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Introducing Iceross Seal-In X Locking Liner and 562 Hybrid Lock

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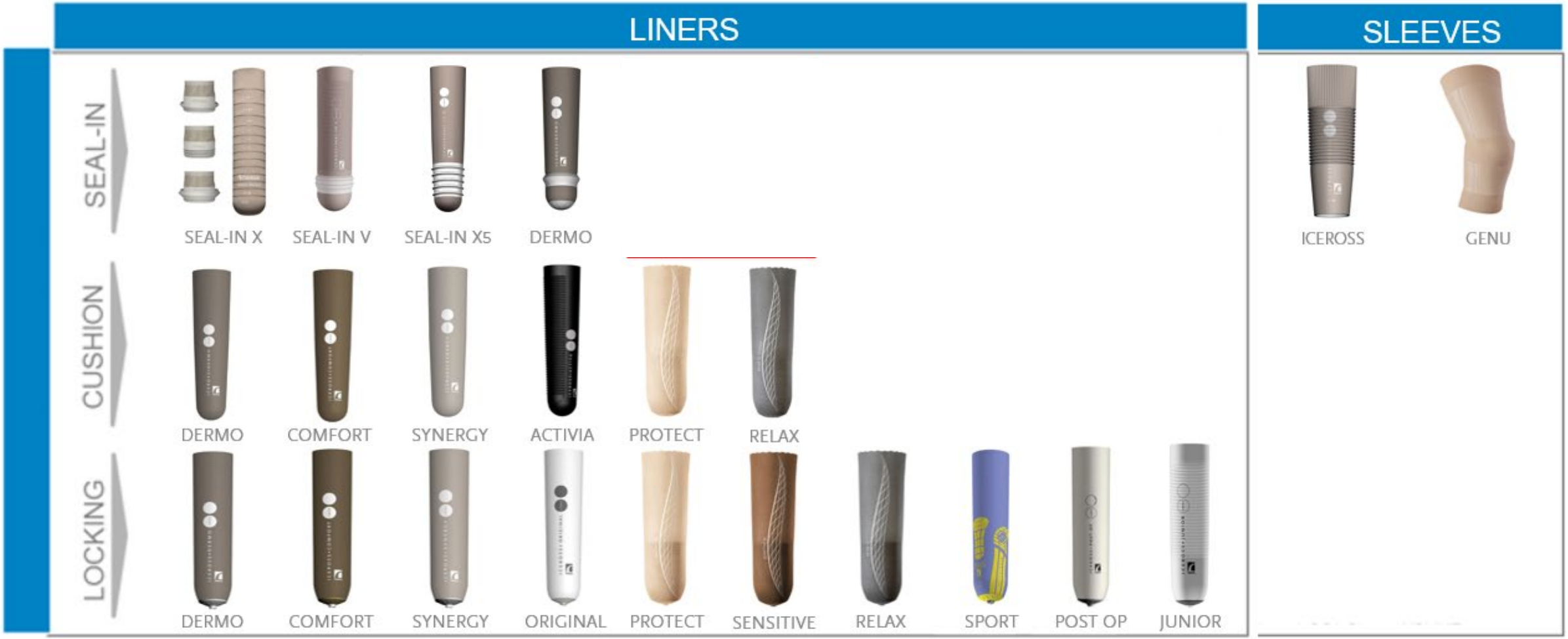
Iceross Seal-In X Locking

- Iceross Liner Overview
- New Liner and Lock Design
  - Benefits of Unity
  - Suspension Options
  - How It Works
  - Sizing Guidelines
- Casting Technique
- Manufacturing Overview

Full TT Liner Range



Transtibial liners - Locking

ICEROSS DERMO LOCKING | ICEROSS COMFORT LOCKING | ICEROSS SYNERGY LOCKING | ICEROSS ORIGINAL LOCKING | ICEROSS SPORT LOCKING | RELAX LOCKING | SENSITIVE LOCKING | PROTECT LOCKING

