

Unity™ For All

Sleeveless Elevated Vacuum Systems



Life Without Limitations®



TT



TF

Advantages of vacuum suspension



Life Without Limitations®

Vacuum

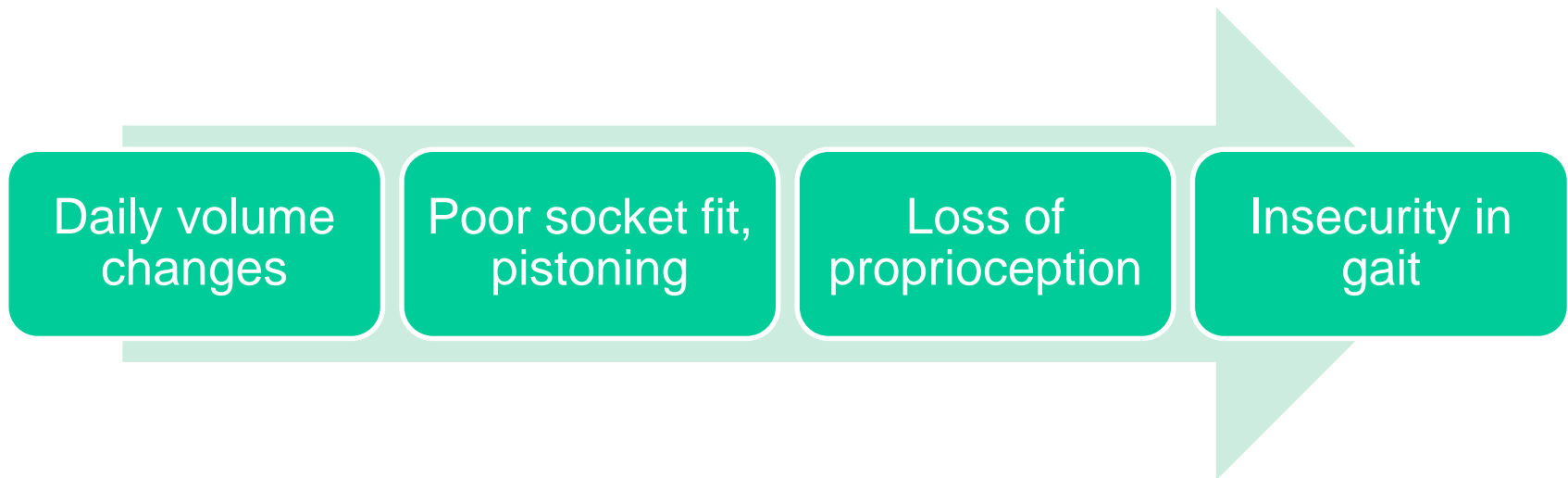


- Very firm suspension providing excellent security and improved proprioception
- Elevated vacuum tends to assist in maintaining more constant limb volume and thus decreasing the need to add additional socks
- Elevated vacuum assists with wound healing by improving circulation through the residual limb
- Provides good distal comfort for bony or sensitive distal ends as long as the socket is fit properly (**volume & length matching**)

Medical Necessity: Active vacuum



*Life Without Limitations**



Conclusion: Control of volume is a necessity¹

¹Board et al. (2001) J Int Prosth & Orth.

Medical Necessity: Active vacuum



Life Without Limitations®

Evidence regarding increased safety:

- Activities-specific Balance Confidence scales (ABC test) were found to be significantly higher in participants using vacuum suspension with 95% confidence, indicating a lower predicted incidence of future falls
- Improved functional outcome¹
skin problems (breakdown and blistering) seemed to be decreased in vacuum users and walking times increased in some users

¹Ferraro, C. Outcomes study of transtibial amputees using elevated vacuum suspension in comparison with pin suspension. J. Prosthet. Orthot. 23(2):78–81; 2011.

The Activities-specific Balance Confidence (ABC) Scale*

For each of the following activities, please indicate your level of self-confidence by choosing a corresponding number from the following rating scale:

0% 10 20 30 40 50 60 70 80 90 100%
no confidence completely confident

"How confident are you that you will not lose your balance or become unsteady when you...

1. ...walk around the house? ____%
2. ...walk up or down stairs? ____%
3. ...bend over and pick up a slipper from the front of a closet floor ____%
4. ...reach for a small can off a shelf at eye level? ____%
5. ...stand on your tiptoes and reach for something above your head? ____%
6. ...stand on a chair and reach for something? ____%
7. ...sweep the floor? ____%
8. ...walk outside the house to a car parked in the driveway? ____%
9. ...get into or out of a car? ____%
10. ...walk across a parking lot to the mall? ____%
11. ...walk up or down a ramp? ____%
12. ...walk in a crowded mall where people rapidly walk past you? ____%
13. ...are bumped into by people as you walk through the mall? ____%
14. ...step onto or off an escalator while you are holding onto a railing? ____%
15. ...step onto or off an escalator while holding onto parcels such that you cannot hold onto the railing? ____%
16. ...walk outside on icy sidewalks? ____%

*Powell, L.E. & Myers AM. The Activities-specific Balance Confidence (ABC) Scale. J Gerontol Med Sci 1995; 50(1): M28-34

Medical Necessity: Active vacuum



Life Without Limitations®

Evidence regarding volume control:

- The vacuum-assisted socket has been shown to eliminate daily volume loss¹.
- Vacuum-assist ensures a good fit during the day in ambulatory trans-tibial traumatic amputees with mature stumps.²
- The combination of reduced pistoning and maintenance of volume is thought to account for the more symmetrical gait observed with the vacuum³
- Elevated vacuum suspension systems manage limb volume fluctuation, a problem that people with limb loss are challenged with.⁴

¹Beil, T. L.; Street, G. M.; Covey, S. J. Interface pressure during ambulation using suction and vacuum-assisted prosthetic sockets. *J. Rehabil. Res. Dev.* 39(6):693–700; 2002.

