Seal-Options Webinar

Webinar

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Introduction

3 New Seal-Rings Options

- Suitable for both TT and TF Seal-In X use:
- Feature an Easy glide coating- no need for donning spray
- More Form proof- prevents stretching
- Feature a textile donning aid- for ease of donning

Casting and modification methods:

- Unity Elevated Vacuum for TT and TF
- NU-FlexSIV (subischial socket design)

Pro-Flex® family update:

- **NEW** Pro-Flex® XC Torsion and **NEW** Pro-Flex® LP Torsion
- Improved durability

Seal-In X-Classic

Seal-In X-Grip

Seal-In X-Volume

Seal-In X TF

Seal-In X

Previous Seal Ring offering

Seal-In X Transfemoral

- Liner profile
  - Standard, Conical
- Available seal sizes
  - 26,28,30,32,35,38,41,44,47,51,55,60,65,70
- Seal height
  - 70mm
- No textile donning aid
- Spray needed for DONNING

Seal-In X Transtibial

- Liner profile
  - 3mm, 6mm
- Available seal sizes
  - 20,22,24,26,28,30,32,35,38,41
- Seal height
  - 50mm + 65mm textile
- Textile donning aid
- Spray needed for DONNING

Seal-Ring Options- *No Donning Spray required*

- The Seal-In Rings consist of a hypobaric membrane and textile donning aid
- Easy-glide (unique anti-friction coating) makes donning and doffing a prosthetic socket easier, without the use of lubricant aids
- When the ring is correctly positioned onto a donned Iceross Seal-In X Liner, it will be held in tension against the silicone bands on the exterior surface of the liner, then compressed against the interior surface of the prosthetic socket.
  - This creates a distal vacuum chamber that reliably suspends the residual limb in the prosthesis

Seal-In X-Classic

Seal-In X-Grip

Seal-In X-Volume

Seal-In X TF

Seal-In X

Seal-Ring Options- *No Donning spray required*

Seal-In X-Classic

- Improved version of current Seal-In X TT Seal with Easy Glide coating and more stable stretching properties
- The classic day-to-day seal ring

Seal-In X-Grip

- An adapted movable version of the Seal-In X5 seal
- For good rotational control

Seal-In X-Volume

- An adapted movable version of Dermo Seal-In and Seal-In TF (HSM)
- Accomodates more volume reduction than the other two options

Seal-In X TF
- Standard or
- Conical -

Seal-In X
- 3mm or 6mm -

Available seal sizes
20,22,24,26,28,30,32,35,38,41,44,47,51,55, 60,65

Benefits of Seal-In®

Benefits of Seal-In®

- Reduces:
  - pistoning
  - volume fluctuations
  - shear forces/pressure
- Improves:
  - skin management and health
  - balance/stability
  - proprioception
  - gait symmetry
  - standing/sitting/kneeling movements
  - mobility

Additional benefits of movable seals:

- General ease of using liner – easier inverting compared to fixed seal
- Ease of donning socket – no spray needed
- Custom seal positioning accommodating individual residual limb shape
- Seal can be moved within the day for relieve/comfort
- Potential to use different seals for different occasion
- Easier for socket making compared to fixed seal liners since casting is done on liner without the seal

H. Goliad, N. A. Abu Osman, A. Sarahi, S. Ali, and N. A. Razak, ***"Transtibial prosthesis suspension systems: Systematic review of literature,"*** *Clin. Biomech. vol. 29, no. 1, pp. 87–97, Jan. 2014.*

H. Gholizadeh, N. A. Abu Osman, A. Eshraghi, S. Ali, and N. A. Razak, ***"Transfemoral prosthesis suspension systems: Systematic review of literature,"*** *Am J Phys Med Rehabil 2014.*

G. K. Klute, B. C. Glaister, and J. S. Berge, ***"Prosthetic liners for lower limb amputees: A review of the literature,"*** *Prosthet. Orthot. Int., vol. 34, no. 2, pp. 146–153, Jun. 2010.*

Features and benefits of new seals

Feature	Benefit
Seal Options	Three different seal types to accommodate different user needs or activities
Textile donning aid	Improves ease of donning: – Easier to position seal – Easier to operate seal for users with impaired hand dexterity
Easy-Glide coating **Warning! Alcohol spray will damage Easy Glide coating**	• Simplifies DONNING process, seal is ready to use as is • Less dust attraction • Eliminates the following negatives of previous non-coated seals: – When not enough lubrication, seal tends to wrinkle – Seal moves proximal when donning, resulting in excessive stretching which leads to size inconsistency – Swelling of the seal due to absorption of used spray/ lotion which leads to size inconsistency
More stable stretching properties	Size consistency over time due to more stable stretching properties (seal might be experienced as stiffer). Users will initially experience some stretching but once the seal has adapted to the residual limb shape, the stretching and size should stabilise. The tighter the initial fit, the more initial stretching will occur.

Indicated User Profile

Indicated User Population

- Transtibial and Transfemoral amputees
- Low to high impact levels
- Sufficient residual limb length
- Cognitive ability for safe usage
- Conical residual limbs can be addressed by use of a distal cup

Contraindications

- Extreme volume fluctuation
- Extremely short residual limbs- refer to table
- Cognitive limitations hindering safe usage

To measure residual limb length:

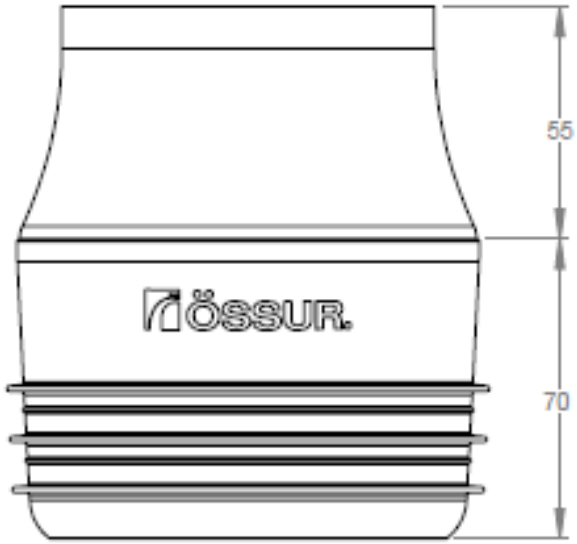
- **Transtibial:** From MPT to distal end
- **Transfemoral:** From perineum to distal end, with the tissue hanging down

