

# Goralign PSA 2

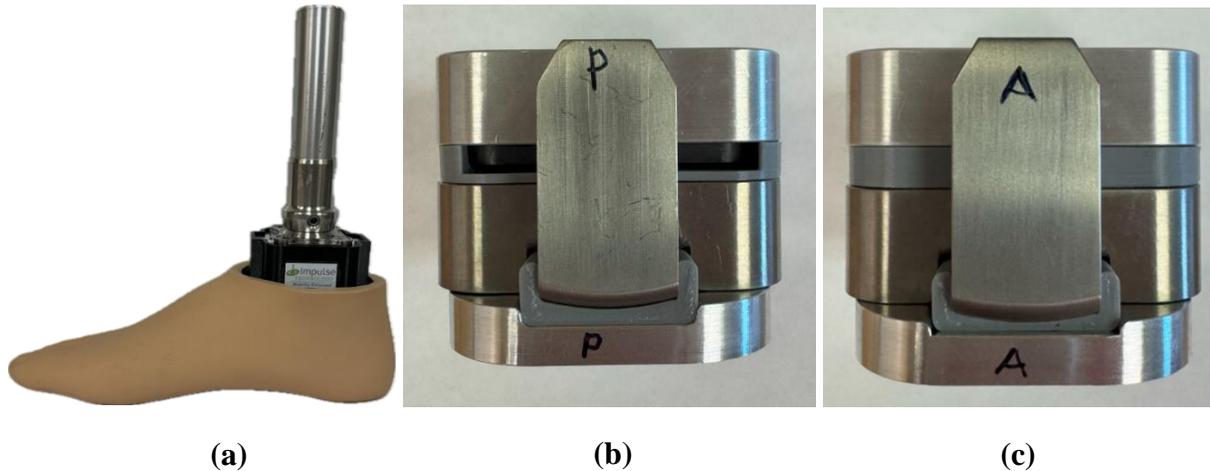
## Product Manual



<https://youtu.be/xPt8uLMCzV4>

Scannable QR-code for product installation companion video.

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 (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** also shows the Posterior-Anterior orientation guide where **(b)** "P" stands for Posterior (rear), and **(c)** "A" stands for Anterior (front); if the letters on a particular side do not match, then flip the base plate so they do. Compliance with this orientation is crucial to proper functioning of the variable stiffness feature.



**Figure A:** (a) Goralign PSA 2 in a typical pylon-ankle-foot assembly. Casing slid off to reveal: (b) Posterior side of the device denoted by "P" (c) Anterior side of the device denoted by "A". If the letters on a particular side of the device do not match, flip the base plate so they do.

#### Intended Use:

Goralign PSA 2 is a prosthetic ankle that enhances patient mobility and comfort.

#### Indications and Patient Selection Criteria:

- Patients who have undergone a lower limb amputation

#### Contra-indications

- None currently known

#### Cleaning and Maintenance

The Goralign PSA 2 is designed to be maintenance free. The included casing is designed to keep unwanted dust and other particulate out of the device and is recommended for general use. If the surfaces of the device become dirty, wipe the surfaces with a wet rag and then wipe the surfaces again with a dry rag. Do not use industrial strength cleaners on the Goralign PSA 2. Do not insert the Goralign PSA 2 into a clothes washer or dish washer.

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.

#### 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

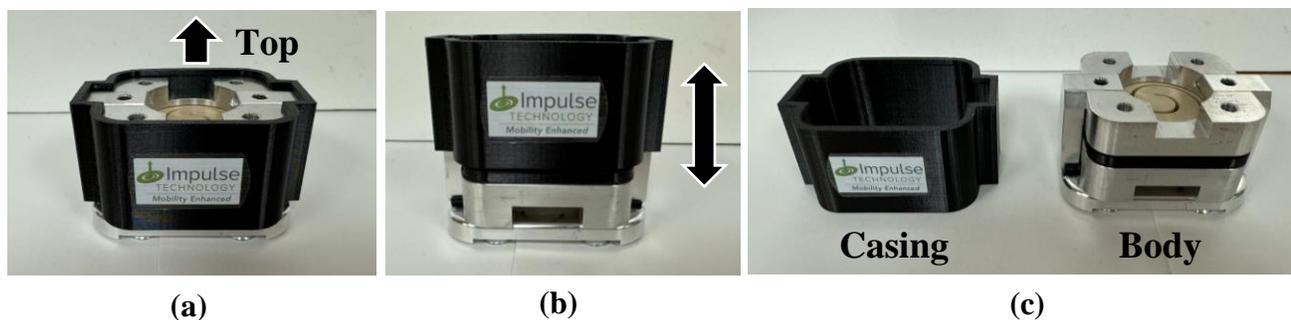
The Goralign PSA 2 (GPSA-2) may be used with or without its optional exterior casing. The casing helps mitigate dust/moisture/water entry and is recommended for general use.