²Goswami, J.; Lynn, R.; Street, G.; Harlander, M. Walking in a vacuum-assisted socket shifts the stump fluid balance. *Prosthet. Orthot. Int.* 27(2):107–113; 2003.

³Board, W. J.; Street, G. M.; Caspers, C. A comparison of trans-tibial amputee suction and vacuum socket conditions. *Prosthet. Orthot. Int.* 25(3):202–209; 2001.

⁴Sanders, Joan E., et al. Effects of elevated vacuum on in-socket residual limb fluid volume: case study results using bioimpedance analysis. *Journal of Rehabilitation Research & Development*, 2011, 48. Jg., Nr. 10.

Medical Necessity: Active vacuum



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Evidence addressing fit, comfort and limb health:

- When limb volume decreases, the socket is loose-fitting, often causing pressure to bony prominences, which may result in pain and/or injury to the limb¹.



¹Sanders, Joan E., et al. Effects of elevated vacuum on in-socket residual limb fluid volume: case study results using bioimpedance analysis. *Journal of Rehabilitation Research & Development*, 2011, 48. Jg., Nr. 10.

Primary benefits of the Unity™ system



Life Without Limitations®

Unity™

- + **SLEEVELESS:** Increased knee flexion range (TT) with greater comfort and user acceptance
- + **LIGHT WEIGHT AND DISCREET:** 130g added weight and housed within foot shell
- + **SIMPLE AND EFFICIENT:** Quick and easy to elevate and release vacuum levels
- + **INDEPENDENT PUMP:** does not depend on shock mechanisms and can be added to a wide range of performance Flex-Foot systems to meet every mobility need.
- + **VOLUME STABILISATION:** Optimizes socket stability, proprioception and comfort throughout the day while limiting the need to add socks
- + **INCREASED RELIABILITY:** Minimizes risk of leaks and puncture issues associated with sleeve dependent vacuum methods
- + Integrates **PERFORMANCE FLEX-FOOT** technology to meet all activity requirements

Candidate Profiling



Life Without Limitations®

User

- **Indicated User Population:**
 - Transtibial and transfemoral amputees
 - Low to high impact levels



- Weight limit is entirely based upon the recommended foot and knee modules
 - Sufficient length to use Seal-In V (TT) and Seal-In X (TF) are ideal for Unity
 - Very conical limbs may be addressed with use of a Distal Cup
- **Contraindications for use:**
 - Very short residual limbs that cannot use Seal-In V or Seal-In X
 - When total contact cannot be maintained distally between liner and limb
 - When expecting significant volume changes

Building Blocks of the Unity™ system



Life Without Limitations®

Unity™

1: Proven Seal-In Technology



**Seal-In® V
(TT)**



**Seal-In® X
(TF)**

2: Socket Connection



Unity™ TT Valve



Unity™ TF Valve Kit

3: Performance Flex-Foot



**Re-Flex® Series
LP Rotate
Vari-Flex Series
Proprio
Balance Foot**

4: Vacuum Pump Mechanism



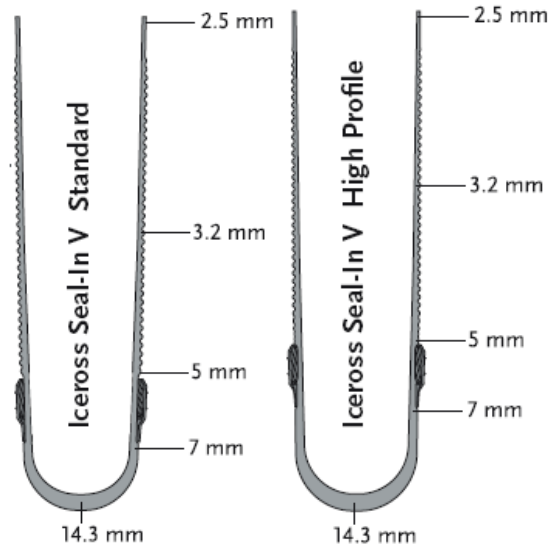
Unity™ Pump

Iceross Seal-In® V



Life Without Limitations®

Liner



Iceross Seal-In V

- + Dual sealing membrane enhances seal retention while volume adaptive blades accommodate volume changes
- + DermoGel Silicone – softest durometer available
- + Active Skin Care and Silken inner surface
- + **Compatible with elevated vacuum AND expulsion-only sockets**
- + Designed and tested in combination with Unity™
- + Available with low-profile and high-profile (+35mm higher) seals

Benefits over previous TT Seal-In's



Life Without Limitations®

Liner

Compared to HSM:

- 2nd seal increases security
- Less prone to fold or buckle
- Evenly fills in space between liner and socket with the Volume Adaptive Blades
- Better rotational control



Compared to X5:

- More forgiving fit with respect to shear force distributed to tissues around the seal
- In case of volume loss, socks can be tucked under seal to obtain up to 8 ply volume adaptation
- Superior seal retention with respect to tissue movement (i.e. muscular contractions inside the socket)



Product Sizing and Fitting



Life Without Limitations®

Liner

- Measure circumference 4cm from end of soft tissues.
- Select a liner as measured or next size below the indicated measurement
- Standard or High Profile Seal will depend on LIMB LENGTH (See Chart)
- On average the minimum residual limb length is 10-13cm(Std.) and 13-16cm(High Profile) depending on liner size

Measurement @ 4cm level = 28cm >> Select liner size 28
Measurement @ 4cm level = 24cm >> Select liner size 23.5



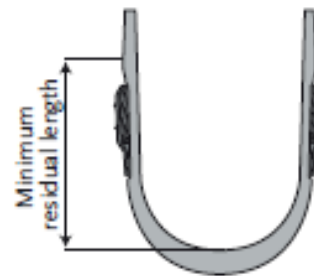
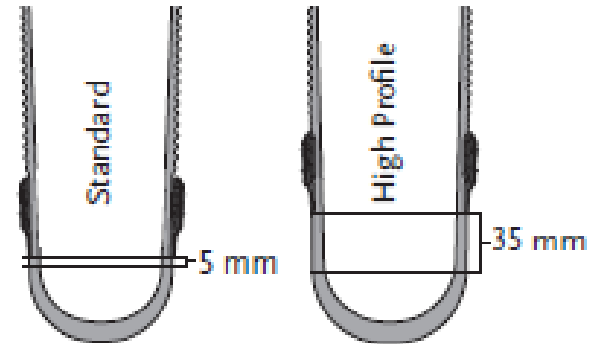
Product Sizing and Fitting



Life Without Limitations®

Seal-In V seal height is fixed at 5mm and 35mm from the start of the distal radius

Liner "cup" size varies, which affects **minimal residual limb length**:



LINER SIZE	MINIMAL RESIDUAL LENGTH*	
	STANDARD	HIGH PROFILE
18-20	10cm	13cm
21-25	11cm	14cm
26-30	12cm	15cm
31-36	13cm	16cm

PART#	PROFILE	DESCRIPTION
I-4713XX	Wave 3mm	Seal-In V
I-4723XX	Wave 3mm	Seal-In V High Profile

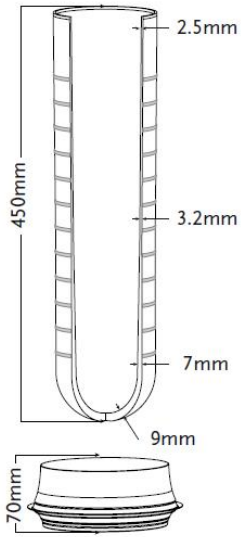
Liner

Iceross® SEAL-IN® X TF Liner System



Life Without Limitations®

Liner



FABRIC COVER



ACTIVE SKIN CARE



SILKEN INNER SURFACE



CONICAL

- Modular Seal-Rings are sized and positioned to meet individual needs:
 - Shape
 - Sensitivity
 - Tissue consistency
 - Skin condition
- Standard and Conical profiles
- Slightly stiffer to give better stability and support to proximal tissues
- Thinner distal thickness for better conformance to limb shapes
- New textile cover with 2X adhesion strength and abrasion resistance compared to existing range