TRANSTIBIAL	
Liner Size	Min. Length (cm)
16-23,5	11
25-30	12
32-36	13
40	14

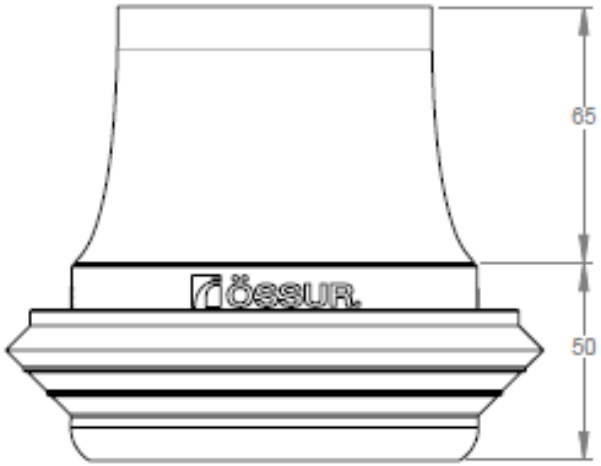
TRANSFEMORAL	
Liner Size	Min. Length (cm)
23,5-28	16
30-34	17
36-40	18
45	19
50	20
55	21

Product Dimensions

Seal-In X-Classic



Seal-In X-Grip



Seal-In X-Volume

Size Selection – Utilising Seal-In® X Kit

The preferred method of determining correct size is by utilising an Iceross Seal-In X kit

1. Place Seal-Ring from the Iceross Seal-In X Kit at appropriate location on liner, considering the recommended distance between lowest socket edge and uppermost seal lip (Figure 1).
2. Assess for any deformation of the Seal-Ring and residual limb. The Seal-Ring should sit securely in place without excessive compression (Figure 2).
3. If the Seal-Ring does not fit at the appropriate location, select another size or relocate if appropriate, to obtain proper tension.

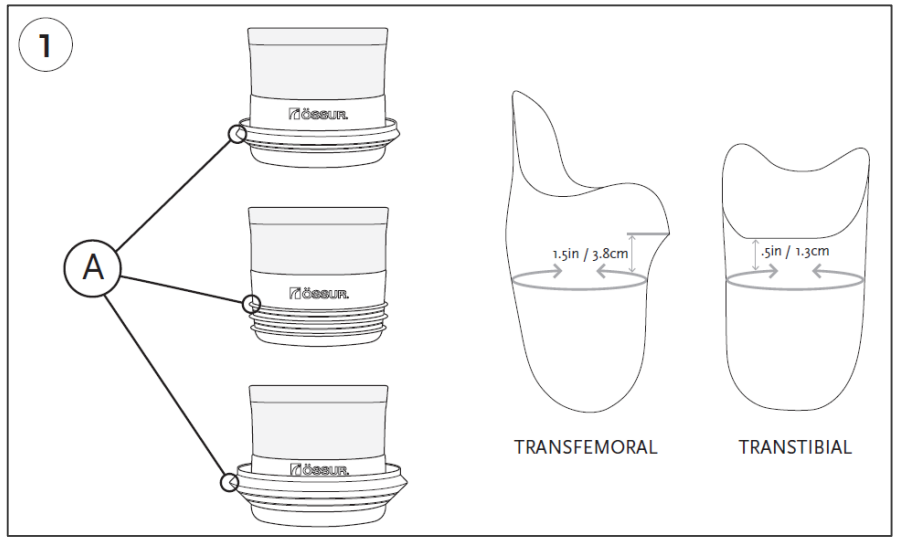


Figure 1

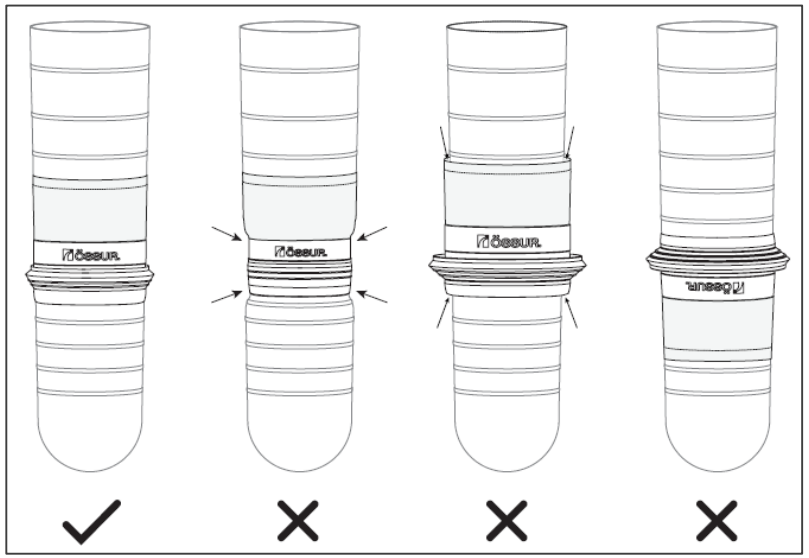


Figure 2

Size Selection – Measuring directly on the Residual Limb

1. Measure the circumference (cm) at optimal location, directly on skin
2. Refer to the graph in Figure 1 to estimate correct Seal-Ring size

Examples:

Circumference of 40cm corresponds to device sizes 44 or 47
Circumference of 26cm corresponds to device sizes 28 or 30

