Goralign PSA 2

Product Manual

This user manual should be read before fitting and followed to ensure proper installation with the rest of the patient's prosthesis. A pylon-ankle-foot assembly using industry standard 4-hole pyramid adapters is shown in ***Figure A*** as a quick reference of a typical configuration for Goralign PSA 2; other configurations may be valid depending on the needs of the patient.

Figure A: *Goralign PSA 2 in a typical pylon-ankle-foot assembly.*

Warranty:

3 years from the date of fitting.

The warranty will be voided if the user weight rating is exceeded, the ankle (including the external casing) is modified in any way, or the fitting instructions are not followed causing any device damage.

Product Specifications

The Goralign PSA 2 (GPSA-2) may be used with or without its optional exterior casing. The casing helps mitigate dust/moisture/water entry and is recommended for general use.

Configuration	User Weight Limit	Build Height	Ankle Weight
Without Exterior Casing	275lbs (125 kg)	1.73in (44mm)	0.67lbs (304g)
With Exterior Casing	275lbs (125 kg)	1.81in (46mm)	0.72lbs (327g)

Provisional Patent Application Number 63/500,373

Installation:

Goralign PSA (Plus Shock Absorption) 2 can be used with or without the optional exterior casing. To properly orientate the GPSA-2, the casing should first be removed from the body if it is attached. To remove the casing, slide the casing upwards towards the proximal (top) side and completely off the GPSA-2 as shown in ***Figure B***. When re-attaching the casing, simply slide the casing downwards over the proximal (top) side and ensure the thicker lip of the casing is touching the top of the body.

Figure B*: (a) GPSA-2 with case installed. (b) Case being slid upwards to remove or downwards to attach. (c) Case completely removed from GPSA-2.*

The GPSA-2 is designed to be used with industry standard 4-hole pyramid adapters. In the following steps, a female pyramid adapter will be depicted on the distal (bottom) side and a male pyramid adapter will be depicted on the proximal (top) side of the GPSA-2. The GPSA-2 comes with 4 appropriate length screws for the distal (bottom) side of the device.

Flip the GPSA-2's body upside down so the distal (bottom) side is facing upwards. Next, remove the 4 visible screws from the base plate. **This will free the base plate. Do not remove or reorient the base plate relative to the GPSA-2 body.** Slide the pyramid adapter and optionally a spacer into the provided slot of the base plate so both of their 4-hole patterns line up. Re-insert the 4 screws through the pyramid adapter and tighten to bind the pyramid adapter and base plate to the GPSA-2 body. Refer to ***Figure C*** for details on using the provided screws. If alternative screws are desired, refer to ***Figure E*** for guidelines on appropriate screw length.

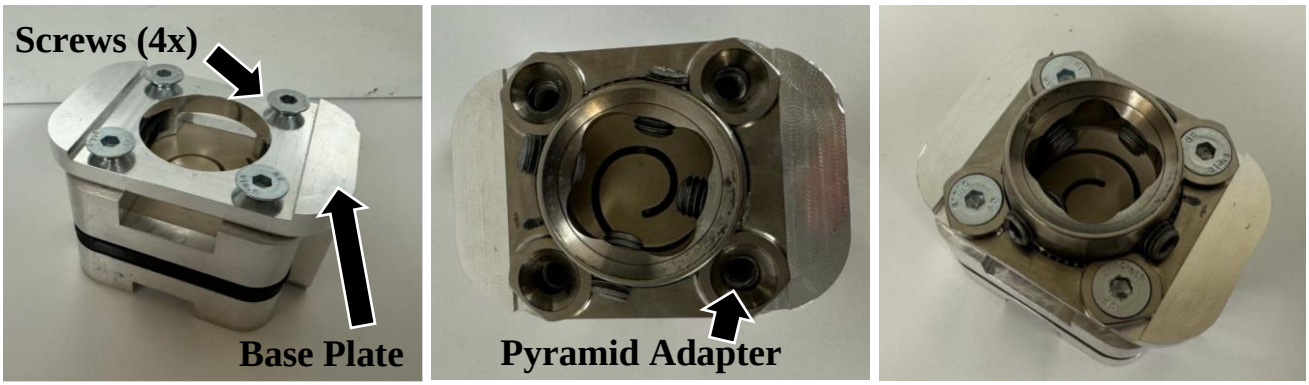


***Figure C**: (a) GPSA-2 flipped upside down with distal (bottom) side facing upwards, exposing base plate and screws. (b) Screws removed and female pyramid adapter slid into place. (c) Screws re-inserted into pyramid adapter and tightened.*

