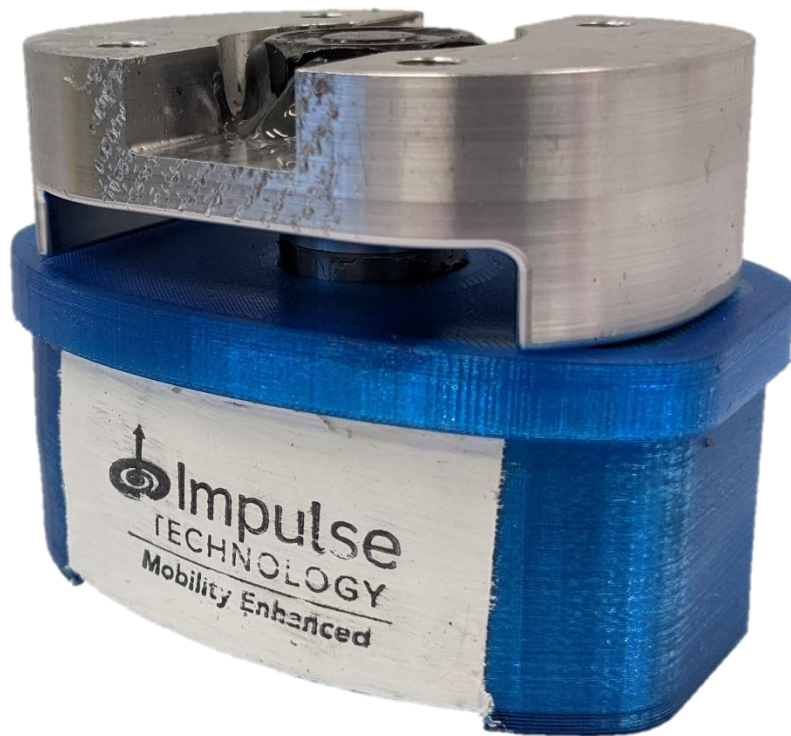


Goralign PSA

Product Manual



This user manual should be read before fitting and followed to ensure proper installation with the rest of the patient's prosthesis.

Warranty:

Metal parts: 3 years from the date of fitting.

Polymer casing and shock-absorbing filler: 1 year from the date of fitting; Will be checked annually for potential replacement for up to 3 years.

The warranty will be voided if the user weight rating is exceeded, or the ankle (including the external casing) is modified in any way.

Product Specifications

User Weight Limit	Build Height	Ankle Weight
275lbs (125 kg)	2.1in. (54 mm)	1.1lbs (520 g)

Patent 10857008

Installation:

Goralign PSA (Plus Shock Absorption) ankle should be used with the visible aluminum component up (connected with the pyramid and pylon in Figure A) and the flat side facing anteriorly.

