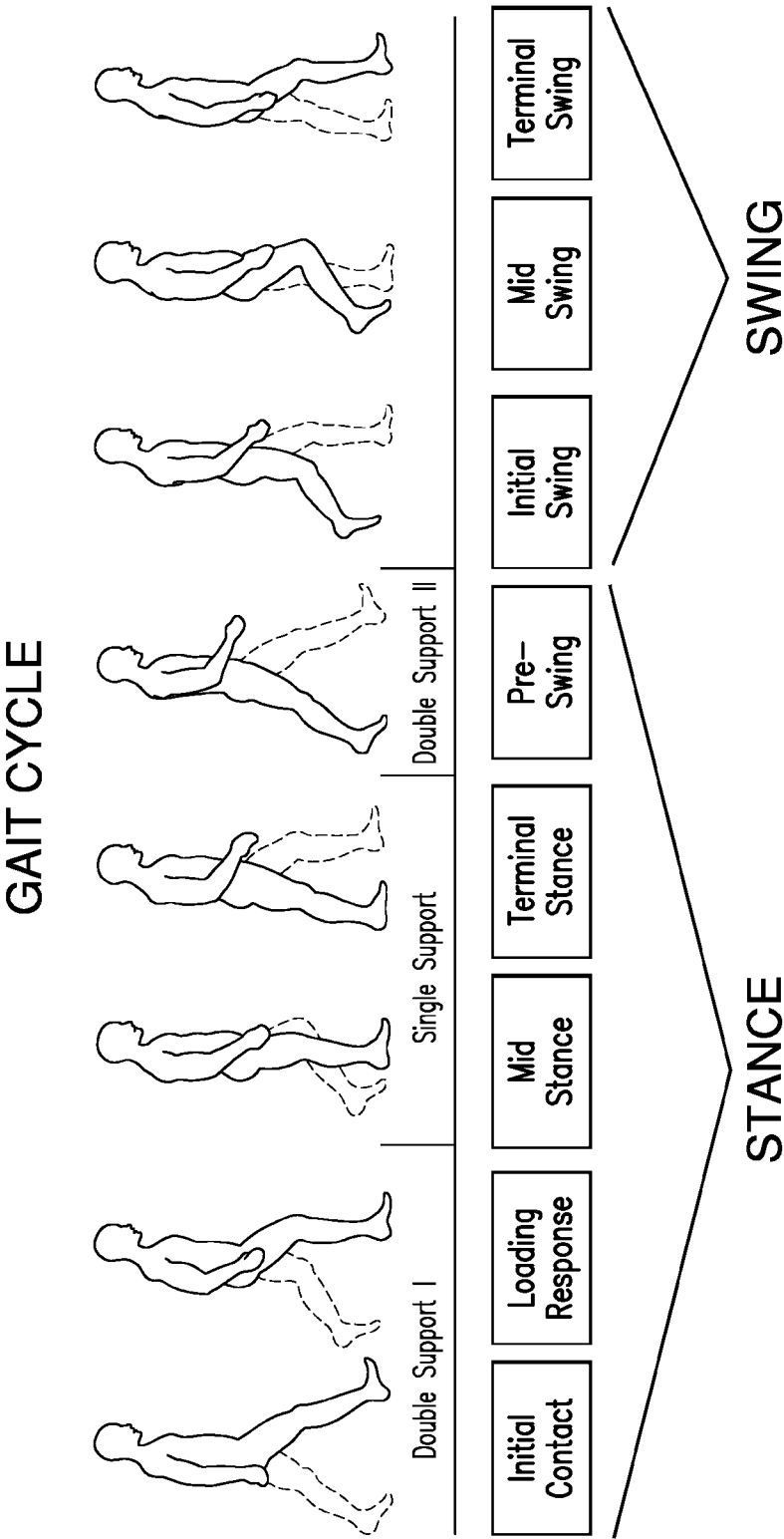


FIG. 2

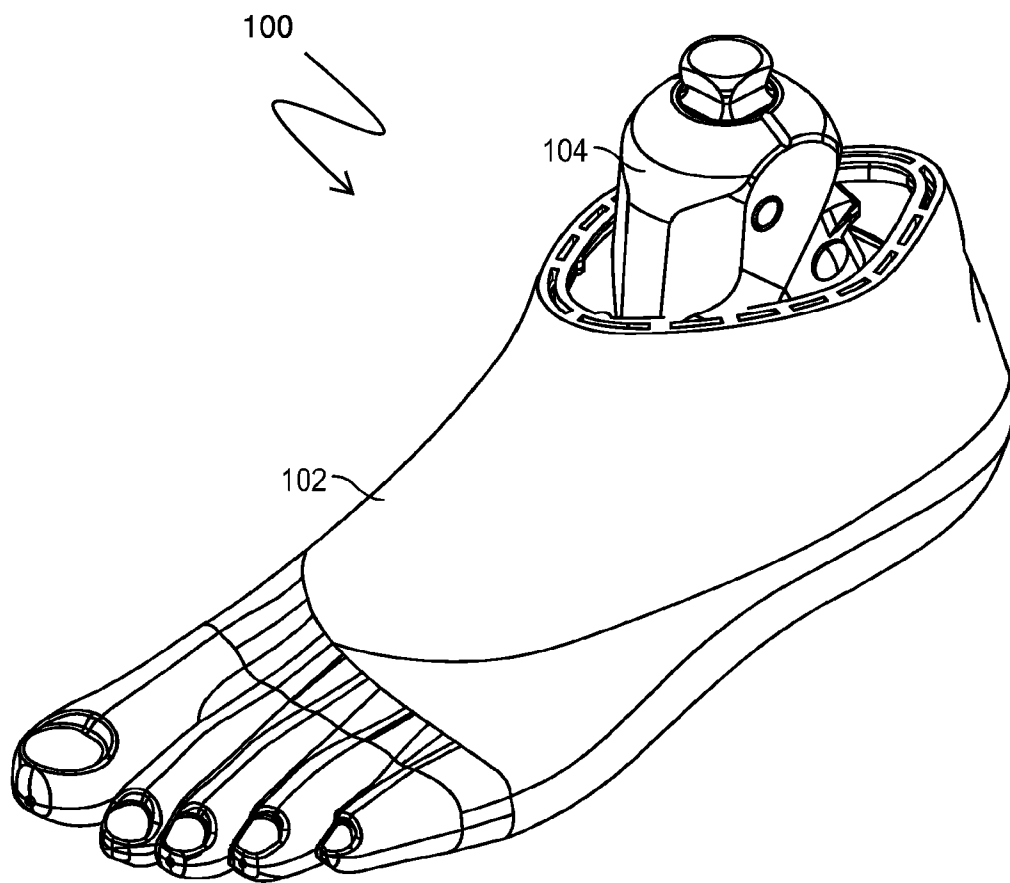


FIG. 3

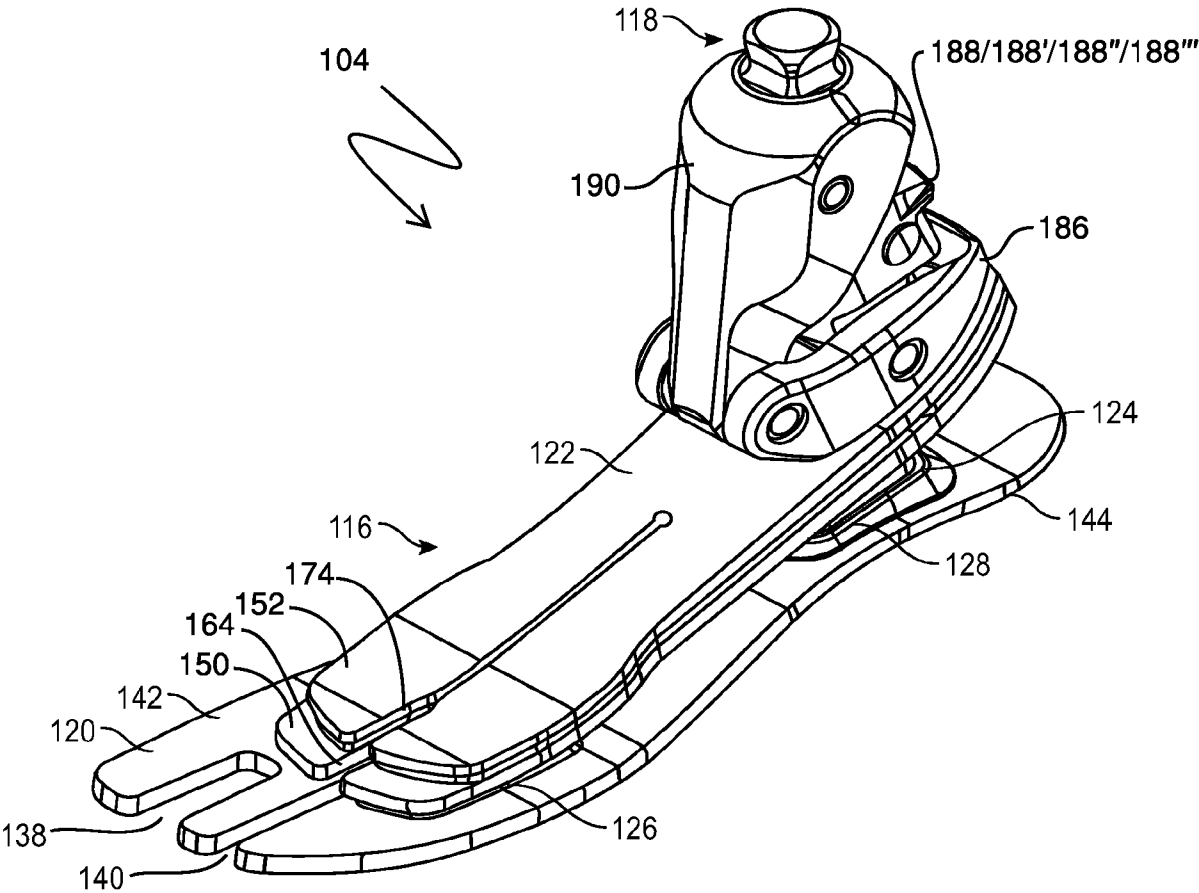
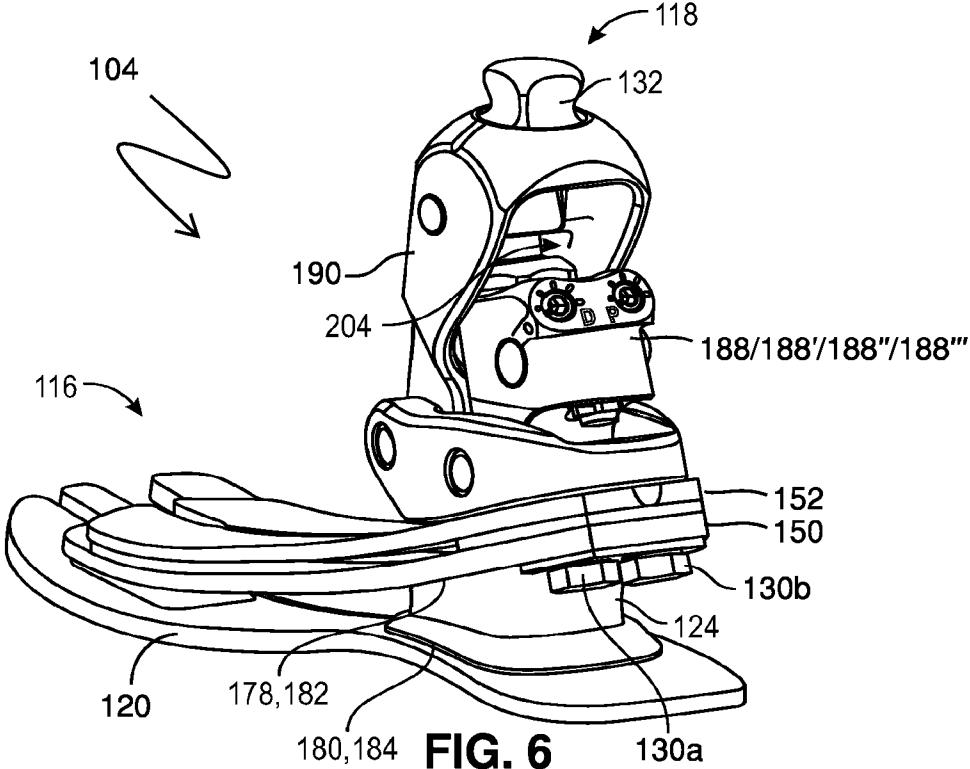
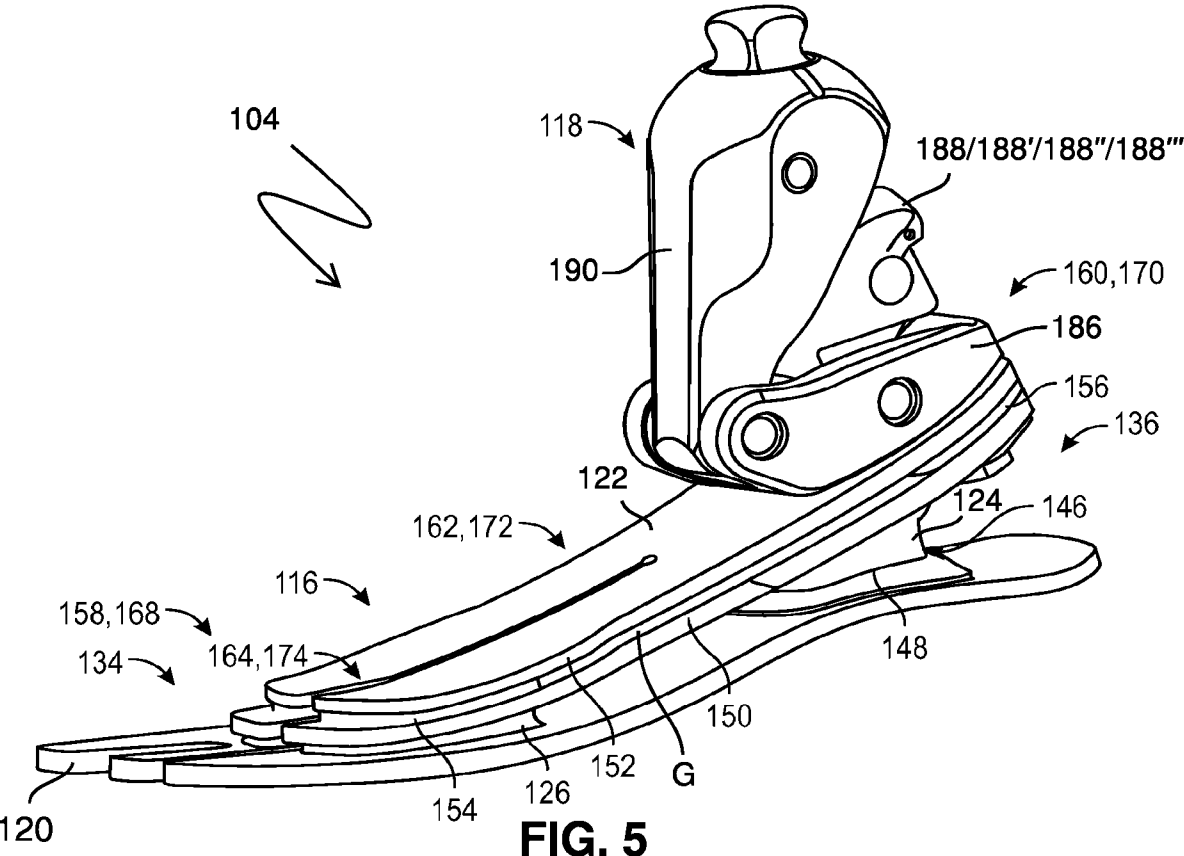