Transtibial liners – Seal-In

ICEROSS SEAL-IN X

ICEROSS SEAL-IN X LOCKING

ICEROSS SEAL-IN V

ICEROSS SEAL-IN X5 TT

ICEROSS DERMO SEAL-IN

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
- 3mm or 6mm

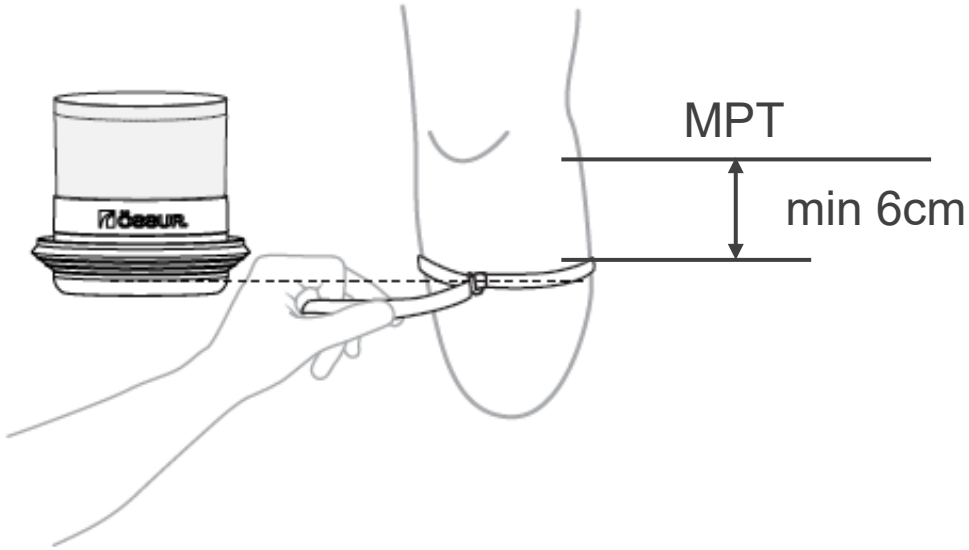
Seal-In X Locking
- 3mm or 6mm

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

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

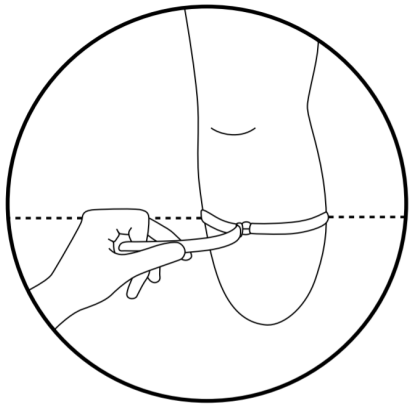


Size Selection – Measuring directly on the Residual Limb

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



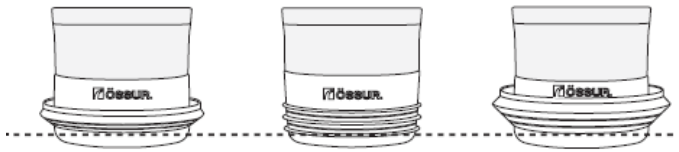
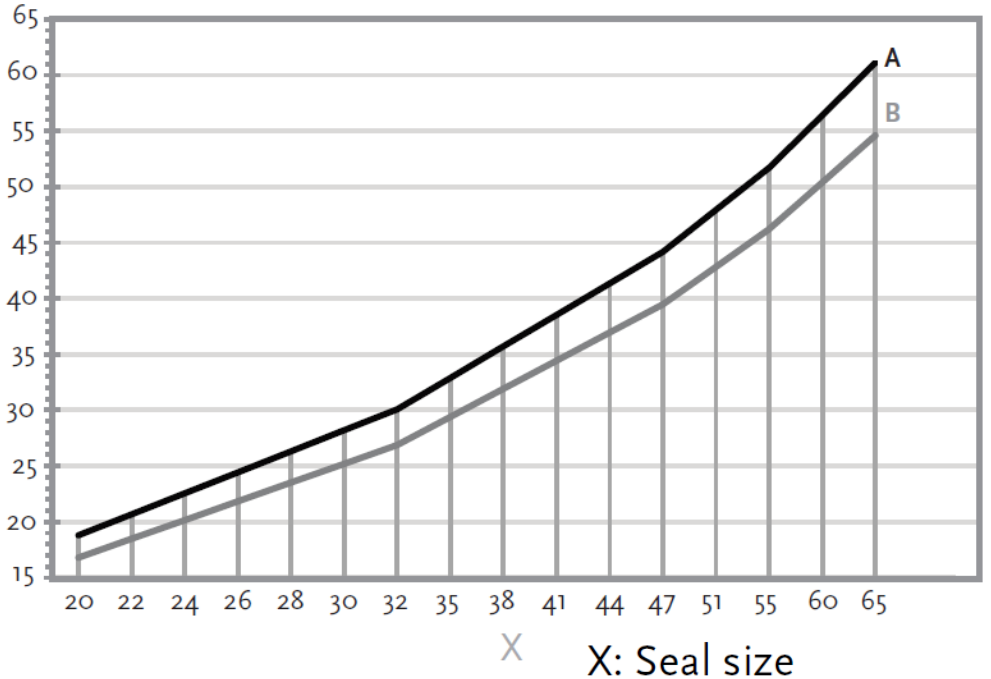


