New Additions to the Unity® Sleeveless Vacuum System: Seal-In® X (TT), Vari-Flex XC, Balance J and Assure

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Össur Australia

Building Blocks of the Unity® system

Unity™

1: Proven Seal-In Technology

Seal-In® V (TT)

Seal-In® X (TT & TF)

2: Socket Connection

Unity® TT Valve

Unity® TF Valve Kit

3: Performance Flex-Foot

Re-Flex® Series

LP Rotate

Vari-Flex Series

Vari-Flex XC

Proprio

Balance Foot

Balance J

Assure

4: Vacuum Pump Mechanism

Unity® Pump

Primary benefits of the Unity® system

Unity™

- **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:** Not dependent 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

Clinical benefits of elevated vacuum

Unity™

AOPA CLINICAL FEATURE

Contemporary Prosthetic Suspension Choices: A comparison of functional strengths

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Modern prosthetic interface designs have evolved dramatically over the past three decades and have been driven by the need to reduce movement between limb and socket, reduce shear and high pressure areas, support skin health and improve proprioception and control of the prosthesis. Contemporary integrated prosthetic interface and suspension systems include:

- Distal attachment suspension ('pin' locks, lanyards)
- Suction suspension (expulsion valve + cushion liner + suspension sleeve)
- Hypobaric suspension (expulsion valve + hypobaric seal liner)
- Vacuum assisted suspension (vacuum pump, cushion liner + sleeve, OR hypobaric seal liner)

The seeds of this technological revolution began with the development of Össur Kristinsson's ICEROSS® (Icelandic Roll-On Suction Socket). Silicone was chosen as an optimal interface material due high biocompatibility characteristics, high strength, good elastic properties (conforms to shapes), and excellent memory. ICEROSS® liners set a new industry standard by minimising socket movement, reducing shear forces[1,2,3,6] and improving skin health with respect to the residual limb[4,5,6].

Table 1: Distal Attachment Suspension ('pin' lock, lanyard)

STRENGTH	CHALLENGE
High security and assurance (positive lock)	Distal cushioning may be insufficient for bony or sensitive limbs
Good for bulbous shapes (using lanyard)	Unusual shapes (especially distal) may not be accommodated by pre-fabricated liners
Good for medium to short residual limbs (<12cm) where sufficient clearance is available for lock	Longer limbs with insufficient clearance for lock
Accommodates significant volume changes with socks (up to 10 ply)	Compromised rotational control with increased sock ply
Excellent stabilisation and reduction of shear forces on soft tissues[1,2,3,6]	Elongation of tissues (due to nature of suspension distally) may not be comfortably tolerated in all cases
No additional donning aids required	Some individuals with increased redundant distal tissue find alignment of pin difficult during donning

Suction suspension systems utilizing a cushion liner (typically silicone or urethane composition) and sleeve (various materials) have been used for several decades, typically in conjunction with an expulsion valve as an alternative to the distally suspending 'pin' system. For the transtibial amputee with a longer limb and/or distal limb sensitivity issues, these systems have vastly improved comfort, limb health, and provided very positive and secure suspension. Unfortunately, the suspension sleeve itself remains the weak link in the design. Issues of limited knee flexion, heat, punctures and tears have led to other advancements and alternatives in suspension and interface design.

Table 2: Suction suspension (expulsion valve + cushion liner + suspension sleeve)

STRENGTH	CHALLENGE
Good security and assurance with sleeve extending across knee onto thigh	Increased heat & perspiration
Accommodates wide range of limb lengths	Compromised knee flexion
Accommodates significant volume changes with socks (up to 10 ply)	Sleeve punctures compromise firm suspension
Accommodates wide range of limb shapes	Semi-frequent repair/replacement of sleeves
Good distal comfort and protection of bony or sensitive limbs	
Liners tend to have good durability characteristics as they do not suspend the limb	
No additional donning aids required	

Development of an advanced Hypobaric Sealing Membrane (HSM Seal-In™) liner by Össur in 2003 solved some remaining challenges and offered a suction suspension alternative, eliminating the need for a suspension sleeve. Seal-In™ technology enabled fitting of longer limbs, sensitive distal ends[7] and unusual shapes, improved rotational control, reduced pistoning and promoted greater user acceptance and mobility[8].

Table 3: Hypobaric suspension (Seal-In™ Interfaces by Össur + expulsion valve)

STRENGTH	CHALLENGE
Accommodates medium to longer limbs with limited clearance for locks (>12cm)	Shorter limbs (<10-12cm)
Superior rotational and longitudinal control[8]	Volume fluctuations for expulsion fit (>3-6 ply)
Excellent cushioning for bony or sensitive distal limbs[7]	Must use lubricant spray for donning socket
New versions (Seal-In™ X) with modular seals ease donning and accommodate a variety of limb shapes and sealing heights	
No suspension sleeve required; easier knee flexion, decreased heat, less maintenance	

The most recent and advanced hypobaric Seal-In™ V & X designs by Össur (Figure 1) address the issue of volume fluctuation by adding the capacity to use the hypobaric liners under vacuum with a simple and efficient pump integrated into a Flex-Foot (Unity® Sleeveless Vacuum System). Since introduction in 2001 by TEC Interface Systems, elevated vacuum suspension has been clinically proven in a number of studies to assist in stabilizing socket volume[9,10,11], assist in wound healing[13,14,15,16], promote skin health[17], and improve safety and mobility[12,17].

Table 4: Össur Unity® Sleeveless Elevated Vacuum System

STRENGTH	CHALLENGE
Most firm suspension providing excellent security and proprioception[12,17]	Shorter limbs (<10-12cm) may be difficult to achieve vacuum with seal
Assists in maintaining more constant limb volume and minimises use of additional socks[9,10,11]	Must use lubricant spray to don socket
Improves limb circulation and in some cases may promote wound healing[13,14,15,16]	May not be appropriate for limbs where complete contact between liner and skin cannot be achieved
Superior distal comfort for bony and/or sensitive limbs[7]	More precise socket fitting (length, shape and volume matching) required as poorly fitting sockets may cause damage to tissues
Seal height may be customized to limb length with Seal-In™ X thus optimizing surface area of applied vacuum	
Increased comfort and range of knee motion by eliminating suspension sleeve	
Light weight (130g), discrete and efficient pump housed within foot shell that operates independently	
Suitable for variety of mobility levels using Flex-Foot technology	
Transtibial and transfemoral compatibility	

Figure 1. Seal-In™ X for transtibial amputation with modular seal ring.

Elevated vacuum ultimately provides the greatest number of clinical and functional benefits to clients.

