



Pro-Flex® LP Align Webinar

Sarah Mulroy-Lang (CPO)

July 2018

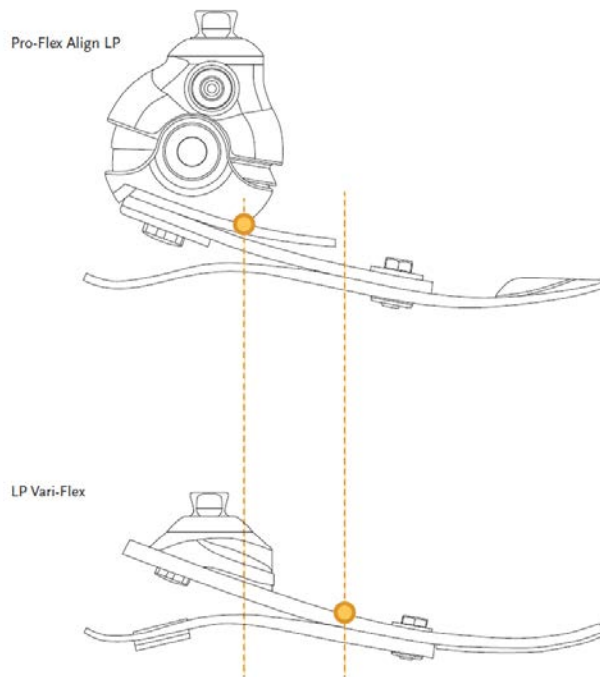
Launching the New Pro-Flex LP Align

- The Pro-Flex LP Align gives the user the freedom to wear the appropriate footwear for any occasion without compromising the alignment of the prosthesis.
- The users can adjust the alignment of the foot to match different heel heights, while maintaining the optimal overall prosthetic alignment set by their prosthetist.



Pro-Flex LP Align

- The concept is based on the Pro-Flex LP design. Top and middle blades are the same as Pro-Flex LP.
- Bottom blade based on Pro-Flex LP with a slight curvature of the toes for good fit at different heel height settings



- **Mid-blade is reversed tapered** allowing more flex anteriorly.
- Posterior part of the mid-blade is thinner and gets gradually thicker anteriorly towards the sole blade attachment bolts.
- Functional ankle joint center of Pro-Flex® LP and Pro-Flex® LP Align is closer to anatomical than LP Vari-Flex

Pro-Flex LP Align

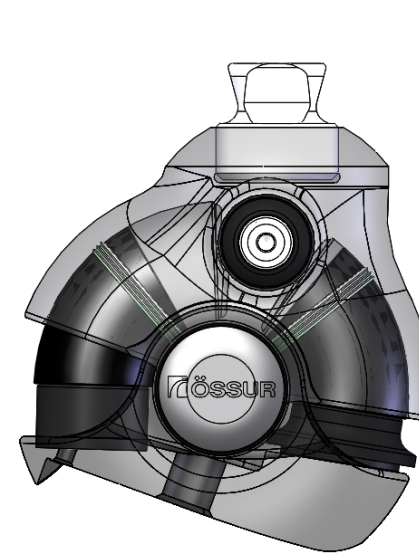
- The foot has a narrow foot cover and can be fitted with calf cosmesis. (Size 22-26 Cat 1-5 only)
- The curved flexible toe and narrower foot cover for the smaller sizes allows for better fitting in shoes.
- The heel height can be adjusted **up to 7 cm**
- Curved toe piece on bottom blade ensures full compatibility with the foot cover for all angles of the ankle
- The foot is **weatherproof**
 - Fresh water, splashing



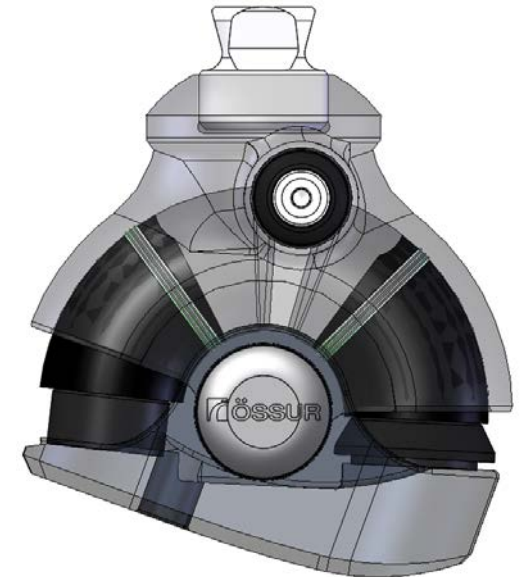
Hydraulic Housing

- Two versions of hydraulic housing
 - Small housing (size 22-26 cat 1-5)
 - Standard housing (size 25-26 cat 6 and size 27-28 cat 1-6)
 - Left and right housings
- 0-7cm (2.76inch) heel height adjustability

0-7cm



Small housing



Standard housing

Lock and Release Button

- Heel height adjusted through a simple push of a button
- Button is designed to be in open or closed position
 - Open position – heel height can be adjusted
 - The device **SHOULD NOT** be used in the unlocked position for weight-bearing.
 - Closed position – unit locked/non adjustable
- Press the medial (inner) side of the Lock/Release button to unlock the ankle, and lateral (outer) side to lock
- Good usability of button through cosmesis/spectra socks
 - Clear open and close feedback (feel and sound)
- When not used for some time button may become stiffer
 - Loosens up after first movement

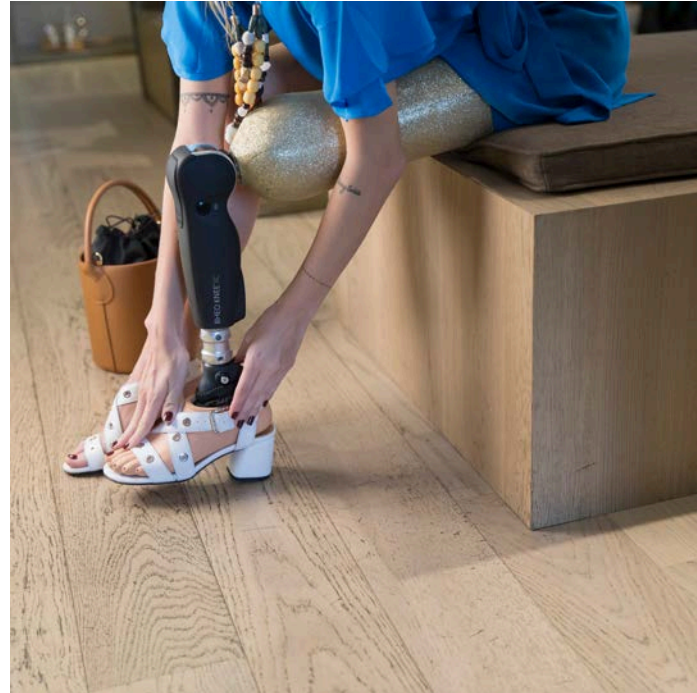
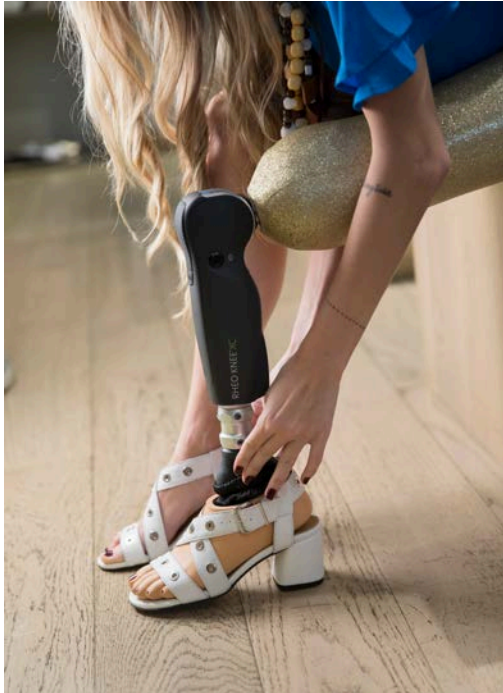


Unlocked ankle (open position of button)



Locked ankle (closed position of button)

