

Unity™

Sleeveless Elevated Vacuum System



Life Without Limitations®



Advantages of vacuum suspension



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Vacuum



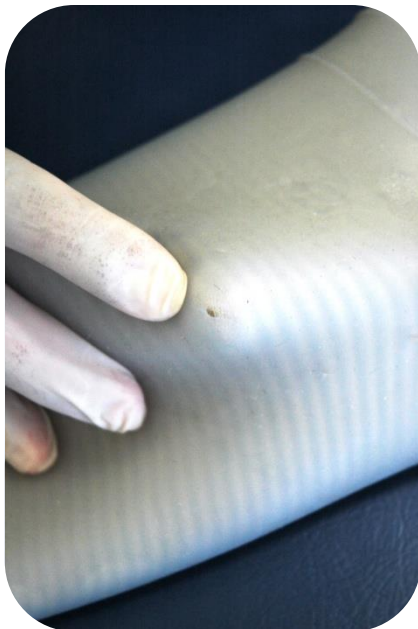
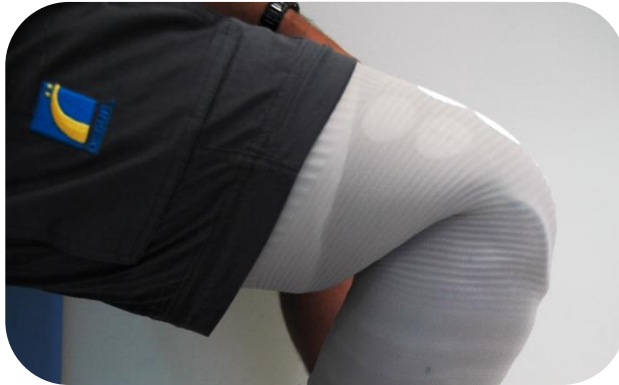
- Very firm suspension providing excellent security and improved proprioception
- Elevated vacuum tends to assist in maintaining more constant limb volume and thus decreasing the need to add additional socks
- Elevated vacuum assists with wound healing by improving circulation through the residual limb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

Challenges of vacuum suspension



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Vacuum



- Conventional systems require use of sleeves which restrict knee flexion and require frequent repair and/or replacement
- Conventional pumps may increase weight and bulk of the prosthesis
- Socket fit must be precise as ill fitting sockets can cause tissue damage
- Suspension is compromised if seal fails typically due to sleeve punctures or tears
- Potentially more maintenance with respect to the vacuum pump mechanism
- Increased expense compared to basic expulsion systems

Primary benefits of the Unity™ system



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- + **SLEEVELESS:** Increased knee flexion range 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



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User

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



- Weight limit is entirely based upon the recommended foot module
 - Cylindrical shaped residual limbs with sufficient length to use Seal-In V 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
 - When total contact cannot be maintained distally between liner and limb
 - When expecting significant volume changes

Building Blocks of the Unity™ system



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1: Proven Seal-In Technology



Seal-In® V

2: Socket Connection



Unity™ TT Valve

3: Performance Flex-Foot



Re-Flex® Shock
Re-Flex® Rotate
LP Rotate
Vari-Flex
LP Vari-Flex
Proprio

4: Vacuum Pump Mechanism



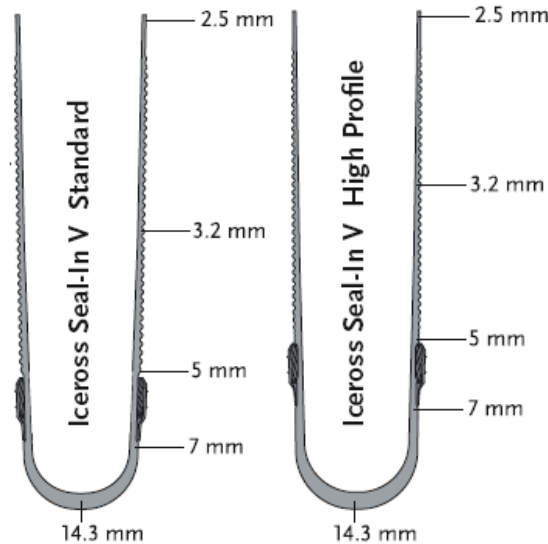
Unity™ Pump

Iceross Seal-In[®] V



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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



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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



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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



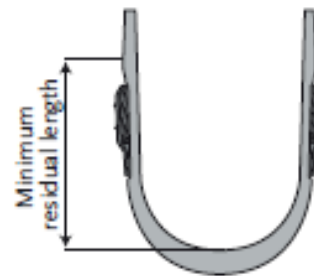
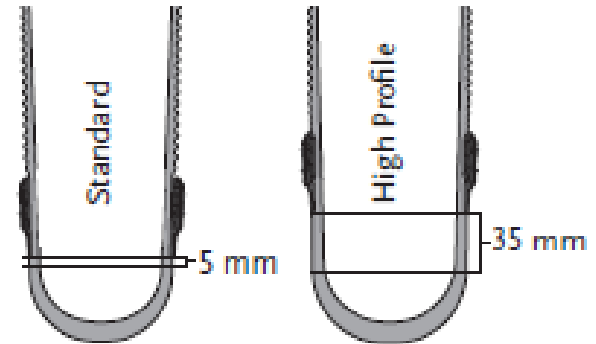
Product Sizing and Fitting



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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