Clinical Feature in latest AOPA Gazette (June 2015) will compare strengths and challenges of contemporary suspension systems including Unity®.

Complete w/scientific references (17).

Useful quick reference guide to choose between product systems for particular clients.

Potentially useful information for reimbursement support for Unity®.

Candidate Selection

User

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

  - Weight limit is entirely based upon the recommended foot module
  - 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 X
  - When total contact cannot be maintained distally between liner and limb
  - When expecting significant volume changes

ICEROSS® SEAL-IN® X

Iceross Seal-In X is the TT version of moveable seal technology introduced with Seal-In X TF

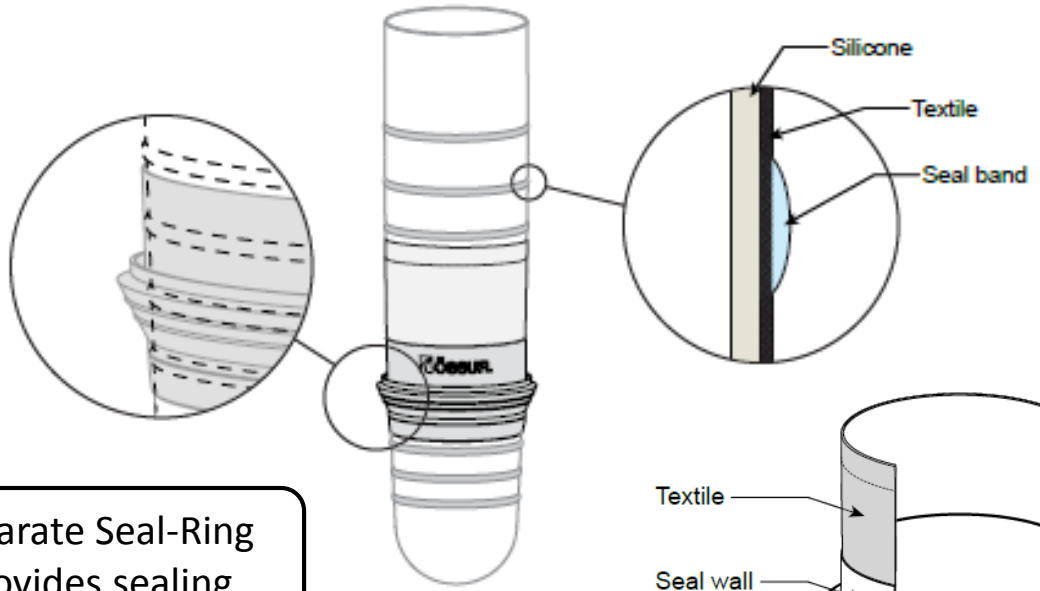
Combination of a specifically designed Seal-In Ring and a cushion Seal-In liner

Seal placement is customized to individual

Donning and doffing is made much easier than with previous Seal-In designs

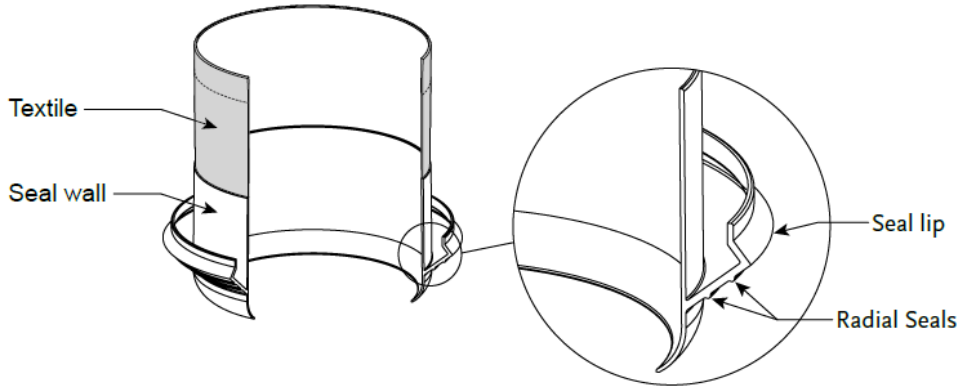
If Seal-In Suspension is not practical for all circumstances, Seal-In X is still an excellent cushion liner in combination with Iceross Sleeve

Seal-In® X Mechanics



Seal bands on the liner make sealing through fabric possible

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

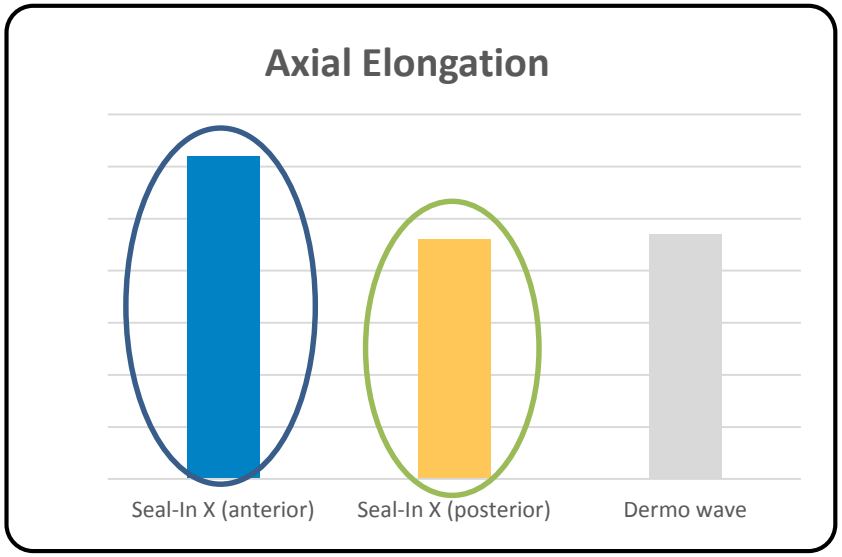


Seal lip is specially designed to resist buckling. Two extra radial seals provide redundancy of sealing

Anatomy Conforming Fabric
(ACF) – Patent Pending

Seal-In® X features a unique, seamless fabric with flexible anterior surface.