NOTE: If the base plate is accidentally removed or reorientated, it will need to be properly orientated relative to the GPSA-2 main body. The base plate has a groove on each side, with the deeper groove being on the posterior (heel) side and the shallower groove on the anterior (toe) side. The GPSA-2's main body has a corresponding shock absorbing component that has an "L" shaped opening on the posterior (heel) side and no opening on the anterior (toe) side. Re-align the base plate into position as shown in ***Figure C*** using the information in ***Figure D***.

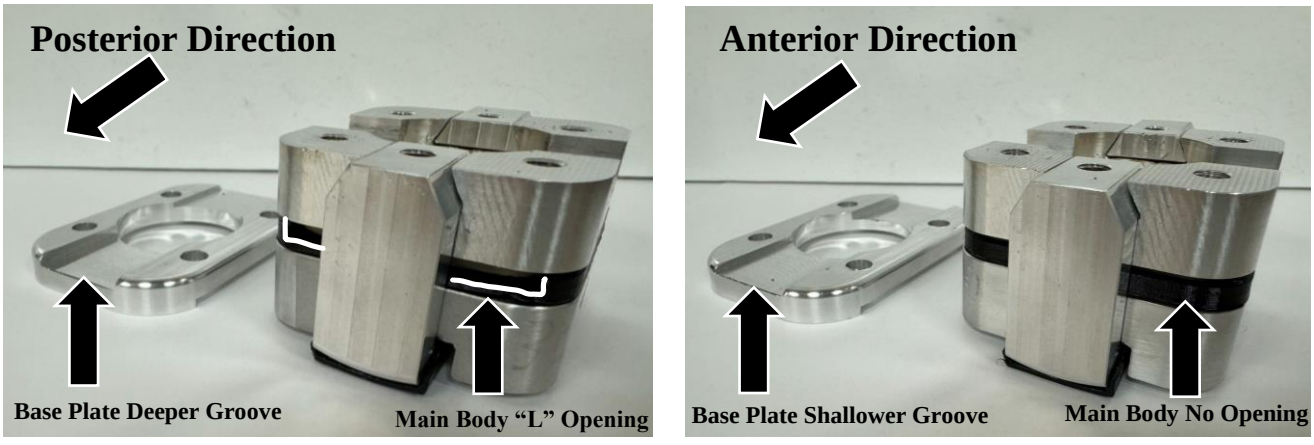


***Figure D**: (a) Posterior (heel) side of base plate and GPSA-2 body shown. (b) Anterior (toe) side of base plate and GPSA-2 body shown.*

With the distal (bottom) pyramid adapter attached, flip the GPSA-2 so that its proximal (top) side is once again facing upwards. Using 4 screws (not provided), attach the proximal (top) side pyramid adapter and optionally a spacer. Refer to ***Figure E*** for appropriate screw length.

Both the proximal and distal sides of the device may be used with a spacer in addition to the pyramid adapter.

Bolts into the proximal (top) side should not protrude from pyramid adapter & spacer more than:

- 8mm

Bolts into the distal (bottom) side should not protrude from pyramid adapter & spacer more than:

- 14mm

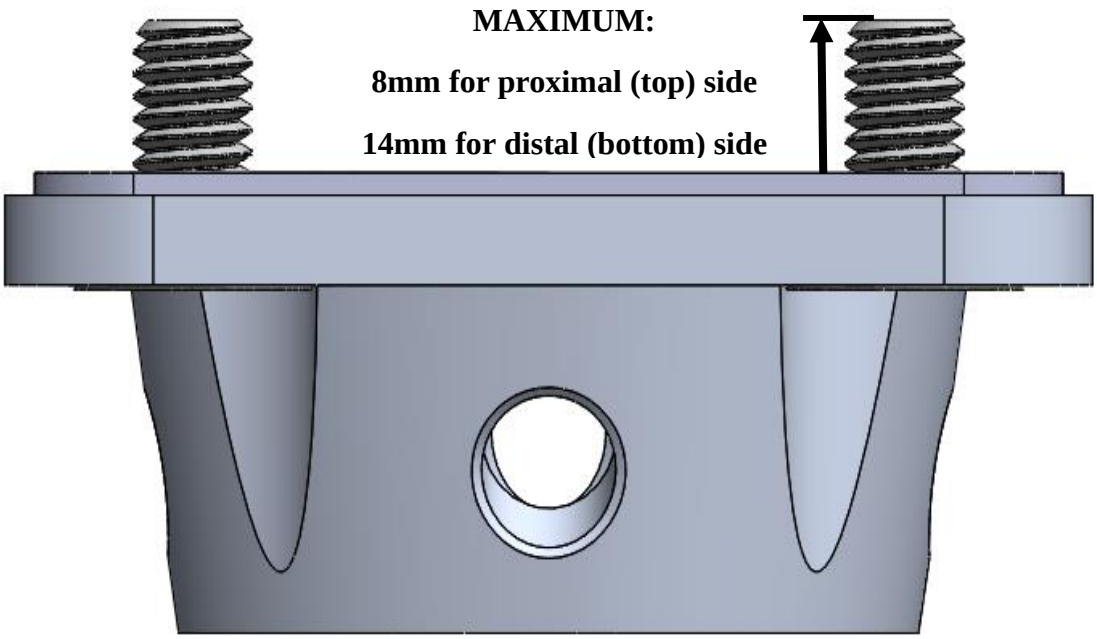
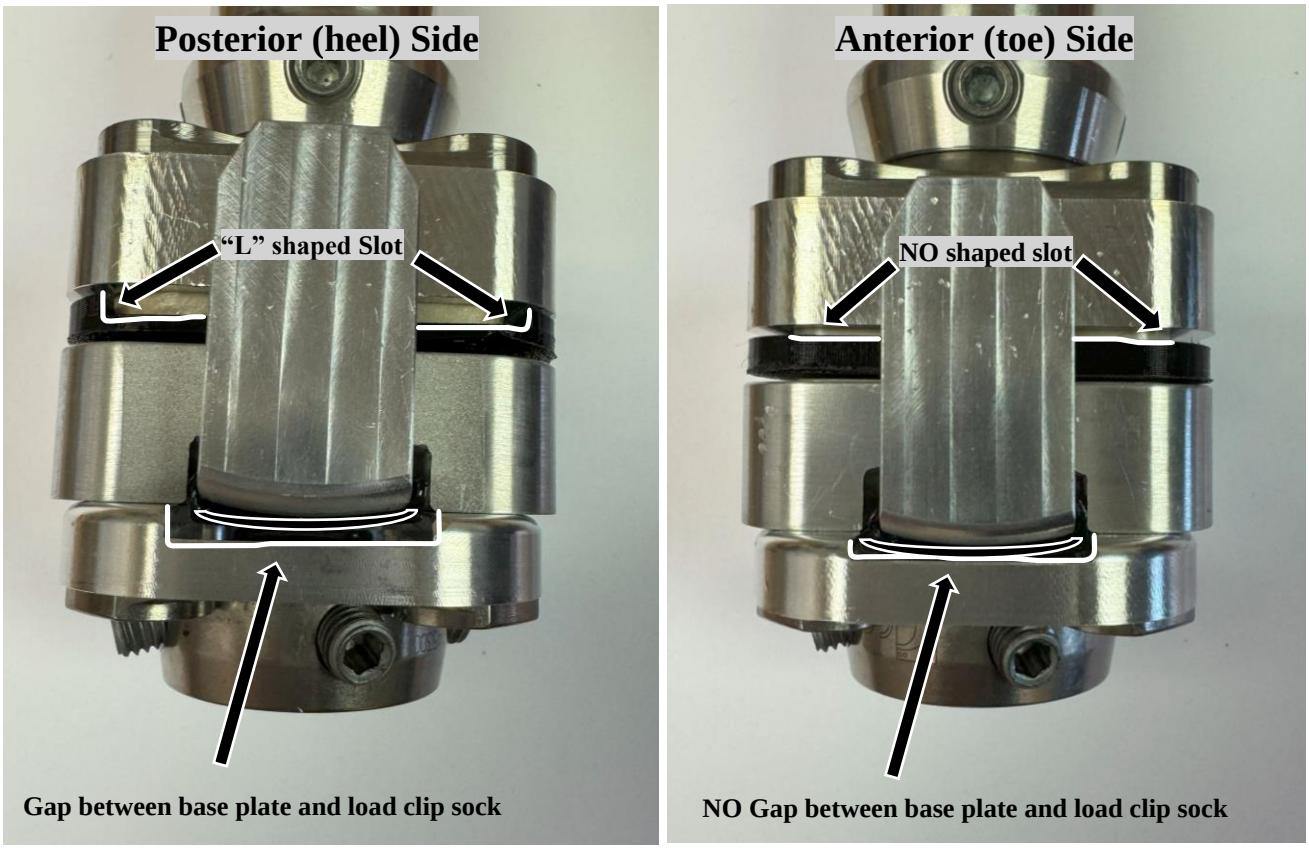