Configuration	User Weight Limit	Build Height	Overall Height	Ankle Weight
<b>Without Exterior Casing</b>	275lbs (125 kg)	1.65in (42mm)	1.73in (44mm)	0.69lbs (312g)
<b>With Exterior Casing</b>	275lbs (125 kg)	1.65in (42mm)	1.81in (46mm)	0.72lbs (327g)

Provisional Patent Application Number 63/500,373

Installation:

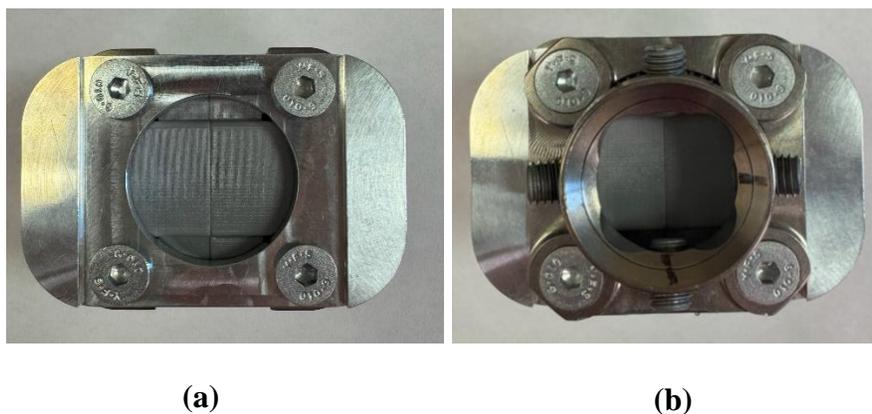
**Goralign PSA (Plus Shock Absorption) 2** can be used with or without the optional exterior casing. To properly orientate the GPSA-2, the casing should first be removed from the body if it is attached. To remove the casing, slide the casing upwards towards the proximal (top) side and completely off 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 four M6x1 16mm length screws for the distal (bottom) side of the device, and four M6x1 12mm length screws for the proximal (top) side of the device. Do not use unapproved or alternative screws as it can cause premature compression of the spiral spring structure and inhibit the multi-axial motion.

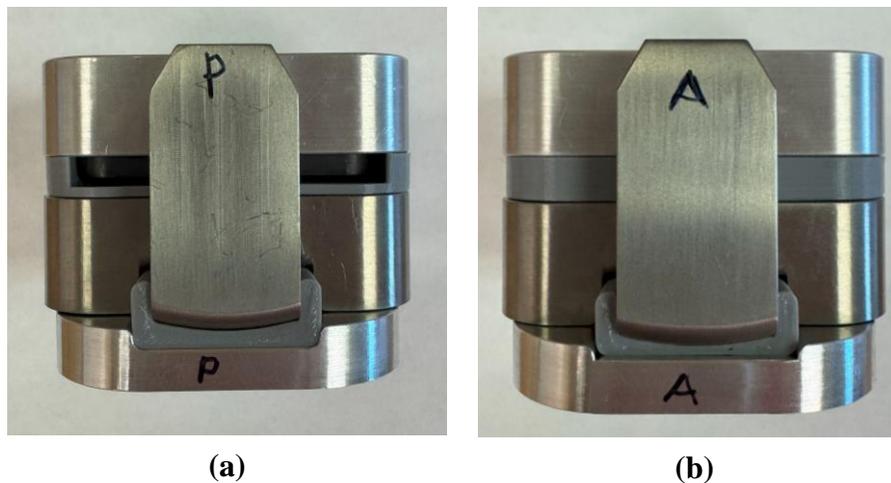
Flip the GPSA-2's body upside down so the distal (bottom) side is facing upwards. Next, remove the 4 visible screws from the base plate. **This will free the base plate. Do not remove or reorient the base plate relative to the GPSA-2 body.** Slide the pyramid adapter into the provided slot of the base plate so both of their 4-hole patterns line up. Re-insert the same 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.



**Figure C:** (a) GPSA-2 flipped upside down with distal (bottom) side facing upwards, exposing base plate and screws. Remove the screws but do not reorient the base plate (b) GPSA-2 with distal pyramid installed. Slide the distal pyramid adapter into place and re-insert the screws that were removed in the previous step.