Adjusting Heel Height

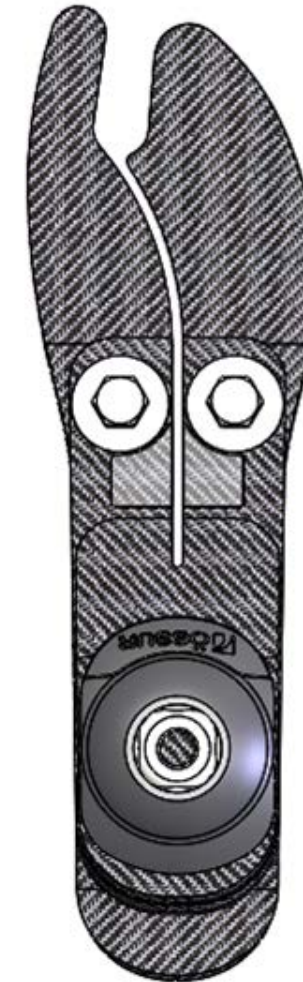
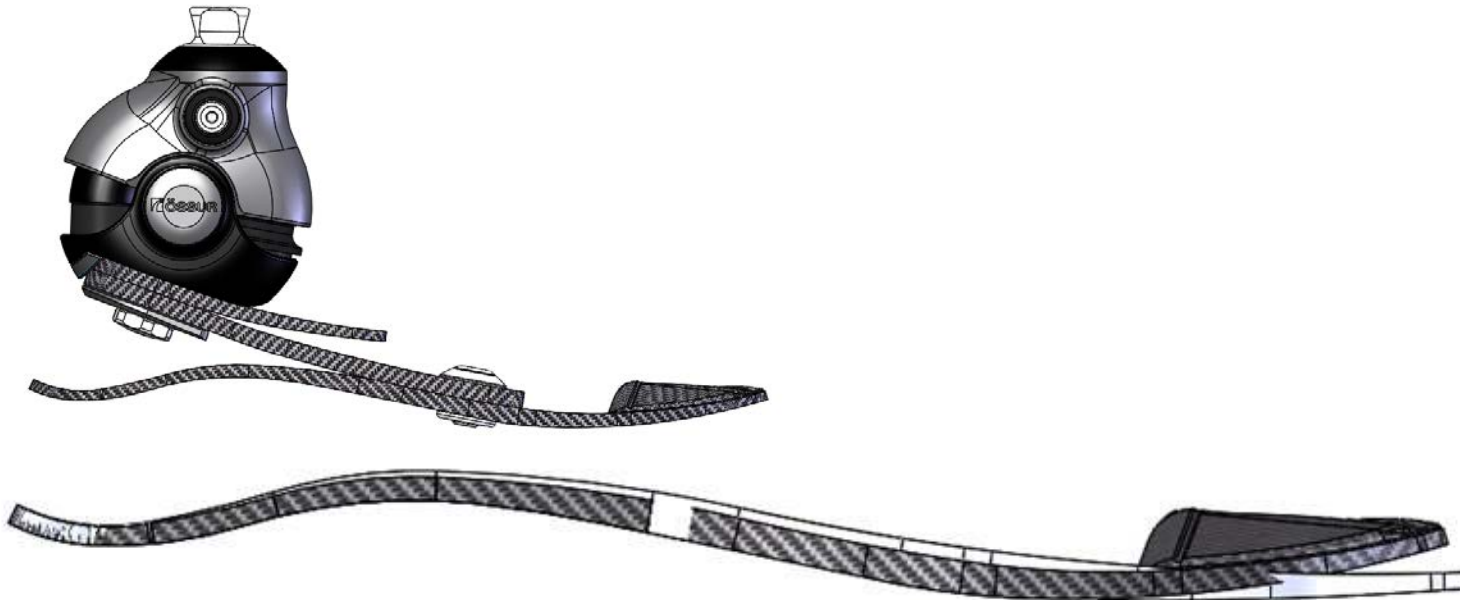


The user can adjust the ankle to the appropriate heel height in sitting, by pressing on the toe or heel, or adjusting on a flat surface such as a table top

The pylon or shin section should be perpendicular to the floor or flat surface

Pro-Flex LP Align vs Pro-Flex LP

- Bottom blade based on Pro-Flex family with a slight curvature of the toes for good fit at different heel height settings
- Hybrid lay-up in bottom blade (glass/carbon fiber) allows for more flexible toe to adjust to high heel shoes.
- Toe piece ensures full compatibility with the foot cover for all angles of the foot



Pro-Flex LP



Pro-Flex LP Align

Foot Cover Options

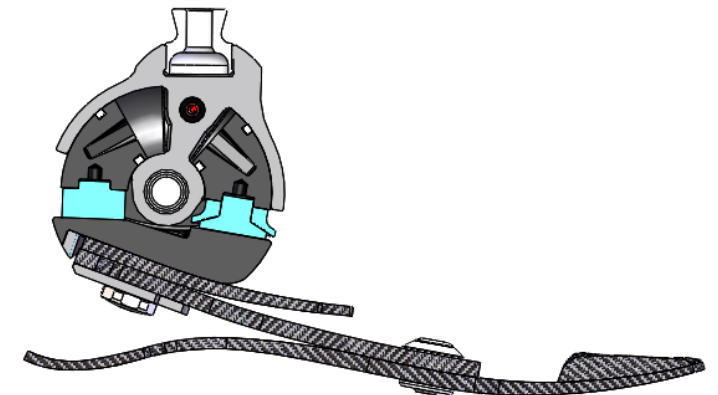
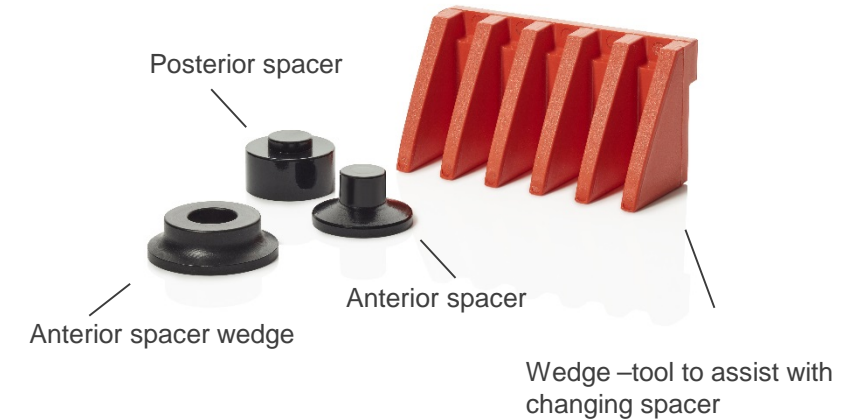
- Two types of footcovers for Pro-Flex LP Align (see table).
 - Available in beige and brown
- FSF is a narrow footcover for sizes 22-26 categories 1-5
 - FSF has no attachment plate, and lower opening
 - Calf Cosmesis can be used with FSF footcover
- FST is standard Pro-Flex footcover for sizes 27-28 and for categories 6 in size 25-26
 - Has attachment plate
 - No Calf Cover available

		Size							
		22	23	24	25	26	27	28	
Category	1	Small housing FSF Footcover Calf Cosmesis					Standard housing FST Footcover No Calf Cosmesis		N/A
	2								
	3								
	4								
	5								
	6	N/A							



Pro-Flex LP Align: Maintenance

- The Pro-Flex LP Align features spacers which sit in the anterior and posterior of the hydraulic housing.
- The spacer is stiff, allowing the dynamic movement of the foot to come from the 3 carbon blades
- Spacers in Pro-Flex LP Align compensate for play in units caused by external temperature changes
 - **Oil shrinks in cold temperatures**
 - **Spacers press against pistons removing play**
- Play may develop if spacers are worn out after a long period of time
 - If experiencing play, remove the footcover and inspect the spacer wedges for signs of wear or tear.
 - Replace spacers if necessary