FIG. 4



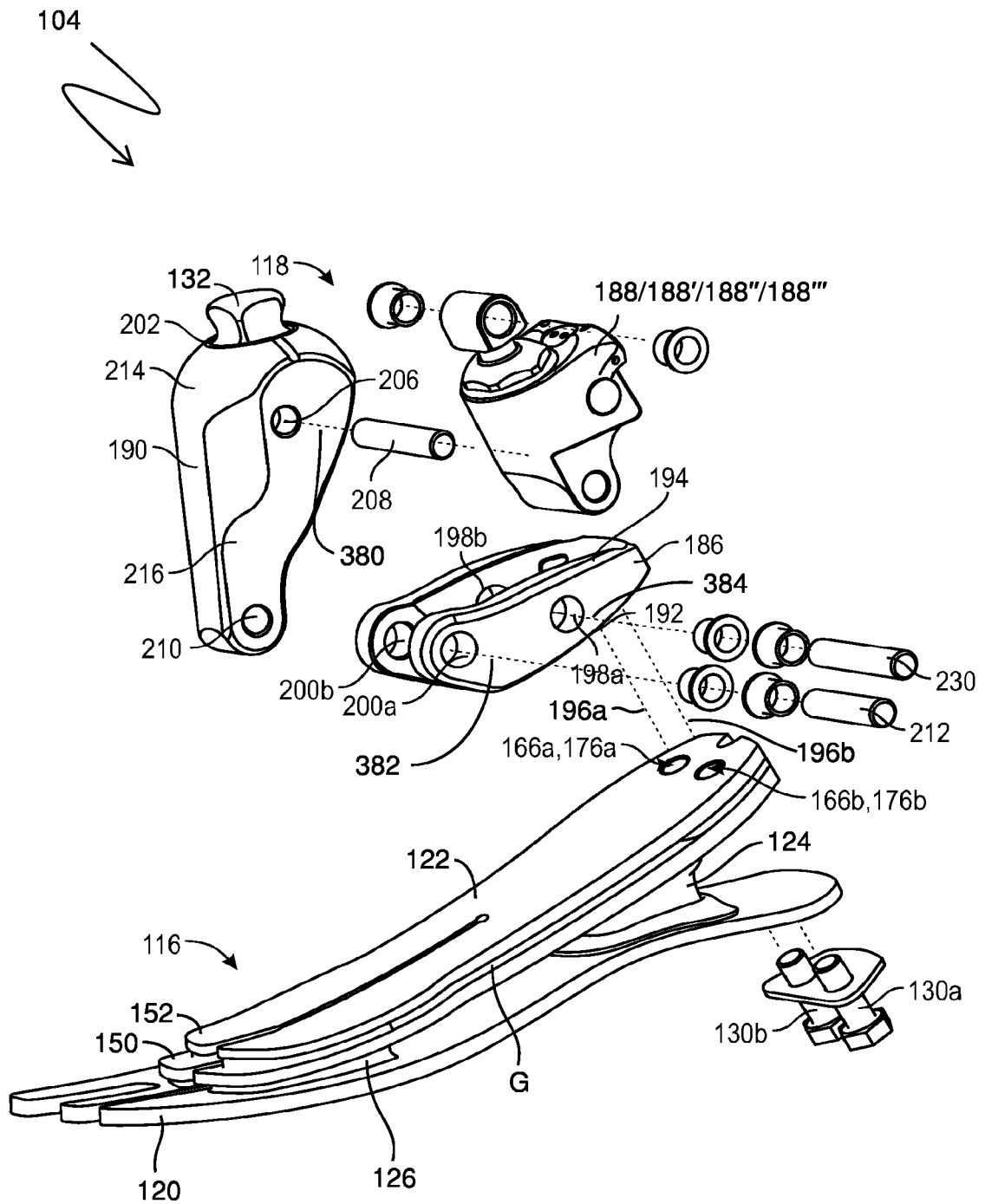


FIG. 7

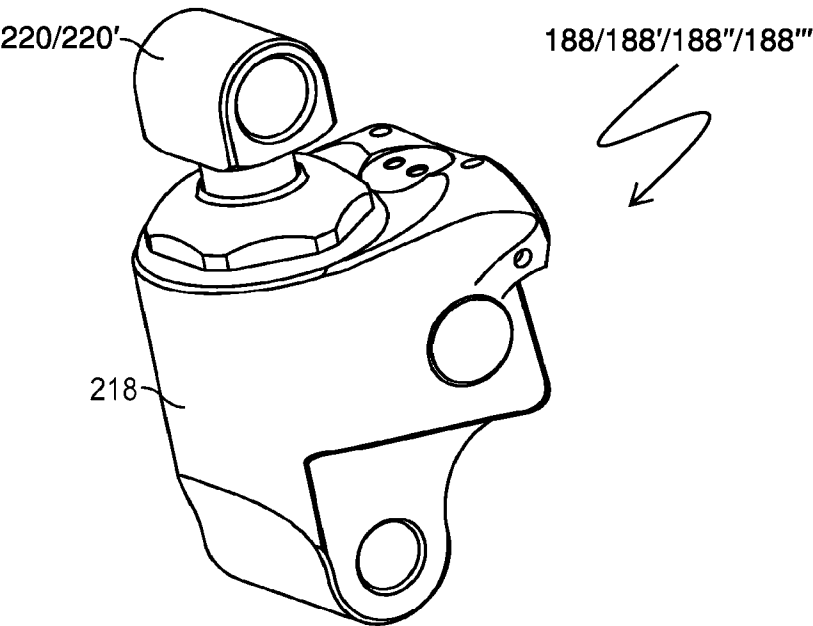


FIG. 8

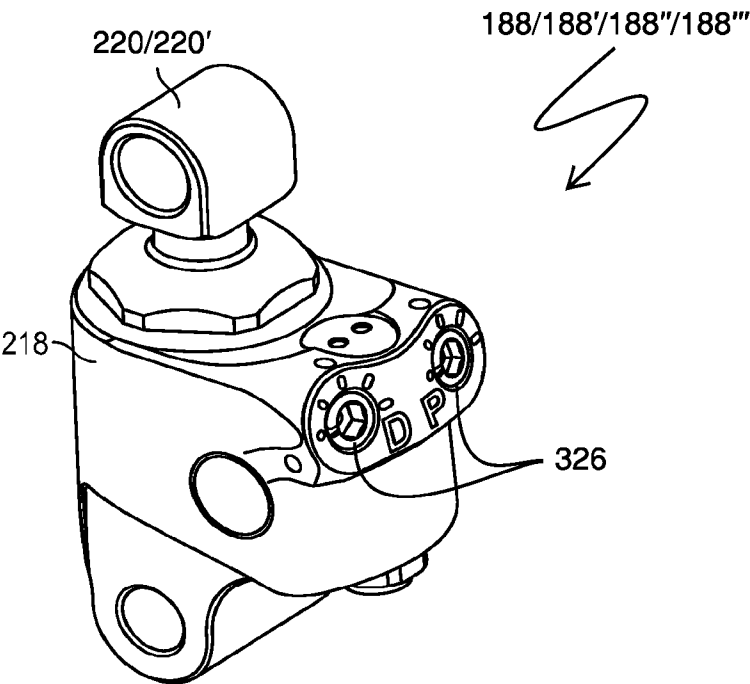


FIG. 9

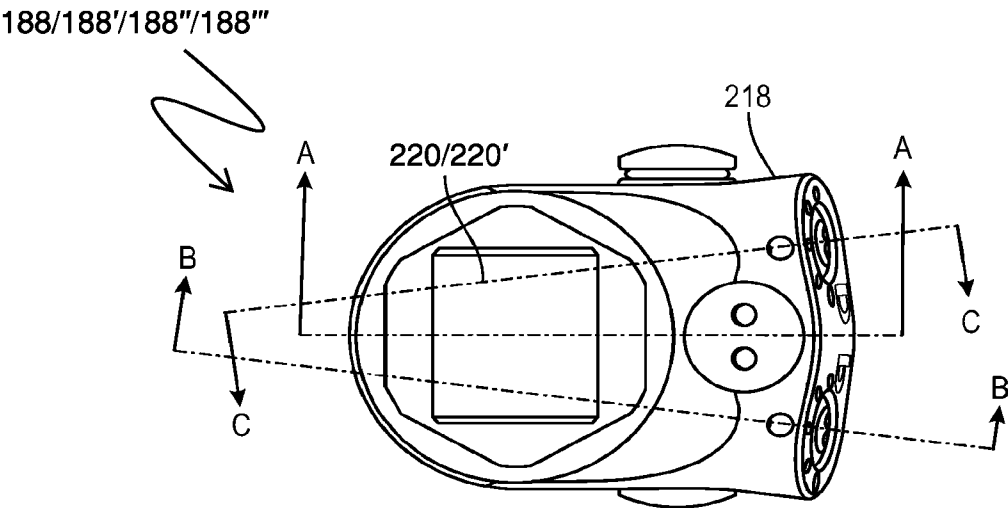


FIG. 10

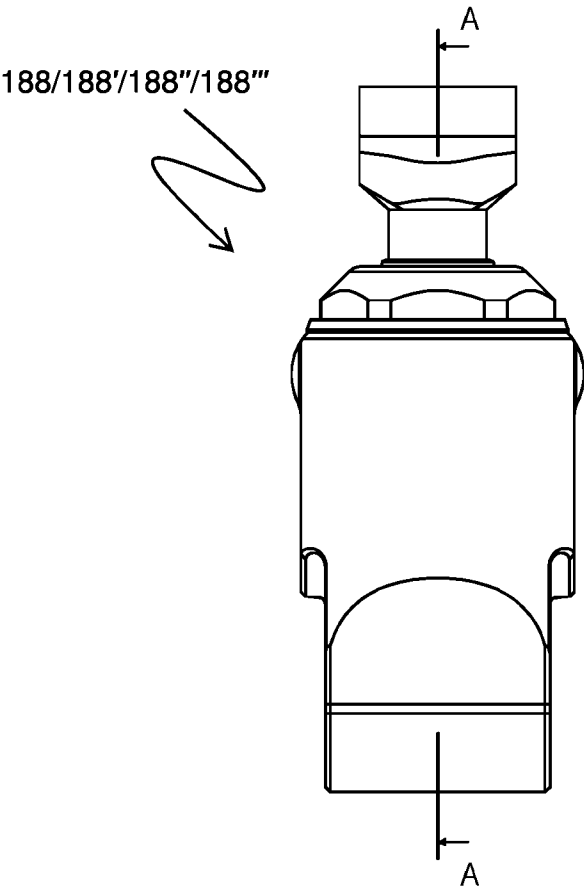