With the distal (bottom) pyramid adapter attached, flip the GPSA-2 so that its proximal (top) side is once again facing upwards. Using the four M6x1-12mm screws (provided separately), attach the proximal (top) side pyramid adapter.

**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. Reversal of either the Base Plate or Goralign PSA 2 itself into an incorrect configuration will cause the multi-axial motion to be inhibited. The posterior (heel) side of the GPSA-2 has a “P” for posterior written on both the base plate and the main body of the device. The anterior (toe) side of the GPSA-2 has an “A” for anterior written on both the base plate and the main body of the device. If the letter on the side of the base plate does not match, then the base plate must be flipped. Figure D shows how to determine the orientation of the GPSA-2.**



**Figure D:** GPSA-2 orientation visual. (a) shows the posterior (heel) side of the GPSA-2 with a “P” written on both the base plate and main body. (b) shows the anterior (toe) side of the GPSA-2 with an “A” written on both the base plate and main body. If the letters on a particular side of the device do not match, flip the base plate so they do.

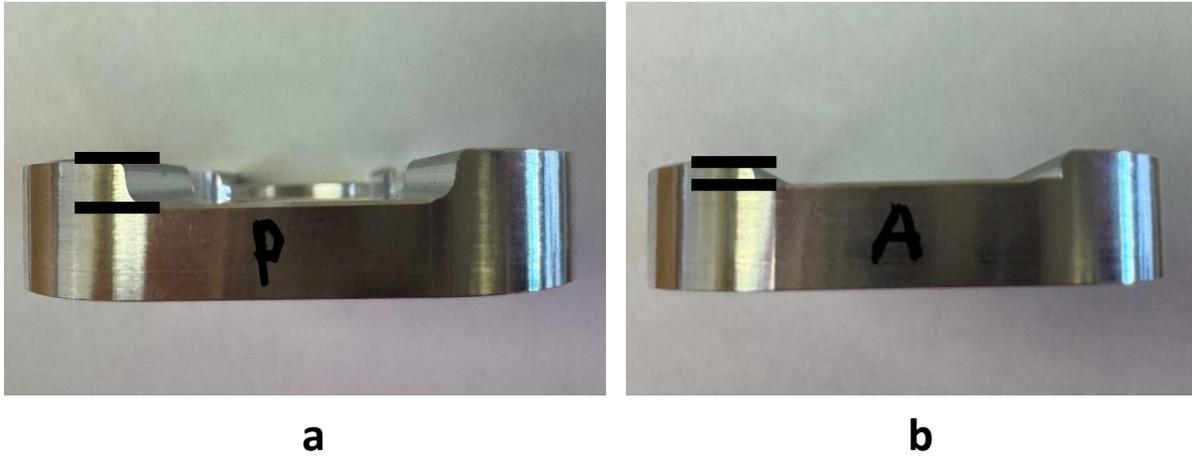
In case the “A” and “P” markings have washed away or become illegible, **Figures E and F** show how to determine the anterior-posterior orientation using the geometry of the device itself. The base plate must be aligned correctly relative to the main body of the device, and the entire device must be aligned correctly relative to the patient.

Posterior:

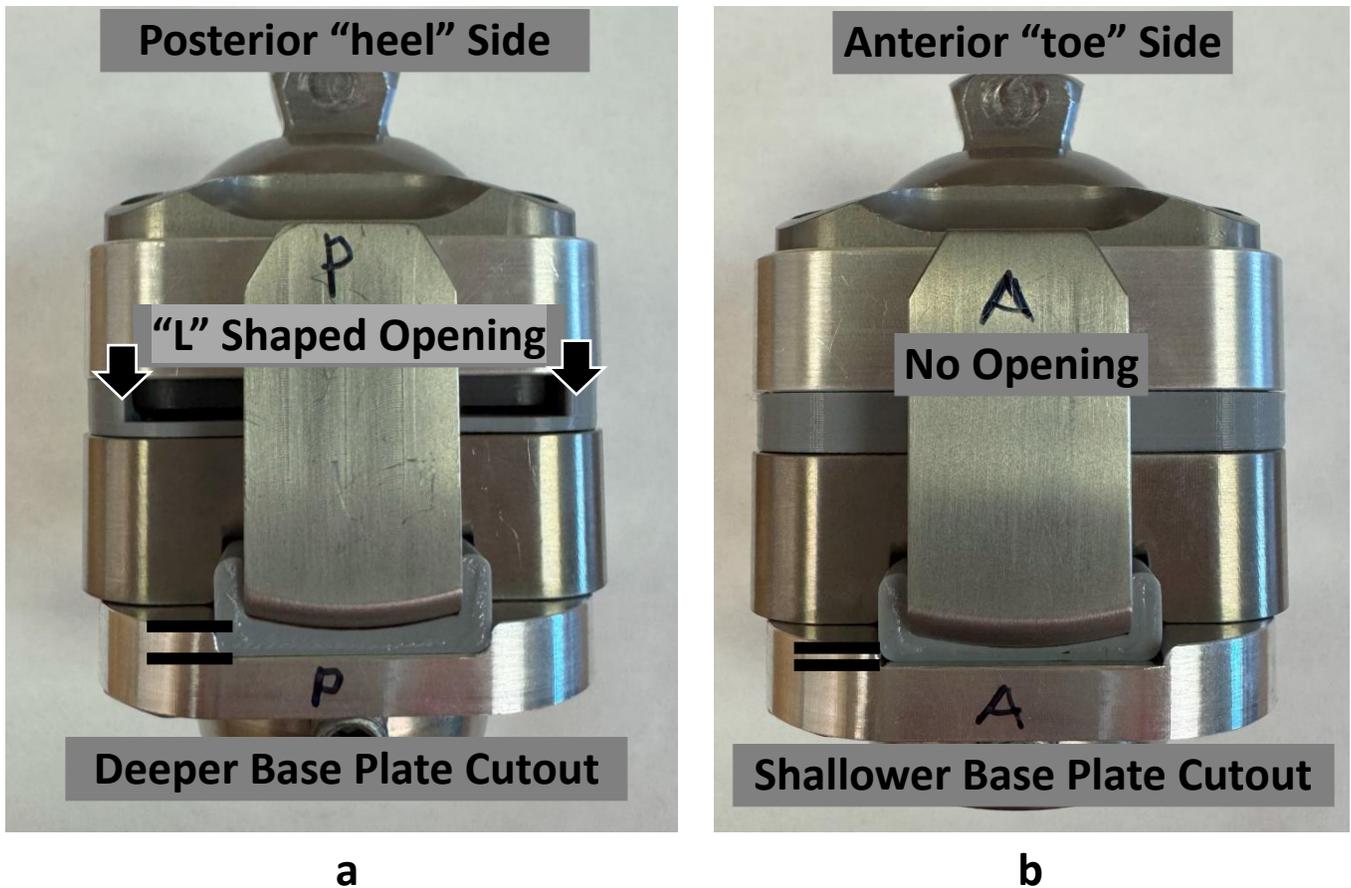
- “L” shaped opening on the main body’s TPU shock-absorbing component
- Base Plate side with the deeper groove

Anterior:

- No “L” shaped opening on the main body’s TPU shock-absorbing component
- Base Plate side with the shallower groove.