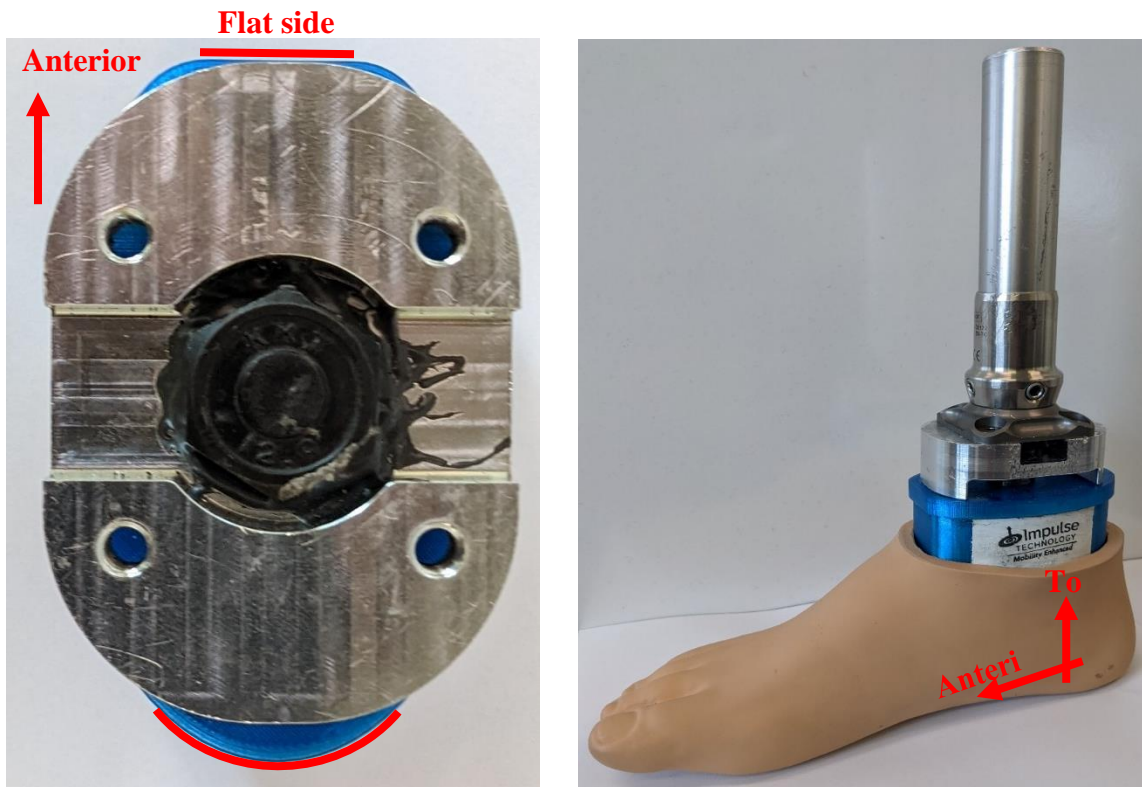


Figure A: Goralign PSA correct orientation in a pylon-ankle-foot assembly.

Male and/or female pyramid adapters may be used on both the proximal and distal sides of the Goralign PSA. Please refer to Figure B.

Place at least one spacer between the bottom of the Goralign PSA and the distal pyramid adapter.

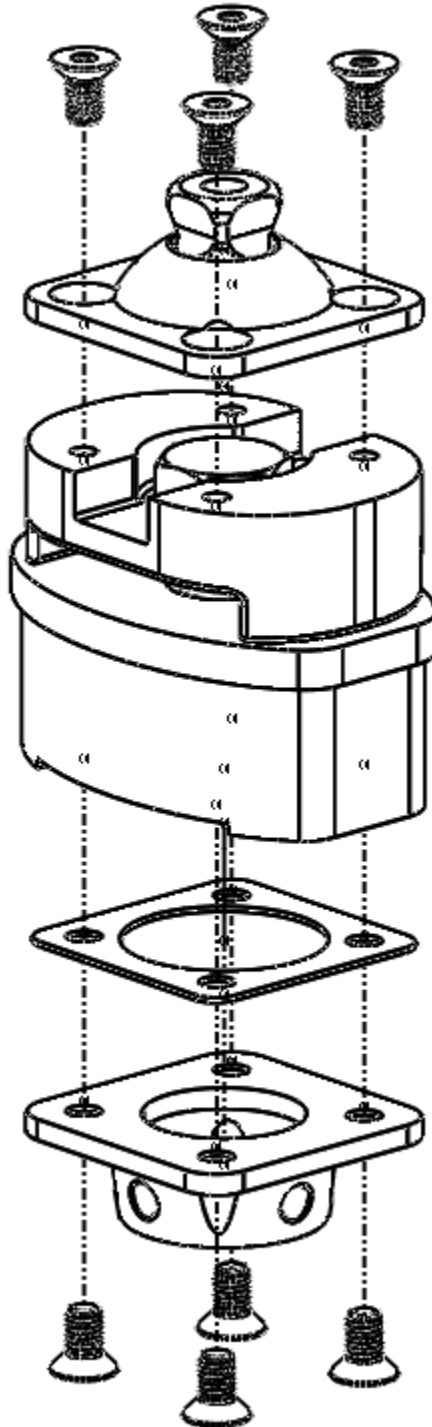


Figure B: Method of assembly if male and/or female pyramid are used.

Bolts into the distal side should not protrude from pyramid adapter & spacer more than 8 mm. Please refer to Figure C below