Figure E*. Proper spacer thickness will limit the protruded section of the bolts to 8mm on the distal (bottom) side and 14mm on the proximal (top) side.*

The GPSA-2 must be properly orientated relative to the patient's anterior and posterior (front and back) for proper functionality of its variable stiffness feature. The posterior (heel) side of the GPSA-2 has an "L" shaped slot and a gap between the base plate and the load clips. The anterior (toe) side of the GPSA-2 does not have a shaped slot and no gap between the base plate and the load clip's soft plastic sock. *Figure F* shows how to determine the orientation of the GPSA-2.



(a) **(b)**

***Figure F**: GPSA-2 orientation visual. (a) shows the posterior (heel) side of the GPSA-2. (b) shows the anterior (toe) side of the GPSA-2.*

Figure G shows the GPSA-2 properly orientated in a pylon-ankle-foot assembly with optional casing now re-attached; casing lip should sit firmly against the top of the device. Refer back to ***Figure B*** for details on casing installation if necessary.

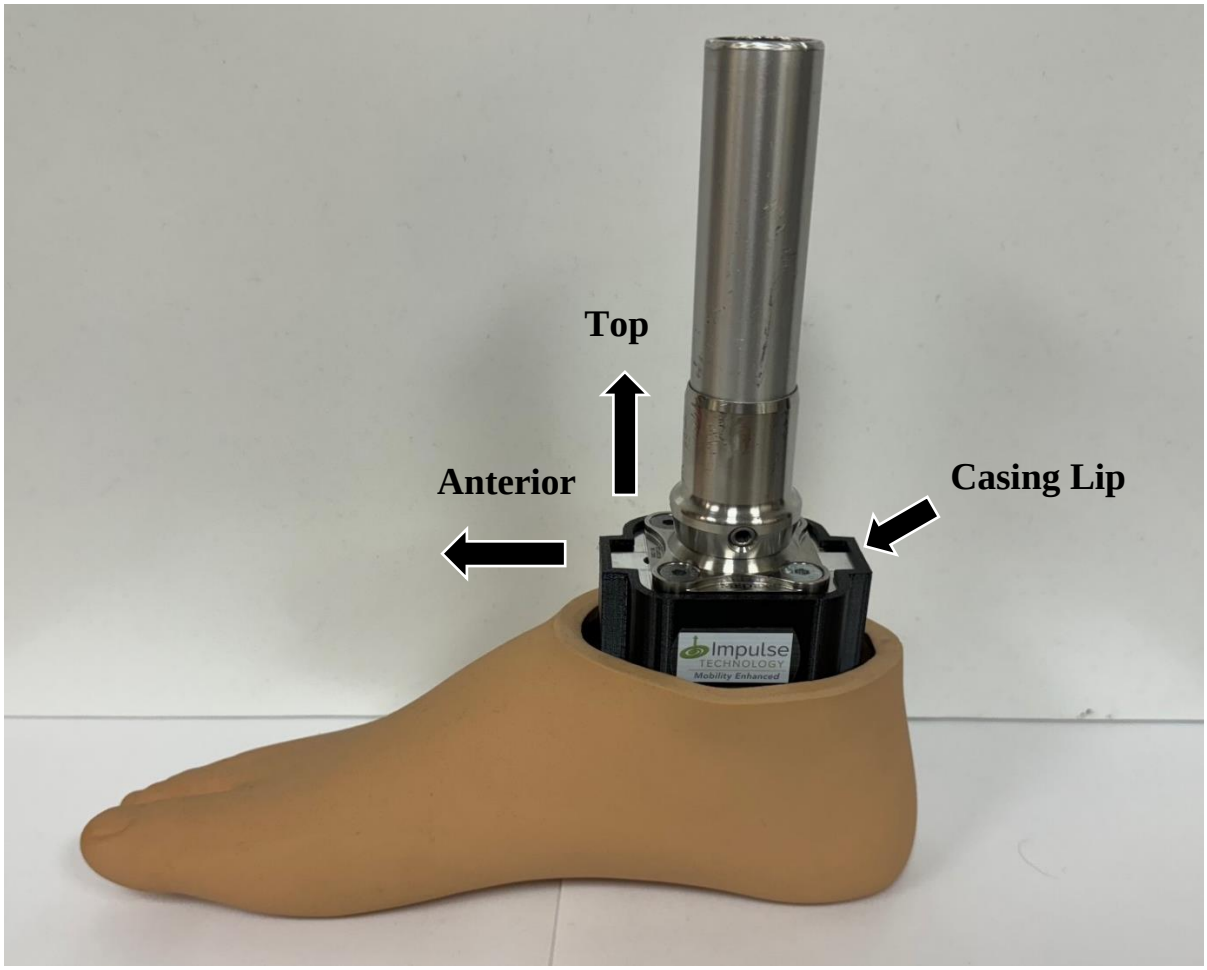


Figure G*: GPSA-2 with Optional Casing in a pylon-ankle-foot assembly.*

Maintenance and Care:

The GPSA-2 is weather-resistant. However, it is not intended to be submerged in water for any period of time.

Any increase in noise or changes in performance should be reported to the prosthetist.

Recommended L-codes: L5986 + L5988

Justification:

L5986

The GPSA-2 is, upon load application, compliant in all 3 planes of motion: sagittal, coronal, and transverse. ***Figure 1*** shows a side view of the GPSA-2.

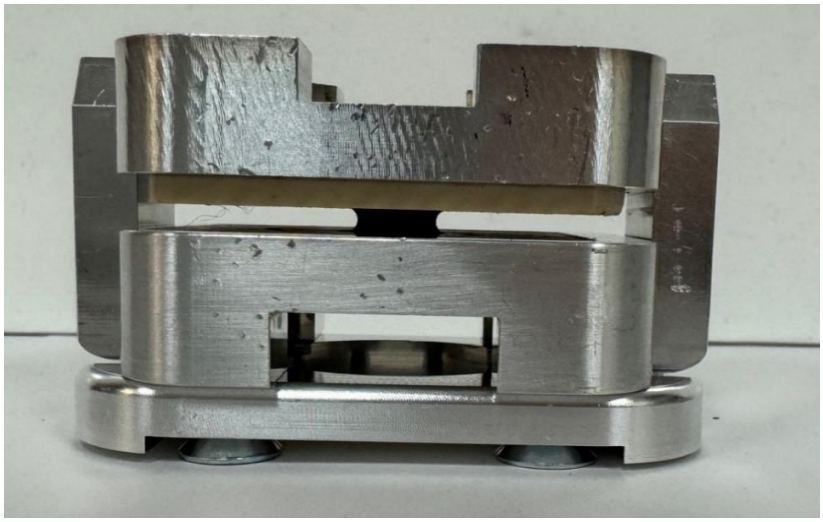
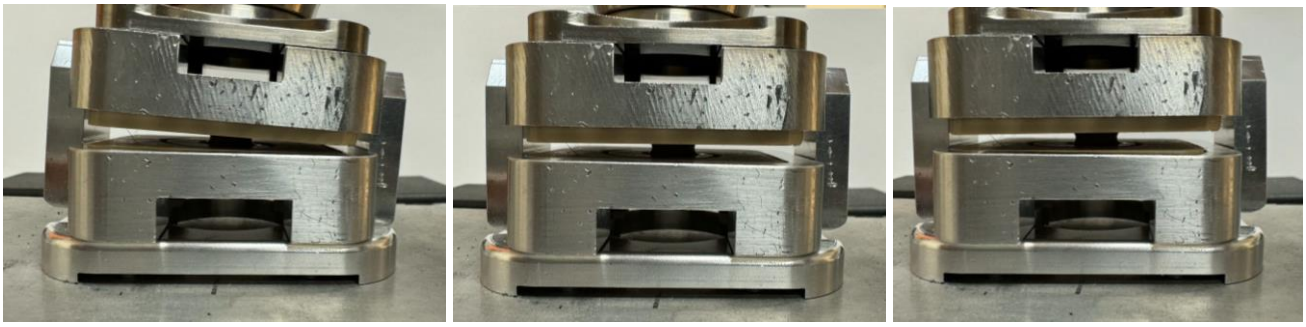