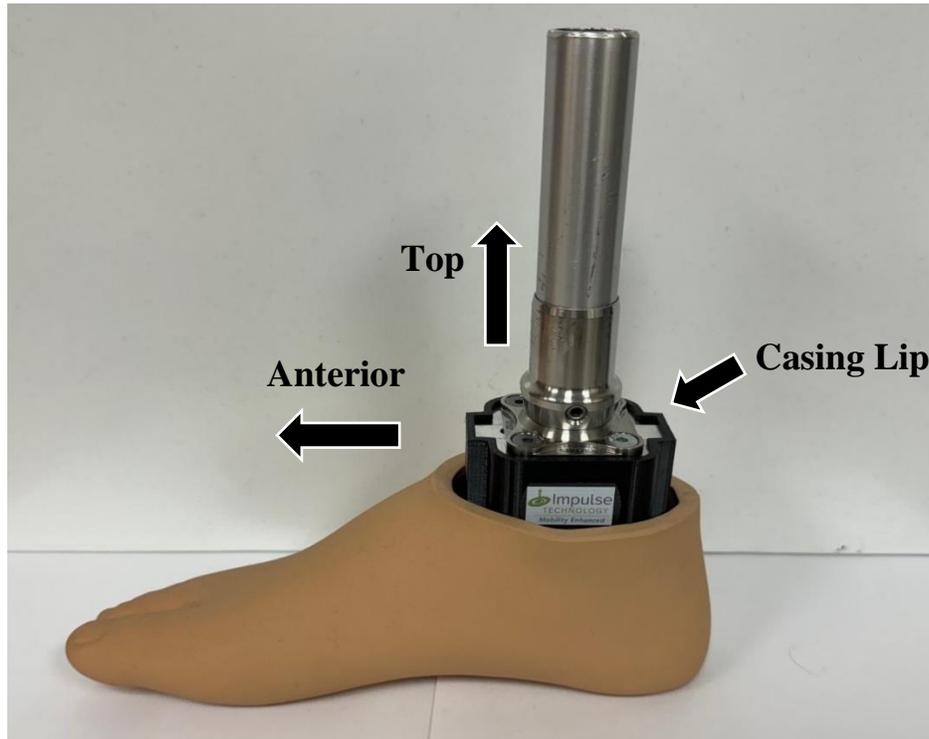


**Figure E:** Base Plate orientation visual (a) Posterior (heel) side of base plate shown with the deeper groove. (b) Anterior (toe) side of base plate shown with shallower groove.



**Figure F:** GPSA-2 orientation visual with pyramids attached. (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 H** shows a scannable QR-code for a youtube video of these installation instructions to serve as a companion guide.



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



<https://youtu.be/xPt8uLMCzV4>

**Figure H:** Scannable QR-code for product installation companion video.

Recommended L-codes: L5986 + L5988

Justification:

**L5986**

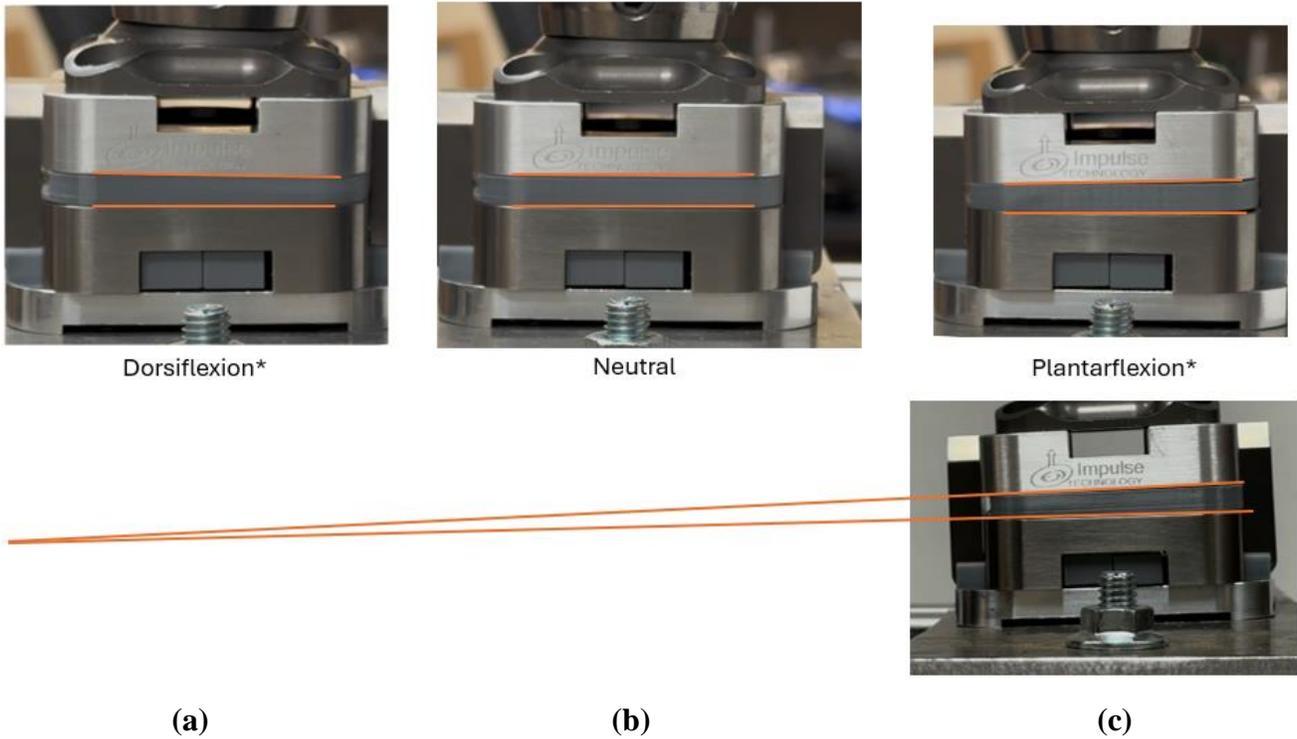
The GPSA-2 is, upon load application, compliant in all 3 planes of motion: sagittal, coronal, and transverse. **Figure 1** shows a side view of the GPSA-2.