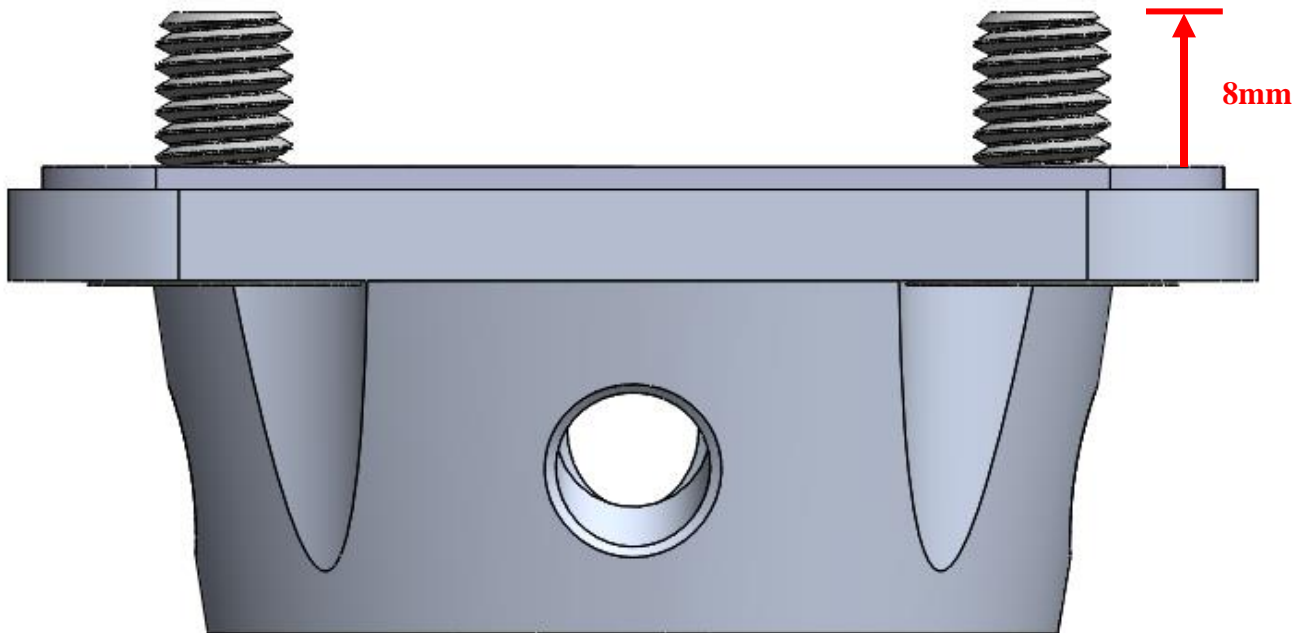


Figure C. Proper spacer thickness will limit the protruded section of the bolts to 8 mm.

Maintenance and Care:

The Goralign PSA is filled with a fine rubber powder. Over time, the user may notice some black powder coming from between the exposed aluminum component and the top of the polymer casing. This can be cleared by wiping with a paper towel or using compressed air to blow the rubber powder out. If the user notices excessive amounts of black powder being released, it should be reported to the prosthetist immediately.

The Goralign PSA 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.

L-coding Information for Clinicians:

Recommended L-codes: L5986 +5988

Justification:

L5986



Figure 1: A side view of the Goralign ankle.

In the following figures, additional componentry has been attached to the Goralign ankle to more easily demonstrate its multi-axial functions.

Impulse Technology's Goralign Ankle allows 5° of plantarflexion (Figure 2a) and 2° of dorsiflexion (Figure 2c) in the sagittal plane.

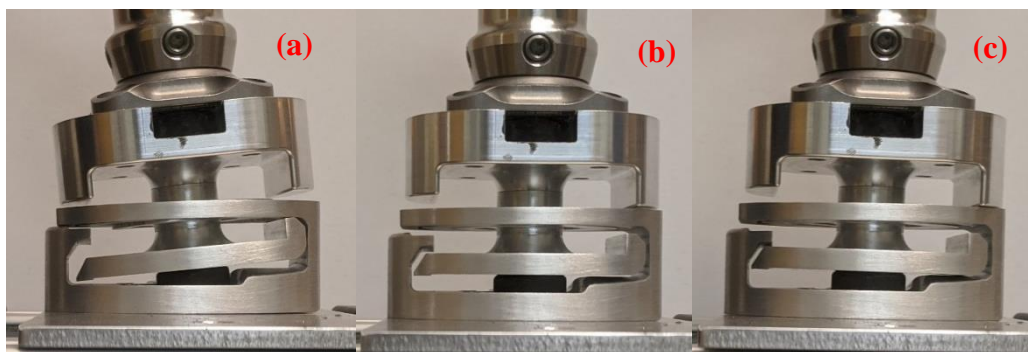


Figure 2. Side view of Goralign ankle in (a) plantarflexed, (b) neutral, and (c) dorsiflexed positions.

Additionally, the Impulse Technology Goralign Ankle provides up to 5° each of inversion (Figure 2a) and eversion (Figure 3c).