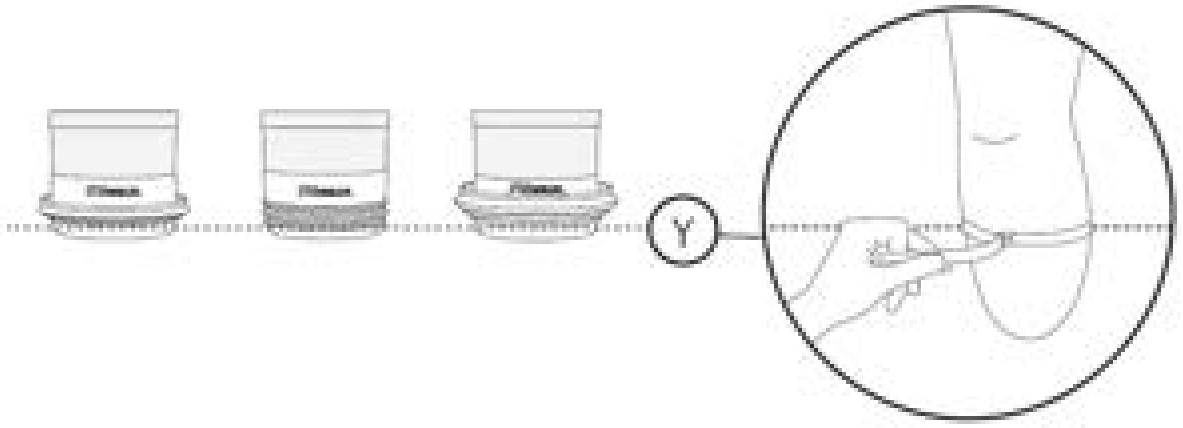
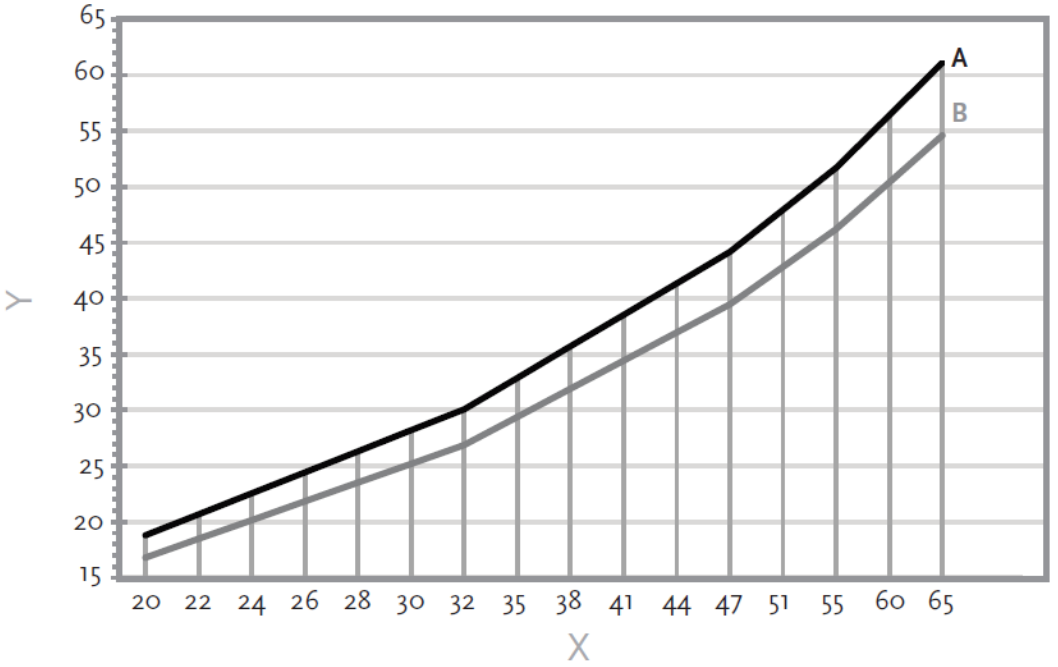


Figure 1

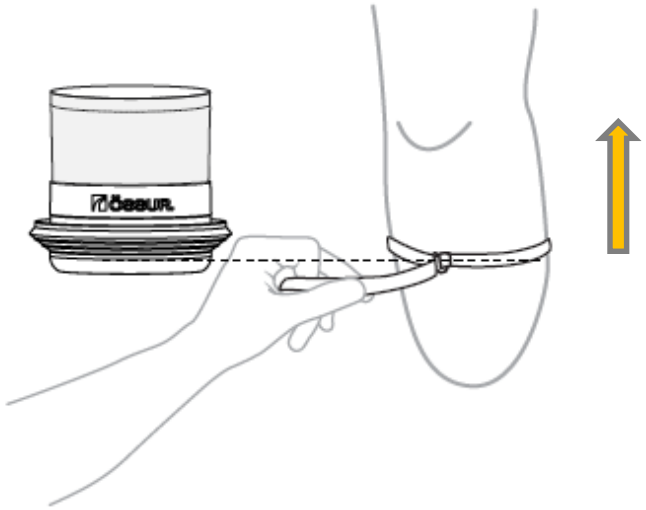


X: Seal size
Y: Circumference (cm)
A: Tight fit
B: Loose fit

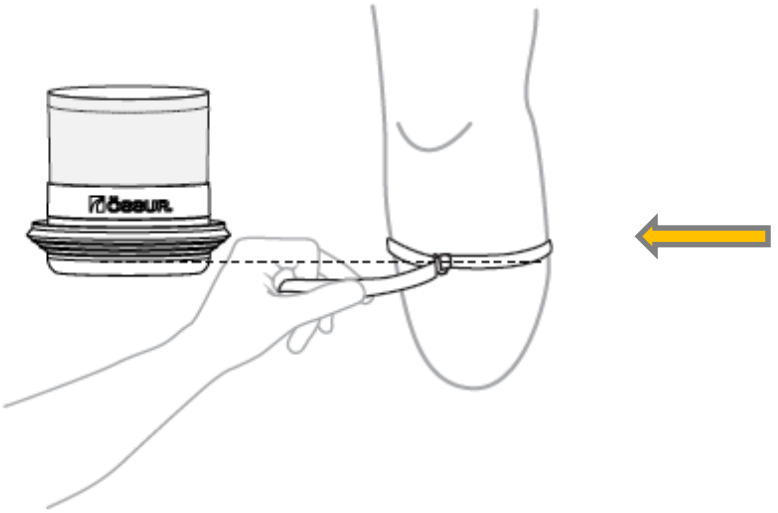
Seal Sizing-Old seals VS New Seals

- Previous Seal version was prone to stretching/swelling over time
- This could result in seal migrating to a more proximal position
- New seals= More FORM PROOF
- Seals may feel ‘stiffer’ to user but will initially stretch and adapt to residual limb shape and become more stable and consistent in size