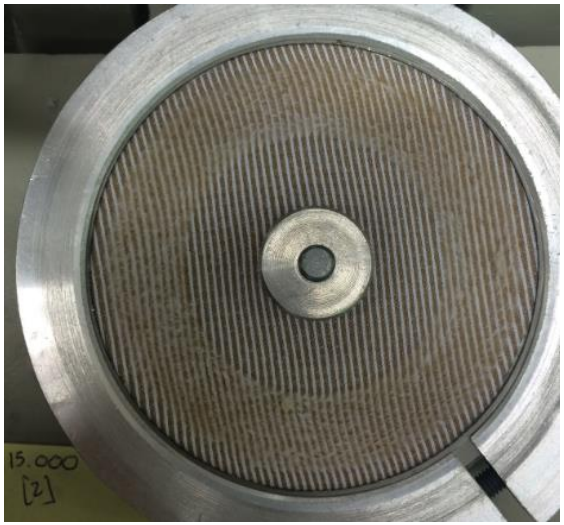
Elongation and pistoning control is achieved posterior, while the anterior is allowed to flex.



Notes on Testing- Summary

Mechanical Testing-Textile Durability

Abrasion testing: 15.000 Cycles. Hole in current supplex TT textile (Dermo Cushion)



Posterior side of new textile intact after 15.000 cycle.

Anterior side of new textile intact after 15.000 cycles.

The new textile starts to unravel after about 50.000 cycles.

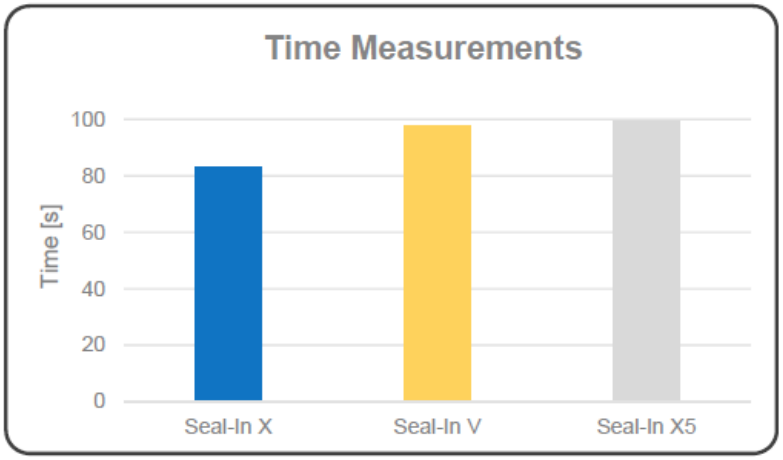
Notes on Testing- Summary

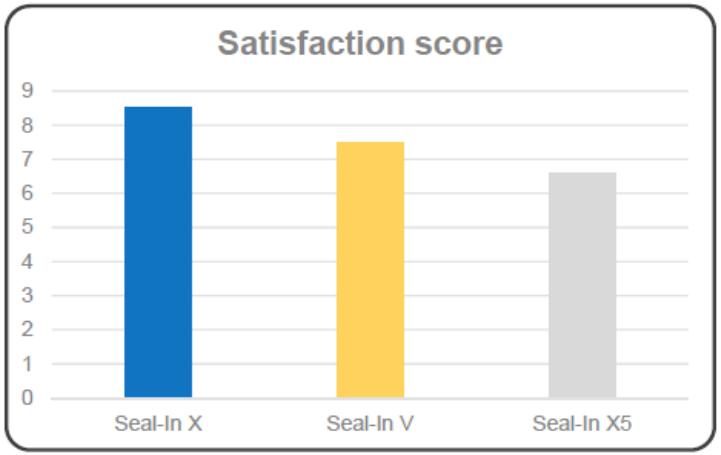
Usability Testing

10 users, average age 62,4years

Less overall time to use (invert, don, doff) compared to Seal-In® V and X5

Higher satisfaction with the donning/doffing process





Notes on Testing- Summary

Retrofit Testing

9 users

Cushion liners with MSS sockets

Suspension obtained in 8 out of 9 cases

Comfort same or better compared to previous in 8 out of 9 cases

Seal-In X				
	With Seal ring		With sleeve	
	Suspension obtained?	Socket fit comfort	Suspension obtained?	Socket fit comfort
User 1	No	-	Yes	Better
User 2	Yes	Better	Yes	Better
User 3	Yes	Better	Yes	Same
User 4	-	-	-	-
User 5	Yes	Better	-	-
User 6	Yes	Same	Yes	Same
User 7	Yes	Better	Yes	Better
User 8	Yes	Better	Yes	Better
User 9	Yes	Better	Yes	Better
User 10	Yes	Worse	Yes	Better

Seal-In® X for TT

Performance Summary

Seal-In suspension can be achieved

Easier donning than with Seal-In X5 and Seal-In V

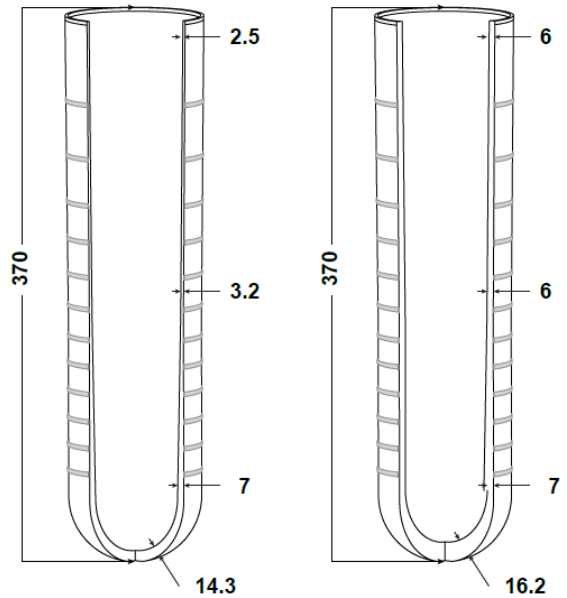
Holds vacuum sufficiently to facilitate elevated vacuum suspension in normal use

Fabric elongates easier over liner anterior (ACF)

Functional equivalence to other Seal-In TT solutions

Can be used without Seal Ring as a retrofit to existing TT Cushion liners from Össur

Seal-In® X Dimensions



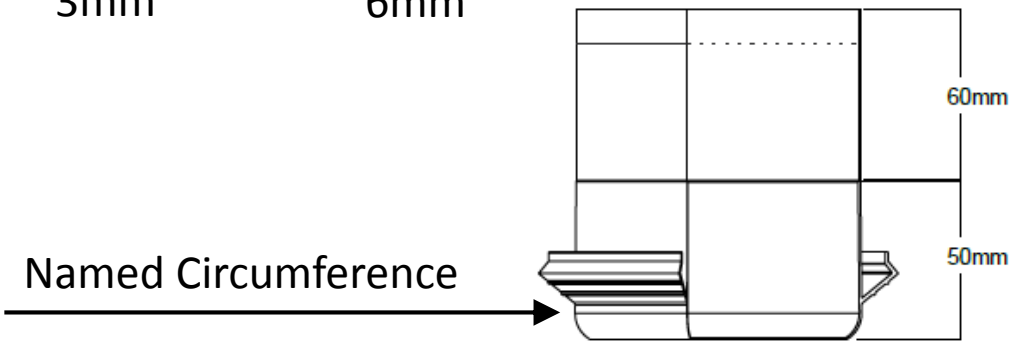
3mm 6mm

Iceross Seal-In X is the exact same profile as Iceross Dermo Cushion

Seal bands on the liner are spaced 20mm distally and up to 45mm proximally

Seal Rings are 50mm tall, named circumference(size) is at distal, above narrowing edge

Textile top makes it easy to don the Seal Ring



Seal-In® X User Profile

Prescription Considerations

Iceross Seal-In X was developed specifically to address the handling and donning challenges of the elderly and/or dysvascular amputee, where hand dexterity is commonly severely compromised.