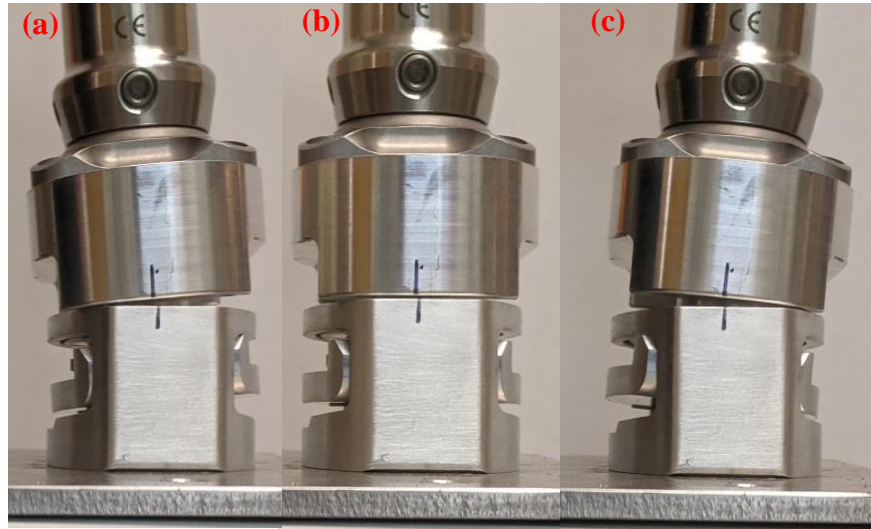


Figure 3. Front (anterior-to-posterior) view of Goralign ankle in (a) inverted, (b) neutral, and (c) everted positions

Finally, the Impulse Technology's Goralign Ankle provides up to 5° internal (Figure 3a) and external rotation (Figure 4c).

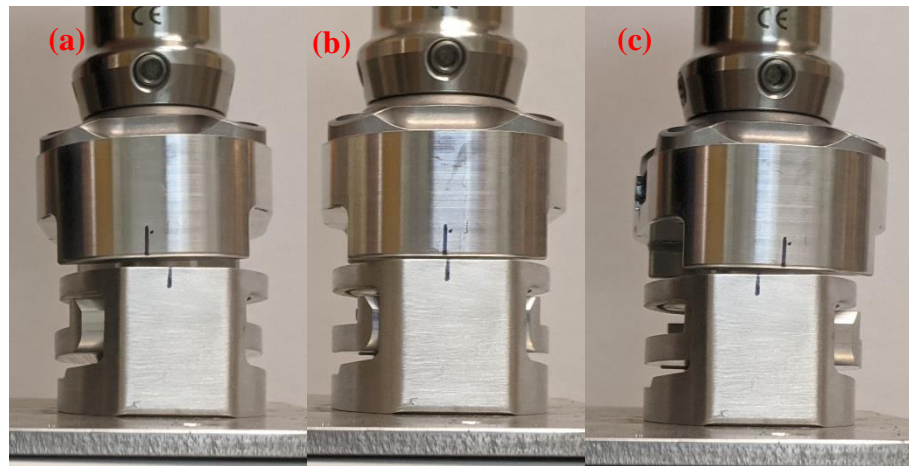


Figure 4. Front (anterior-to-posterior) view of Goralign ankle in (a) internally rotated, (b) neutral, and (c) externally rotated positions

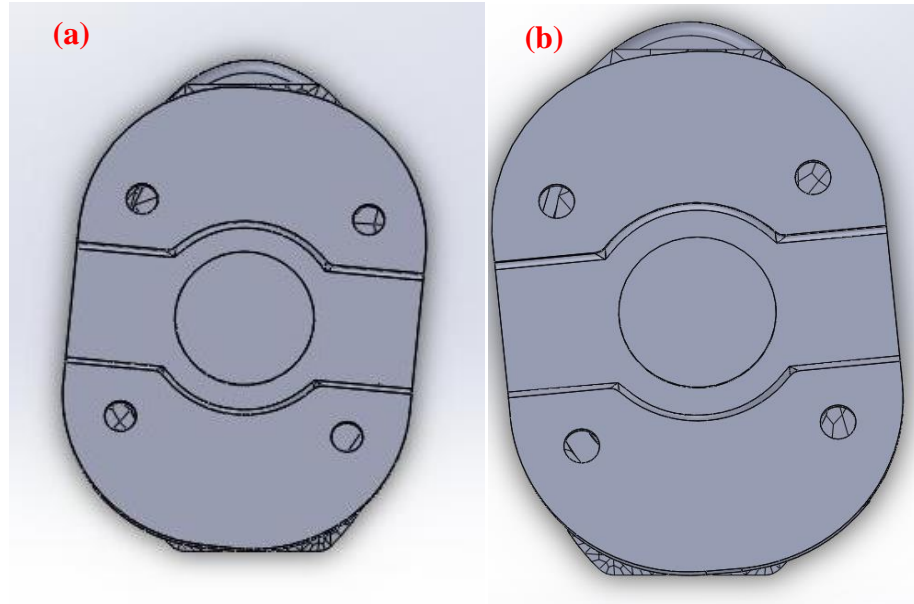


Figure 5. Top view of Goralign ankle in (a) internally rotated and (b) externally rotated positions

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The Goralign ankle's shock absorbing casing (GoraliSA) is filled with a fine rubber powder to provide vertical shock absorption throughout the stance phase of gait.