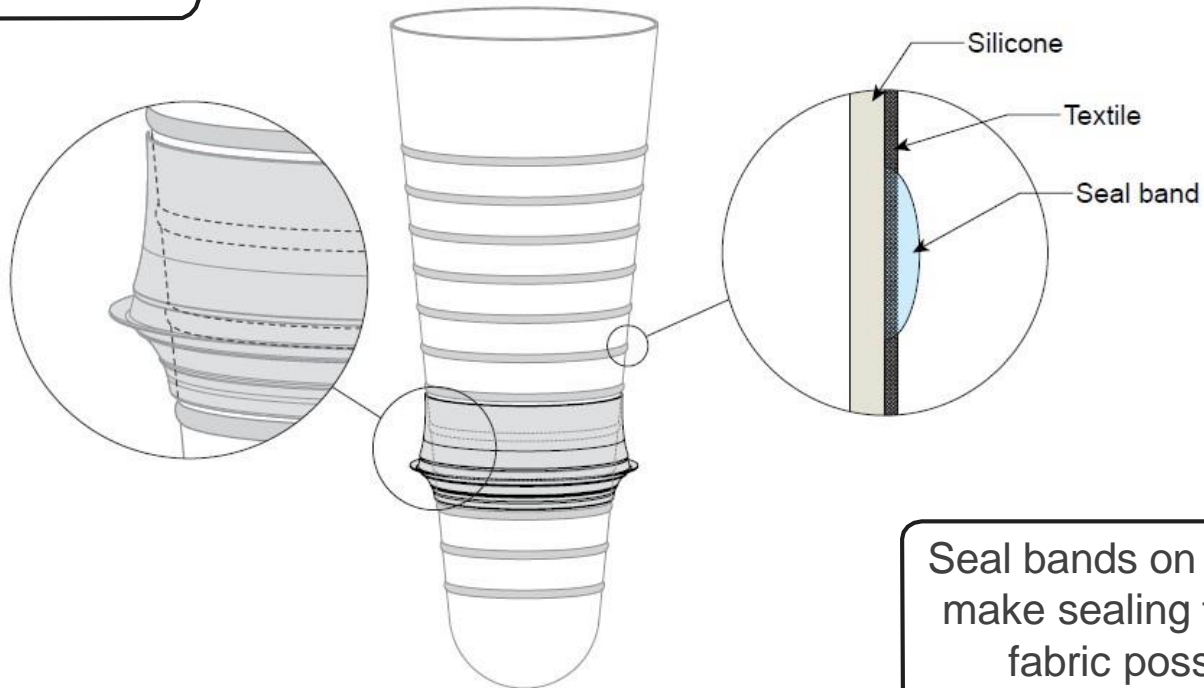
Mechanics of Seal-In® X



Life Without Limitations®

Liner

Separate Seal-Ring provides sealing bridge to the socket inner wall



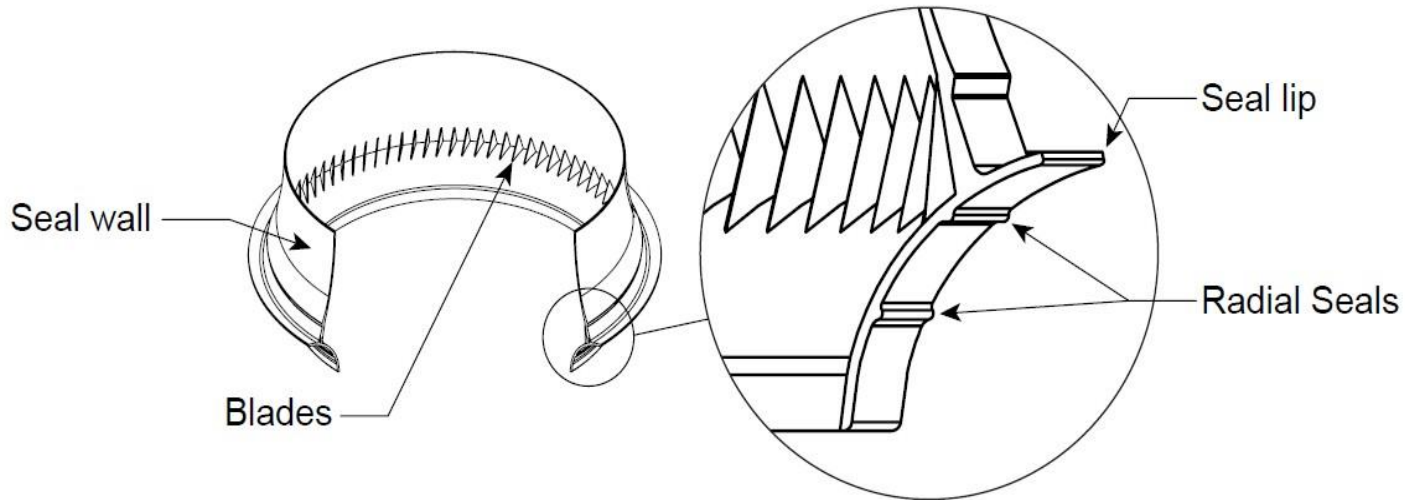
Seal bands on the liner make sealing through fabric possible

Mechanics of Seal-In® X



Life Without Limitations®

Liner



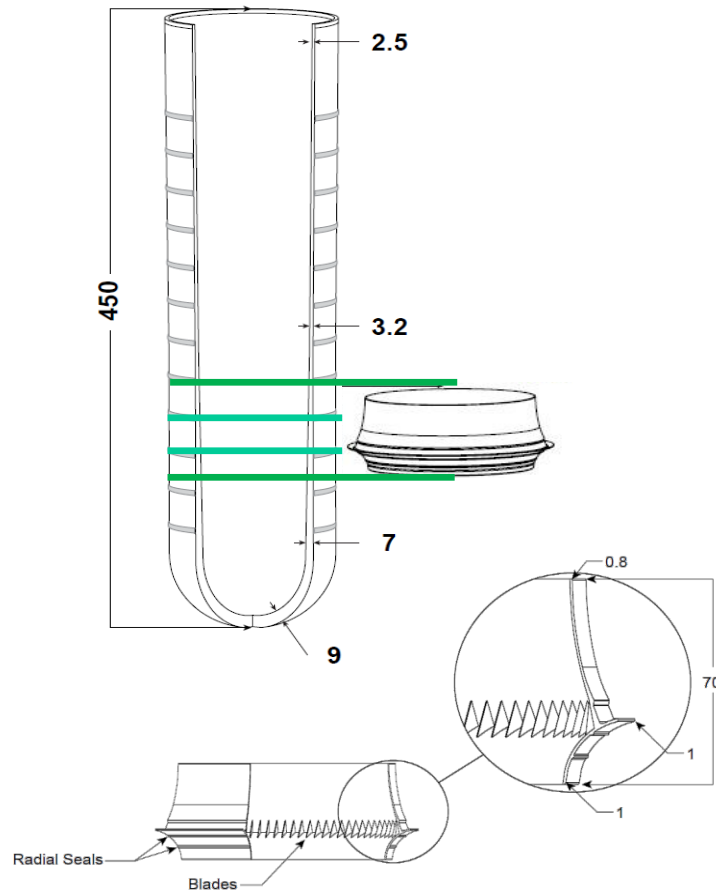
Volume Adaptive Blades resist collapsing of the seal in difficult areas, keeping seal lip expanded towards the socket inner wall