	Seal-In X	Seal-In V	Seal-In X5
Typical candidates	Elderly and/or hand compromised patient with or without Unity. Atypical shape or length of residuum	Younger patient with typical stump length suitable for a fixed seal, with or without Unity	Younger patient requiring rotation and pistoning control without Unity
Volume Fluctuation capacity	Good	Excellent	Fair
Ease of inverting and donning	Very easy	Needs fair hand strength	Needs fair hand strength
Speed of inverting and donning	Fastest of all three with elderly patients / compromised hand dexterity. Younger patients may prefer single-step donning of Seal-In V or X5.	Very fast for capable hands, not suitable for elderly / compromised hand dexterity	Very fast for capable hands, not suitable for elderly / compromised hand dexterity
Complies with irregular stump shapes	Very good compliance with complex shapes	Fair compliance	Fair compliance
Rotation control	Good	Fair	Excellent
Pistoning	Excellent pistoning control with Unity, good control with expulsion	Very good pistoning control with Unity	Excellent pistoning control in expulsion setup
Ease of socket modifications	Very straightforward, cast without Seal-In ring and apply Unity style modifications	Simple but frequently requires taking seal placement and thickness into account	Straightforward for expulsion, specific modifications for Unity not defined
Unity compatibility	Excellent	Excellent	Fair
Expulsion compatibility	Excellent	Excellent	Excellent

Seal-In® X User Profile

Prescription Considerations

Contraindication

-Very short residual limbs **less than 10cm** in length (when used with a Seal-In Ring, does not apply when used with a sleeve)

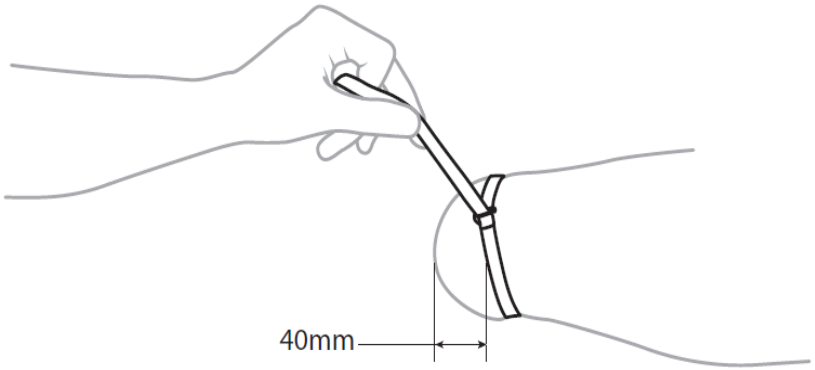
Targeted User Population:

-Transtibial, Dysvascular amputees
-Users with compromised hand dexterity
-Candidates for Seal-In technology
-Candidates for Unity® technology

Seal-In® X: Liner Sizing

Conventional method is used to select liner:

Measure 4cm from distal end
Round down if between sizes



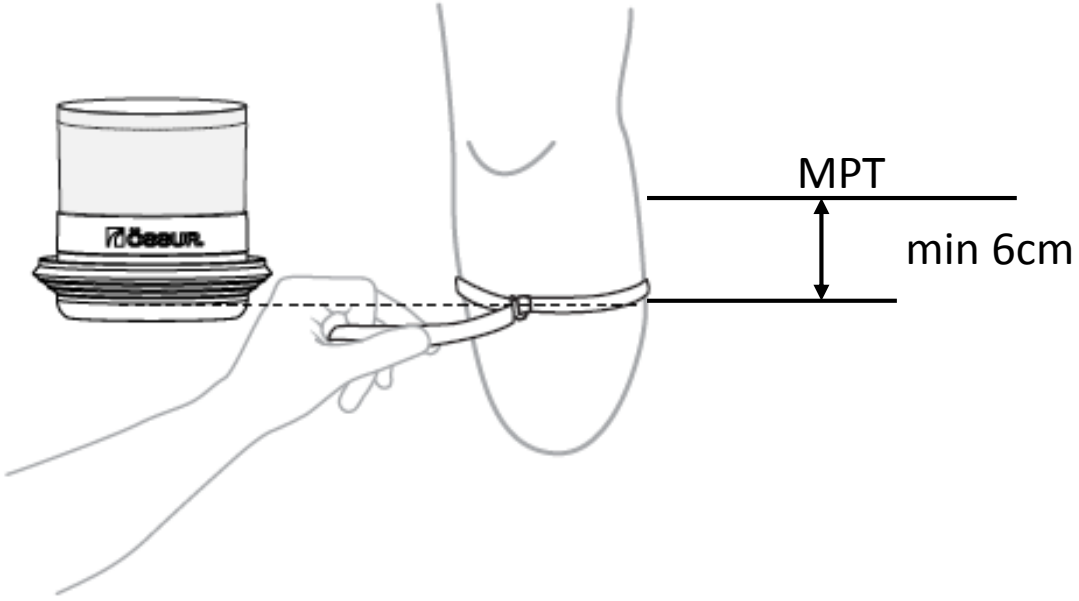
Seal-In® X: Seal Ring Sizing

Measure circumference distally, where the seal edge will sit

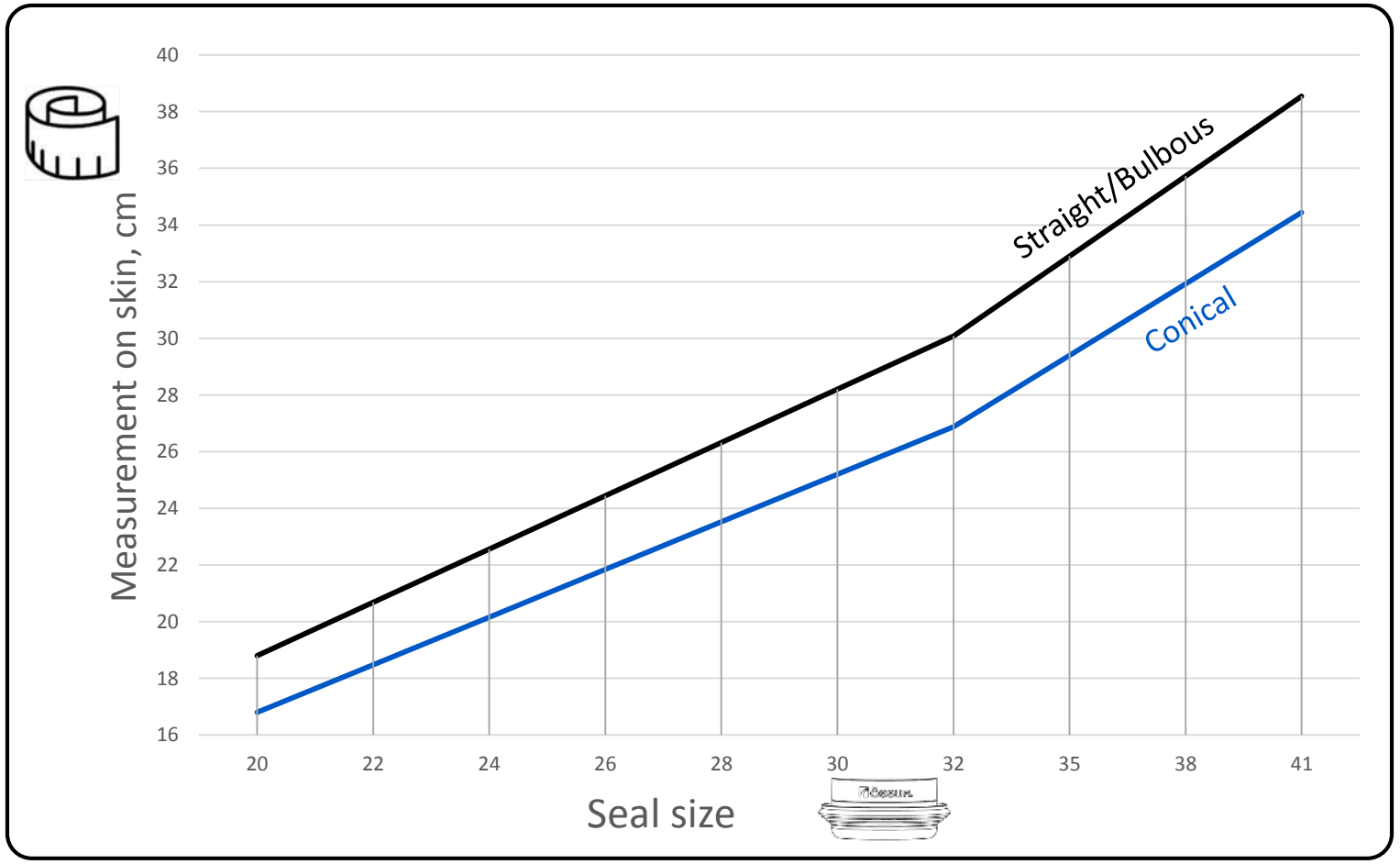
- Measure on skin
- Commonly, **6cm below MPT**

Pick appropriate seal from the chart:

- Note: When measurement is taken for 6mm liner, one may need a step larger size seal (3mm extra liner thickness is 19mm in circumference), or at least pick towards the right side of the fitting chart



Seal-In® X: Seal Ring Selection Chart



For straight and bulbous stumps, pick close to the Straight/Bulbous line **(+1 size up)**
Conical stumps need **LARGER** sizing (to right) **(+2 sizes up)**
The chart applies for 3mm liners, 6mm liners may need one size up

Seal-In® X

Evaluating Seal Ring sizing

Seal too small, lip of seal is compressed around circumference of limb

Optimal seal size, small gap but may be partially touching

Seal too large, wide gap

For optimal sizing, use a Seal Ring fitting kit.

Two sets available with fully functional Seal Rings.

Seal-In® X: Seal Placement

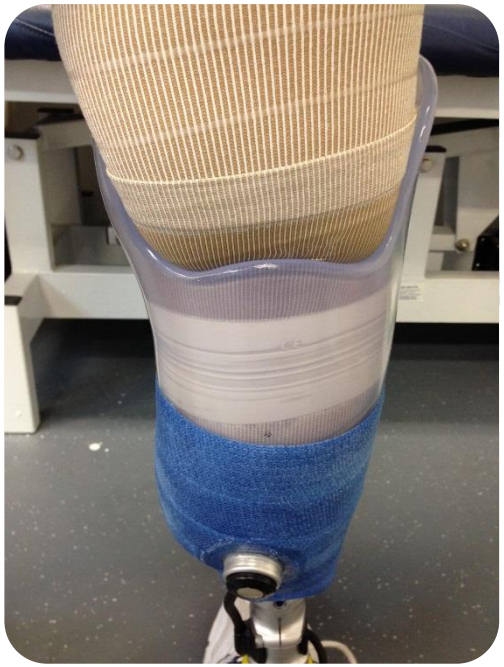
Avoid extreme proximal seal placement. Seek feedback from the user.

More proximal is not always better for suspension

Measure minimum 6cm below MPT

Seal should remain below trim line for security

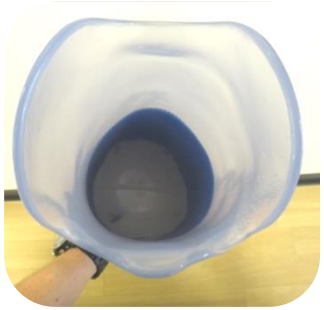
Seal-In® X: Seal Placement



Seal should ideally seat 1-2cm below posterior trim line and show even pressure around the circumference of the limb. If seal appears folded or migrated, re-don socket with lubricant spray. If issues continue, re-verify sizing and placement of seal.