Old seals tended to stretch and therefore move more proximal over time



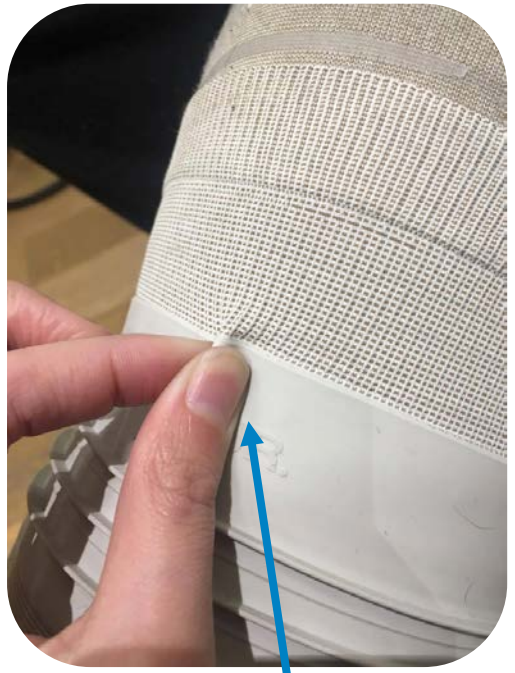
New seals are more form-proof and will hold their position better



Seal-Ring Sizing: X-Grip example

Seal Ring too tight, seal compressing the liner

Seal Ring is optimal size, no proximal gapping or compression of liner



Seal Ring too Large: Seal-Ring-lacking proximal connection to liner

Seal-Ring Sizing: X-Volume example

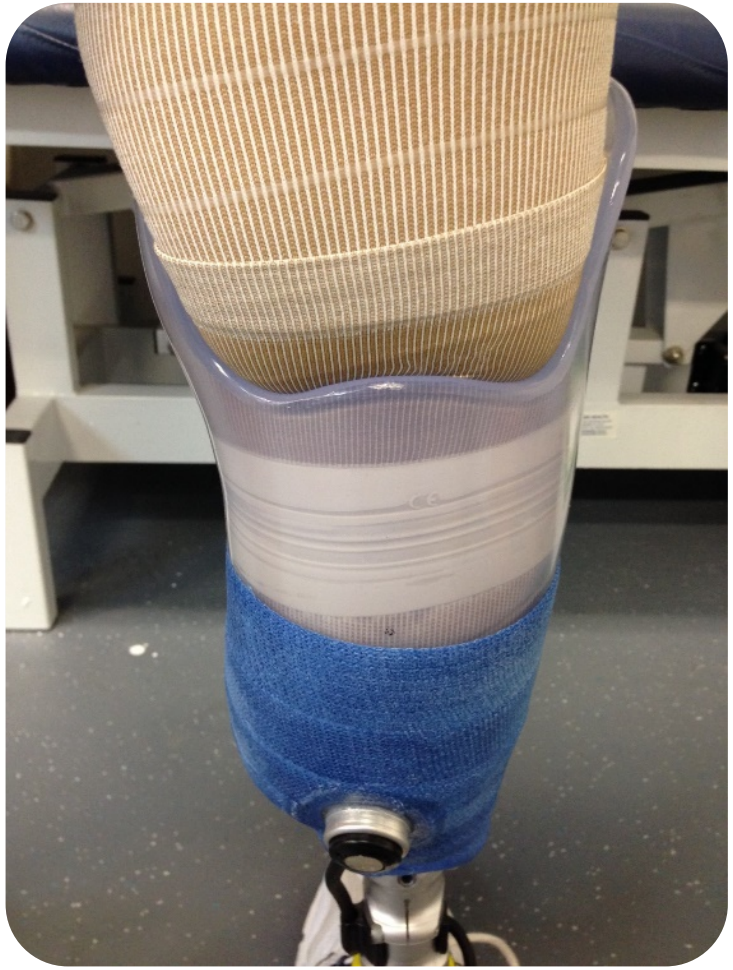
Seal too large-wide gap

Optimal seal size: small gap but may be partially touching

Seal ring too tight-liner compressed

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



Daily Care and Cleaning: Easy-Glide Coating

NB: The residual limb should be inspected daily by the user, to verify that skin/limb health is satisfactory

Cleaning:

- Rinse the silicone portion of the Seal-Ring with water daily, and dry with a lint-free cloth. This will prevent the build-up of dirt and other residue, which may affect the Seal-In properties and hygiene of the Seal-Ring overtime.

Do NOT use soap or any other cleaning aids to clean the Seal-Ring
Do NOT use boiling water
Using soap or alcohol/donning spray will remove Easy-Glide Coating

Warranty: Össur offers a 6-month (from invoice date)

Retrofitability

- Retrofitability is dependent on the socket fit, current liner type and whether it is for TF or TT
- Evaluate on an individual basis as a part of good practice of evaluating socket fit
- Clinical study shows strong indication that seal options can retrofit to previous sockets
- Clinical Study included 30 amputees using HSM, Seal-In X5, Seal-In V, Seal-In X - majority of users were retrofitted

General Recommendation:

- Transtibial:
  - For TT and tight socket fit, the **X-Classic** and **X-Grip** seals may fit but **X-Volume** likely not
  - For TT and loose socket fit the **X-Classic** and **X-Volume** seals may fit, but likely not **X-Grip**.
  - **X-Volume** will likely not fit for the smaller sizes and triangular shaped sockets

- Transfemoral:
  - For TF and tight socket fit, all Seal-In X Seals, **X-Classic**, **X-Grip** and **X-Volume**, may fit
  - For TF and loose socket fit, **X-Classic** and **X-Volume** may fit, but likely not **X-Grip**
  - For TF it should be noted that Seal-In X TF is 5mm thinner distally than other Iceross Seal-In TF liners- therefore you may require the use of distal pads

Retrofitability

NB. Table is for guidance only. Retrofit shall in all cases be tested on individual basis.