**Figure 1:** Side view of the GPSA-2.

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

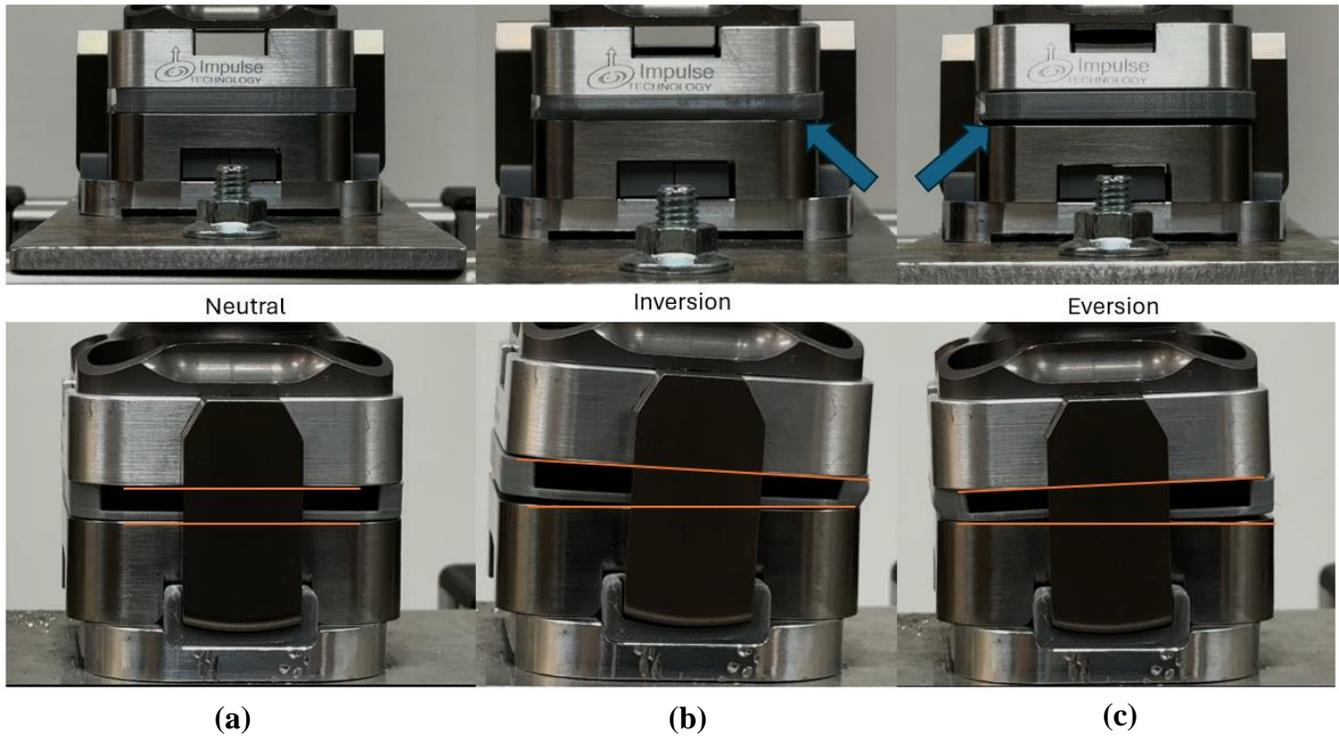
Impulse Technology's GPSA-2 allows dorsiflexion (**Figure 2a**) and plantarflexion (**Figure 2c**) in the sagittal plane. This is the primary rotational axis during normal ambulation. It should be noted that the dorsiflexion is stiffer than the plantarflexion for a softer heel strike and a stiffer toe push off. The dorsiflexion is typically between 0 and 2 degrees, while the plantarflexion is typically between 0 and 5 degrees. The total range of motion is therefore 7 degrees.