Casting & Modification Methods

Check 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:

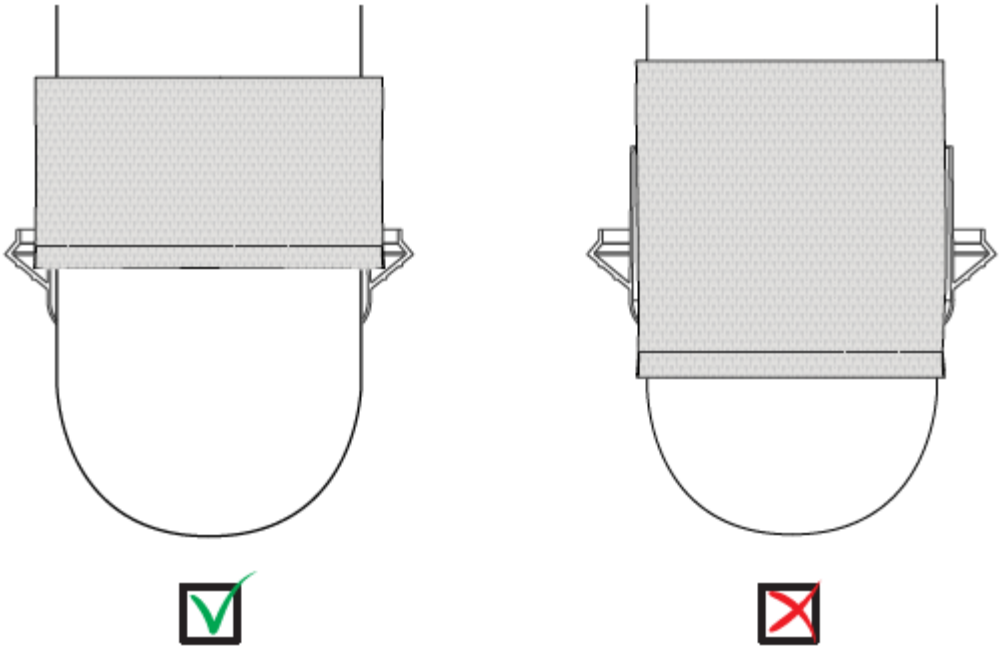
- Measure: Circumferences & ML
- Neutral cast (Elastic + Rigid)
- Proximal >> Distal wrap
- 3-5° knee flexion
- Avoid tightening the cast and any distortion to limb shape
- Casting under vacuum is NOT required

Modification:

- Correct ML dimension
- Level out seal area on positive
- Global 3-4% initial volume reduction (from patient measurements). Reductions up to 6% are possible for definitive socket fittings.
- Remove 6mm distally
- Remember to attach valve insert when pulling the check socket.

Volume Loss – Adding Socks

Seal-In volume socks can be used, but only outside the seal wall
Tucking under seal lip is OK



Seal-In® X: Retrofit and Sockets

Iceross Seal-In X retrofits Iceross Cushion sockets

Seal-In HSM, Seal-In X5 and Seal-In V sockets have also been commonly retrofitted with Seal-In X

PETG is by far the best socket surface.

When fabricating a laminated socket, pull a thin PETG layer first to prevent unnecessary leakage across/through the socket interface

When donning, ALWAYS use plenty of lubricant spray. Lack of lubricant can cause the seal to move or pull up the liner when sliding into the socket.

New Unity® compatible Flex-Foot solutions

Suit range of mobility levels with retrofittable pumps

Balance – Ideal for **K1-K2** level ambulators
(136kg weight limit, Sizes 23-28cm)

Vari-Flex XC – Ideal for **K3-K4**
(166kg weight limit, Sizes 22-30)

Balance J – Ideal for **K2** level ambulators
(136kg weight limit, Sizes 22-30cm)

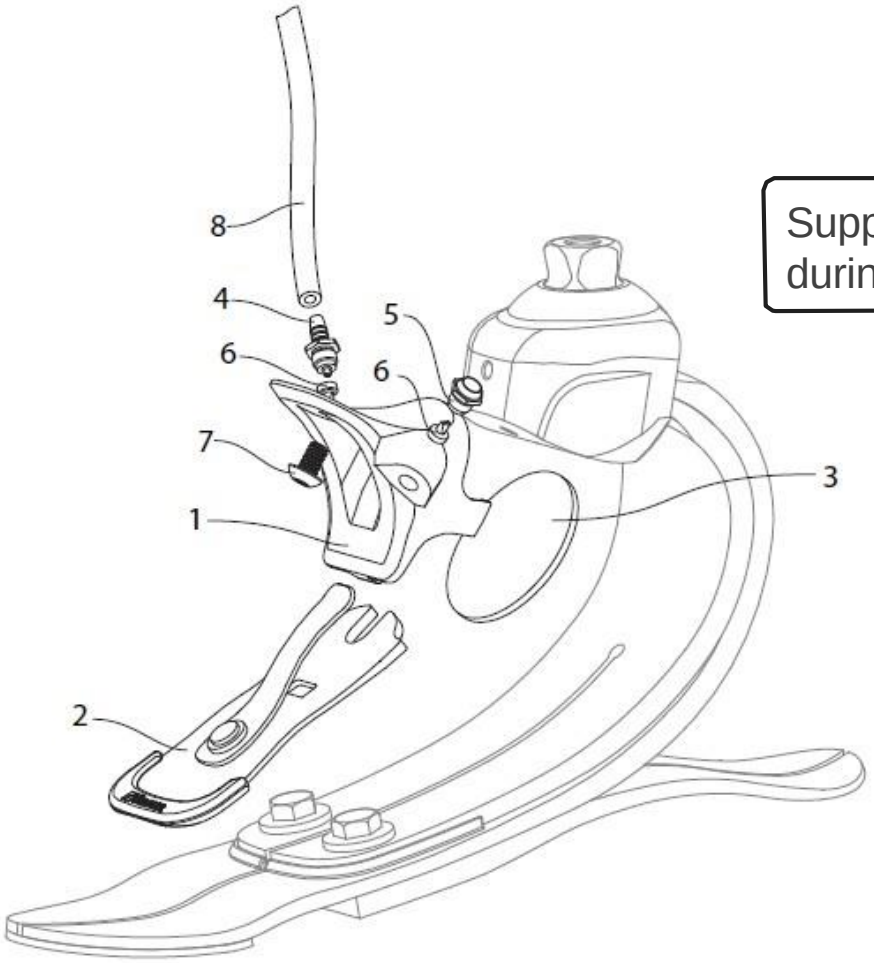
Assure – Ideal for **K2-K3** level ambulators
(136kg weight limit, Sizes 19-30cm)

Retrofitting Unity® for Vari-Flex XC

Vari-Flex XC pumps can be retrofitted to new foot modules.
Fully compatible production expected by **June 2015.**