	Current Seal-In Liner	Socket fit	Seal-In X Seal	Retro-fitability
Transtibial	Seal-In X5	Loose	Classic	✓
			Grip	✗
			Volume	!
		Tight	Classic	✓
			Grip	✓
			Volume	✗
	Seal-In V	Loose	Classic	✗
			Grip	✗
			Volume	!
		Tight	Classic	✓
			Grip	✓
			Volume	✗
	Dermo Seal-In	Loose	Classic	✗
			Grip	✗
			Volume	!
		Tight	Classic	✓
			Grip	✓
			Volume	✗
	Seal-In X	Loose	Classic	✓
			Grip	✗
			Volume	!
		Tight	Classic	✓
			Grip	✓
			Volume	✗

	Current Seal-In Liner	Socket fit	Seal-In X Seal	Retro-fitability
Transfemoral	Seal-In X5*	Loose	Classic	✓
			Grip	✗
			Volume	✓
		Tight	Classic	✓
			Grip	!
			Volume	✓
	Seal-In HSM*	Loose	Classic	✗
			Grip	✗
			Volume	✓
		Tight	Classic	✓
			Grip	!
			Volume	✓
	Seal-In X	Loose	Classic	✓
			Grip	✗
			Volume	✓
		Tight	Classic	✓
			Grip	!
			Volume	✓

* Seal-In X5 liners are 5mm thicker distally compared to Seal-In X TF. Possible to add patch to distal end

✗	Is not retrofitable
✓	Is retrofitable
!	Could be retrofitable in larger sizes, but not in smaller sizes

* Socket fit reference: Loose fit - up to 8ply, Tight fit - less than 3ply. 1ply=0.4mm

Unity® Elevated Vacuum: Advantages of vacuum suspension

- **Very firm suspension** providing excellent security and improved **proprioception**
- Elevated vacuum tends to assist in maintaining more **constant limb volume**, thereby 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 and sensitive distal ends; as long as the socket fits properly with good **volume and length matching**

Primary benefits of the Unity® system

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:** Optimises socket stability, proprioception and comfort throughout the day while limiting the need to add socks
- **INCREASED RELIABILITY:** Minimises risk of leaks and puncture issues associated with sleeve dependent vacuum methods
- Integrates **PERFORMANCE FLEX-FOOT** technology to meet all activity requirements

Unity® TT Casting and Modification

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

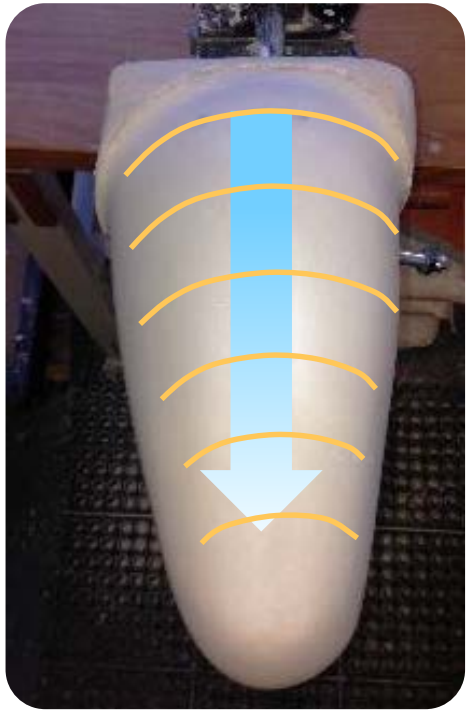
- Measure circumferences and M/L
- Take Neutral Cast (1 Elastic and then rigid)
- Proximal to Distal wrap
- 3-5° Knee flexion
- Avoid tightening the cast and distorting the limb shape
- Casting under vacuum is NOT required

Modification

- Correct M/L dimension
- Level out seal area on positive (if using Seal-in V)
- Global reduction 3-5% from patient measures depending on tissue consistency
- For larger residual limbs reductions of 6% are possible for definitive fittings
- **Remove 6mm distally**
- If using Unity TT/TF valve-use valve insert (dummy) before pulling check socket

TF Casting and Modification

- Standard plaster cast- Casting over Seal-Ring is not required
- Use elastic plaster then rigid
- Do a graduated reduction of 3-5% proximally from patient measures
- Reduce up to 6mm distally (with Unity application)



Subischial Socket Design: NU-FlexSIV

- Ryan Caldwell and Stephania Fatone have worked with Northwestern University- developed a teachable technique for flexible subischial vacuum sockets:

Northwestern University Flexible Sub Ischial Vacuum Socket
(NU-FlexSIV Socket)

- NU-FlexSIV trim lines typically sit **25mm below the ischial tuberosity** and **50mm below the greater trochanter**

<u>Lower trim lines achieved by:</u>

- Global compression of soft tissue to relieve pressure on the distal femur
- Utilises TT/TF liners which are undersized 10-30% depending on tissue consistency
- Definitive socket consists of a full flexible inner socket and carbon fibre outer socket
- User benefits from increased ROM as socket wall no longer limits movement
- Research has shown that elevated vacuum increases socket comfort with the Nu-FlexSIV

[6]Prosthetics and Orthotics International: Northwestern University Flexible Subischial Vacuum Socket for persons with transfemoral amputation-Part 1: Description of technique. Stefania Fatone and Ryan Caldwell

7Prosthetics and Orthotics International: Northwestern University Flexible Subischial Vacuum Socket for persons with transfemoral amputation: Part 2 Description and Preliminary evaluation. Stefania Fatone and Ryan Caldwell

Recommended Liners

Relax 3C Cushion:

- Users with soft tissue
- **Recommend downsizing 10-15%**

Synergy Cushion:

- Users with firm tissue
- **Recommend downsizing 20%**
- Users with a mixture of firm and soft tissues, or users with prominent/bony distal end
- **Recommend downsizing 30%**

Seal-In X TF:

- Long TF/TK
- Sport applications
- When using a sleeve is not preferred
- **Recommend downsizing 15-20%**

[6]Prosthetics and Orthotics International: Northwestern University Flexible Subischial Vacuum Socket for persons with transfemoral amputation-Part 1: Description of technique. Stefania Fatone and Ryan Caldwell

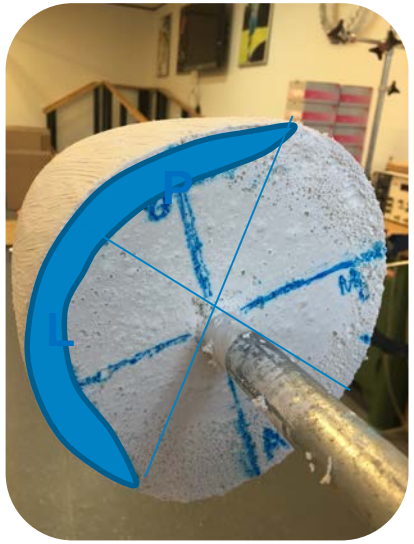
Subischial Casting Method

- Mark Anterior Mid-line and Adductor Longus
- Cast with client sitting, with residual limb flexed at 90° and abducted using Fibreglass tape
- Start casting proximally on the lateral side, wrapping medially
- Take note of how easy/hard it is to remove the mould
- Classify the residual limb as symmetrical or asymmetrical
- Casting tape: 404DP