Figure 1: *Side view of the GPSA-2 with shock absorbing componentry removed.*

In the following figures for this section: additional componentry is included to demonstrate the multi-axial functionality of the GPSA-2.

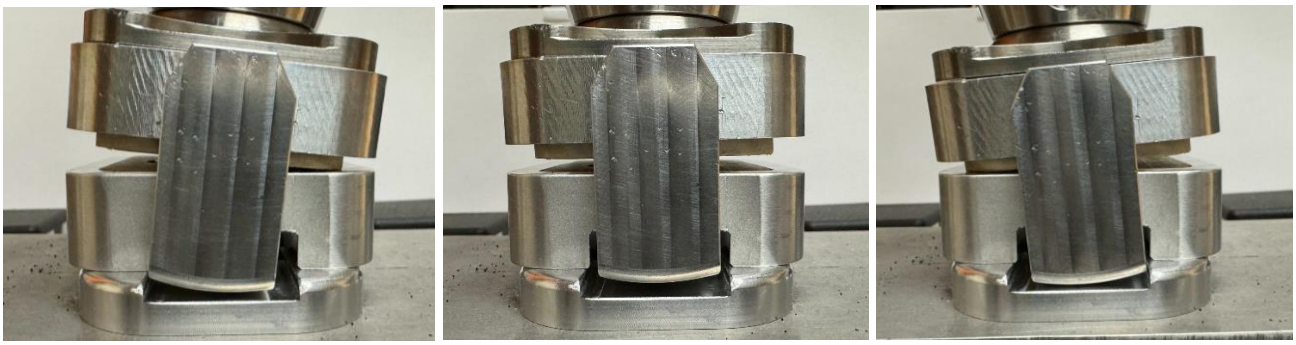
Impulse Technology's GPSA-2 allows 5° of plantarflexion (***Figure 2a***) and 2° of dorsiflexion (***Figure 2c***) in the sagittal plane. This is the primary rotational axis during normal ambulation.



(a) **(b)** **(c)**

Figure 2*: Side view of GPSA-2 in (a) plantarflexed, (b) neutral, and (c) dorsiflexed positions.*