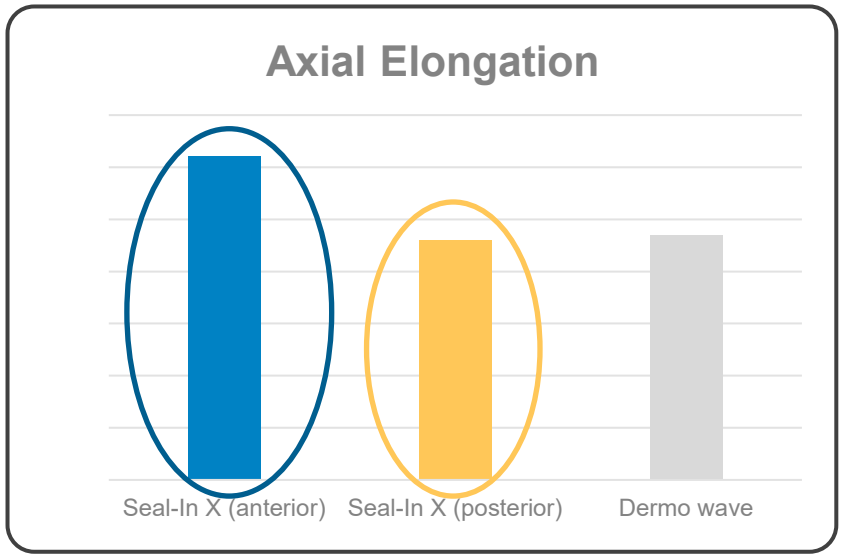
Figure 1



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

Flexible Fabric

- Seal-In X TT features a unique, seamless fabric with flexible Anterior side
- Elongation and pistoning control is achieved posterior, while the Anterior is allowed to flex



ÖSSUR ACADEMY

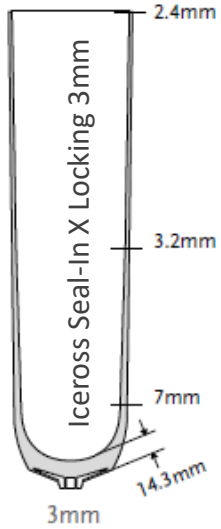
Iceross Seal-In X Locking

Designed to provide pin lock users with a Seal-In or elevated vacuum solution to minimise pistoning.