[6]Prosthetics and Orthotics International: Northwestern University Flexible Subischial Vacuum Socket for persons with transfemoral amputation-Part 1: Description of technique. Stefania Fatone and Ryan Caldwell

Modification

- Transfer Anterior reference mark and line of progression to positive model
- Reduce cast to recommended reductions
- Focus reduction in the proximal posterior and lateral area, flattening them into a ‘boomerang’ shape
- Blend in these modifications creating a round barrel like shape
- Smooth rest of cast removing any bumps



[8]Notes from AAOP meeting, Chicago Illinois, March 2017 “NU-FlexSIV workshop’

Nu-FlexSIV socket with Seal-In® X TF and X-Grip

Bring the seal as proximally as possible

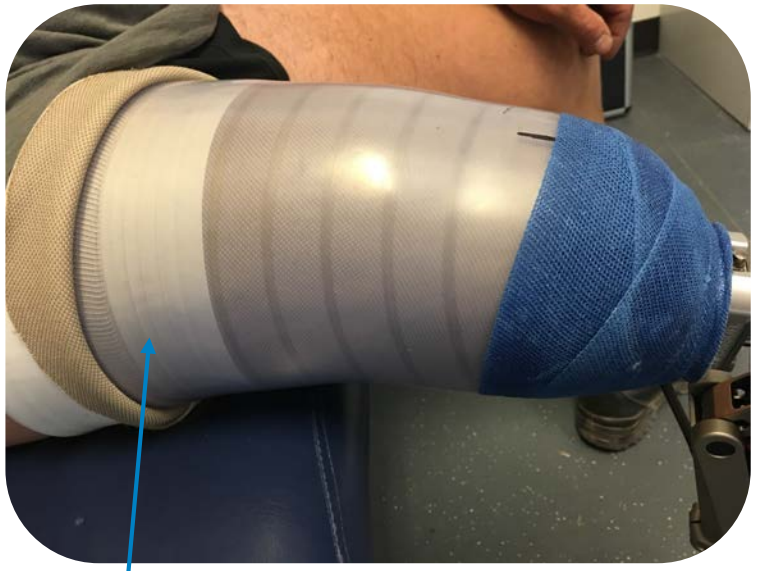
Look for even compression of seal

Seal too large-will buckle when donning

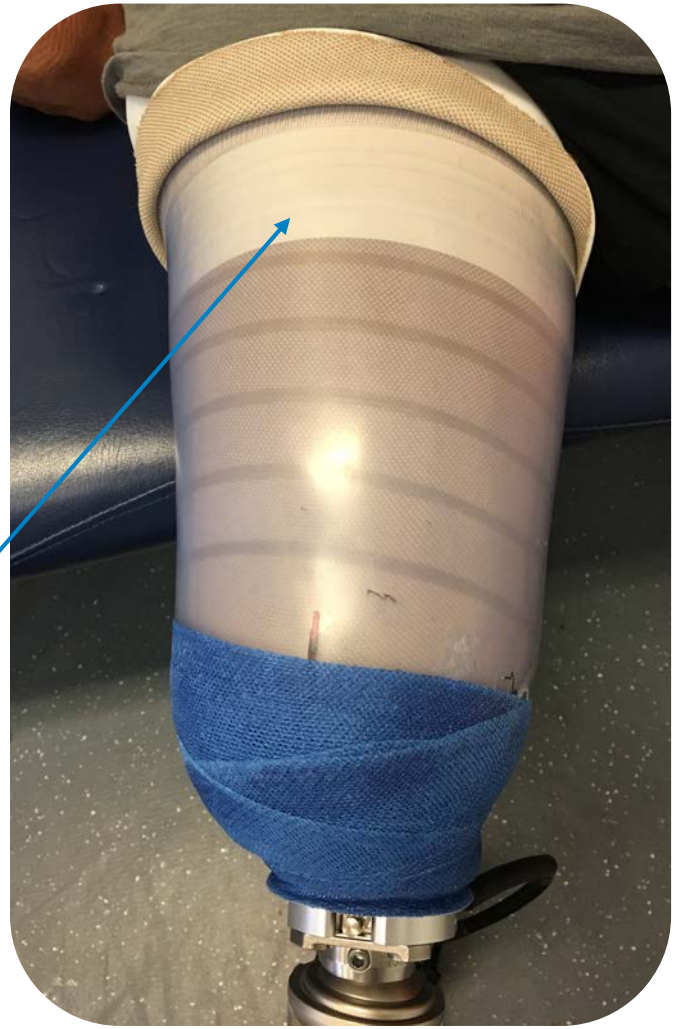
Seal-In® X Classic and Volume example (Nu-FlexSIV socket)

Seal-Ring too big- lacking distal contact to the liner

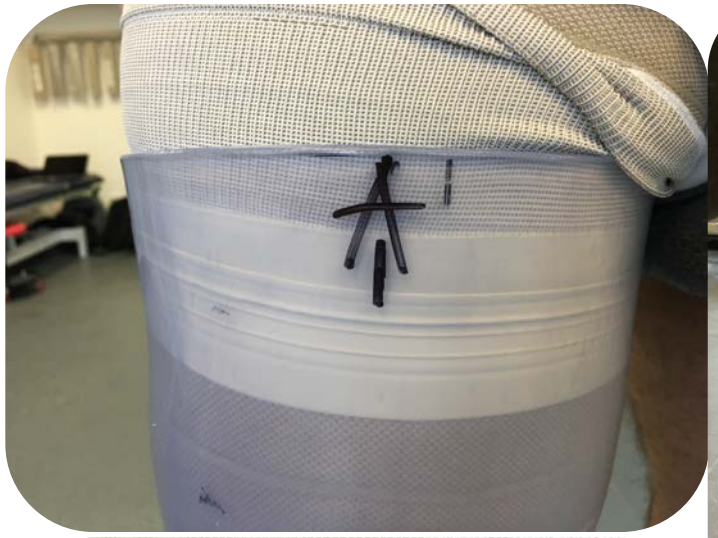
Optimal Seal size: small gap but may be partially touching