FIG. 11

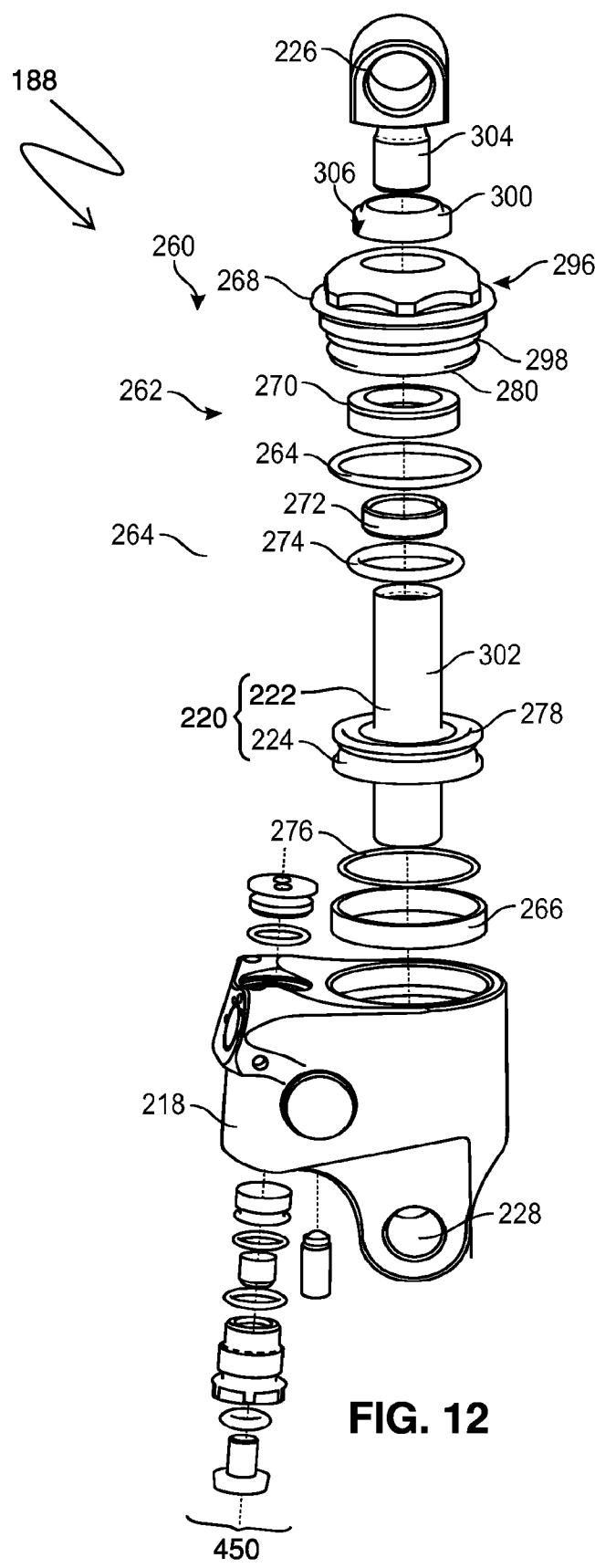


FIG. 12

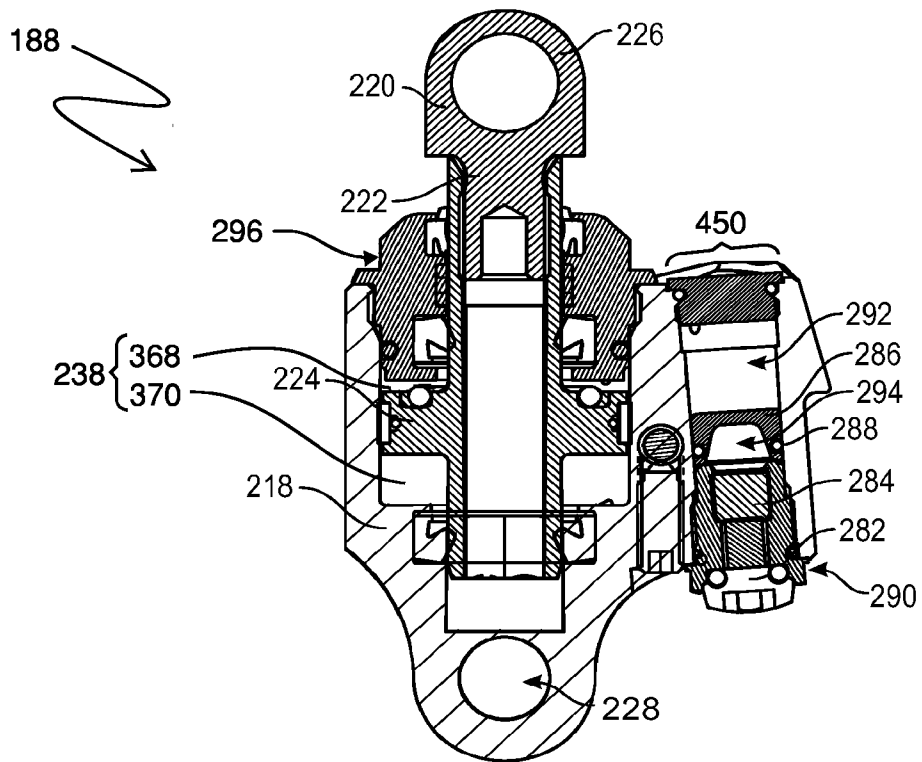


FIG. 13

11/32

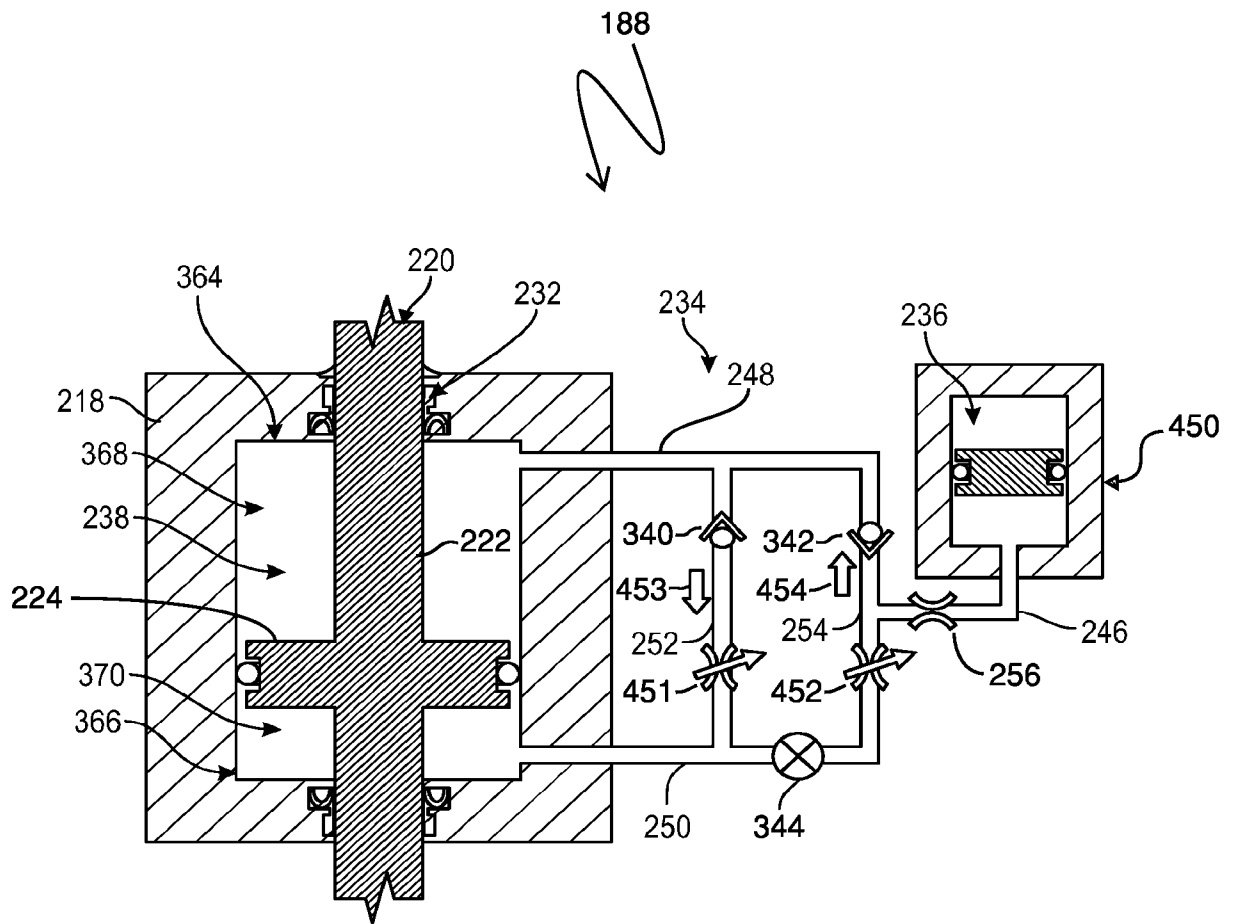


FIG. 14

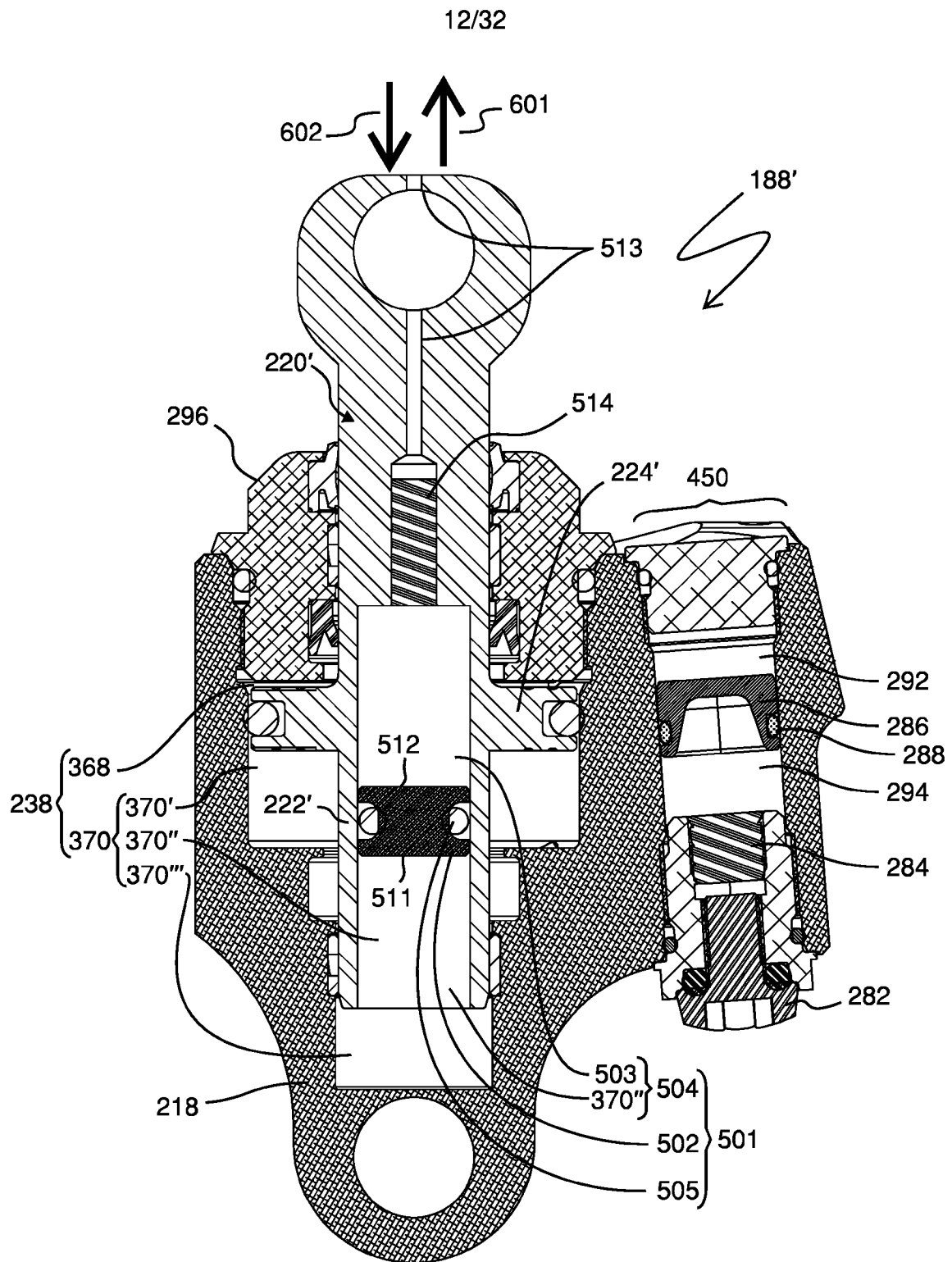


FIG. 15

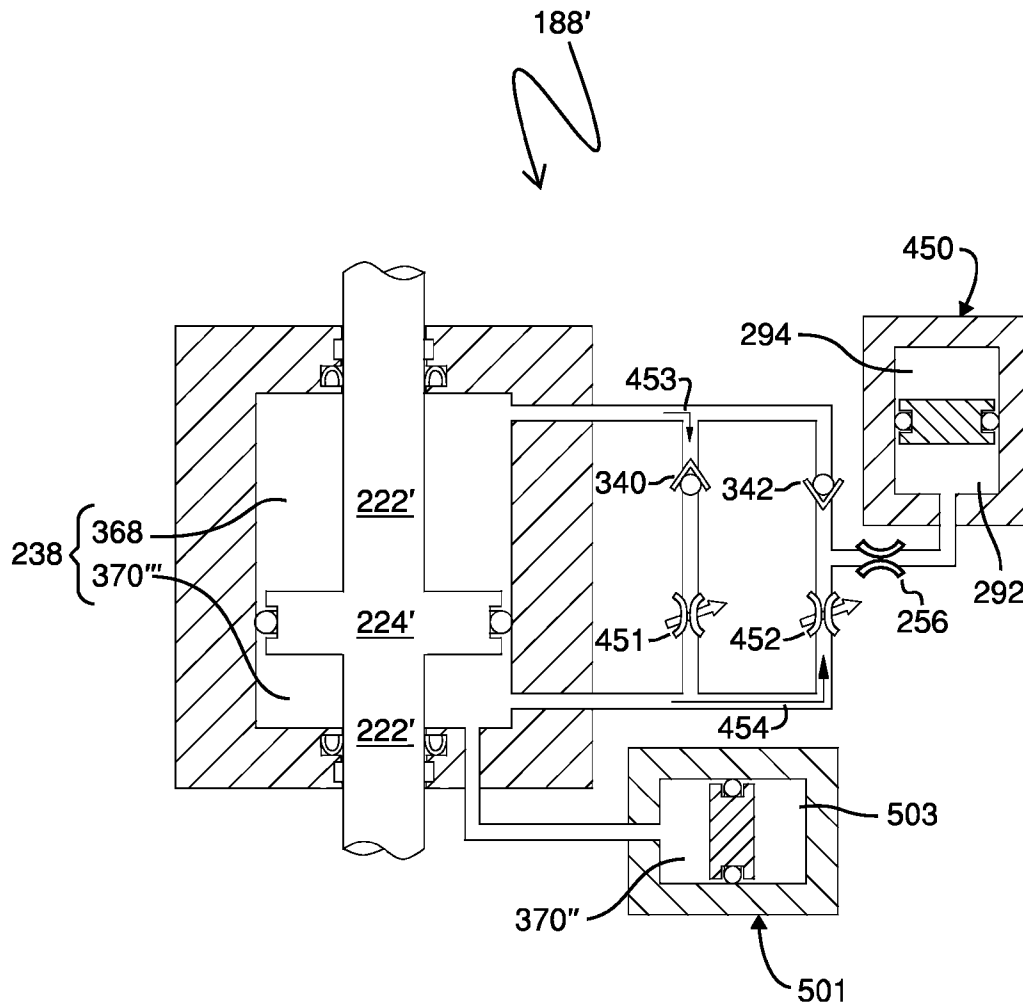