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

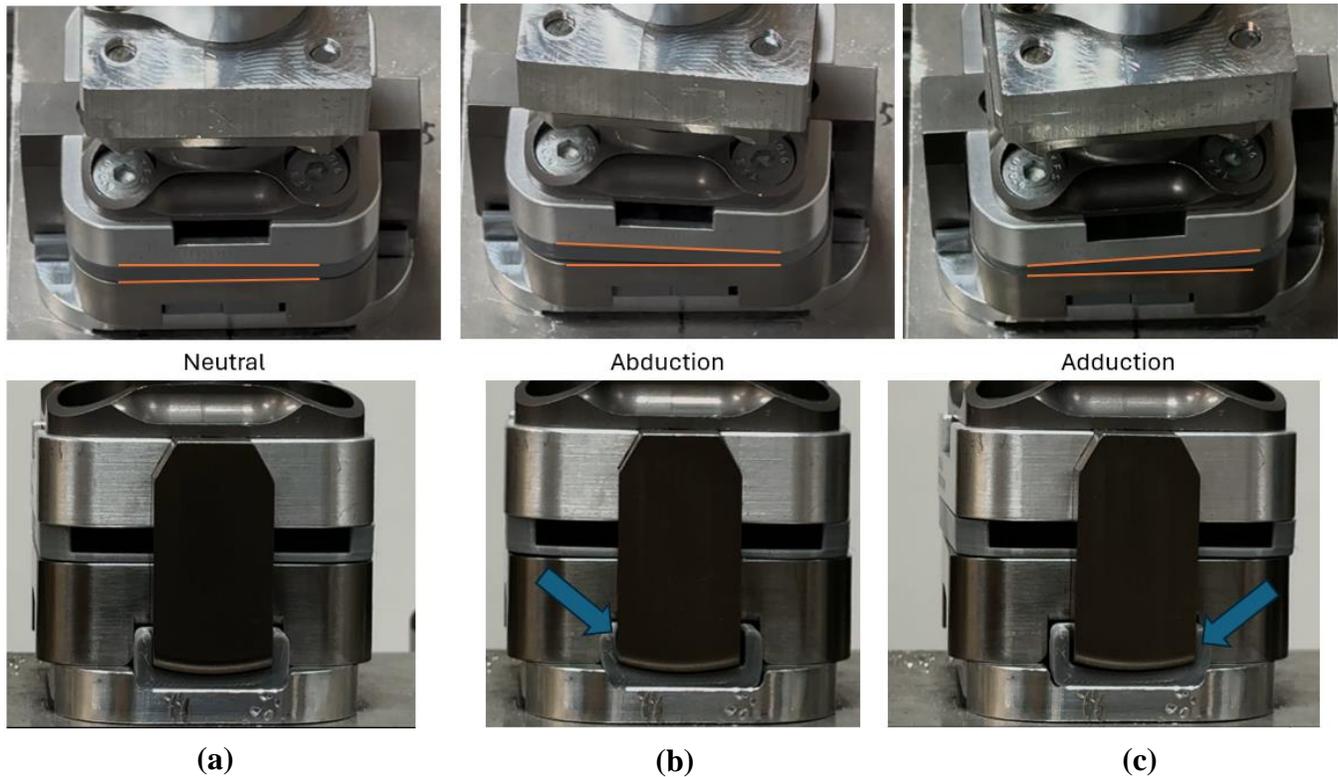
*\*Dorsiflexion is stiffer than Plantarflexion*

Additionally, the Impulse Technology GPSA-2 provides inversion (**Figure 3b**) 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. The angular rotation is typically between 0 and 5 degrees in either direction, for a total range of motion of 10 degrees.



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

Finally, the Impulse Technology GPSA-2 provides up to 5° abduction (**Figure 4b**) and adduction (**Figure 4c**) in the transverse plane. This type of compliance is typical when pivoting or rotating the pelvis relative to the foot. The angular rotation is typically between 0 to 5 degrees in either direction, for a total range of motion of 10 degrees.



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

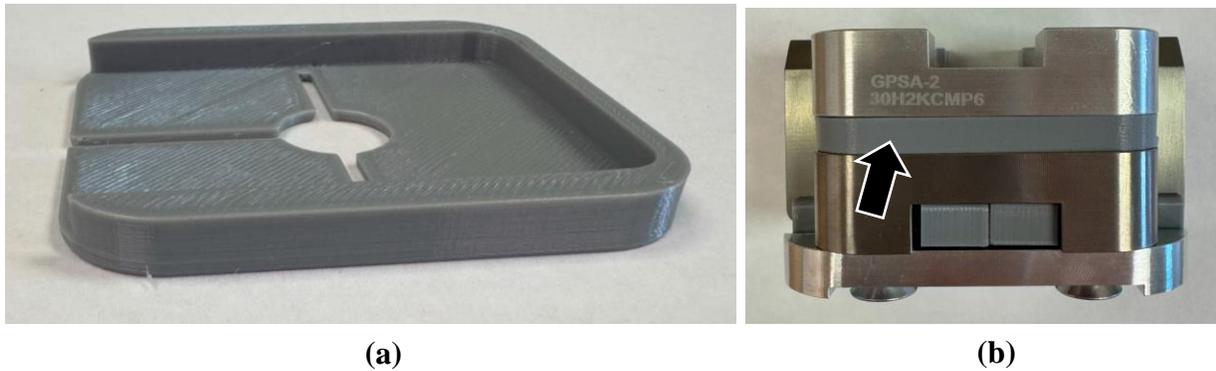
Additional notes on Code L5986

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.