Unity® for Vari-Flex XC

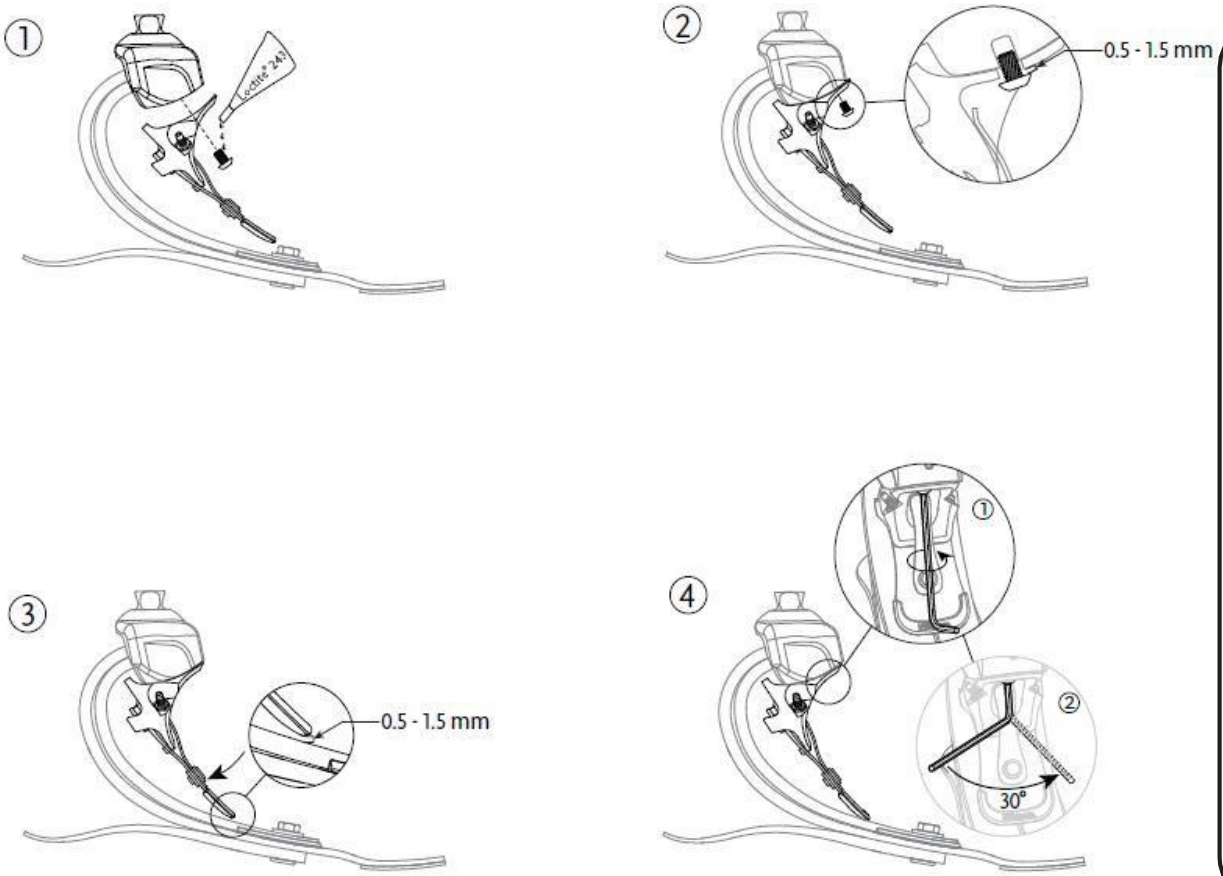
System Components & Function



1: Housing
2: Pump Blade
3: Membrane
4: Inlet Barb Connector
5: Outlet
6: Check Valves, Duckbill
7: Fastener Screw
8: Tube

Unity® for Vari-Flex XC

Pump attachment and Adjustment



Do not fully tighten until adjustments(3) have been made.

Leave clearance of 0,5-1,5mm between foot blade and pump blade.

Set screw to tight with long end of hex key.

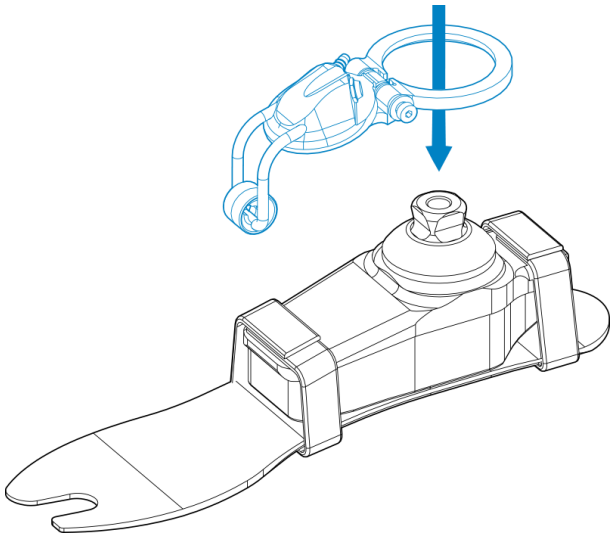
Add 30° (“5-minutes”) as a torque setting

Unity® for Vari-Flex XC

Flex-Foot Spectra Sock

For good access to the pump, and to prevent interference of sock and pump mechanism, don Flex-Foot sock between foot and pump blade

Retrofitting Unity® for Balance Foot



Balance – Ideal for **K1-K2** level ambulators (136kg weight limit, Sizes 23-28cm)

For the household and limited community ambulatory seeking a compliant and light weight foot for low impact activities of daily living.

Simplest retrofit. Attaches directly to pyramid attachment via clamp ring. Harnesses forefoot deflection to activate pump module.

Unity® for Balance J and Assure

Sleeveless elevated vacuum options for lower activity users

Pump module **retrofits** new pyramid design on foot modules **(JULY 2015)**

Pumps activated with forefoot deflection in mid-late stance

Balance J – Ideal for K2 level ambulators
(136kg weight limit, Sizes 22-30cm)