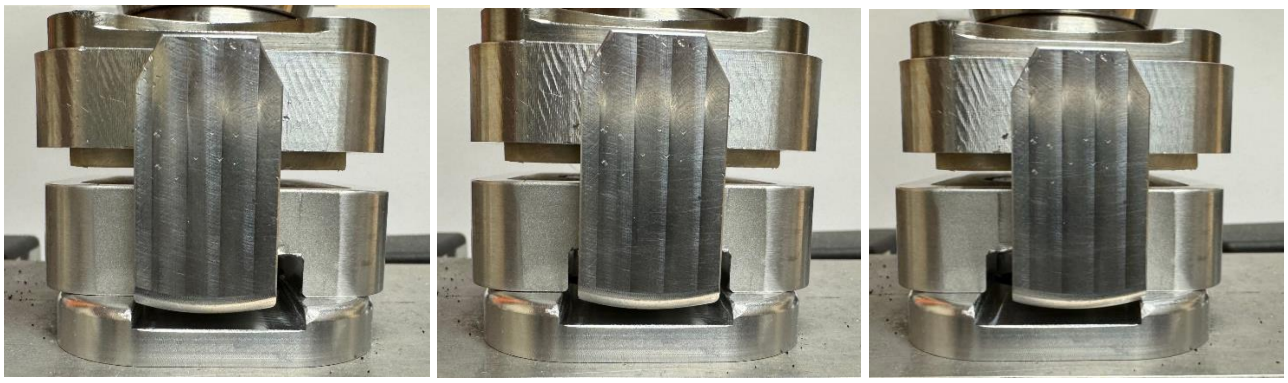
Additionally, the Impulse Technology GPSA-2 provides up to 5° each of inversion (***Figure 3a***) and eversion (***Figure 3c***) in the coronal plane. This type of compliance is typical when rolling the foot inwards or outwards relative to the pelvis.



(a) **(b)** **(c)**

Figure 3. *Rear view of GPSA-2 in (a) inverted, (b) neutral, and (c) everted positions.*

Finally, the Impulse Technology GPSA-2 provides up to 5° adduction (***Figure 4a***) and abduction (***Figure 4c***) in the transverse plane. This type of compliance is typical when pivoting or rotating the pelvis relative to the foot.



(a) **(b)** **(c)**

Figure 4*. Rear view of GPSA-2 in (a) adducted, (b) neutral, and (c) abducted positions.*

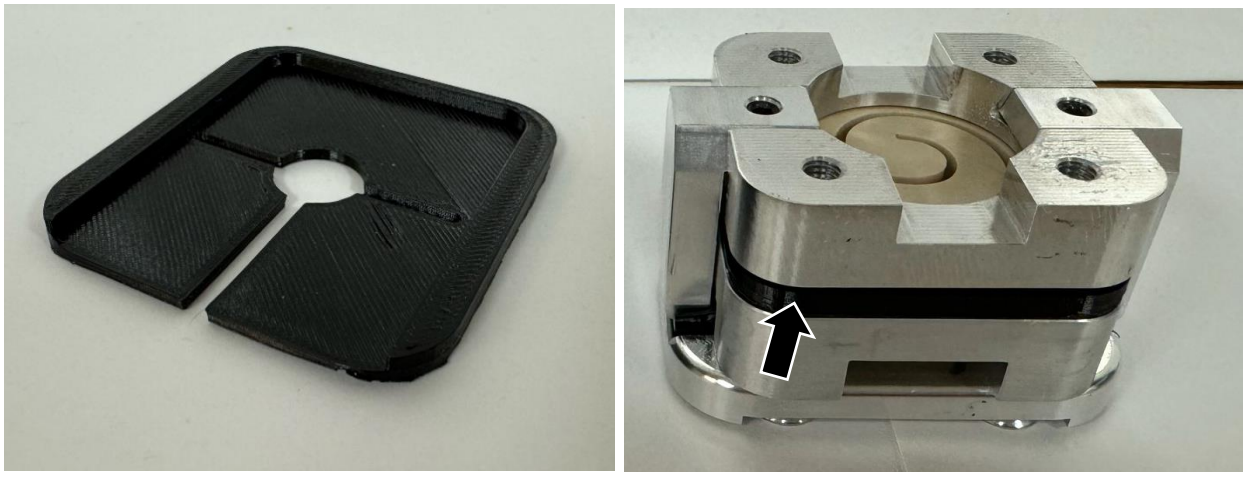
Additional notes on Code L5986

The spiral spring in the GPSA-2 is a similar structure as in version 1 of the product, that is, Goralign PSA 1 (GPSA-1). This structure in the GPSA-1 was approved for HCPCS Code L5986 by PDAC in 2021.