FIG. 16

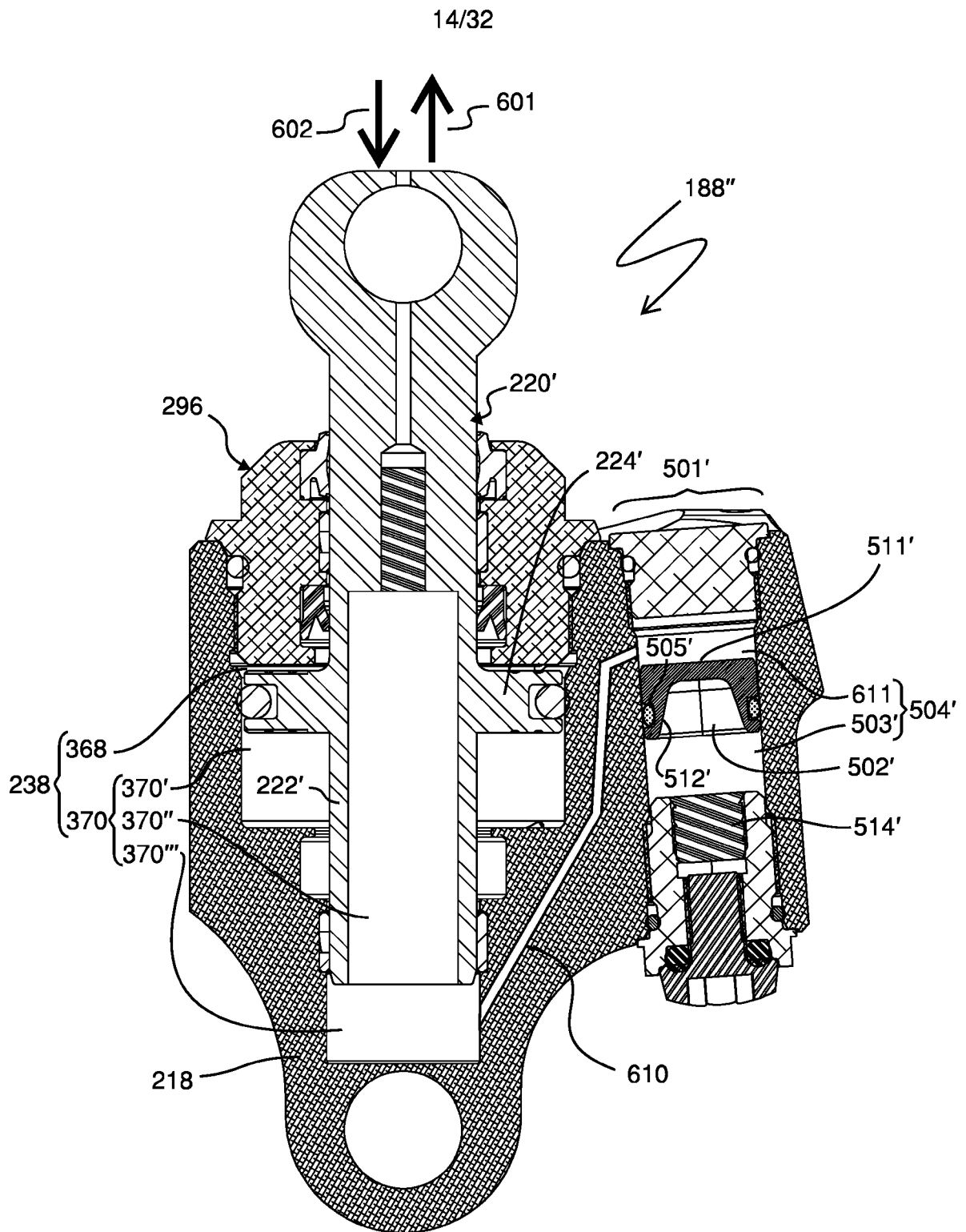


FIG. 17

15/32

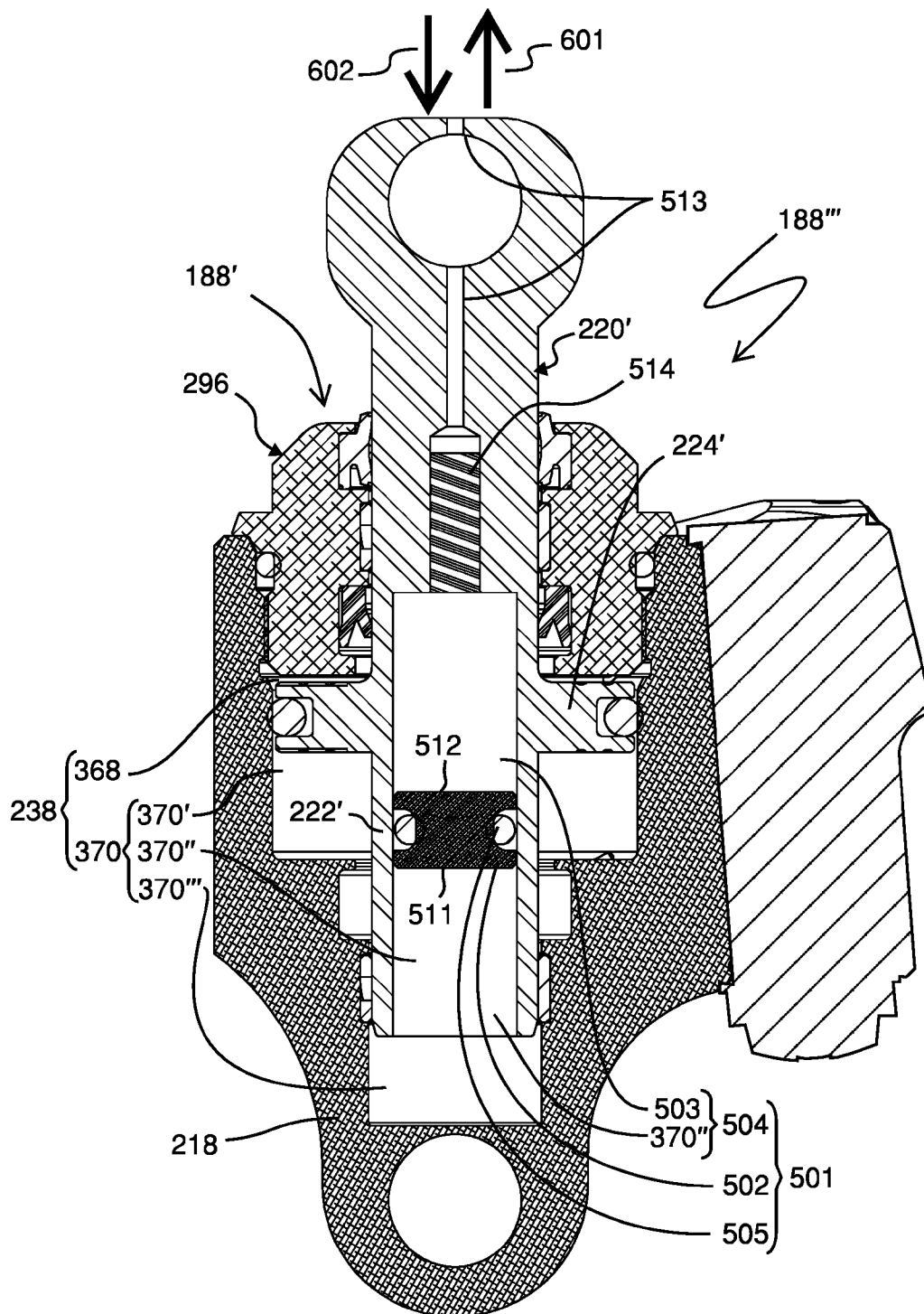


FIG. 18

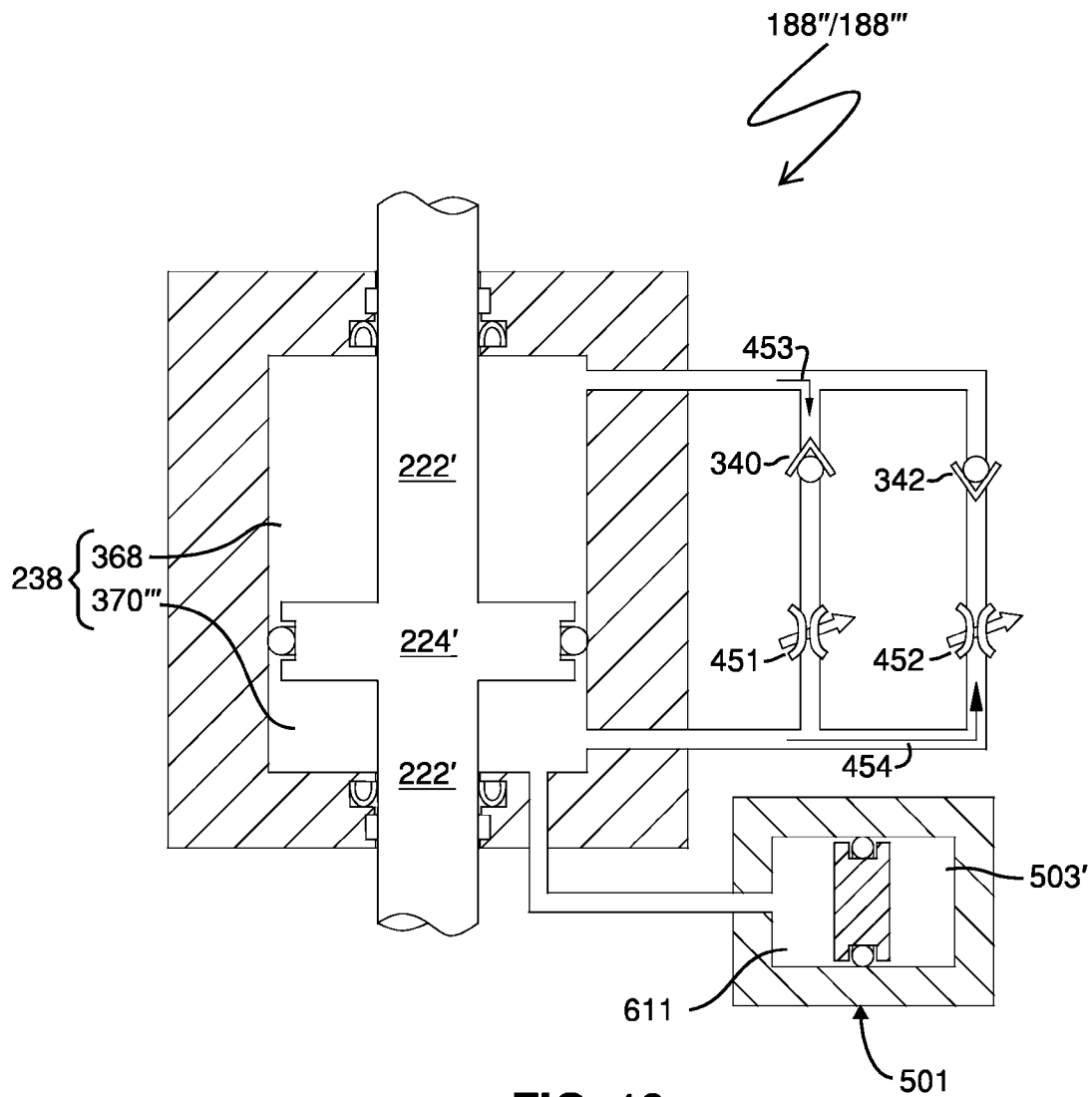


FIG. 19

17/32

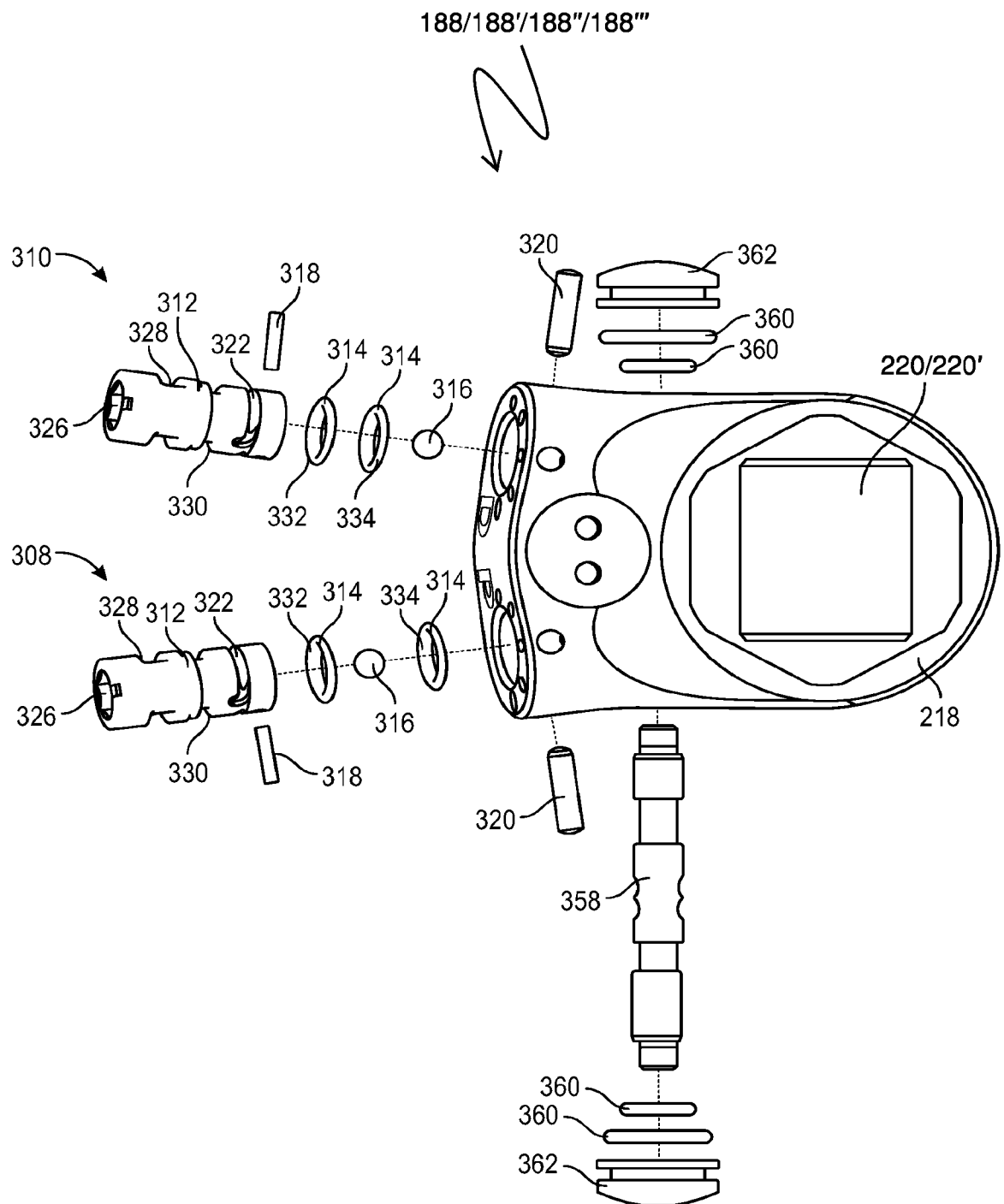


FIG. 20