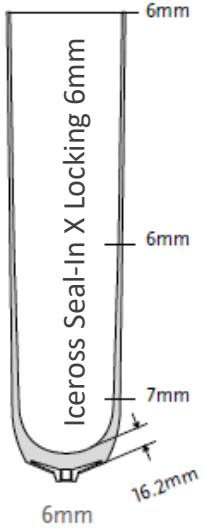
UNITY COMPATIBLE

Seal-In X Locking Liner

I-SXL3XX



I-SXL6XX



Dual suspension silicone liner which provides the user confidence and security

User profile

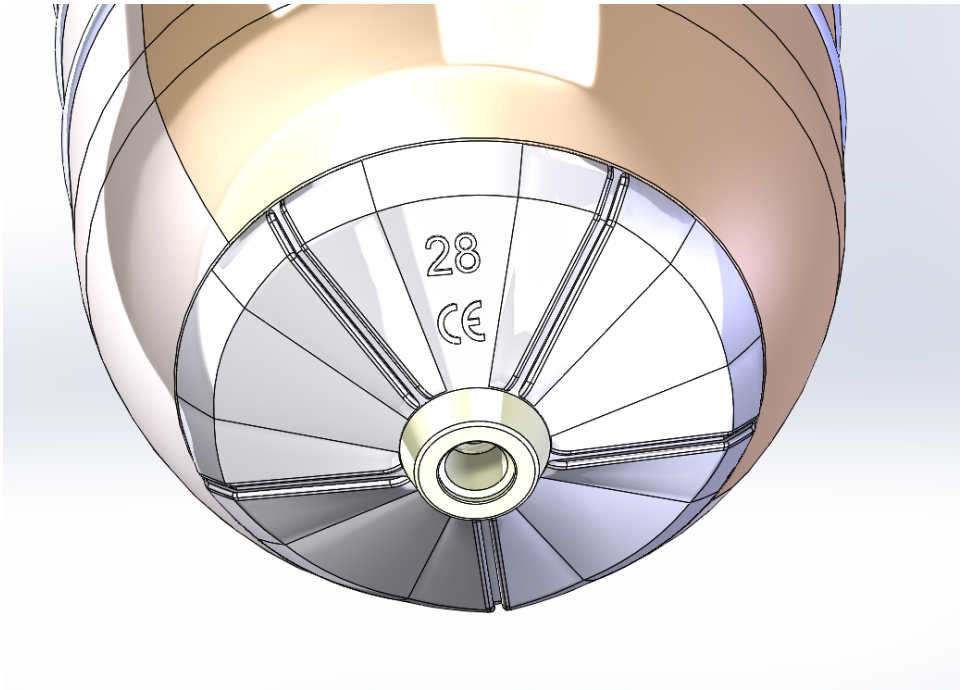
- Transtibial
- Sizes 16-45
- All K-levels

Key features:

- Dual suspension
- Active skin care
- DermoGel Silicone
- Seamless fabric for easy knee bending
- Use with Unity or expulsion
- 3mm or 6mm
- 3 different seal options (easy glide seals)

Seal-In X Locking System

- The umbrella of the liner sits perfectly on the lock lamination ring ensuring a **good fit** and **stability**.
- Air channels on distal umbrella ensure **unobstructed airflow** through the lock when liner is fully donned into socket.
- Allows for elevated vacuum suspension **simultaneously** to mechanical suspension.
- This creates a vacuum up to the Seal-In X rings.