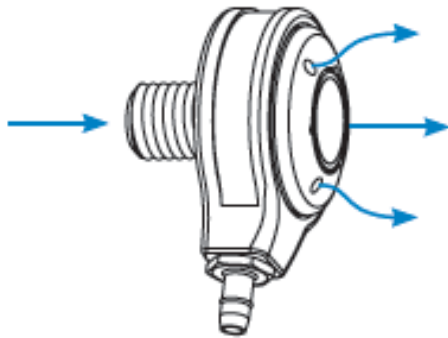
Liner

TT Unity™ tri-function valve



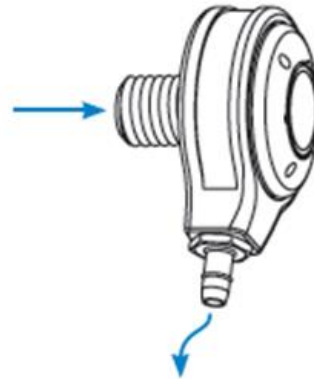
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Definitive Socket



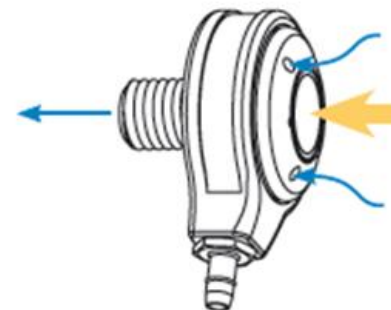
EXPULSION

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



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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

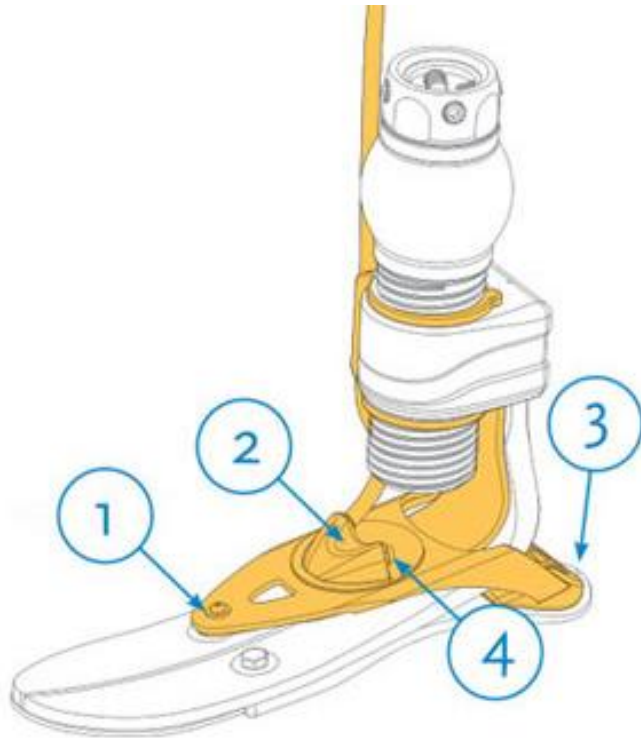


Integrated Unity™ Pump & Flex-Foot



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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 expands, air is efficiently drawn out of the socket.

Flex-Foot with Unity™



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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.



Flex-Foot compatible with Unity™



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UNITY® FOR PROPRIO FOOT
Adaptive prosthetic device for low to moderately active below-knee amputees that mimics natural foot motion



UNITY® FOR LP VARI-FLEX
Natural gait with less fatigue for users with long residual limbs



UNITY® FOR VARI-FLEX
High energy return and superior roll-over characteristics for active users

UNITY® FOR LP ROTATE
Compact energy-storing foot featuring rotational shock absorption designed to reduce shear forces on the residual limb



UNITY® FOR RE-FLEX ROTATE™
Dynamic energy return and comfort with shock absorption and rotation, for active users requiring a high performance everyday foot



UNITY® FOR RE-FLEX SHOCK™
Exceptional energy return and superb shock absorption, for users who enjoy high-impact activities and sport



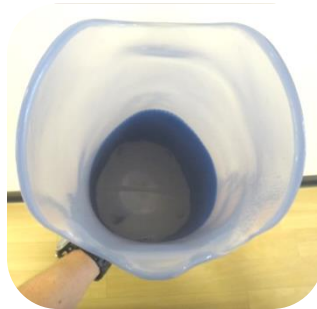
Proprio Foot, LP Vari-Flex, Vari-Flex, LP Rotate, & Re-Flex Series

Casting Method



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Test Socket



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 6mm distally
- Remember to attach valve insert when pulling the check socket

Evaluating the check socket



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Test 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



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

Test 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.

Evaluating the check socket



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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®

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

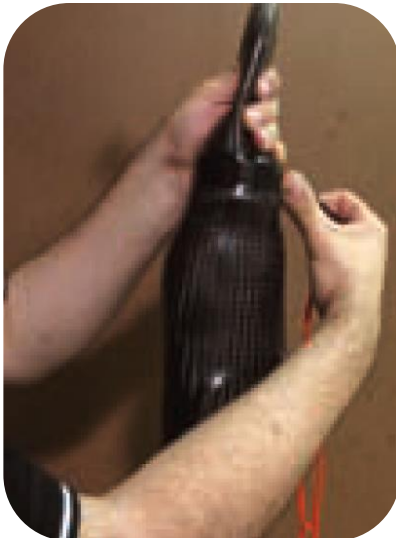


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Definitive Socket



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



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



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- Standard Flex-Foot warranty applies to foot module
- **Unity Pump Kit – 24 Months**
- **Unity Membrane – 12 Months**
- **Seal-In V – 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



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- There is no training certification requirement to fit the Unity system.
- Unity training and fitting support can be held at your facility by request.
- Order Forms (online and fax version) are currently available to make ordering the Unity system simpler and easier.
- Full brochure on Unity to be released in March.
- Complete listing of all Unity system components in 2014 catalogue to be released in March.

Unity™

Sleeveless Elevated Vacuum System



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