Pro-Flex LP Align - Adjusted Heel Height



Pro-Flex LP Align: Barefoot Walking



Pro-Flex LP Align: High Heels

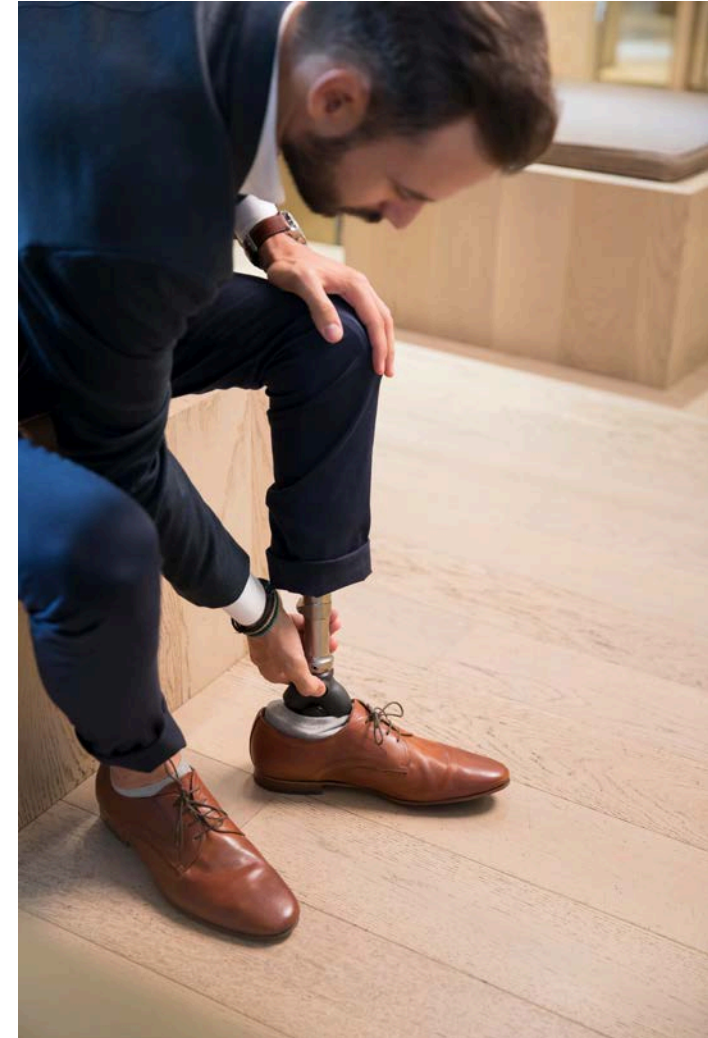


Pro-Flex LP Align: Calf Cover



User Profile

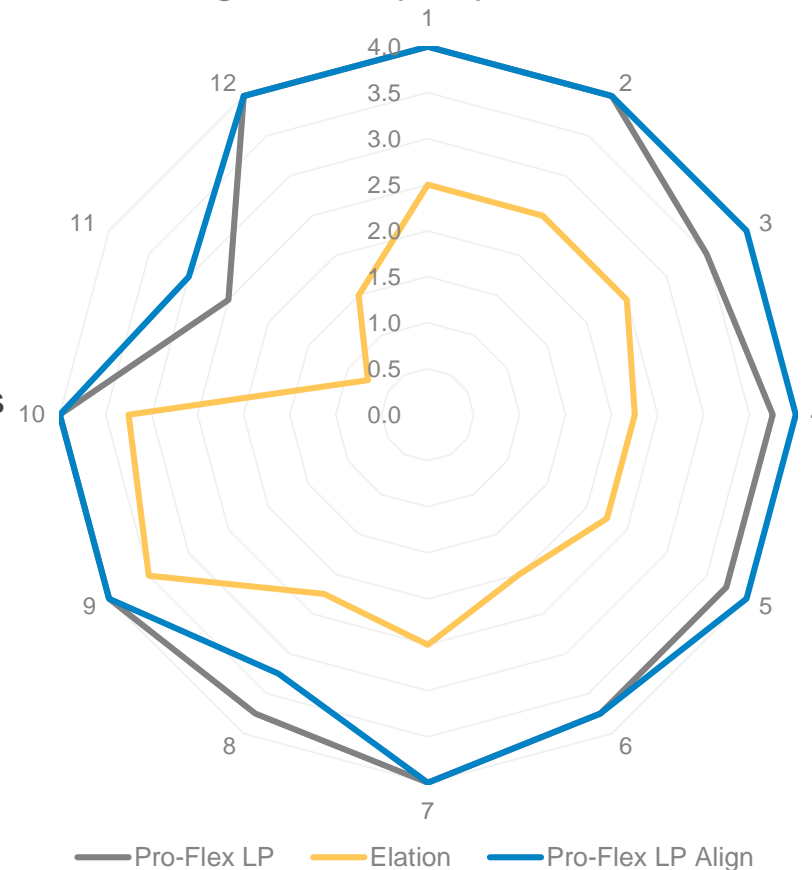
- Transtibial, Knee disarticulation, Transfemoral, and Hip disarticulation amputees
- K-Level: K2-K3
- Impact Level: Low to Moderate
- Male and female users that value the ability to change shoes without compromising alignment or dynamics of the prosthesis.
- Users that participate in different daily activities that may require different shoes or the removal of their shoes.
 - Changes or removal of shoes could be due to seasonal, cultural or religious reasons.
 - Different activities require different footwear, such as business, casual or recreational activities.
- Weight limit: 100kg-116kg



Prosthetic Evaluation Questionnaire(PMQ) Score: Mobility Subscale

1. To walk
2. To walk in confined space
3. To walk up stairs
4. To walk down stairs
5. To walk up a steep hill
6. To walk down a steep hill
7. To walk on sidewalks and streets
8. To walk on slippery surface
9. To get in and out of a car
10. To sit down and get up form a chair
11. To run a block
12. To walk for up to two hours

Average answer per question in PMQ



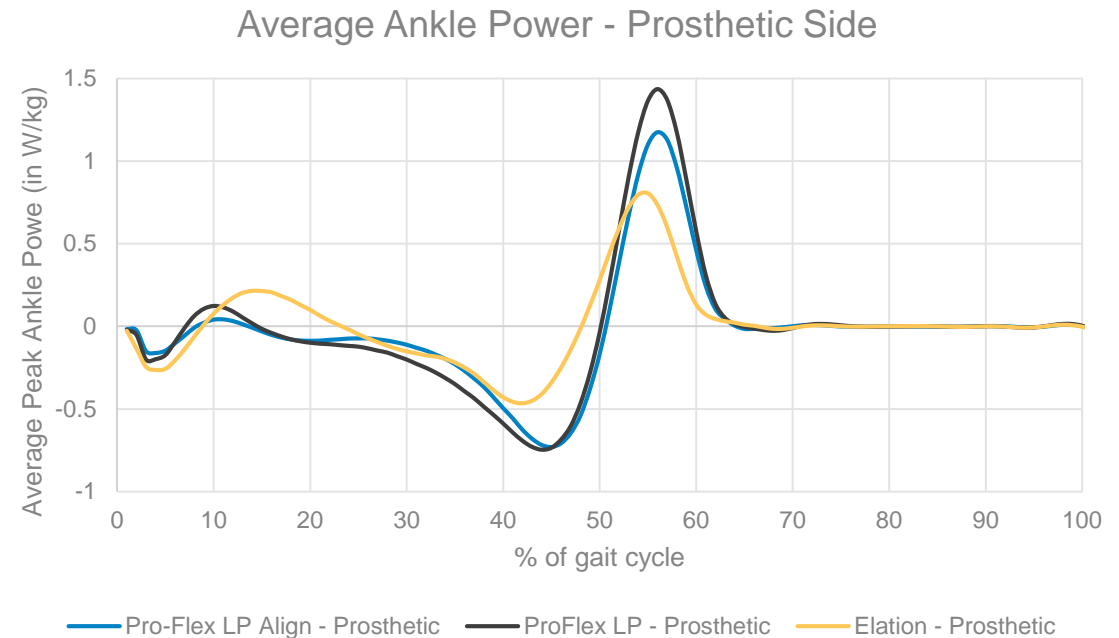
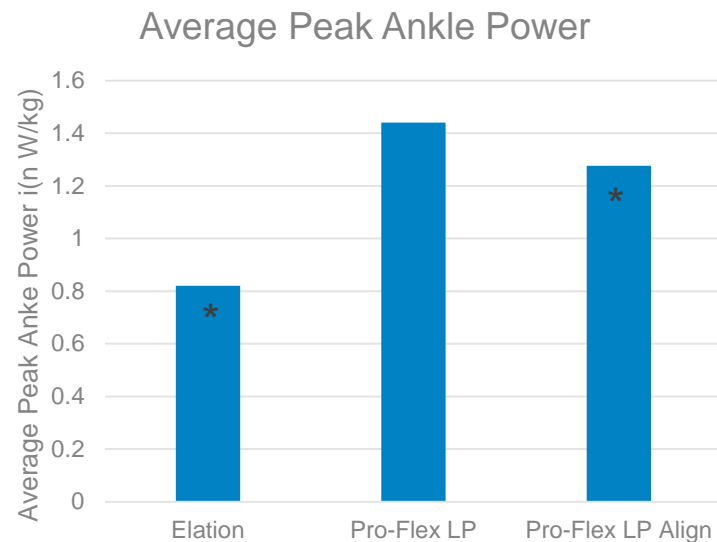
- Highest satisfaction Pro-Flex LP Align
 - Small difference between Pro-Flex LP Align and Pro-Flex LP
 - Pro-Flex LP Align scored higher in all questions compared to Elation