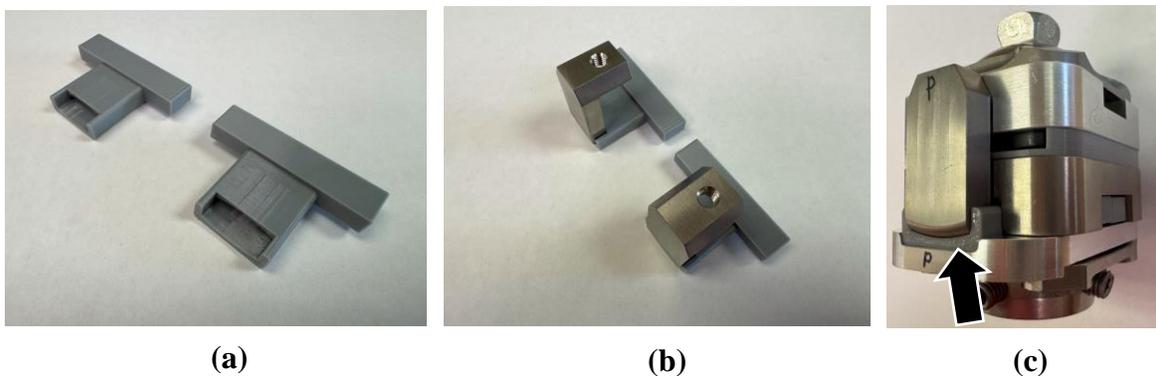
**L5988**

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.



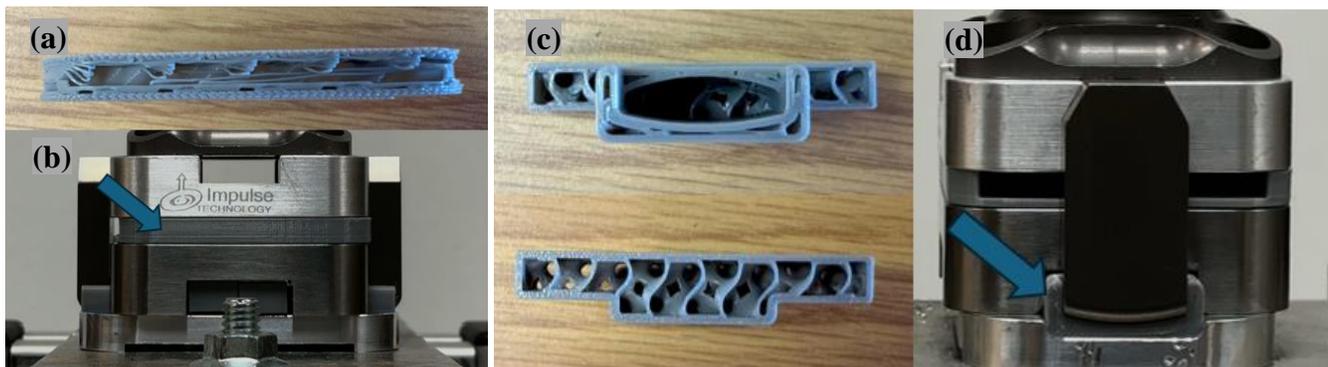
**Figure 5:** (a) shock absorbing component alone (b) Side View diagram showing shock absorbing component location in Goralign PSA 2.

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**.



**Figure 6:** (a) Additional Shock absorbing component alone. (b) Additional Shock absorbing component installed around load clip. (c) Rear View diagram 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. These components are able to absorb shock through deformation because the material is made of a semi-hollow, pliable TPU as demonstrated in **Figure 7**.



**Figure 7:** (a) Shock absorber cross-sectional view of semi-hollow interior and (b) diagram showing its position in Goralign PSA 2 (c) Load Sock cross-sectional view of semi-hollow interior and (d) diagram showing its position in Goralign PSA 2.

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.

Compliance Information

Goralign PSA 2 is classified as a non-invasive class I Medical Device by the US FDA and EU MDR.



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The following compliance items are applicable in the European Union.



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Malta