Seal-In® X Dimensions



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Liner



- Iceross Seal-In X TF is approximately 5cm longer than previous Iceross TF models
- Seal bands on the liner are spaced 25mm apart
- It is recommended to place the Seal-Ring over **2 seal bands**
- One seal band should be visible "just below" and "just above" the Seal-Ring

Seal-In® X Sizing and profile Selection

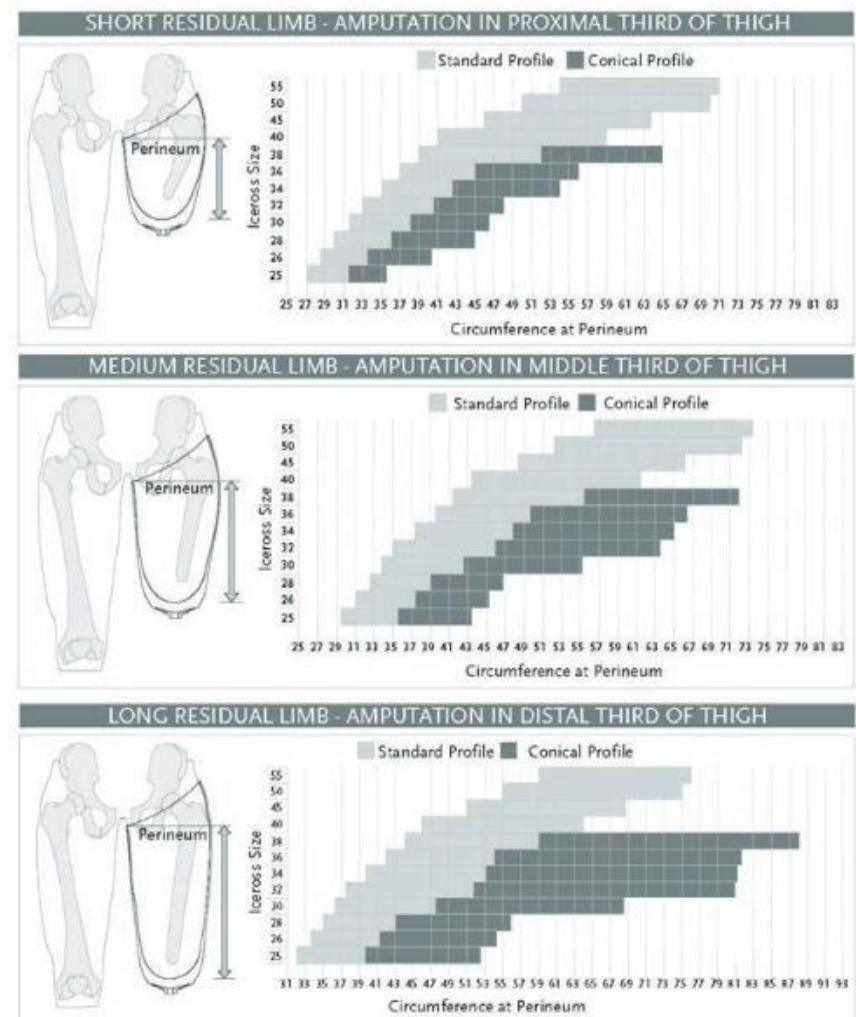
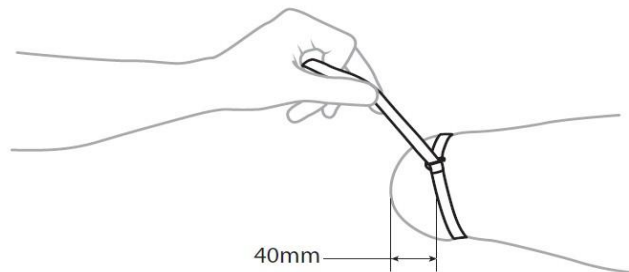


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Liner

Conventional ICEROSS sizing and profiling methods are used to select liner:

- Measure 4cm from distal end of the soft tissues to determine size.
- Choose the size measured or if between sizes, the size below.
- Take perineal circumference and reference profile charts – Conical or Standard



Seal-Ring Sizing



Life Without Limitations®

- Decide preferred Seal-Ring placement on the limb
- Recommend placement at least 10-15cm below perineum
- Take a circumference measurement directly over the limb where the **lower edge** of the Seal-Ring is expected to rest
- Choose the closest Seal-Ring size to the measurement. If between sizes, choose the smaller size.
- **Conical or "fleshy" limbs may require downsizing one ring size**



Liner

RIGHT



TIGHT



When test fitting a liner with a selection of Seal-Rings, observe tension of ring on limb and interface.

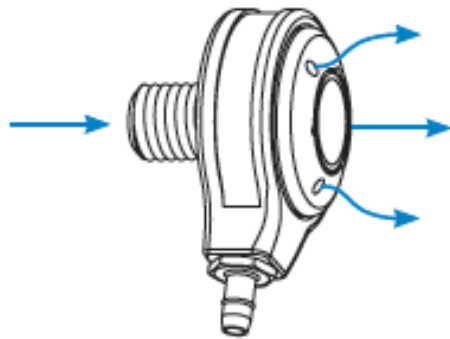
Seal-Ring should flatten out on liner without deforming the limb shape.