	Average score of PMQ (question1-12)
Pro-Flex LP Align	3.84*
Pro-Flex LP	3.75
Elation	2.31*

* Statistically significant differences between Pro-Flex LP Align and Elation

Peak Ankle Power – Sport Shoes

- Higher peak ankle power in Pro-Flex LP Align compared to Elation
- Highest peak ankle power in Pro-Flex LP
 - Less in Pro-Flex LP Align due to flexible toe (hybrid lay-up)

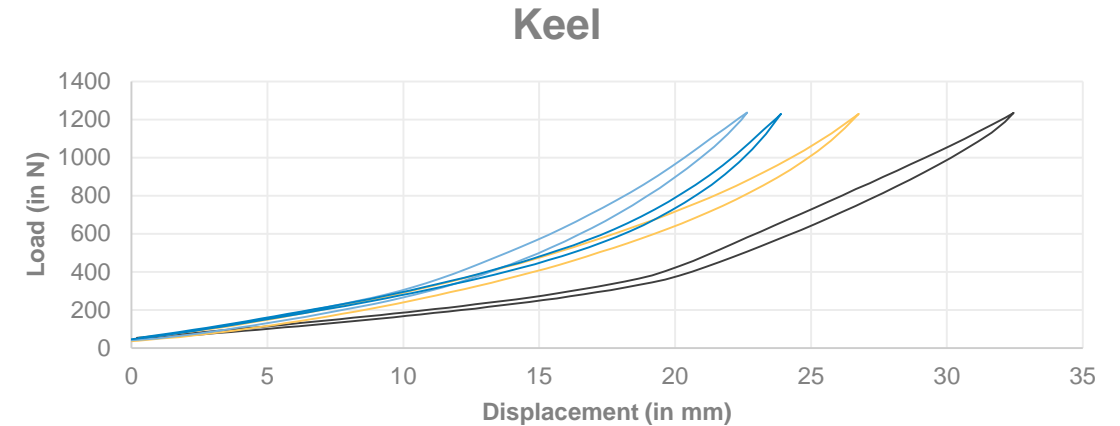


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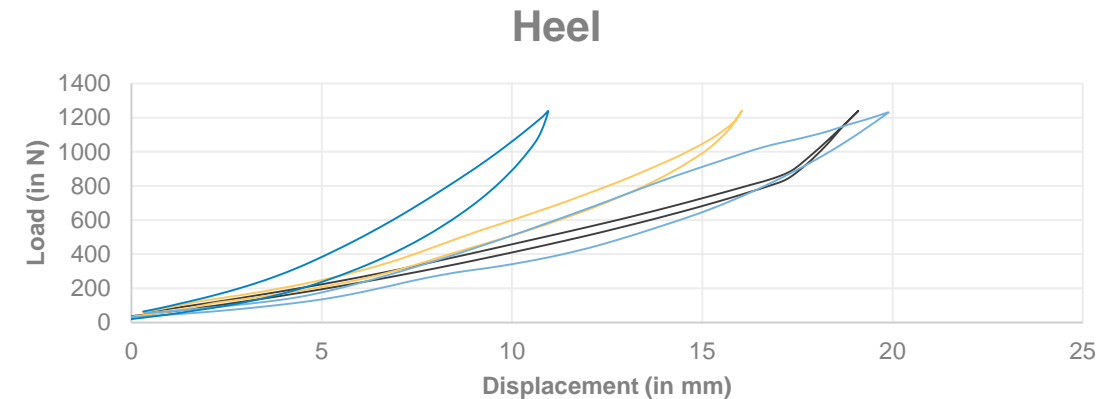
Toe – Keel Stiffness Characteristics – Mechanical Testing

- Progressive stiffness of Pro-Flex LP Align
- Pro-Flex LP Align shows lower stiffness during first part of the loading curve in both Keel and Heel compared to competitive feet.
- Clinically this indicated lower resistance to initial dorsiflexion for Pro-Flex LP Align and less moment needed for the residium of the amputee to load the foot. Higher displacement for the Pro-Flex LP Align indicates more ankle range of motion.

Energy Return	Keel	Heel
Pro-Flex LP Align - size 24 cat 3	92%	93%
Elation - size 24	90%	89%
Brand 1 - size 24	91%	77%
Brand 2 – size 24	95%	74%



— ProFlex LP Align size 24 cat 3 - toe — Elation size 24 - toe
 — Brand 1 size 24 - toe — Brand 2 size 24 - toe



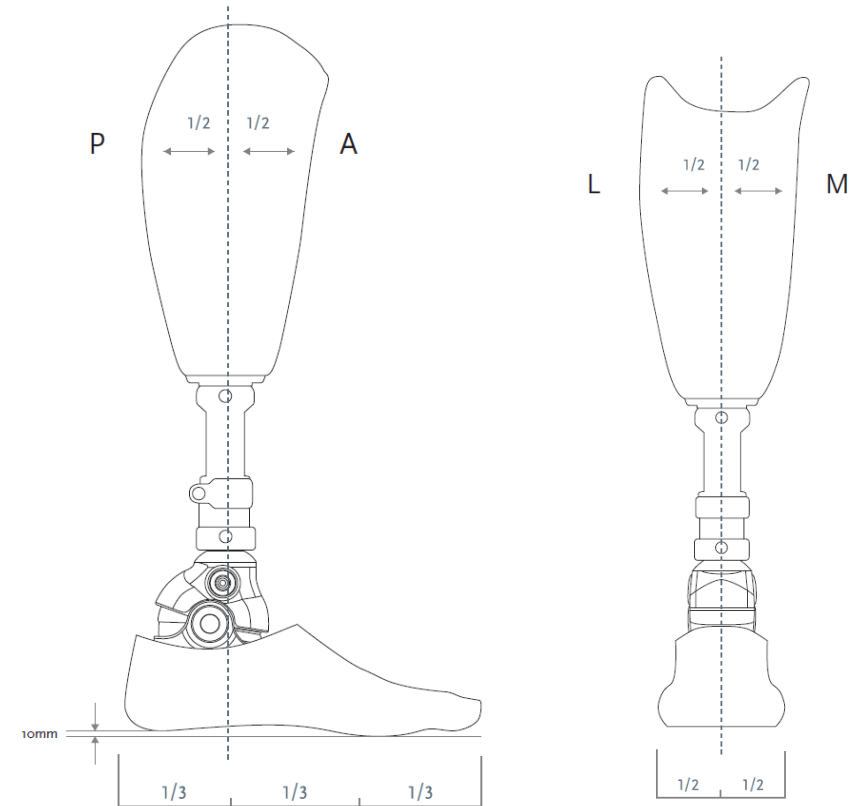
— ProFlex LP Align size 24 cat 3 - heel — Elation size 24 - heel
 — Brand 1 size 24 - heel — Brand 2 size 24 - heel

Overview and Comparison

	Pro-Flex LP Align	Pro-Flex LP	Elation
Weight (size 27 cat 5 with foot cover)	911 gram	646 gram	625 gram
Weight (size 24 cat 5 with foot cover)	703 gram	514 gram	622 gram
Build Height (size 27 cat 5 with foot cover)	132 mm	73mm	87mm
Build Height (size 24 cat 5 with foot cover)	116 mm	67mm	93 mm
Sandal Toe	Yes	Yes	Yes
Roll Over (out of 12)	8,25	9,25	6
User Satisfaction (PMQ MS12.5)	3,84	3,75	2,31
Ankle Power(W/kg)	1,28	1,44	0,8
Peak Dorsiflexion angle (in deg)	12,1	17,7	9,4

Bench Alignment

- Fit foot with selected foot cover
- Adjust foot to appropriate heel height when in shoe
- Introduce appropriate socket angles flexion/ extension and abduction/adduction
- Divide the foot cover into 3 equal portions
- The load line should fall at the junction of the posterior and the middle third portions as shown in a supporting figure
- The 1/3 position is marked on the inside wall of the foot cover














*The reversed-tapered technology of the middle blade makes the usage of heel wedges unnecessary. The use of heel wedges **is not recommended** as it affects the range of motion and the energy storage characteristics of the foot. For this reason no wedges are included in the foot kit

FSF Foot Cover Features (sizes sizes 22-26: cat 1-5 only)

FSF foot cover comes with sizes 22-26 (cat 1-5)