While HCPCS Code L5986 describes the very basic functionalities of the GPSA-2 regarding multi-axial ankle movement, the GPSA-2 contains further premium features that enables it to mimic a human natural ankle. Additionally, the GPSA-2 features **variable stiffness** along its posterior to anterior (heel to toe) axis. The stiffness is at its lowest at the posterior (heel) and is at its highest at the anterior (toe). This allows for additional, less inhibited motion during the initial heel load step where the ankle must act as a swinging hinge for a smooth landing. Conversely, this allows for less, more inhibited motion during the final toe push off step where the toe must act as a very stiff fixture for a strong push off. This variable stiffness, along with the self-aligning internal spiral spring structure, allows the GPSA-2 to be **self-adaptive.** GPSA-2 can self-adapt to gait and terrain changes as well as reduce misalignment issues that can occur over long periods of time. This self-adaptive design leads to less socket moments and increased patient comfort and satisfaction. All these features go beyond the requirements for Code L5986. Finally, while similar functioning ankles may offer these features with the use of microprocessors, actuators, hydraulics, and other active components, the GPSA-2 achieves this functionality with only passive components.

L5988

The GPSA-2 features a shock absorbing component to provide vertical shock absorption throughout the stance phase of gait. The component is shown in ***Figures 5a and 5b.*** The shock absorbing component sits between the slot of the multi-axial spiral spring structure, allowing for direct vertical shock absorption throughout the stance phase.

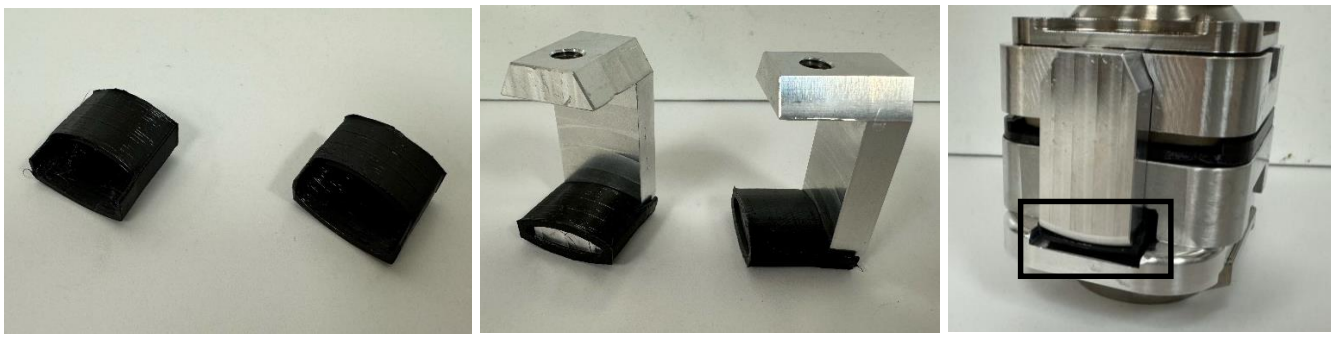


(a) **(b)**

Figure 5: *(a) shock absorbing component alone (b) shock absorbing component installed.*

An additional shock absorbing component is placed around each of the load clips of the GPSA-2. This functions as an additional shock absorbing component when approaching the maximum allowable

rotational values of plantarflexion/dorsiflexion, inversion/eversion, and adduction/abduction that typically occurs during early heel contact and final toe step off. The component is shown in ***Figure 6.***



(a) **(b)** **(c)**

Figure 6: *(a) Additional Shock absorbing component alone. (b) Additional Shock absorbing component installed around load clip. (c) Rear view of GPSA-2 with component installed.*

The shock absorbing components shown in ***Figures 5 and 6***, when placed under load during ambulation, will deform to enable cushioned vertical motion throughout the stance phase of gait. Under typical usage and weight scenarios, the shock absorber will deform to enable an additional 1 to 4 millimeters of vertical motion.

Additional notes on Code L5988

While HCPCS Code L5988 only describes vertical shock absorption, GPSA-2's shock absorber design, in combination with the spiral spring structure, deforms in all 3 planes of motion to provide multi-axial shock absorption going beyond what is required for the recommended code L5988. In addition, by nature of the structure and material of the PEEK spiral spring surrounding the shock absorber, the vertical shock absorption is extended by another millimeter through displacement. This brings the shock absorption maximum value to 5 millimeters of vertical motion through deformation and displacement.