TT Unity™ tri-function valve



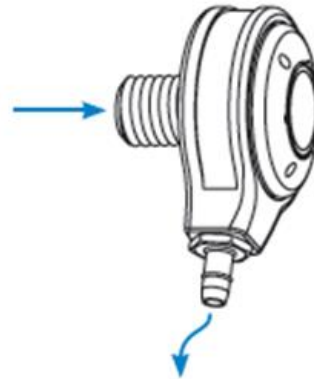
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Definitive Socket



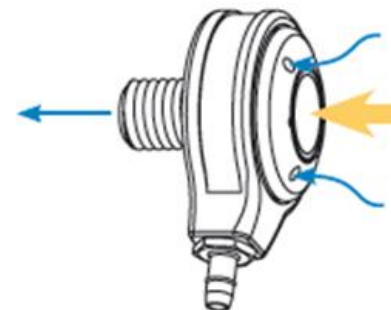
EXPULSION

lets air through easily
when donning the socket



VACUUM BYPASS

lets air into the vacuum
pump via a check valve,
so the socket is still
airtight in the unlikely
event of tube failure



RELEASE BUTTON

lets in air, so the vacuum
is easily released for
doffing the prosthesis

TT Unity™ valve



Life Without Limitations®

Definitive Socket

Unity™ TT Valve:

- + Tri-Function (Expulsion, Vacuum, Release)
- + No increased build height added to prosthesis
- + Built-in particulate filter



- Disassemble valve before trimming thread. Metal shavings in duckbills and seals are no fun!
- Valve thread needs to be sealed to the socket (inner) wall. Use valve insert!.
- Good quality industrial grade silicone sealant suits the job well
- Avoid lateral placement for protection

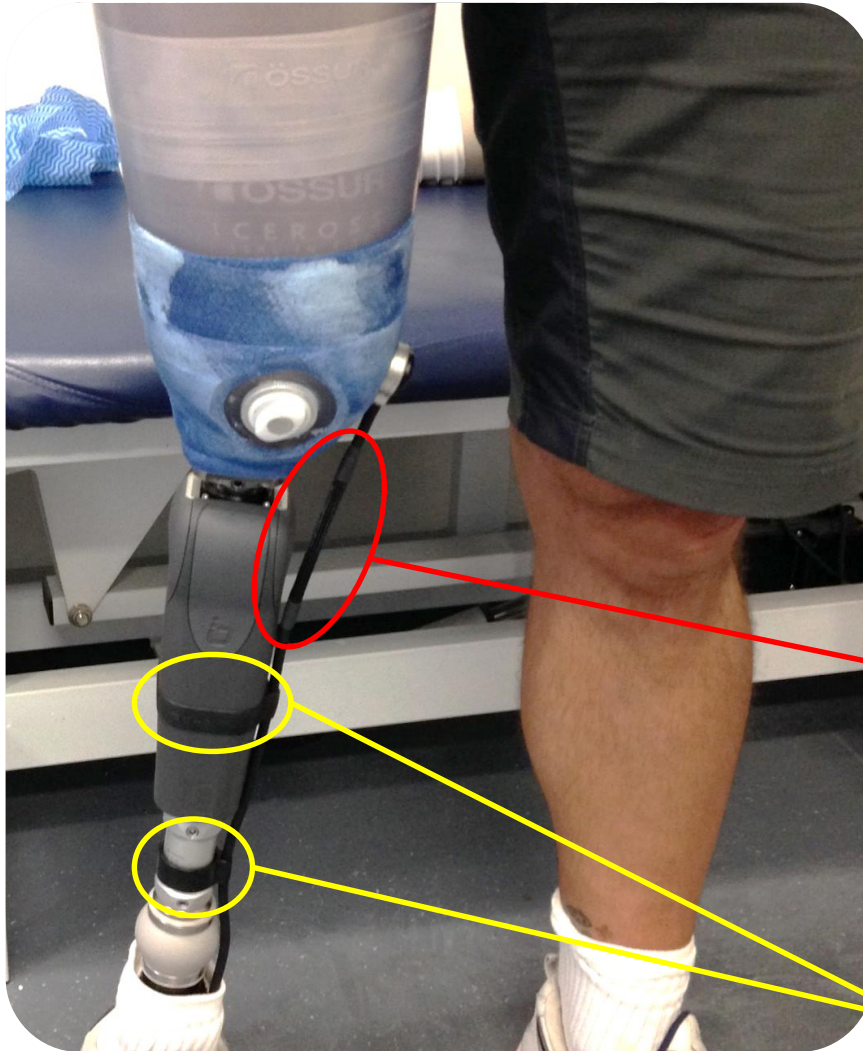


Unity™ TF Kits



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Definitive Socket



Unity TF tubing complete with nylon 'snakeskin' reinforcement. Typically used as reinforcement for electrical cabling, this protective sleeve provides extra resistance to kinks, abrasion and tears.

Clamps and elastic keepers neatly run Unity tubing from foot to socket.