- Lower opening and no attachment plate



	Water proof
	Shoe Fit
	Anatomical features
	Lightweight
	Lower opening
	Full length toe
	Sandal Clamping
	Friction
	Washable
	Toe nails
	Black Sock

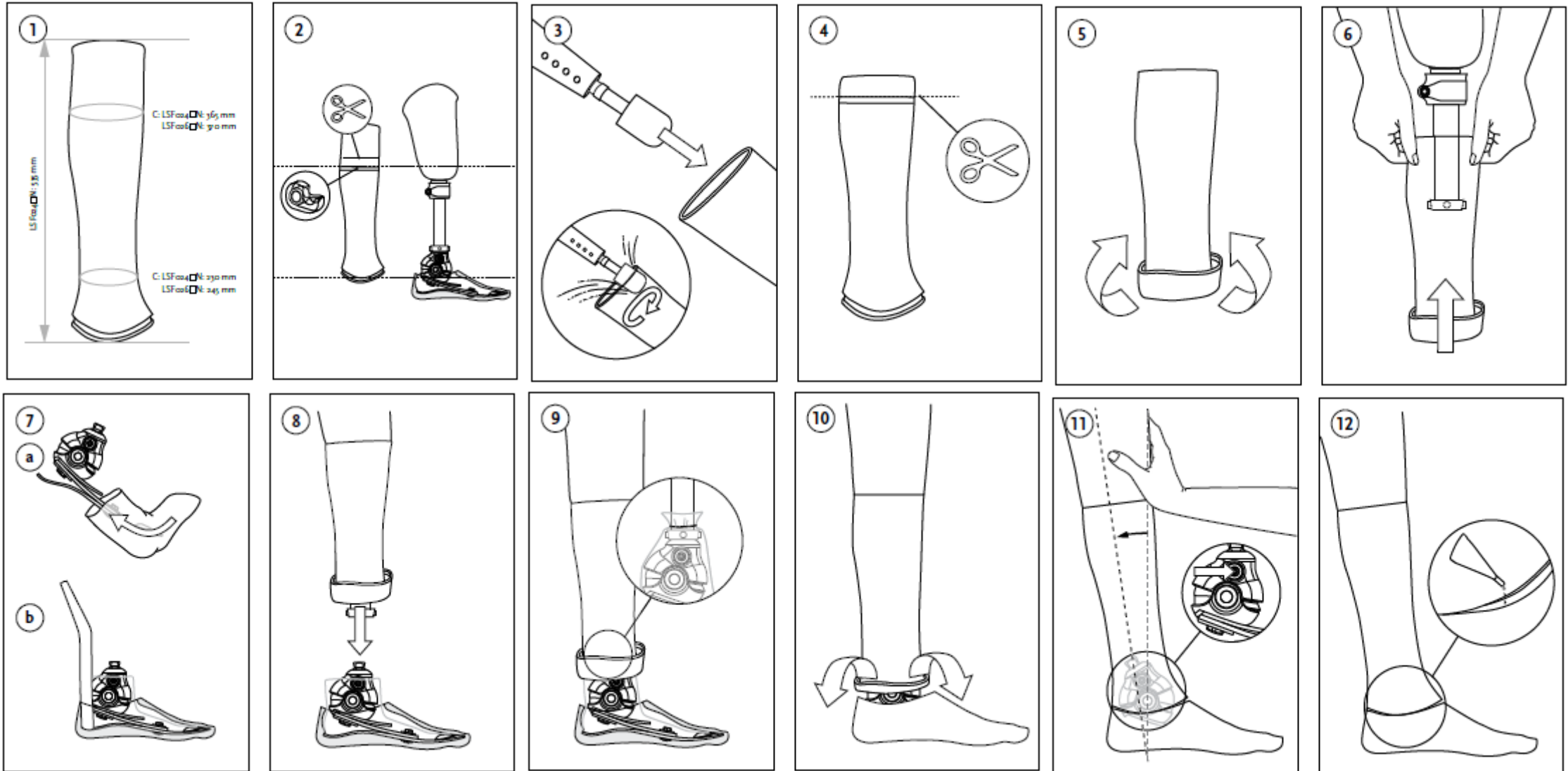
Calf Cosmesis

- Calf Cosmesis is available for FSF foot cover (sizes 22-26, cat 1-5)
- Available in left/right and 2 colours, brown and beige.



		Size						
		22	23	24	25	26	27	28
Category	1	CALF COSMESIS					N/A	
	2							
	3							
	4							
	5							
	6	N/A						

Calf Cosmesis - IFU



CATEGORY SELECTION CHART

Weight kg	45-52	53-59	60-68	69-77	78-88	89-100	101-116
Weight lbs	99-115	116-130	131-150	151-170	171-194	195-220	221-256
Low Impact Category							
Size 22-24	1	1	2	3	4	5	N/A
Size 25-27	1	1	2	3	4	5	6
Size 28	3	3	3	3	4	5	6
Moderate Impact Category							
Size 22-24	1	2	3	4	5	N/A	N/A
Size 25-27	1	2	3	4	5	6	N/A
Size 28	3	3	3	4	5	6	N/A

Items

- Pro-Flex LP Align kit includes:
 - Pro-Flex LP Align
 - Foot cover + black spectra sock
 - IFU
 - Premium packaging

- FSF footcover includes:
 - Footcover
 - Black spectra sock

- FST footcover includes:
 - Footcover
 - Footcover attachment
 - Black Spectra Sock

- Spacer kit includes:
 - Anterior spacer
 - Heel bumper
 - Anterior spacer wedge
 - Wedge – tool to replace spacer

- Calf Cosmesis can be purchased separately for foot sizes 22-26

Product	Item – cat/size
Pro-Flex LP Align	PLA0yxxz <ul style="list-style-type: none"> • <i>y=catagory xx=size z= L/R</i> • <i>Add BR to order number, for brown foot cover</i>
Accessories	Item – cat/size
Calf Cosmesis	LSF024Nz <ul style="list-style-type: none"> • Size 22-24, z=L/R LSF026Nz <ul style="list-style-type: none"> • Size 25-26, z=L/R • <i>Add BR to order number, for brown Calf Cosmesis</i>
FSF Footcover	FSF0xxz <ul style="list-style-type: none"> • Size 22-26, cat 1-5 • <i>xx=size z= L/R</i> • <i>Add BR to order number, for brown foot cover</i>
FST Footcover	FST0xxz <ul style="list-style-type: none"> • Size 27-28, cat 1-6 • Size 25-26, cat 6 • <i>xx=size z= L/R</i> • <i>Add BR to order number, for brown foot cover</i>
Spacer kit	PLA50005 <ul style="list-style-type: none"> • Size 22-24, cat 1-5 PLA50006 <ul style="list-style-type: none"> • Size 25-26, cat 6 • Size 27-28, cat 1-6 PLA50007 <ul style="list-style-type: none"> • Size 25-26 cat 1-5

Pro-Flex® Family



Pro-Flex K2-K3
Rated to 125kg



Pro-Flex XC K3-K4
Rated to 166kg

Pro-Flex XC Torsion K3-K4
Rated to 147kg



Pro-Flex LP K2-K4
Rated to 166kg

Pro-Flex LP Torsion K3-K4
Rated to 147kg

Pro-Flex XC Torsion and Pro-Flex LP Torsion



The torsion-shock unit compensates for physiological rotation and vertical shock absorption of lost joints, delivering more comfort for the end user, and less stress on the residual limb.

Less load and more dynamics means that amputees with a longer limb can enjoy greater comfort in a wide range of activities.