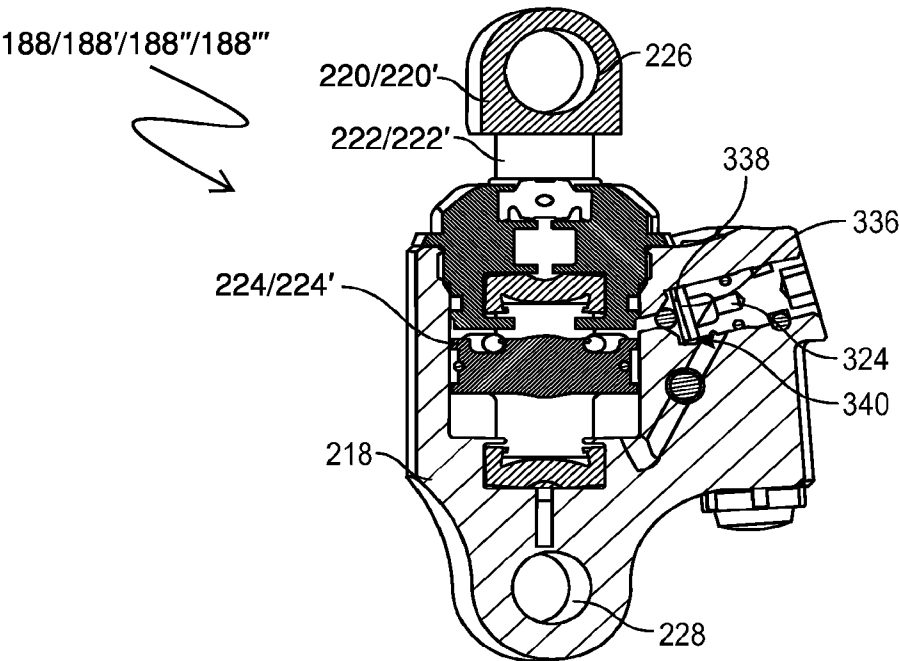


FIG. 21

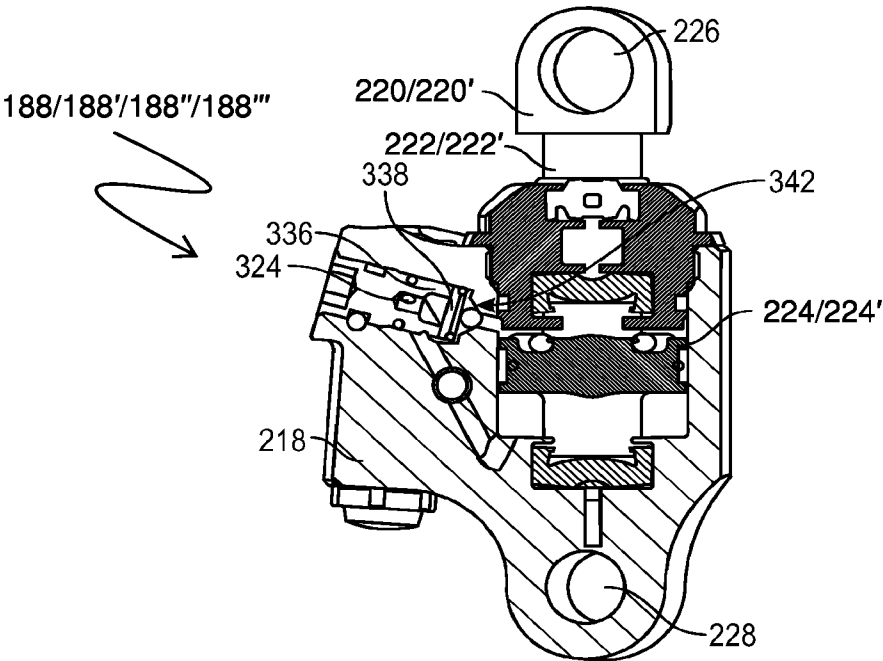


FIG. 22

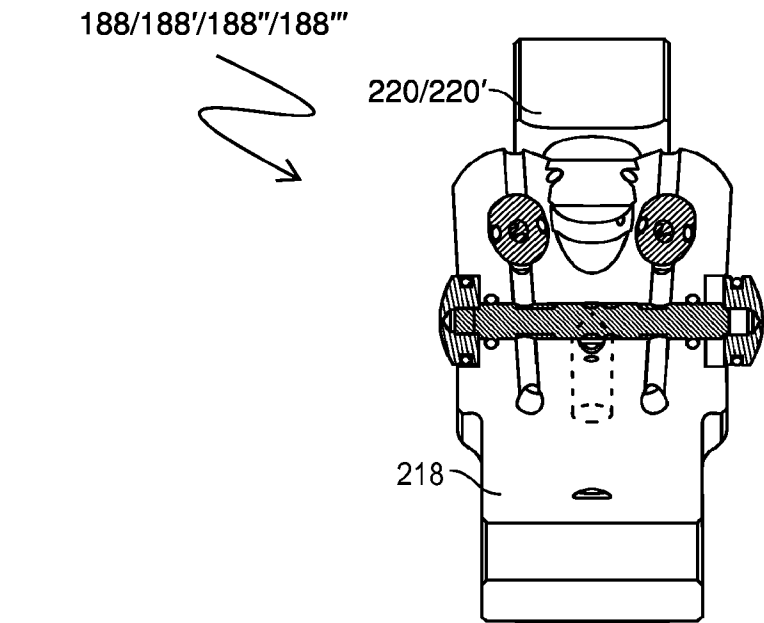


FIG. 23

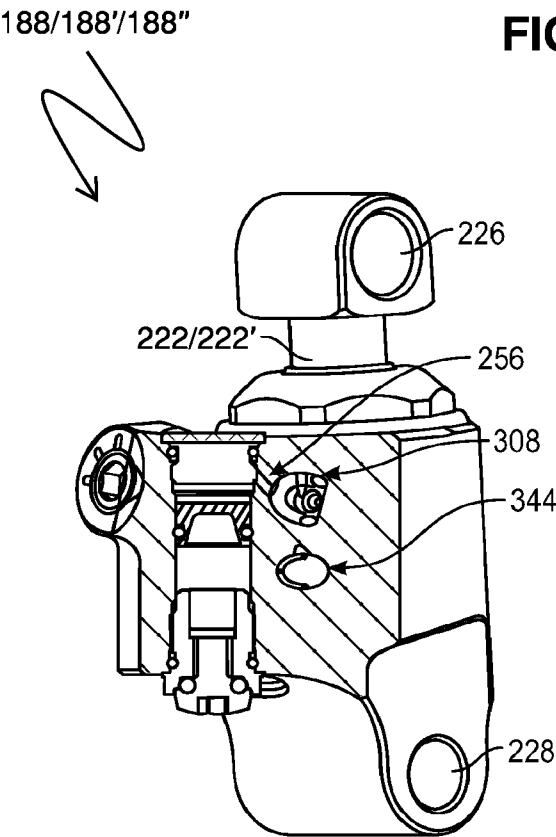


FIG. 24

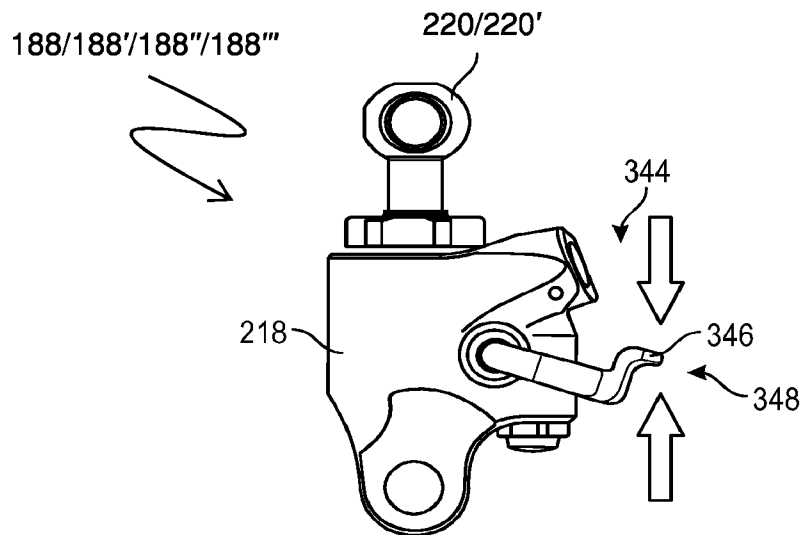