Unity™ TF Kits



Life Without Limitations®

Definitive Socket

Unity TF kit (UTF0001) contains:

- 1 x Nylon reinforced durable TF tube
- 1 x Small elastic tube fixture
- 1 x Large elastic tube fixture
- 1 x clamp for 30 mm pylon
- **1 x Tri-functional Unity valve**



Unity TF tubing & accessory kit (UTF0006) contains:

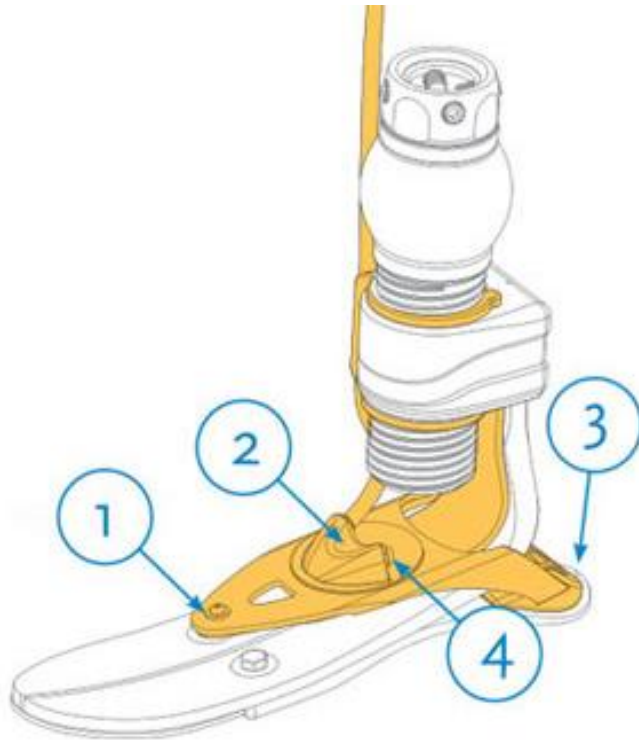
- 1 x Nylon reinforced durable TF tube
- 1 x Small elastic tube fixture
- 1 x Large elastic tube fixture
- 1 x clamp for 30 mm pylon

Integrated Unity™ Pump & Flex-Foot



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Unity™



1. Frame & Support Blade:

Upon heel deflection, the frame moves up and the support blade moves down, thus expanding the membrane.

2. Check valves:

When air is efficiently drawn out of the socket, check valves ensure that air does not flow back into the socket (**Pre-assembled for L side**).

3. Heel pad:

The heel pad acts as a secure support for Unity's upper blade, and as a stop for heel displacement at high load.

4. Membrane:

When the membrane deflects, air is efficiently drawn out of the socket.

Flex-Foot with Unity™



Life Without Limitations®

Foot

Fitting a Flex-Foot with Unity is no different from previous procedures:

- Select appropriate size and category
- Obtain good static alignment
- Remember to use wedges during dynamic alignment

- Unity Pump elevates vacuum up to -22inHg
- **Normal operating pressures are -16 to -20 inHg**
- **Added weight is 130g (Pump, valve, tubing)**
- Running the vacuum tube medially is recommended to prevent impact with foreign objects
- Vacuum/exhaust ports on the Unity™ Pump are exchangeable Right/Left. Default shipping setup is ideal for a left foot.



Knee & Foot Compatibility with Unity™



Life Without Limitations®

	LOW 	MODERATE 	HIGH 
Locking Knee			
Balance Knee			
Total Knee 1900 2000 2100			
Mauch Knee Mauch Knee Plus			
RHEO KNEE 3 SYMBIONIC LEG 3			

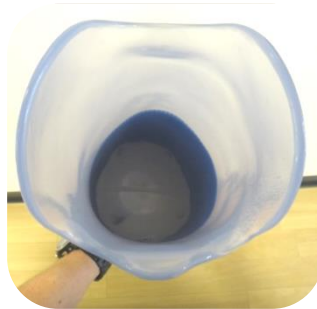
	LOW 	MODERATE 	HIGH 
Balance Foot			
LP Vari-Flex LP Rotate			
Vari-Flex			
Re-Flex Rotate Re-Flex Shock			
PROPRIO FOOT			

TT casting and modification



Life Without Limitations®

TT Casting



Note: *Unity™ should not be used as a remedy for already wide sockets or to counteract discomfort in existing sockets. Cavities and too wide sockets can cause pain and/or serious injury*

Cast:

- Measure: Circumferences & ML
- Neutral cast (Elastic + Rigid)
- Proximal >> Distal wrap
- 3-5° knee flexion
- Avoid tightening the cast and any distortion to limb shape
- Casting under vacuum is NOT required

Modification:

- Correct ML dimension
- Level out seal area on positive
- Global 3-5% volume reduction (from patient measurements)
- Remove up to 6mm distally
- Remember to attach valve insert when pulling the check socket

Evaluating the check socket



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TT Check Socket



Ideal fit places the seal as high as possible on the limb (HP Seal shown here) with equal distribution of pressure around the seal. Seal should fully seat at least 1-2cm below the posterior socket trim lines.

Evaluating the check socket



Life Without Limitations®

Pressure against the V-seal can be "read" in a check socket:

TT Check Socket



Normal pressure.