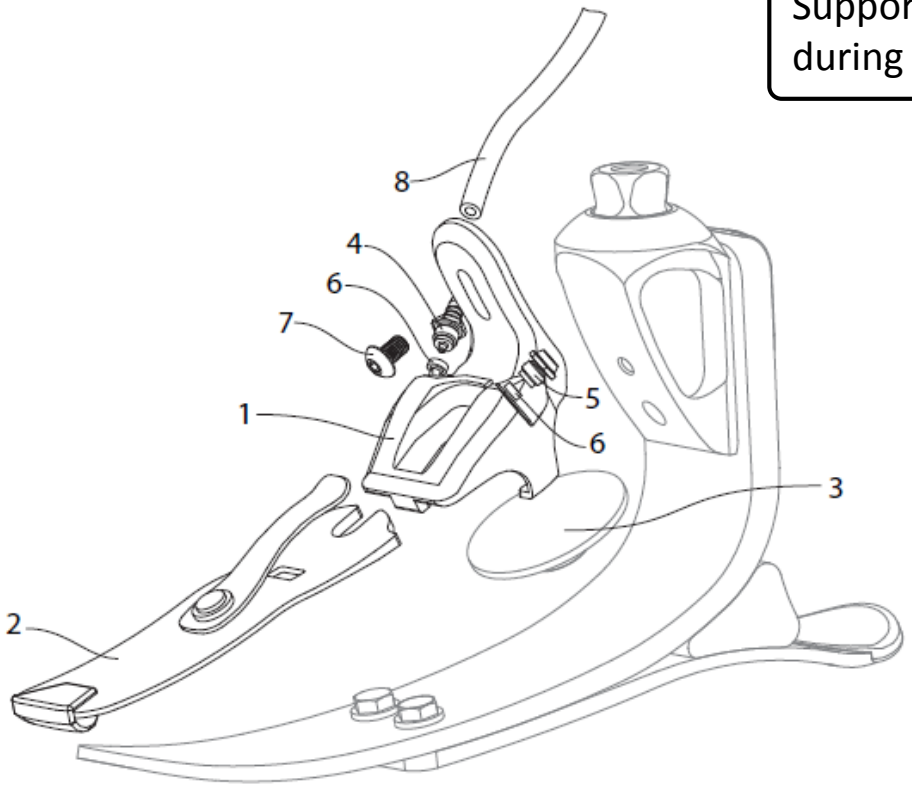
Assure – Ideal for K2-K3 level ambulators
(136kg weight limit, Sizes 19-30cm)

Retrofitting Unity® for Assure and Balance J

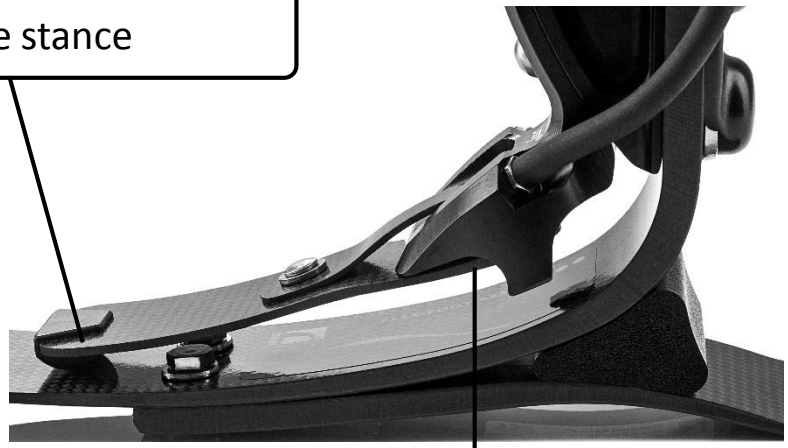
Balance J and Assure pumps can be retrofitted to new foot modules.
Fully compatible production expected by **July 2015.**

Unity® for Balance J and Assure

System components & Function



Support blade is deflected during mid-late stance

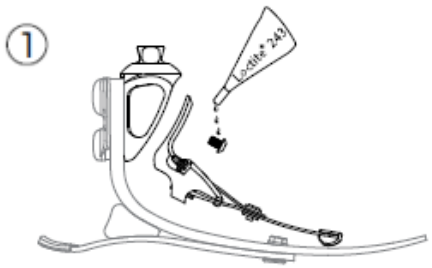


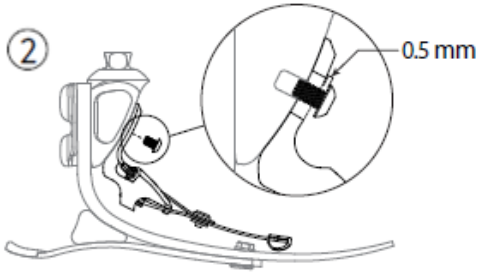
Blade pivots like a seesaw, pulling membrane back

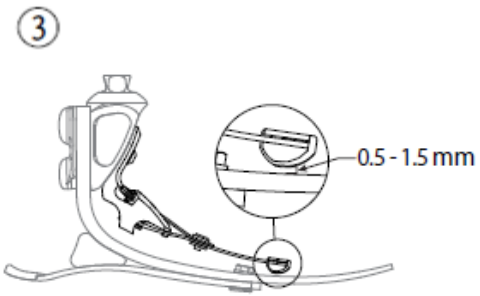
1: Housing
2: Pump Blade
3: Membrane
4: Inlet Barb Connector
5: Outlet
6: Check Valves, Duckbill
7: Fastener Screw
8: Tube

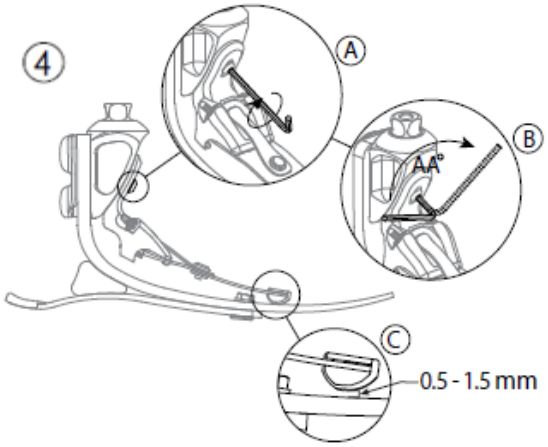
Unity® for Balance J and Assure

Setup - Pump attachment and Adjustment









Do not fully tighten until adjustments(3) have been made.

Leave clearance of 0,5-1,5mm between foot blade and pump blade.

Set screw: tight with long end of hex key.

Seat screw torque setting: 3Nm

Spectra Sock fitted over PUMP & FOOT MODULE

Warranty and maintenance

Standard Flex-Foot warranty and trial period (60 day) applies to foot:
Unity® Pump Kits – 24 Months
Unity® Membrane – 12 Months
Seal-In® V & X Interfaces – 6 Months

Unity® is entirely field serviceable. The entire system can be disassembled, cleaned and individual components replaced as needed. We recommend periodic 6 month inspections of the system.

Maintenance kits are available which include membrane, check valves, barb fittings, tubing, tube fastener and heel pad.

ÖSSUR®

LIFE WITHOUT LIMITATIONS

WE IMPROVE PEOPLE'S MOBILITY