Seal-In X Locking 562 Hybrid Lock

WATERPROOF

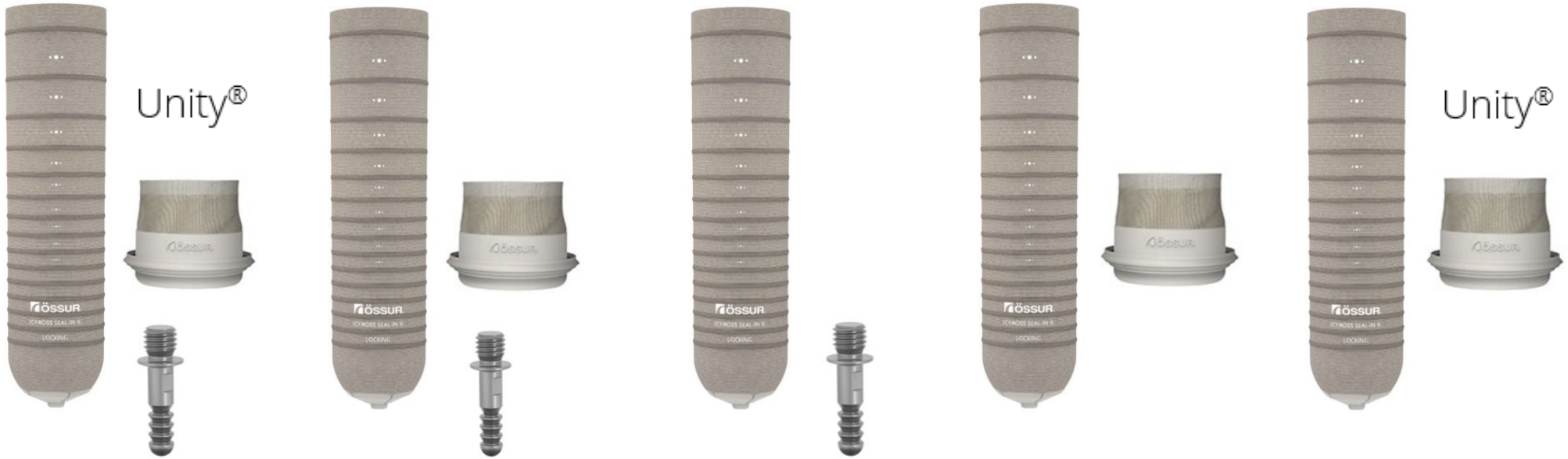
The Icelock 562 Hybrid offers the combination of two independent working suspension mechanisms – vacuum and mechanical locking.

- Low build height with integrated male pyramid.
- The device is rated **waterproof**
- Weight limit: **166kg**
- The system of liner and lock is **Unity*** and **Direct Socket** compatible
- Specialised pin must be used with this system
- Only use this lock with the Seal-In X Locking liner

Seal-In X Locking System

5 Different Suspension Combinations

Pin + Elevated Vacuum (Unity)	Pin + Passive Vacuum	Pin	Passive Vacuum	Elevated Vacuum (Unity)



Advantages of Vacuum Suspension

- **Very firm suspension** providing excellent security and improved **proprioception** and **balance**[1]
- Elevated vacuum manage limb volume fluctuation[2]. A **constant limb volume**, decreases the need for sock management
- Elevated vacuum **assists with wound healing** by improving circulation through the residual limb[3]
- Provides good distal comfort for bony and sensitive distal ends; as long as the socket fits properly with good **volume and length matching**
- The combination of **reduced pistoning** and maintenance of volume is thought to account for the **more symmetrical** gait observed with vacuum[1,4]

Benefits of the Seal-In X Locking with Unity™

- **Waterproof:** Vacuum and Locking option which is rated as waterproof
- **Sleeveless:** Increased knee flexion range (TT) with greater comfort and user acceptance
- **Light weight:** Integrated pyramid weighing only 164g and lightweight foot pump
- **Simple and efficient:** Quick and easy to elevate and release vacuum levels

- **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

Seal-In X Locking User Profile

<u>Indicated user population:</u>

- Transtibial amputees
- K1-K4
- Low to high impact levels
- Users with compromised hand dexterity (ease of donning and doffing)
- Sufficient residual limb length (10cm or more)
- Very conical limbs may be addressed using a distal cup
- Unity and Seal-In candidates

<u>Contraindications for use:</u>

- Very short residual limbs (less than 10cm)