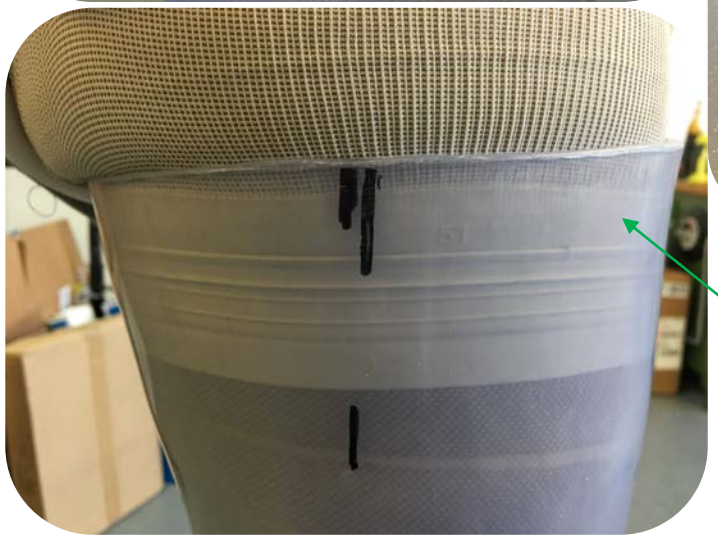


Check Seal in sitting- look for even compression of the seal, and check for any gaps/loss of contact



Seal-In® X Grip example (Nu-FlexSIV socket)





Position ring as proximally as possible
Ensure even seal compression proximally

Pro-Flex® Family- NEW Additions

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

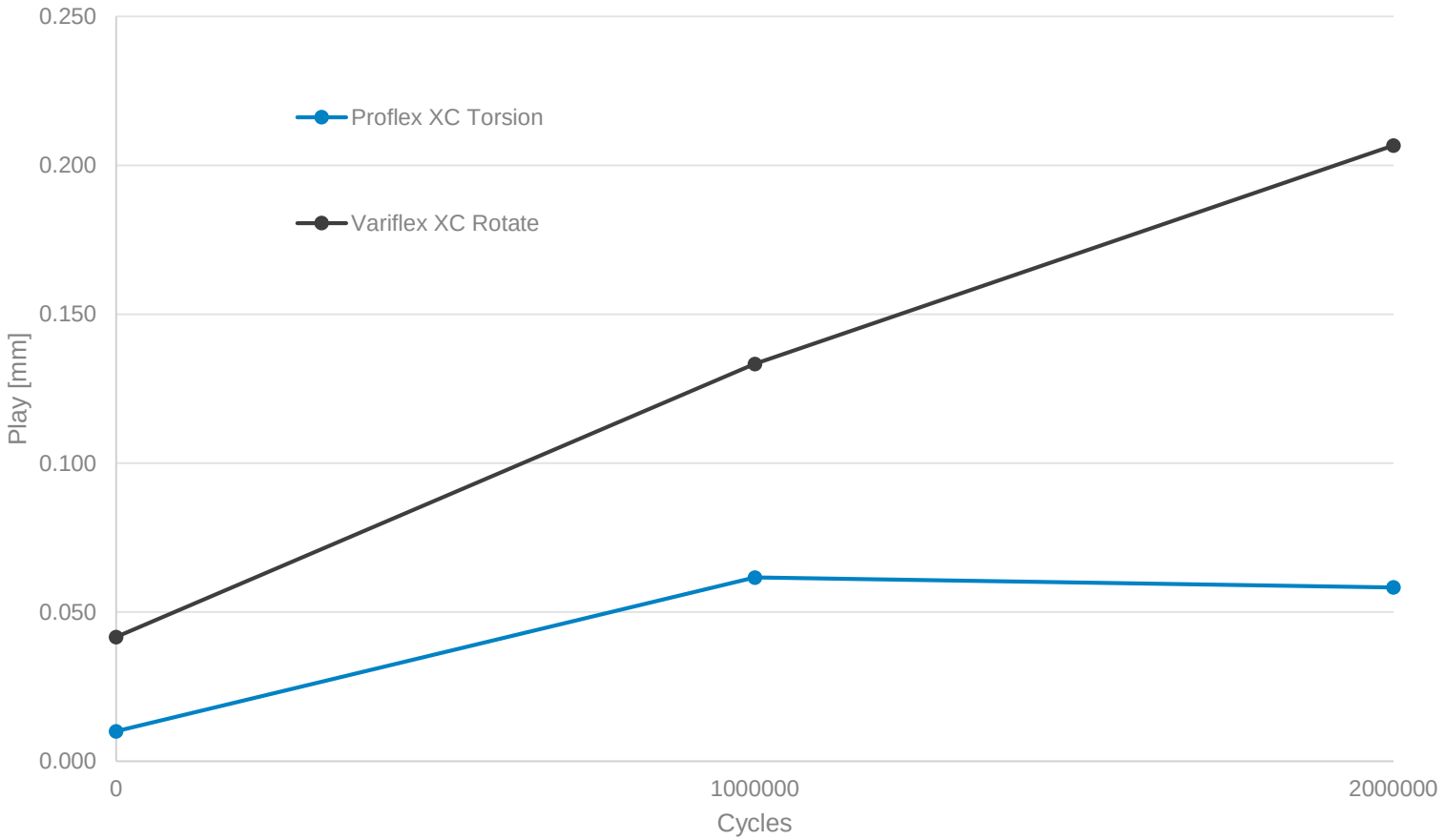
Pro-Flex® XC Torsion with Unity

- C-shaped design provides 10mm of vertical compression
- Axial compression up to 6mm
- The torsion-shock unit compensates for physiological rotation and vertical shock absorption of lost joints
- Increases user comfort- reduces stress on the residual limb

- **<u>Improved durability over the Vari-Flex XC Rotate</u>**
  - Adjusted materials to ensure complete compatability
  - 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
- **Unity compatible**