FIG. 25

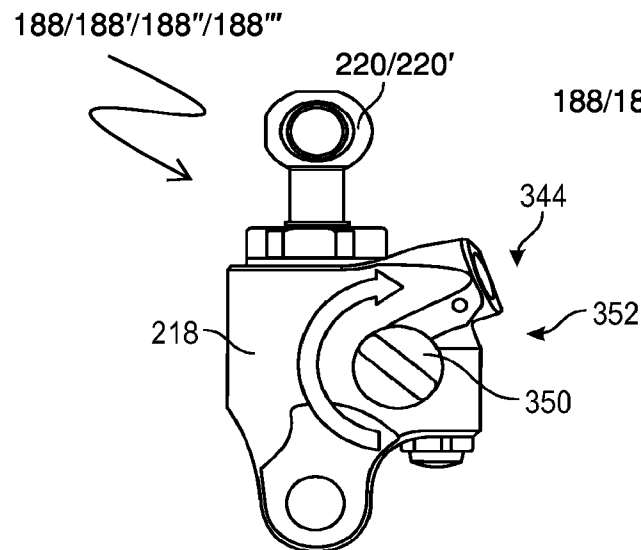


FIG. 26

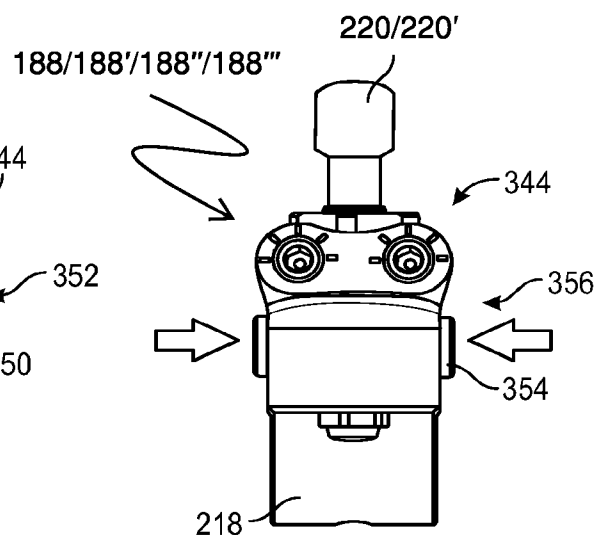


FIG. 27

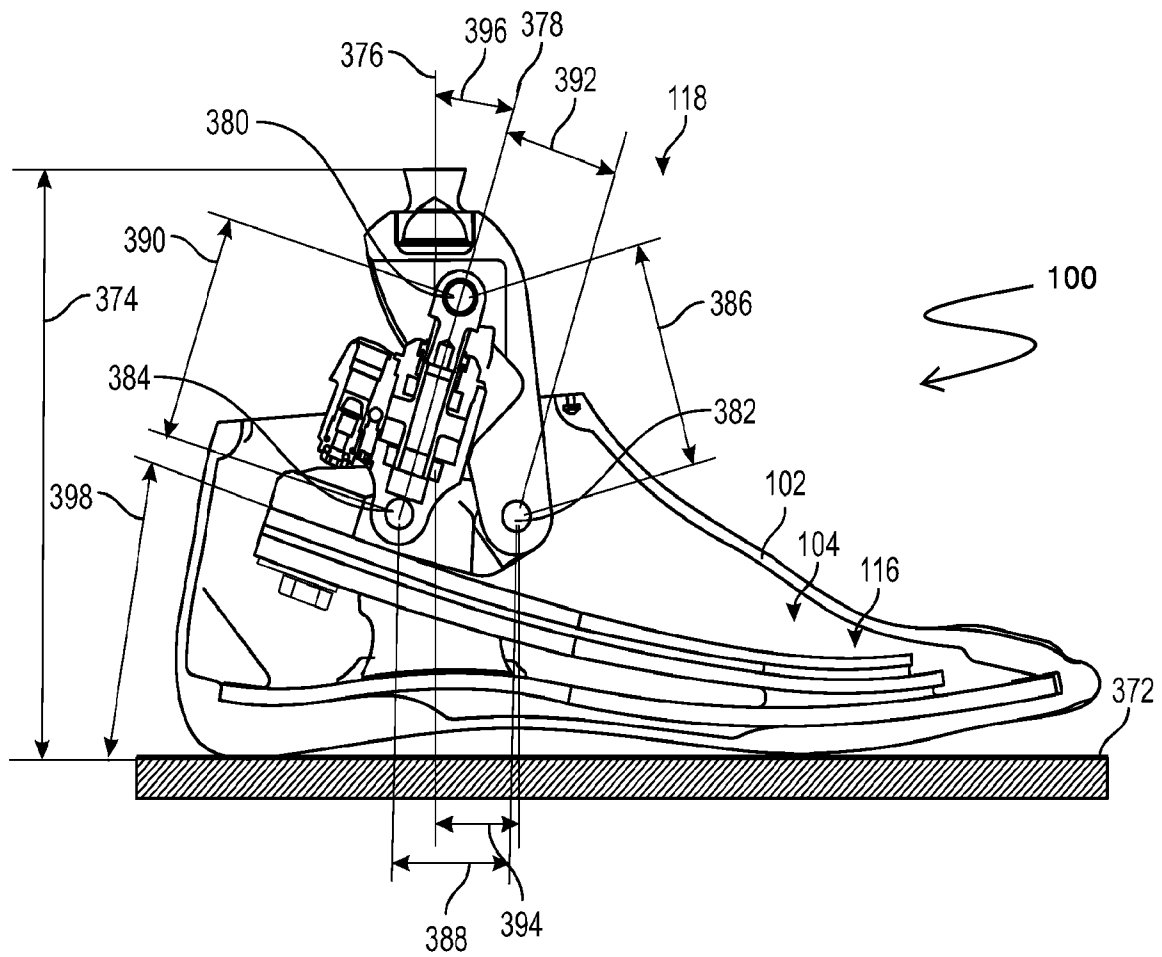


FIG. 28

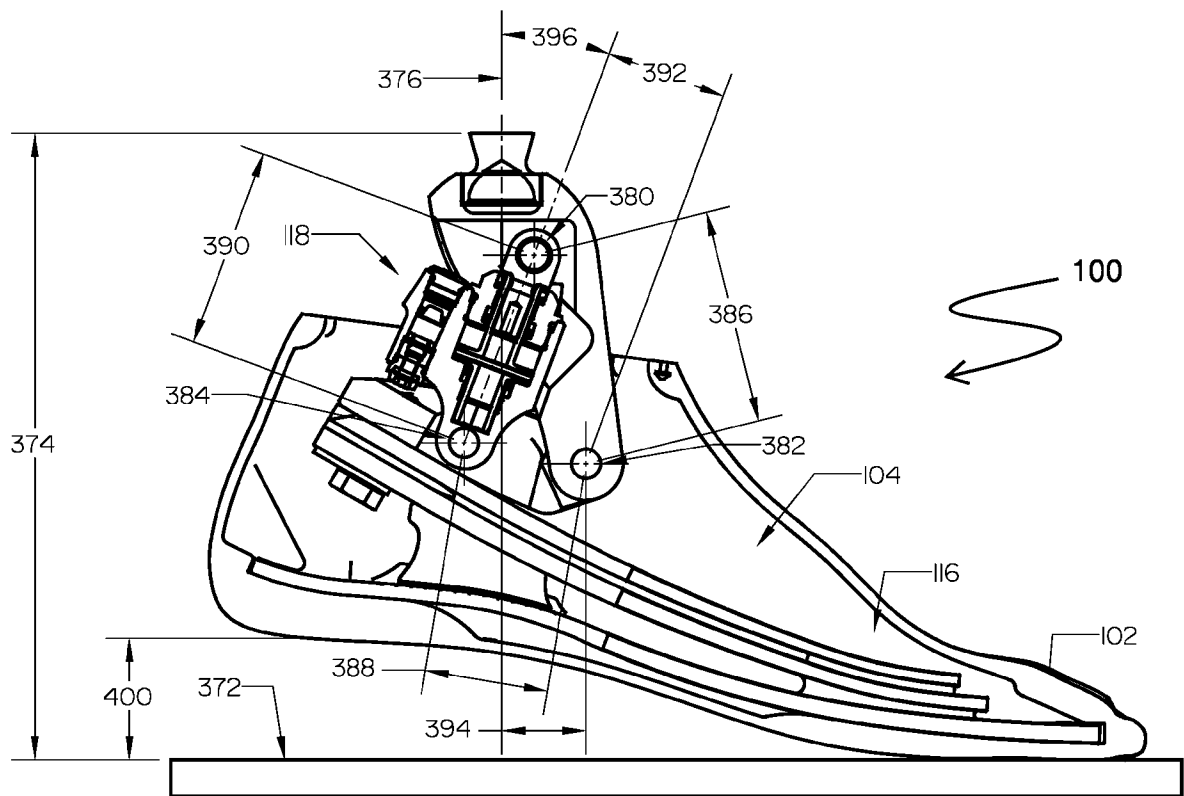


FIG. 29

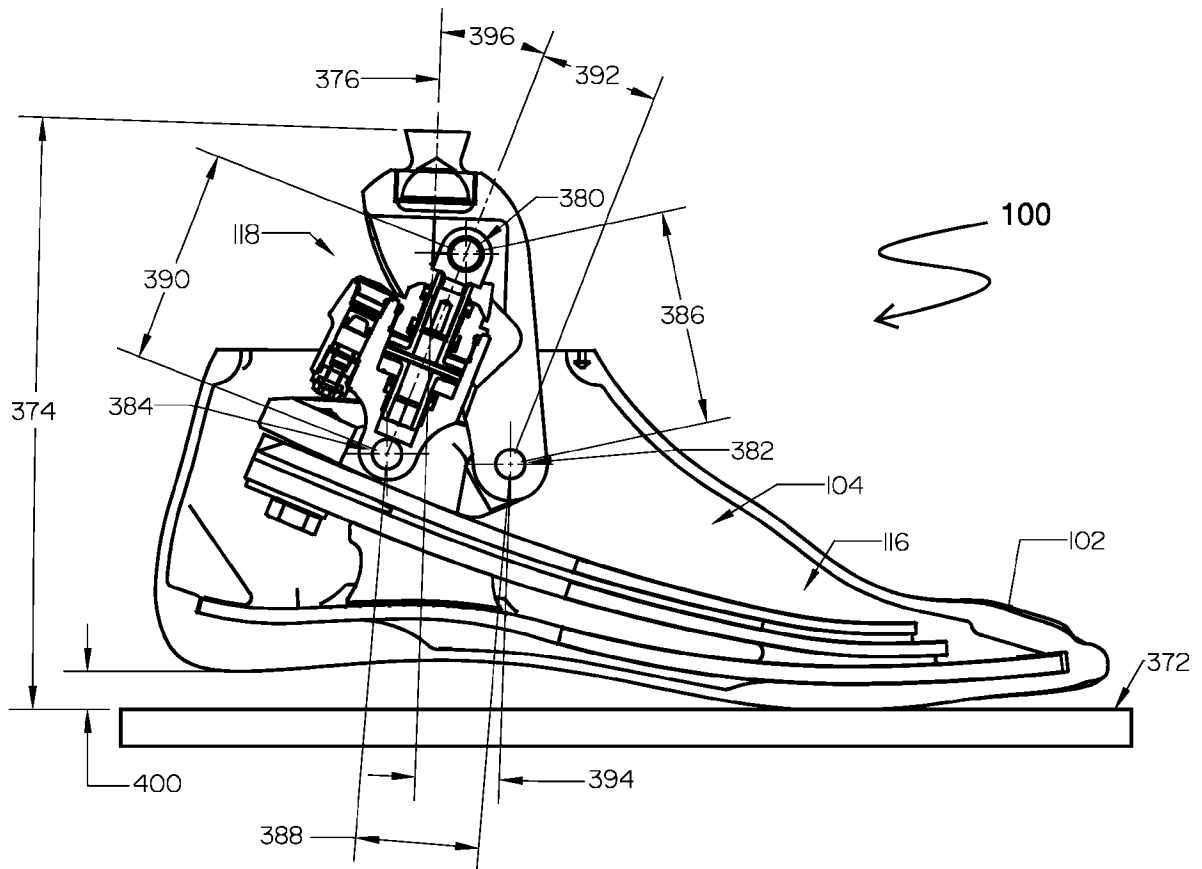