Pro-Flex XC Torsion

- Based on the C-Shaped design of the Pro-Flex XC
- Active users looking to use a single, lightweight foot for their normal daily life, as well as for a range of higher impact activities



Pro-Flex LP Torsion

- Based on the 3 blade design of the Pro-Flex LP
- For users with compromised space who would benefit from shock absorption and rotation

Pro-Flex XC Torsion

Pro-Flex XC Torsion is based on the design of the Pro-Flex XC

- C-Shape design:
 - Increased ankle motion when compared to Vari-Flex and similar when compared with Vari-Flex XC Rotate
 - Vertical shock absorption
 - 10mm of vertical compression from C-shaped design, plus 6mm of axial compression from torsion unit
- Torsion-shock unit:
 - Compensates for physiological rotation and vertical shock absorption of lost joints
 - Increases comfort
 - Reduces stress on the residual limb
- Unity Compatible



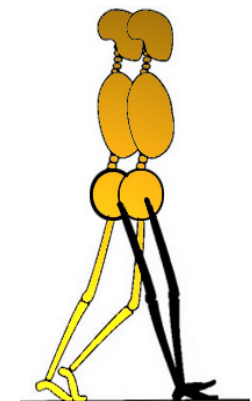
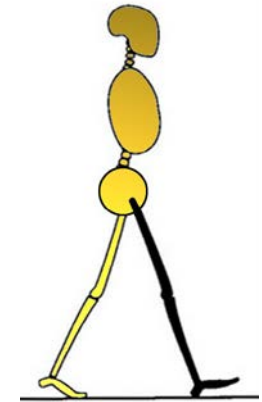
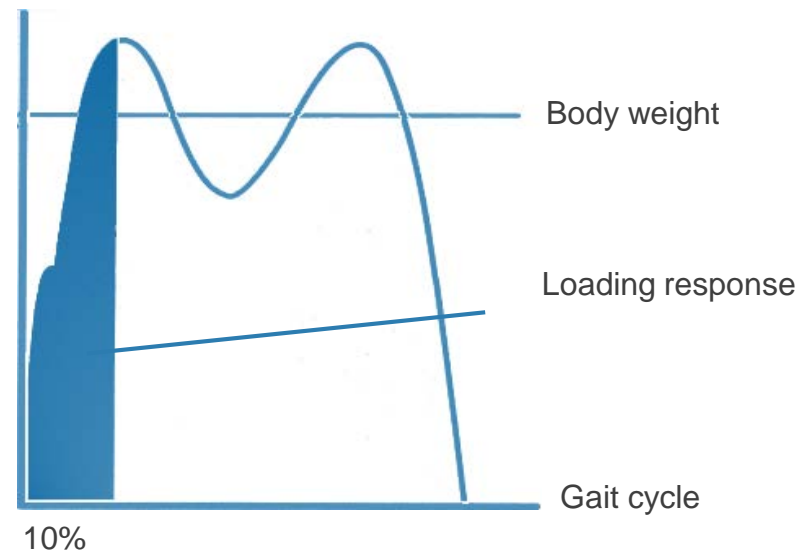
Medical Necessity: Why shock absorption

At initial contact (0-2%):

- The joint motion during this phase allows the transfer of weight onto the new stance phase leg while attenuating shock, preserving gait velocity, and maintaining stability.

At loading Response (2-10%):

- Acceptance of body weight
 - Controlled plantar flexion
 - Controlled knee flexion
 - Fat cushion under the heel
 - S-shape of spine



If circumferencial and logitudinal directed motion of the socket were permitted by introducing transverse rotation and longitudinal translation, the resulting stresses may be reduced

PERMITTED ROTATION AND SHOCK MOVEMENTS REDUCE SHEAR STRESS

- Able-bodied: Ground reaction forces → anatomical foot
- Prosthetic users: Ground reaction forces → prosthesis → residual limb
- Only small amount of forces acts **perpendicularly** on the skin, causing the majority of forces to create **shear stress**



- Forces can be excessive because of shock impact

Twiste M. Transverse rotation and longitudinal translation during prosthetic gait – A literature review. *Journal of Rehabilitation*, 2003; 40: 9-18

If reduced transverse plane moments lower shear stresses applied to the residual limb, torsion adapters will likely reduce discomfort and incidents of injury experienced by lower limb amputees.

LOWER SHEAR STRESSES → REDUCED DISCOMFORT

- n=10 transtibial amputees
- 3 weeks acclimation
- Rigid vs torsion adapter

Segal AD, et al. Transtibial amputee joint rotation moments during straight-line walking and a common turning task with and without a torsion adapter. Journal of Rehabilitation R&D. 2009 46:375-384

The addition of a torsion adapter resulted in small improvements in functional mobility and self-perceived pain interference with activities.

SELF PERCEIVED PAIN REDUCTION

- n=10 transtibial amputees
- 6MWT
- Less pain interference with activities
- Evidence supports prescribing this device for amputees with difficulty navigating the household and community environments

Segal AD, et al. Does a Torsion Adapter Improve Functional Mobility, Pain and Fatigue in Patients with Transtibial Amputation? Clin Orthop Relat Res 2014 472:3085–3092

Shear stress at the stump in transtibial amputees induced by turning movements may be reduced with the use of torsion adapters in the prosthesis.

REDUCED SHEAR STRESS

- n=10 transtibial amputees
- Vari-Flex XC → Vari-Flex XC Rotate
- Shear stress at the stump may increase in stump–socket interface stiffness and may be the reason for residual limb problems. Torsion adapters therefore may be beneficial for comfort and stump condition in individual cases.

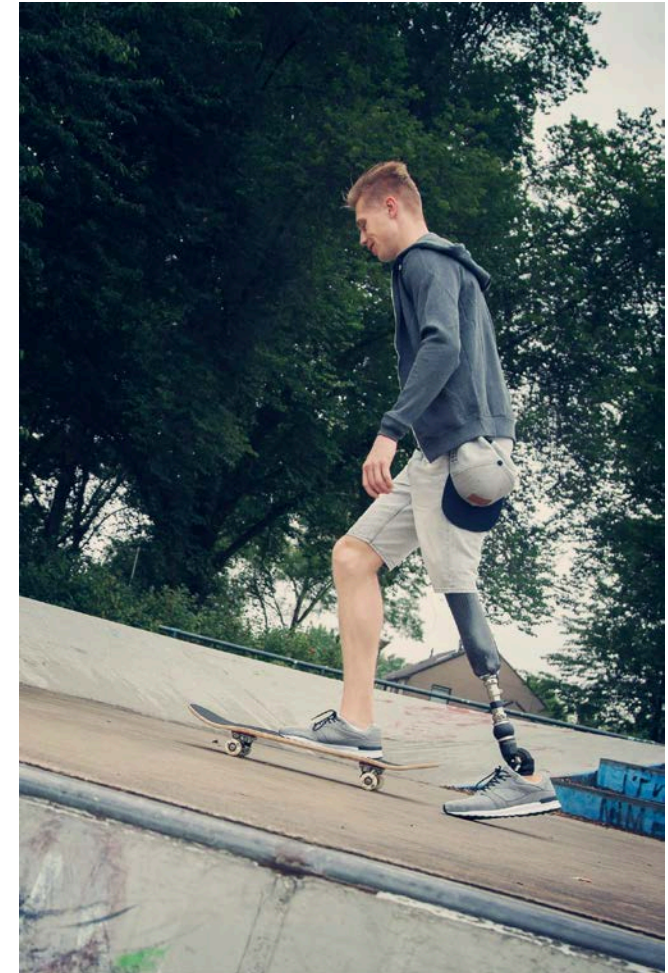
Heitzmann D, et al. Functional effects of a prosthetic torsion adapter in transtibial amputees during unplanned spin and step turns. *Prosthet Orthot Int* 2015; 1-8.

Pro-Flex XC Torsion: Torsion Unit



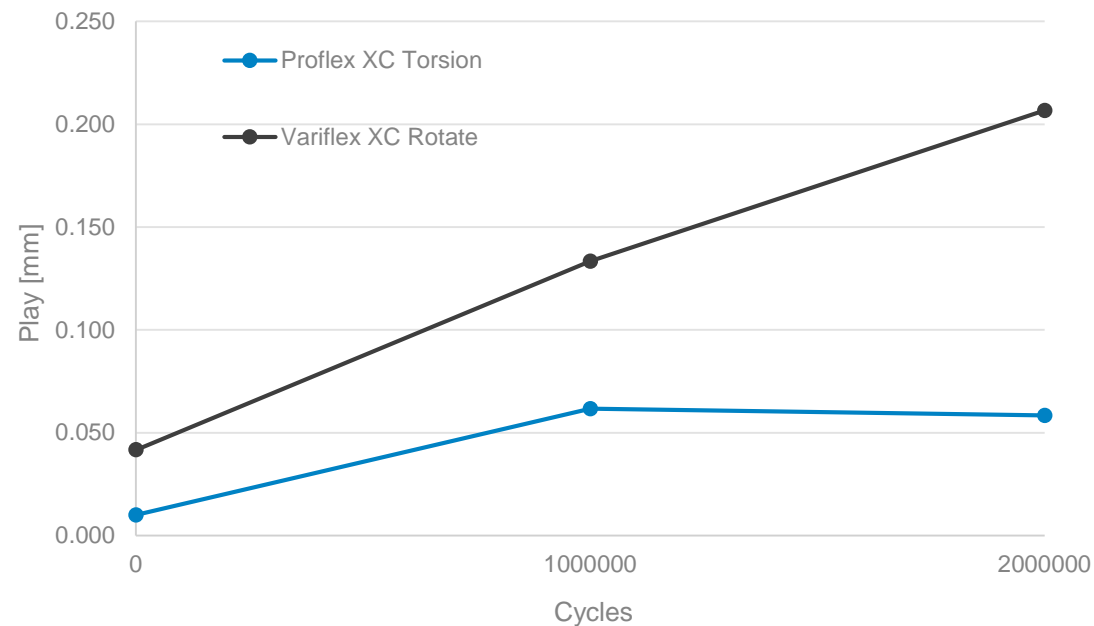
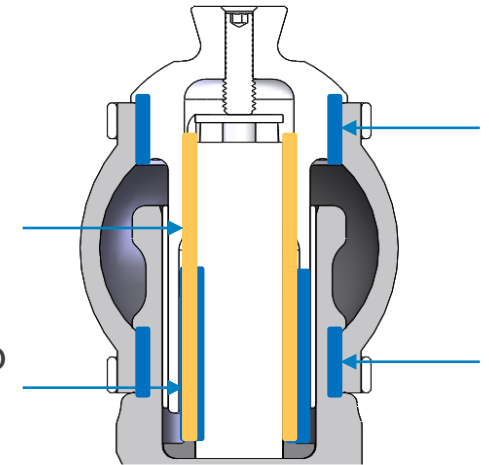
User Profile: Pro-Flex XC Torsion