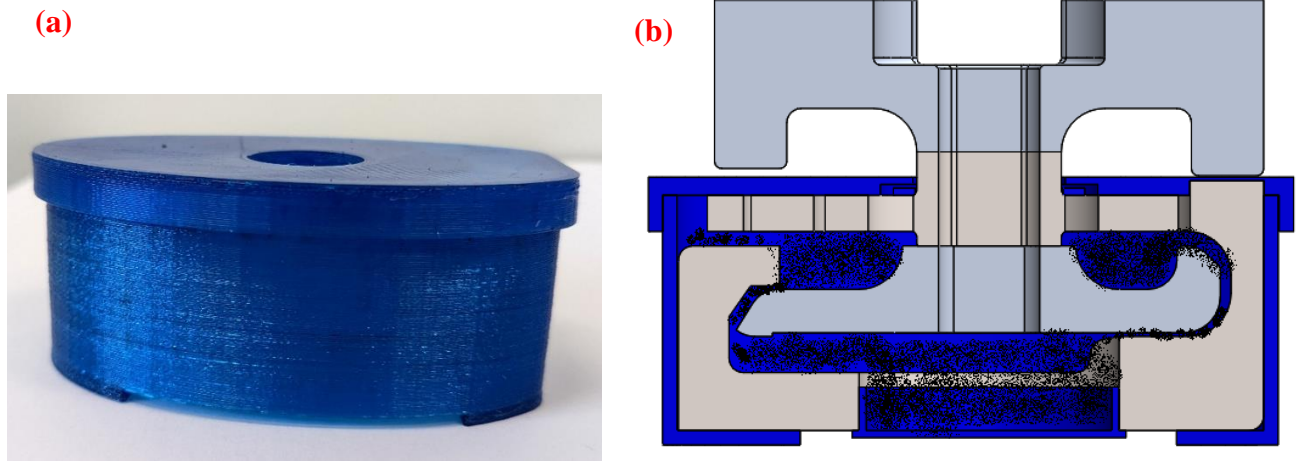


Figure 6. (a) GoraliSA casing and (b) illustration of areas filled with shock absorbing rubber powder

Polyurethane foam is placed on one face of the top adapter and the top of the middle adapter (highlighted with red boxes) to provide additional shock absorption during early stance (heel contact). Additionally, the polyurethane casing contributes to this early shock absorption as well.

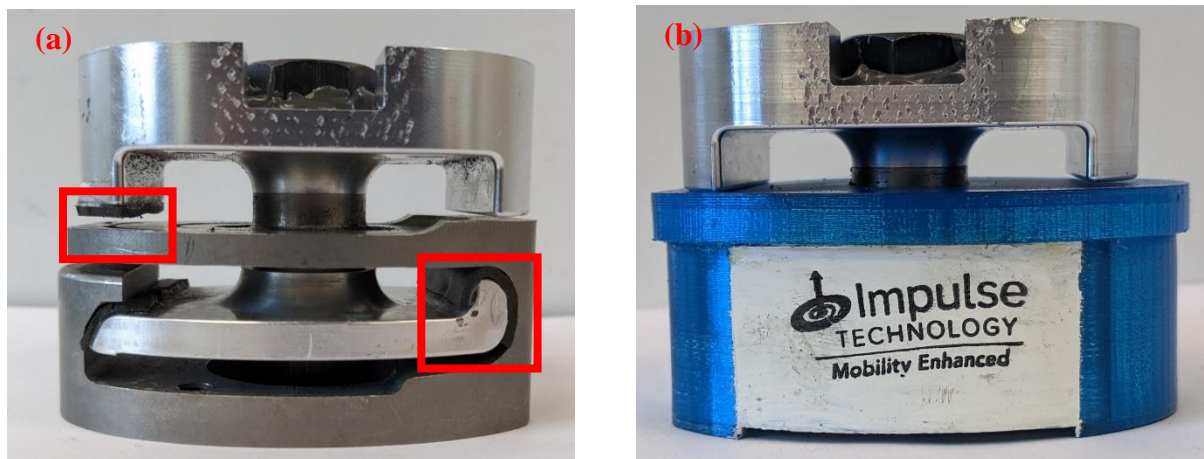


Figure 7. (a) Shock absorbing foam locations and (b) fully assembled Goralign PSA