FIG. 30

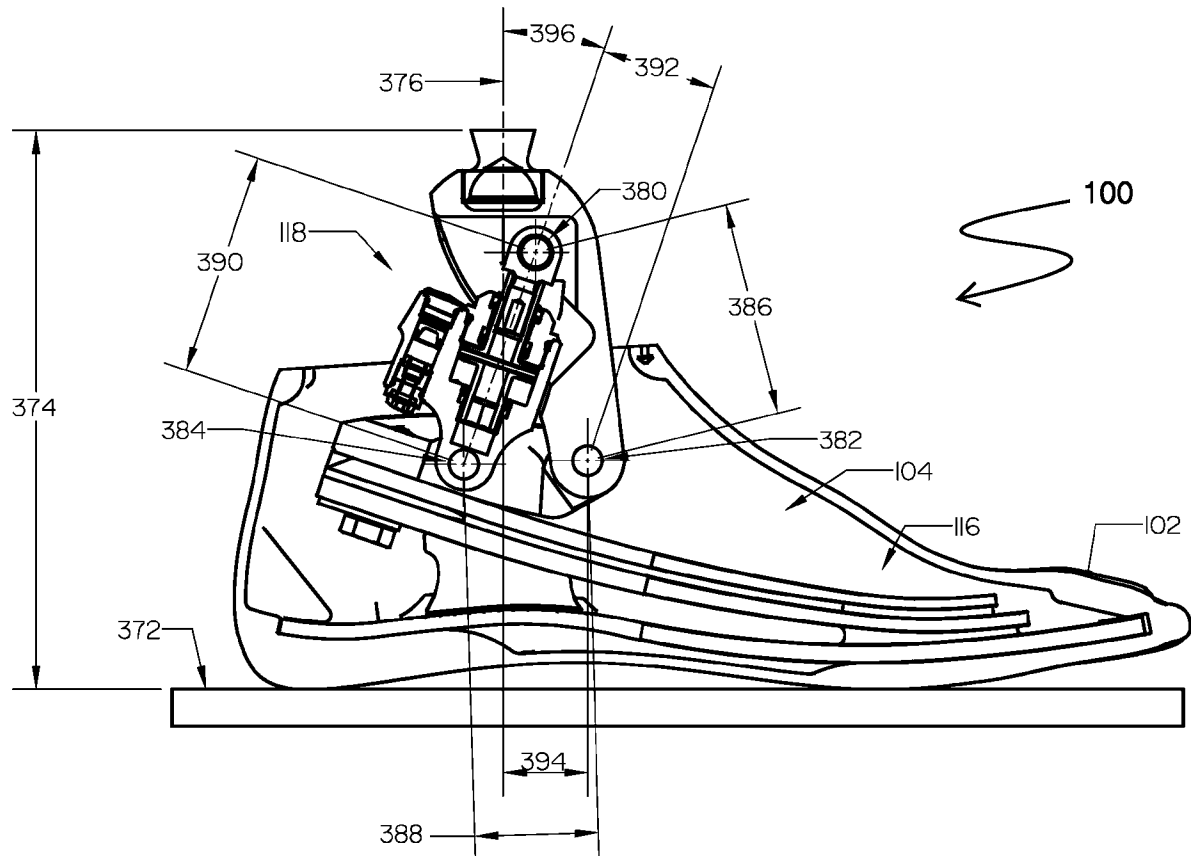


FIG. 31

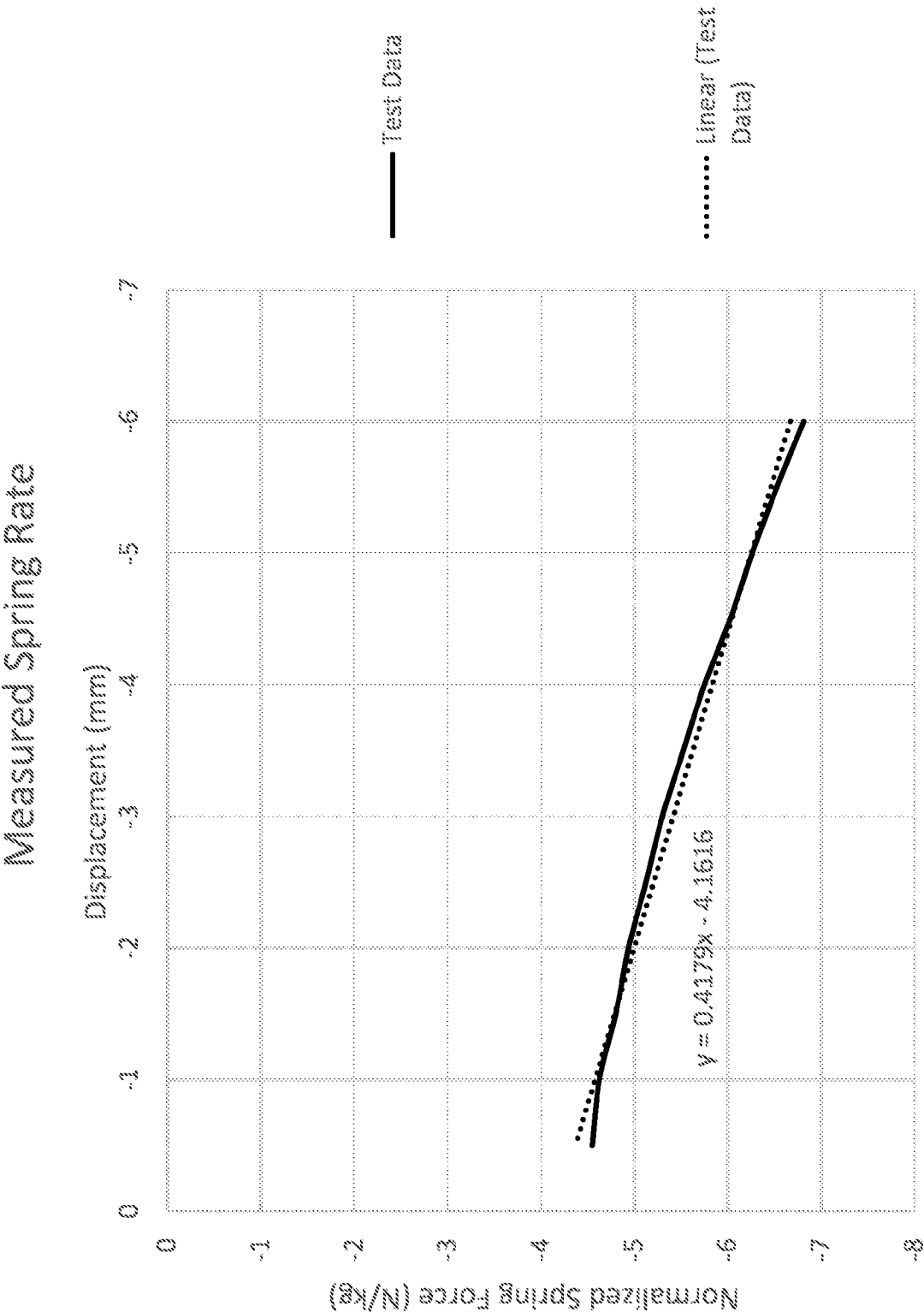


FIG. 32

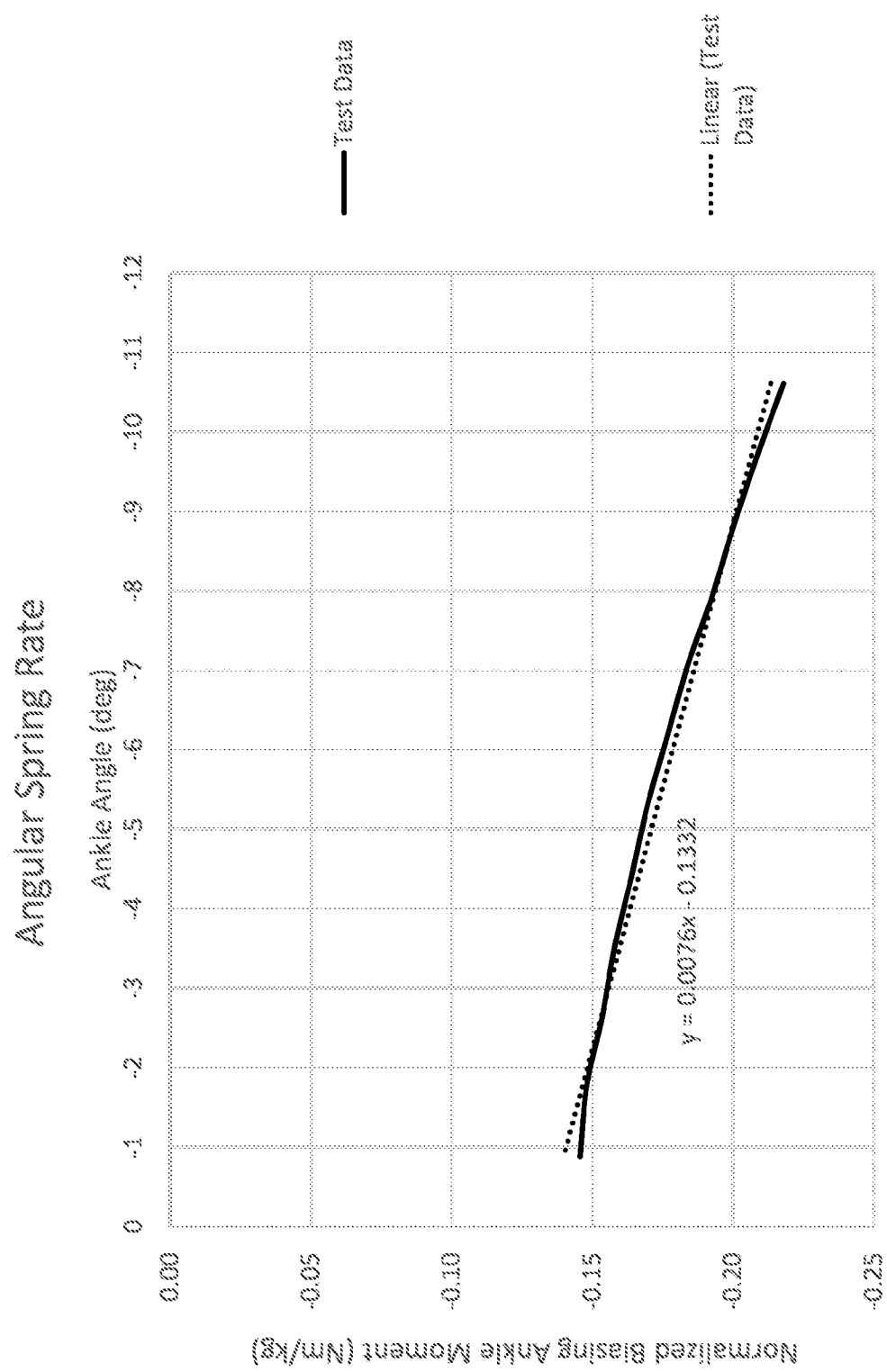


FIG. 33

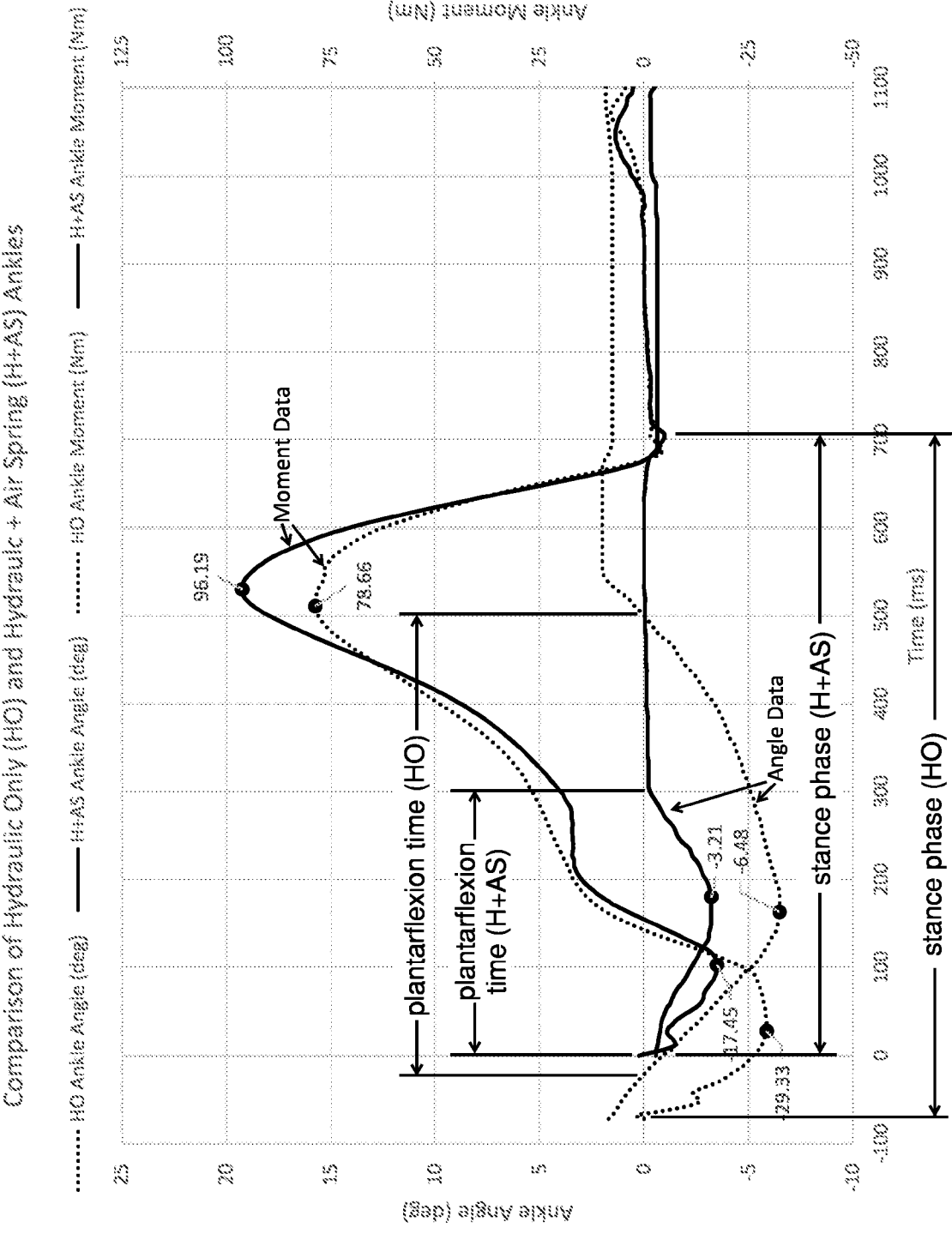
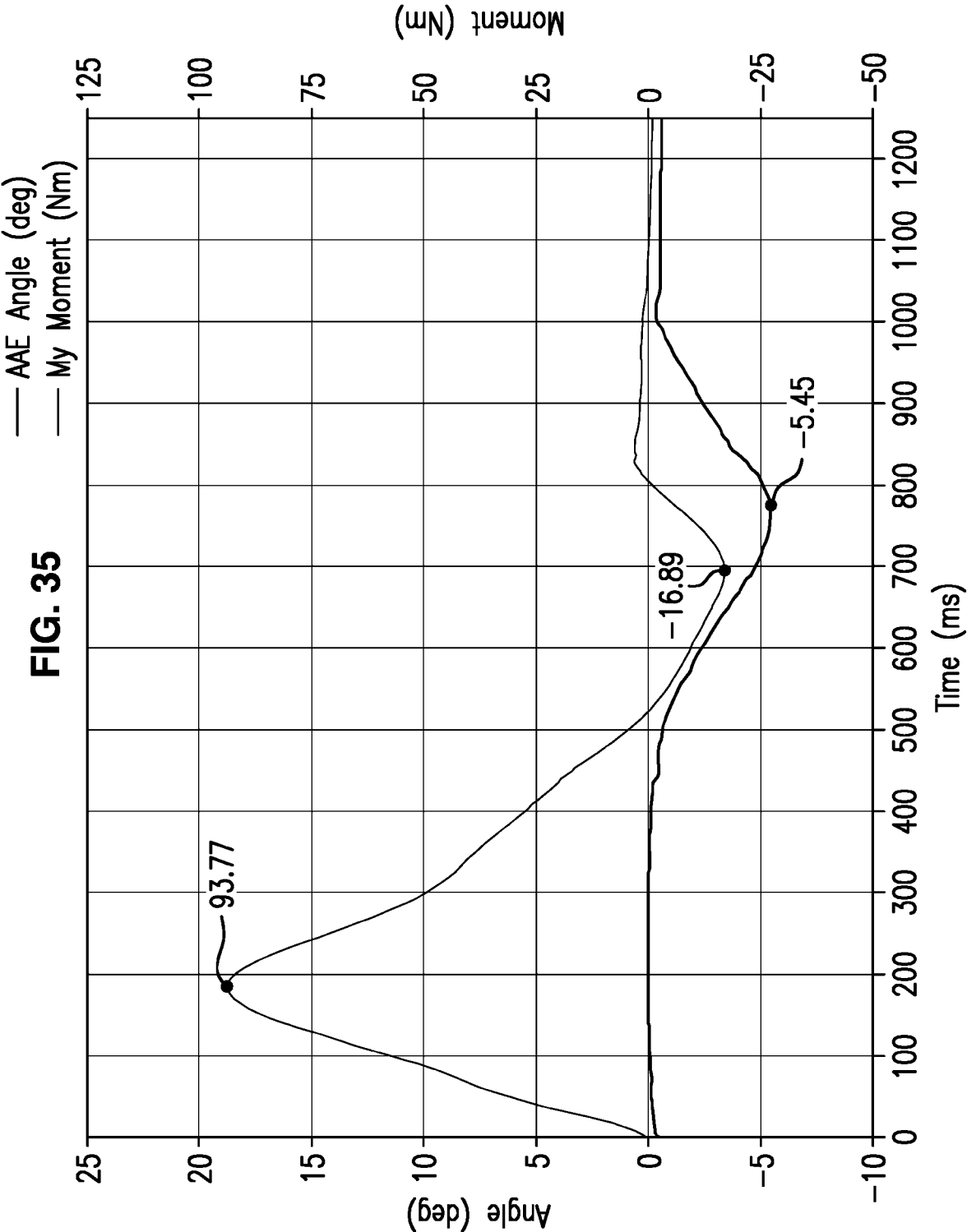