- Transtibial, Knee disarticulation, Transfemoral and Hip disarticulation amputees
- Activity level: K2, K3 and K4
- Impact level: Low to High
- User weight limit: 147 kg for low impact
130 kg for medium impact
116 kg for high impact
- Ideal for active users who want to use a single, lightweight foot for their normal daily life, as well as a range of higher impact activities



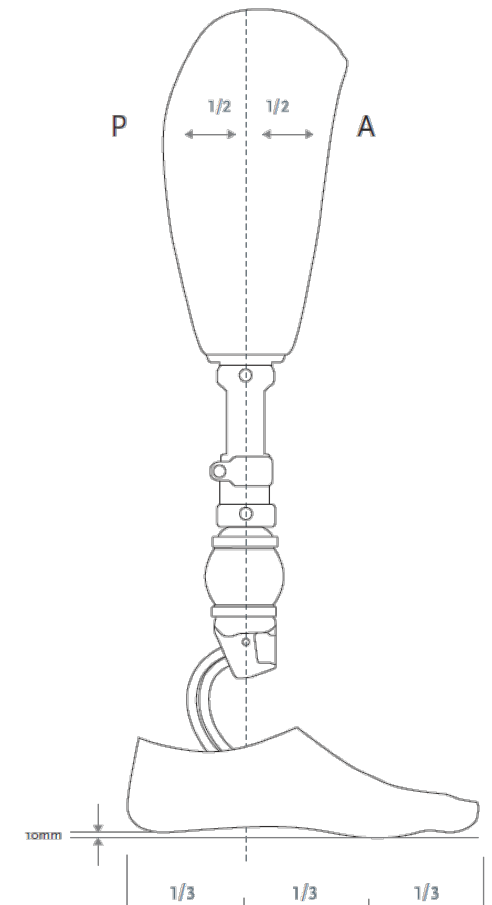
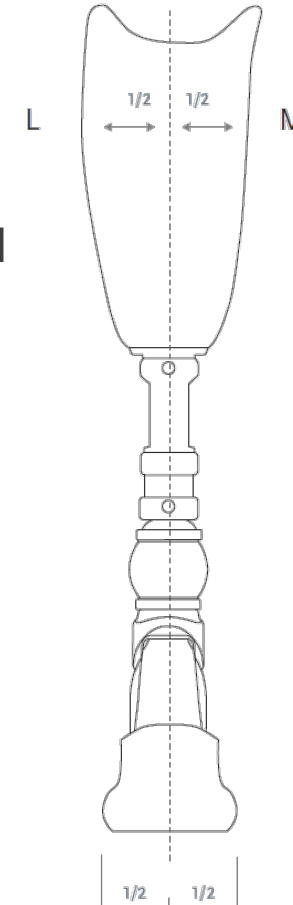
Product Characteristics: Improved Durability

- Pro-Flex XC Torsion features improved durability over the Vari-Flex XC Rotate
 - Adjusted materials to ensure complete compatibility
 - Increased surface area of the rod
 - Self lubricating rod with thicker grease
 - Knurl surface pattern which holds the torsion cell in place is more rough to prevent slip



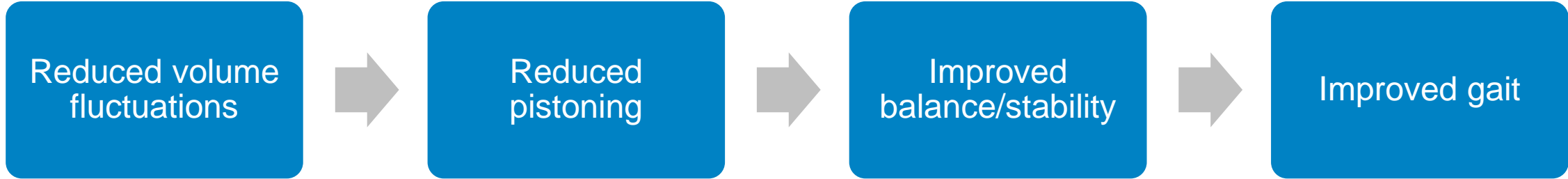
Alignment

- Adjust to appropriate heel height (using the shoe)
- Introduce appropriate socket angles flexion / extension and abduction / adduction
- Alignment reference line from bisection of socket on MPT level should pass through the junction of the posterior and middle third of the foot (mark in footcover).

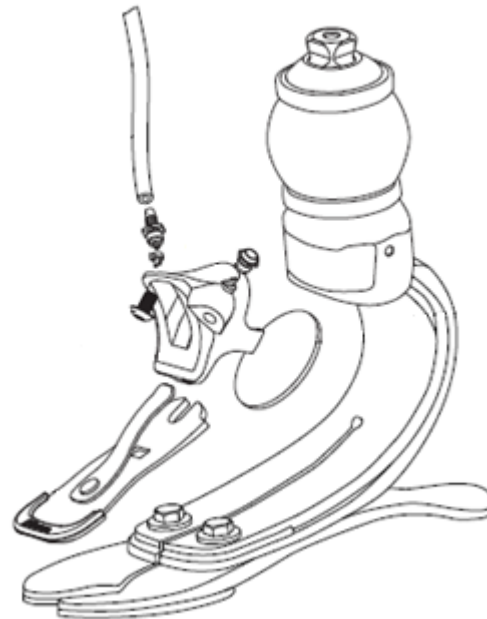


*The use of heel wedges is not recommended as it affects the range of motion and the energy storage characteristics of the foot. For this reason no wedges are included in the foot kit

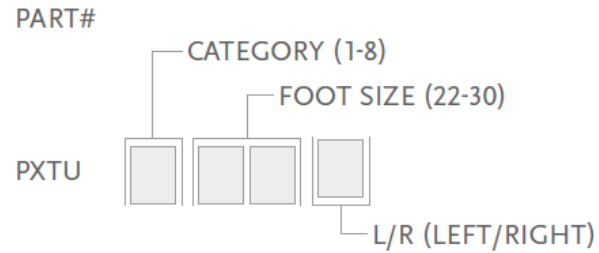
Unity for Pro-Flex XC Torsion



- Sleeveless
- Light weight
- No extra build height
- Retrofittable



Unity for Pro-Flex XC Torsion

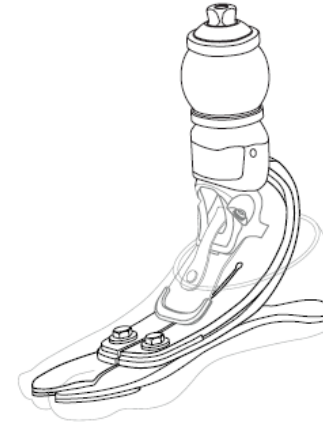


Includes:

- Foot Module
- Removable Foot Cover* with a black Spectra Sock

*For Pro-Flex XC with brown foot cover add a "BR" suffix to the part#.

Note: Unity will come preassembled on the foot if ordered with PXTU.