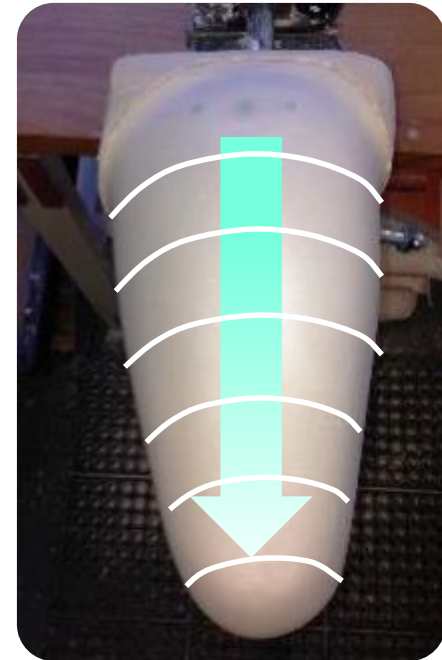
Volume adaptive Blades flatten the seal against the socket wall (up to ~50% compressed when de-weighted, up to 100% upon full weight bearing)

Low pressure area and increased risk of suction loss. Blades are barely pushing the seal to the socket wall.

TF casting and modification

- Standard plaster cast (casting over Seal-Ring is not required)
- Use elastic plaster then rigid
- Avoid excessive proximal weight bearing
- Reduce to midpoint between loose and tight circumference measures
- Reduce up to 6mm distally

TF Casting



Check socket fitting



Life Without Limitations®

TF Check Socket



Lubricate Seal-Ring and socket well to avoid any folding or migration of Seal-Ring.

Seal-Ring should remain in contact with the socket at all times:

- Weight bearing
- Apply negative force
- Sitting
- Hip Flexion

Evaluating the check socket



Life Without Limitations®

TF Check Socket

- Pressure against the Seal-In Ring can be "read" in a check socket:



- Normal pressure, Uppermost lip of Seal-In Ring flattens against socket wall

Area between Seal-In Ring ridges is not touching the wall 100%.

Tight spots in socket tend to deform and pull the Seal-In Ring when donning.

Evaluating the check socket



Life Without Limitations®

Check Socket

BWS Three stage fitting process:

- **B**etter
- **W**orse
- **S**ame

Distal Volume Check

1: Add one **silicone spot** to the bottom of the socket

2: Ask if it feels better, worse or the same:

- **B**etter - you had a void distally, add another spot
- **W**orse – your distal volume was correct, remove the last spot
- **S**ame - you had a void distally, add another spot

3: Repeat until you have gone from **W to B**



Evaluating the check socket



Life Without Limitations®

Check Socket

BWS Three stage fitting process:

- **B**etter
- **W**orse
- **S**ame

Circumferential Volume Check

1: Add one sock, 1 ply, disregard the fact that the seal will not seal

2: Ask if it feels better, worse or the same:

- **B**etter - your socket was too big, add another sock
- **W**orse – your volume was correct, remove the last sock
- **S**ame - your socket was too big, add another sock

3: Repeat until you have gone from **W** to **B**

Correct for volume and length differences on the positive model and fabricate another check socket if necessary.

Definitive socket structure and materials

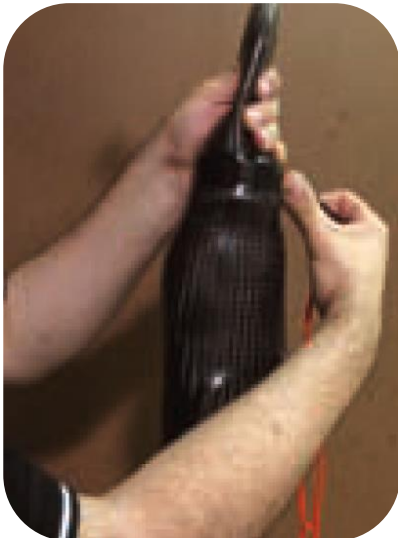


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Definitive Socket



ALWAYS use a PETG layer over the positive
(WITH the valve insert attached to the positive)



Use a conventional laminate overlay.

NEVER create an elevated vacuum socket without first using a plastic inner layer as laminate always leaks!

Identification of socket leaks



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Troubleshooting

When using the recommended PETG to seal a socket interface, there are 3 potential places which may leak:

- Across the seal, especially when walking. Observe test socket well to prevent this from being discovered in the definitive socket.
- Through the seal; a damaged seal can leak, again it can be partly hidden since damaged seal can hold pressure statically.
- Across valve seat. Remember that valve thread needs to be sealed to the PETG inner surface. Use silicone sealant.

Warranty and maintenance



Life Without Limitations®

- Standard Flex-Foot warranty applies to foot module
- **Unity Pump Kit – 24 Months**
- **Unity Membrane – 12 Months**
- **Seal-In V; Seal-In X – 6 Months**
- Unity is field serviceable. The entire system can be disassembled, cleaned and individual components replaced as needed.
- Maintenance kits (UVL00021, UVL00022) are available which include membrane, check valves, barb fittings, tubing, tube fastener and heel pad.

Customer Service and Clinical Support



Life Without Limitations®

- There is no training certification requirement to fit the Unity system.
- Unity training and fitting support can be held at your facility by request – Contact Kris
- **Order Forms** (online and fax version) are currently available to make ordering the Unity system simpler and easier. TF awaiting print.
- **TF Unity brochure** available online – awaiting print
- Complete listing of all Unity system components in **2015 catalogue supplement.**

Unity™ For All

Sleeveless Elevated Vacuum Systems



Life Without Limitations®



TT



TF