FIG. 34



29/32

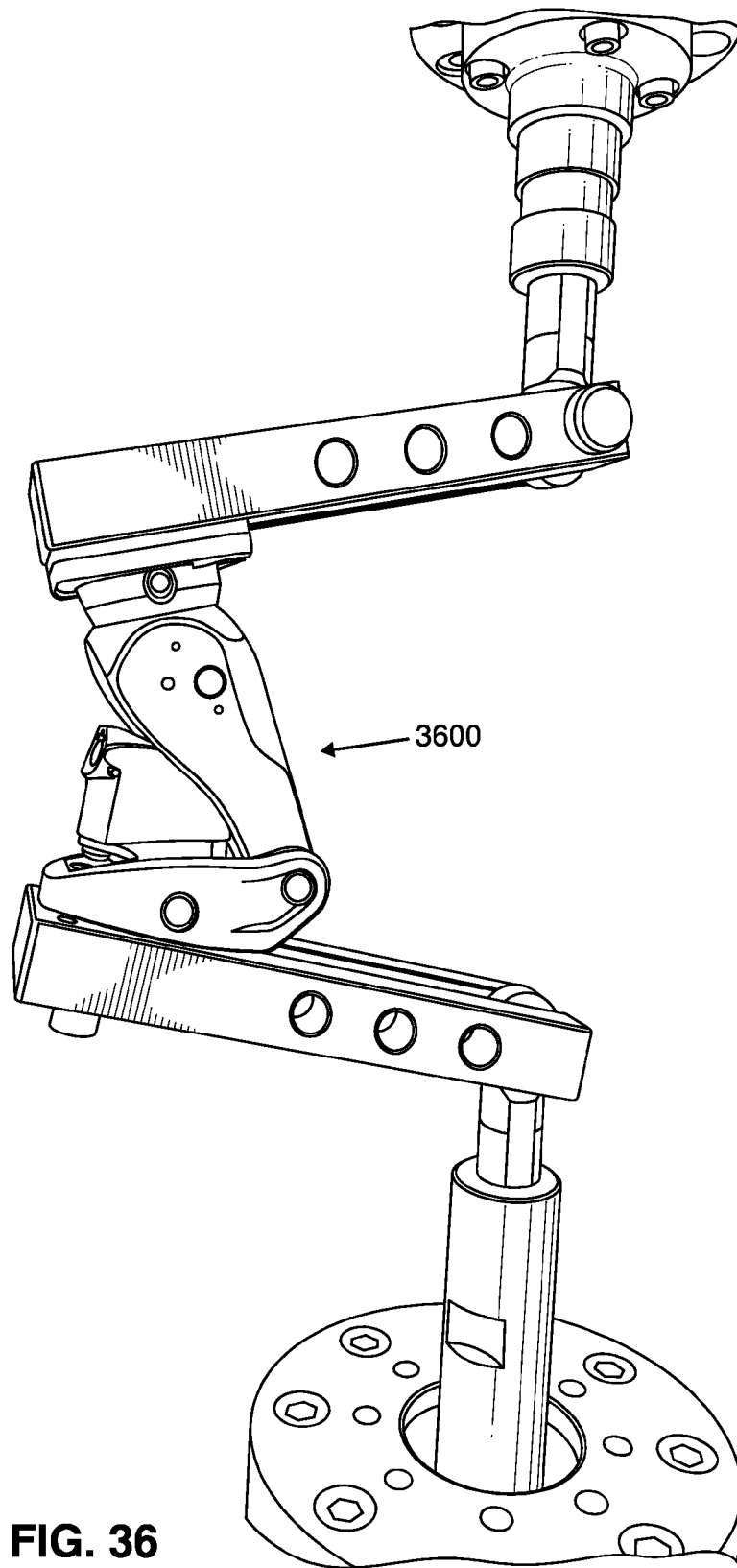


FIG. 36

HO vs H+AS Ankles in Test Fixture

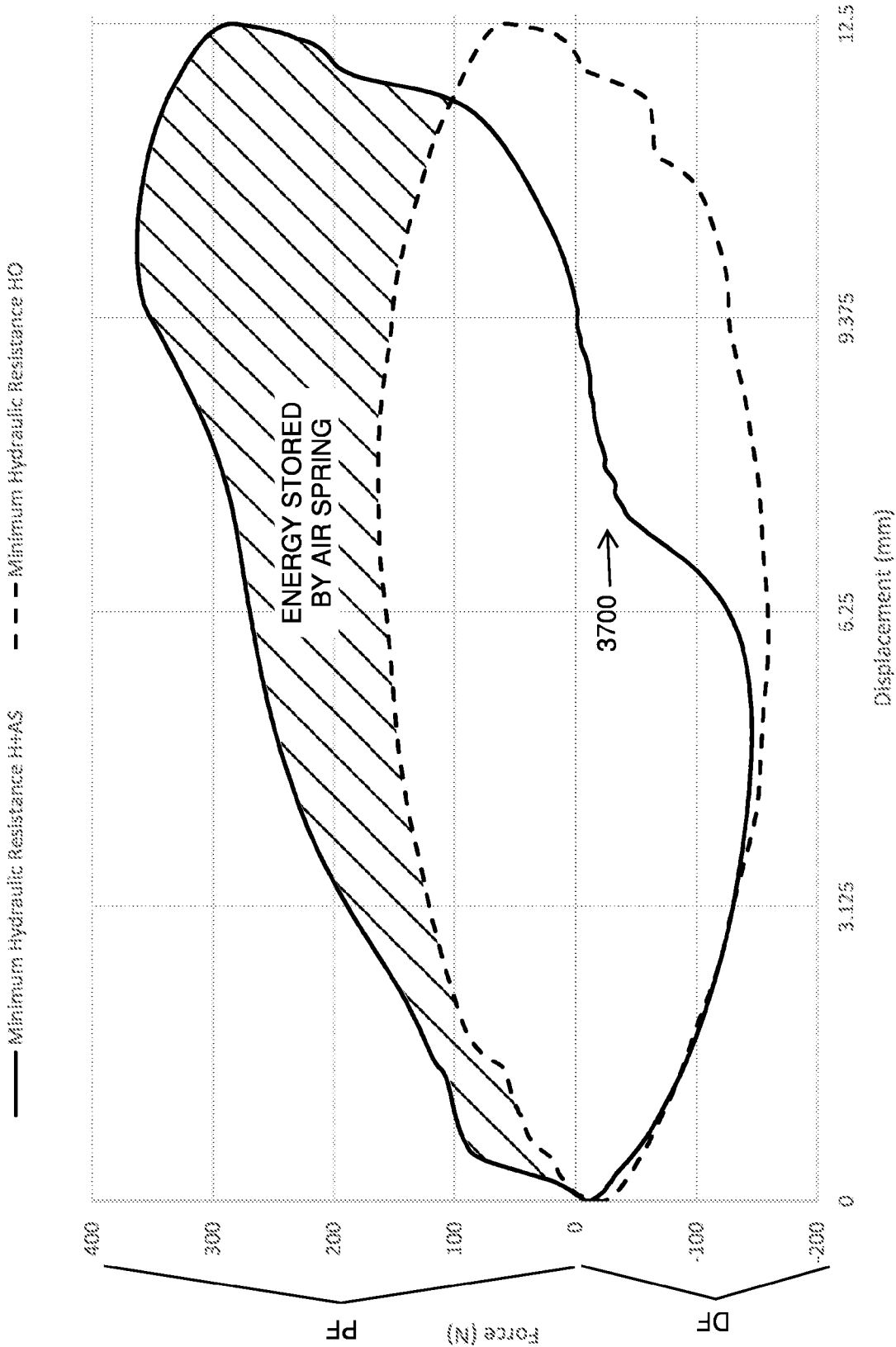


FIG. 37

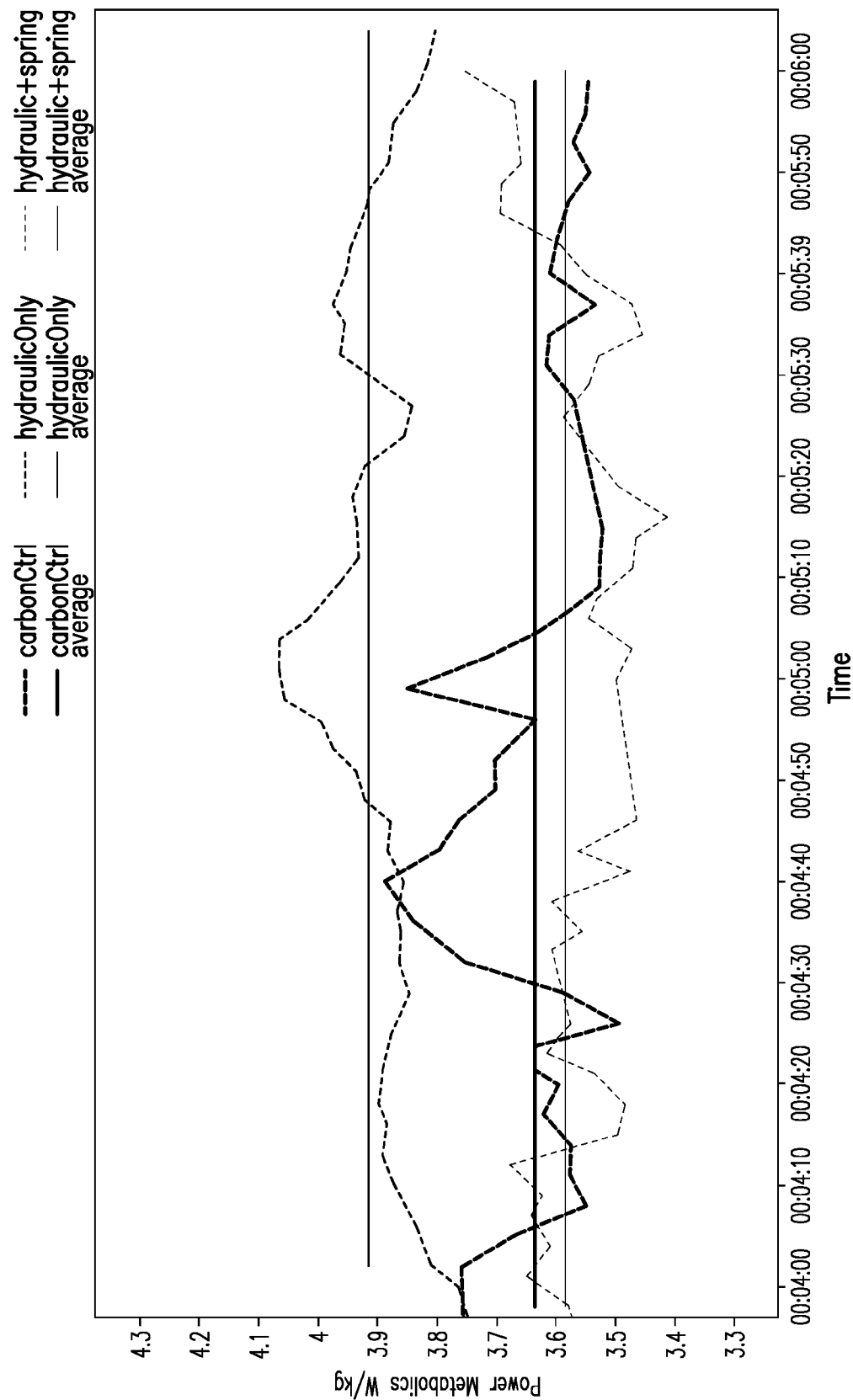


FIG. 38

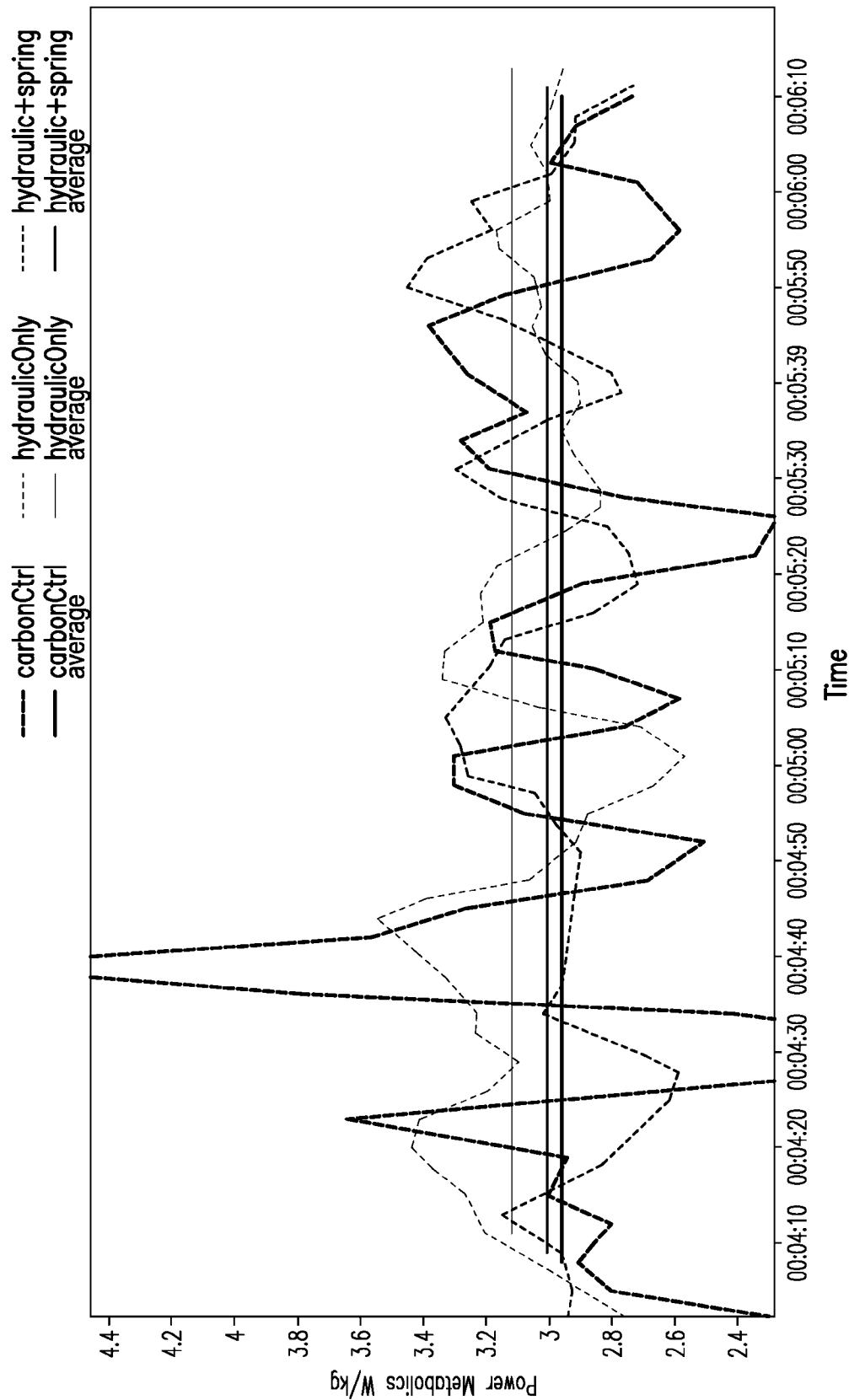


FIG. 39

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2024/036038

A. CLASSIFICATION OF SUBJECT MATTERIPC: **A61F 2/74** (2024.01); **A61F 2/66** (2024.01)CPC: **A61F 2/74; A61F 2/66; A61F 2/604**

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.
X	US 2023/0126674 A1 (DEPARTMENT OF VETERANS AFFAIRS) 27 April 2023 (27.04.2023)	42-45
Y	entire document	1-10, 13, 14, 16-23
X	US 2016/0228265 A1 (MASSACHUSETTS INSTITUTE OF TECHNOLOGY) 11 August 2016 (11.08.2016)	46
Y	entire document	47
Y	US 2002/0094919 A1 (RENNEX et al.) 18 July 2002 (18.07.2002)	1-10, 13, 14, 16-23, 47
A	US 2012/0016492 A1 (CLAUSEN) 19 January 2012 (19.01.2012)	1-47
A	US 2014/0222167 A1 (FREEDOM INNOVATIONS LLC) 07 August 2014 (07.08.2014)	1-47

☒ 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

14 September 2024 (14.09.2024)

Date of mailing of the international search report

25 September 2024 (25.09.2024)

Name and mailing address of the ISA/US

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

Facsimile No. **571-273-8300**

Authorized officer

MATOS
TAIHA

Telephone No. **571-272-4300**

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2024/036038

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2016/0302946 A1 (MOTION CONTROL) 20 October 2016 (20.10.2016) entire document	1-47