UNITY KITS

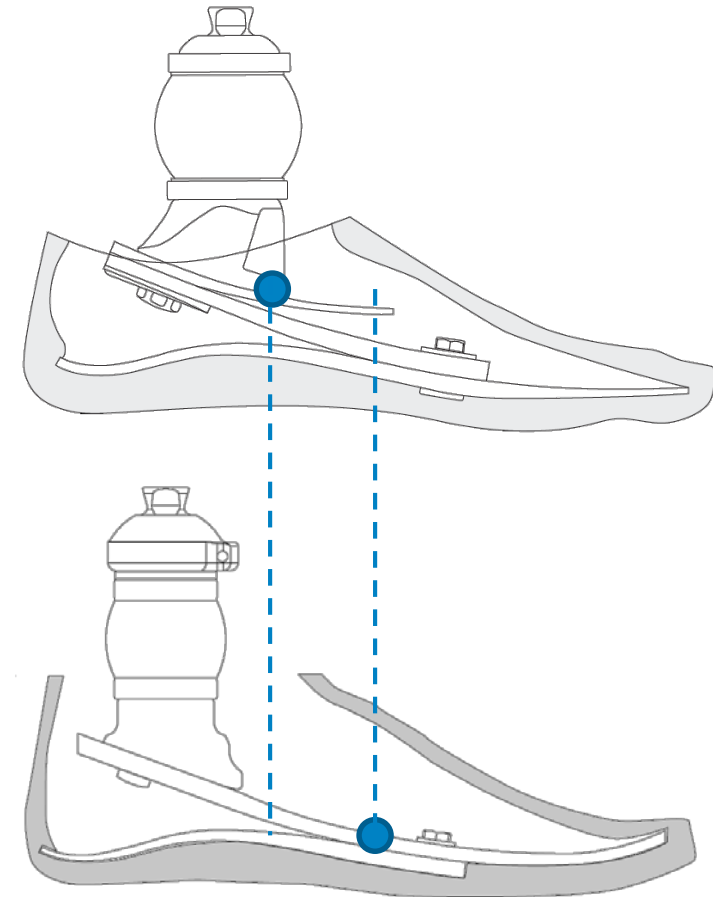
Picture	Part#	Description	Applicable Foot Kits
1	UPC0024	PXC Unity pump S22-24	Pro-flex XC/ XC Torsion 22-24
1	UPC0027	PXC Unity pump S25-27	Pro-flex XC/ XC Torsion 25-27
1	UPC0030	PXC Unity pump S28-30	Pro-flex XC/ XC Torsion 28-30
2	UTT0001	Unity TT Valve Kit	All
3	UTF0001	Unity TF Valve Kit	All
4	UTF0006	Unity TF Tube Kit	All
5	L-544611	Icelock 544 Kit	All

Pro-Flex LP Torsion



Product Characteristics – Reversed tapered mid-blade

- The middle blade **is reversed tapered** allowing for more dynamics
- Posterior part of the mid-blade is thinner and gets gradually thicker anteriorly towards the sole blade attachment bolts.
- Difference in approximate location of the functional joint center between Pro-Flex LP Torsion and LP Rotate



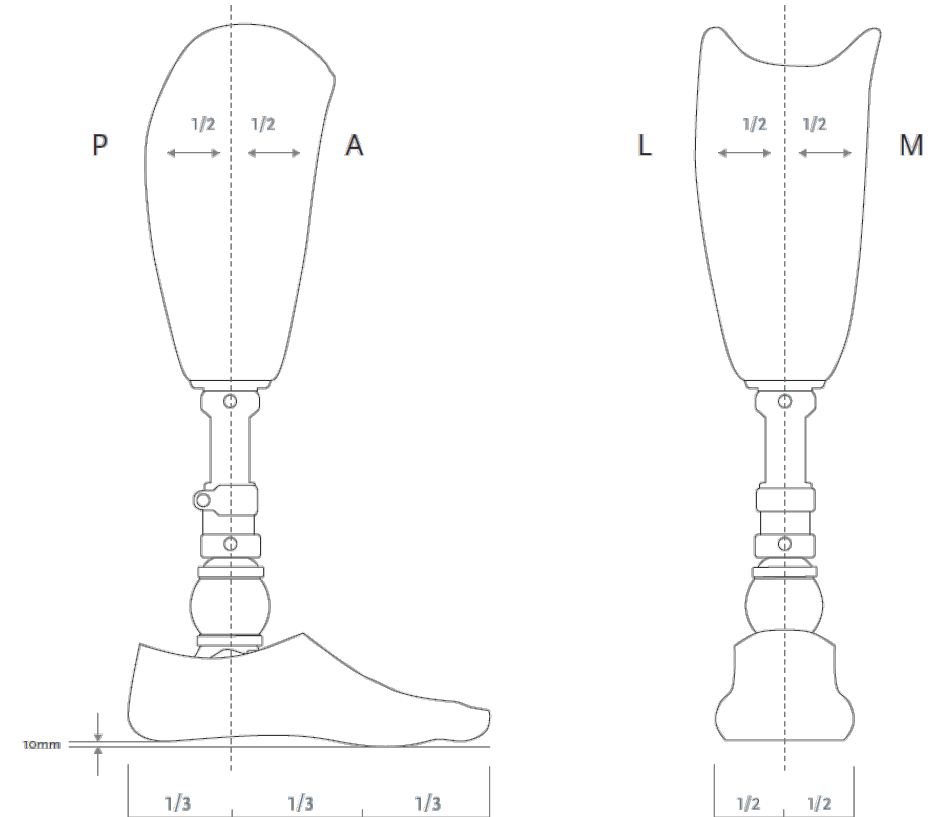
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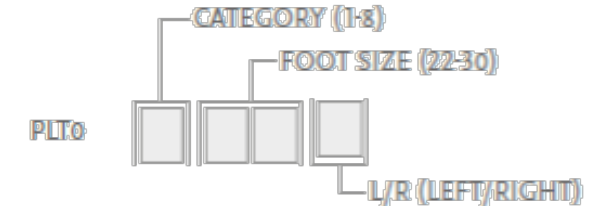
Category Selection

CATEGORY SELECTION CHART

Weight kg	45-52	53-59	60-68	69-77	78-88	89-100	101-116	117-130	131-147
Weight lbs	99-115	116-130	131-150	151-170	171-194	195-220	221-256	257-287	288-324
Low Impact Category									
Size 22-24	1	1	2	3	4	5	N/A	N/A	N/A
Size 25-27	1	1	2	3	4	5	6	7	8
Size 28-30	3	3	3	3	4	5	6	7	8
Moderate Impact Category									
Size 22-24	1	2	3	4	5	N/A	N/A	N/A	N/A
Size 25-27	1	2	3	4	5	6	7	8	N/A
Size 28-30	3	3	3	4	5	6	7	8	N/A
High Impact Category									
Size 22-24	2	3	4	5	N/A	N/A	N/A	N/A	N/A
Size 25-27	2	3	4	5	6	7	8	N/A	N/A
Size 28-30	3	3	4	5	6	7	8	N/A	N/A

PRO-FLEX LP TORSION WITH MALE PYRAMID

PART#

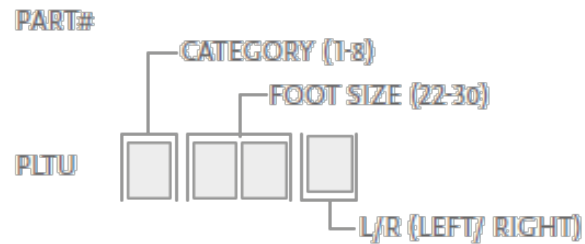


Includes:

- Foot Module
- Removable Foot Cover* with a black Spectra Sock

*For Pro-Flex LP Torsion with brown foot cover add a "BR" suffix to the part#.

Unity for Pro-Flex LP Torsion



Includes:

- Foot Module
- Removable Foot Cover* with a black Spectra Sock



*For Pro-Flex LP with brown foot cover add a "BR" suffix to the part# Note: Unity will come preassembled on the foot if ordered with PLTU

UNITY KITS

Picture	Part#	Description	Applicable Foot Kits
1	UPL0024	PLP Unity Pump S22-24	Pro-Flex LP/ LP Torsion 22-24
1	UPL0030	PLP Unity Pump S25-30 cat.1-5	Pro-Flex LP/ LP Torsion 25-37 cat.1-5
1	UPL0930	PLP Unity Pump S25-27 Cat 6-9 & S28-30 (All categories)	Pro-Flex LP/ LP Torsion 25-27 Cat 6-9 & 28-30 (All categories)
2	UTT0001	Unity TT Valve Kit	All
3	UTF0001	Unity TF Valve Kit	All
4	UTF0006	Unity TF Tube Kit	All
5	L-5446XX	Icelock 544 Kit	All

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