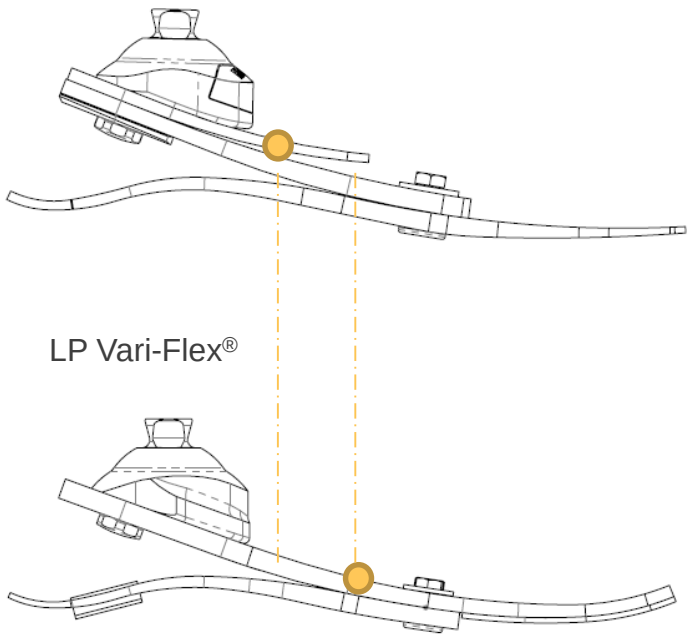
Comparison test: Pro-Flex® XC Torsion

Development of play for Pro-flex® XC Torsion VS Vari-Flex® XC Rotate:



Pro-Flex® LP

Pro-Flex® LP



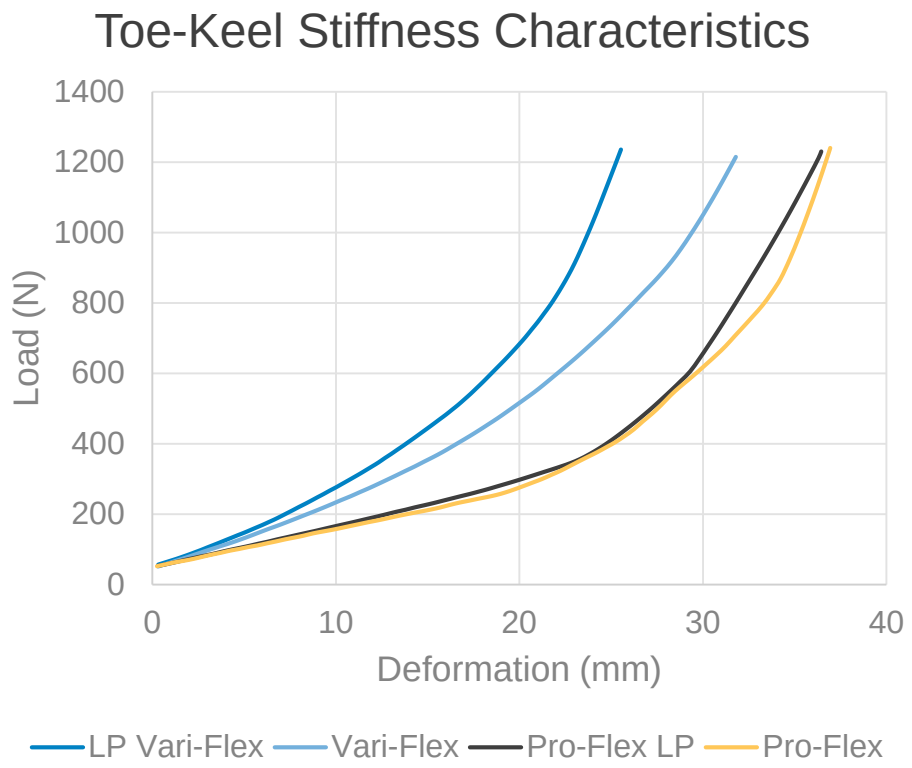
LP Vari-Flex®

- Pro-Flex LP introduces a patent pending blade lay-up technology.
- **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 is closer to anatomical than LP Vari-Flex
- Pro-Flex LP offers greater ankle range of motion than other feet with low build height (LP Vari-Flex)
- **Improved physiological gait**
- **Increased function and satisfaction**

Pro-Flex LP is recommended for clients up to 166kg with longer residual limbs (where clearance is an issue) and moderate to high impact levels.

Test Results

- **Progressive stiffness** of Pro-Flex® LP
- **Much lower stiffness during the first part** of the loading curve for Pro-Flex® LP compared to LP Vari-Flex®
- **Clinically, this indicates:**
  - lower resistance to initial dorsiflexion for Pro-Flex® LP, meaning **less moment needed** from the residual limb to load the foot
  - higher displacement for the Pro-Flex® LP indicates **more ankle range of motion** with the same load.



All samples cat 5 size 27 tested with foot cover.

Pro-Flex® LP Torsion

- Pro-Flex® LP Torsion incorporates a torsion-shock unit
- The Torsion-shock unit compensates for physiological rotation and vertical shock absorption of lost joints
- Reduces shear stress and socket pressures
- The middle blade is reversed tapered allowing for more dynamics
- Unity Compatible
- Rated to 147kg

Seal-Ring Part Numbers

Iceross Seal-In X-Classic:

I-SXC0XX Sizes: 20-65

Ring Kits:

I-RXC001 Sizes: 26-51

I-RXC004 Sizes: 20-65

Iceross Seal-In X- Volume:

I-SXV0XX Sizes: 20-65

Ring Kits:

I-RXV001 Sizes: 26-51

I-RXV004 Sizes: 20-65

Iceross Seal-In X-Grip:

I-SXG0XX Sizes: 20-65

Ring Kits:

I-RXG001 Sizes: 26-51

I-RXG004 Sizes: 20-65

Seal-In X TF:

Standard: I-8532XX

Conical: I-8632XX

Seal-In X TT:

3mm: I-4443XX

6mm: I-4446XX

Summary

3 new Seal Rings compatible for both TT and TF Seal-In X liners:

- **X-Classic**
- **X-Grip**
- **X-Volume**
- All feature textile donning aid for ease of donning
- **Easy Glide Coating-** No donning spray required

Additions to Pro-Flex Range:

- Pro-Flex® LP Torsion
- Pro-Flex® XC Torsion-Featuring increased durability

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WE IMPROVE PEOPLE'S MOBILITY