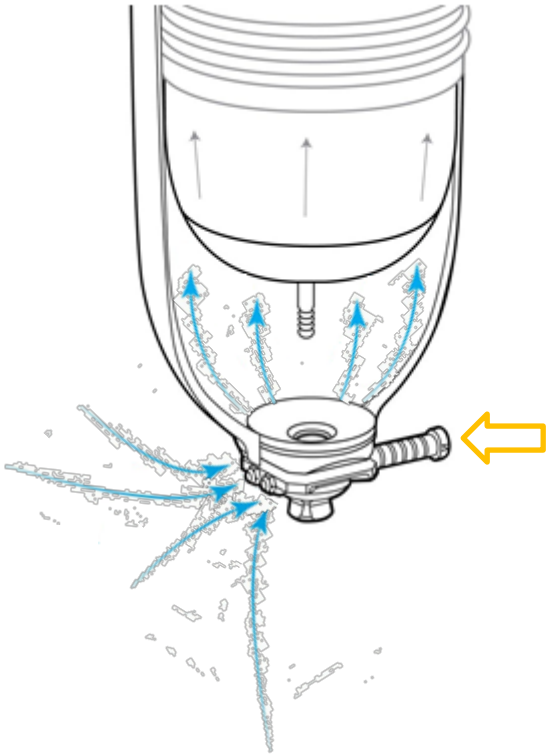
Vacuum action when donning

Air fully expels and attachment pin fully engages lock.

How does it work - Doffing

Press the release button.

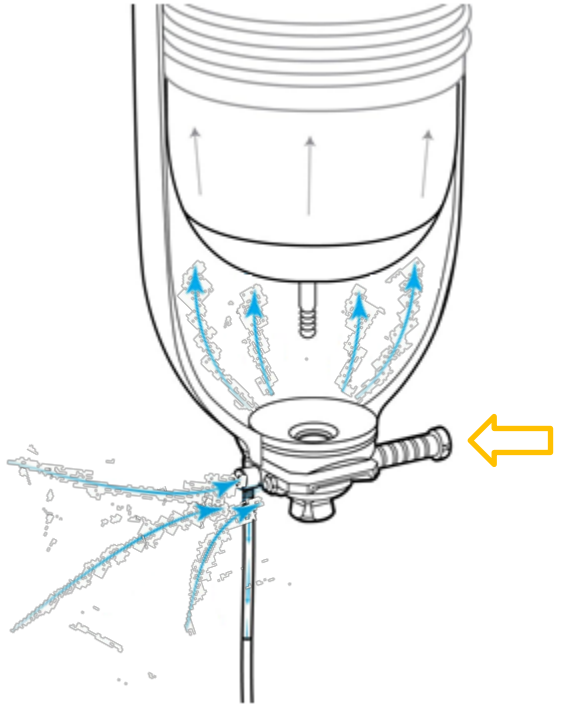
Air will return into the socket and unlock the pin at the same time



Passive Expulsion

While doffing, the air enters the socket through an additional valve.

Release button



With Unity

The vacuum dissolves and the user can easily doff the socket

Unity or Passive Vacuum Lock

The lock comes with the Unity barb attached.

Attach Unity hose from lock barb to foot pump to complete the system.

With Unity

Lock can be converted to passive expulsion

Without Unity

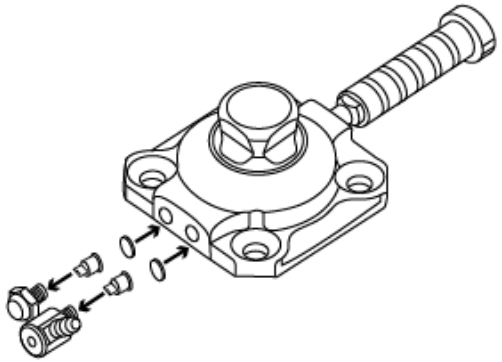
Caution with Pin use:

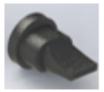
- <u>Exclusively use the pin delivered with the lock!</u>
- Due to the combination with a male pyramid, a pin with a different length could cause serious injuries to the user!

Unity or Passive Vacuum Lock

To convert the lock from Unity to auto expulsion:

- Remove the Unity barb with a 3mm Allen key
- Take care not to lose the duckbill or brass filter
- Add duckbill into spare expulsion filter
- Tighten with 8mm nut spinner or spanner



Part #	Part name	Items included
L-562300	Spare Part Kit	4x  2x  4x 

Iceross Liner Sizing and Fitting

Measure circumference 4cm from end of soft tissues.

Select a liner as measured or next size below the indicated measurement

Take into consideration the residual limb shape and size of umbrella

Measurement 4cm up from distal end = 28cm > Select liner size 28

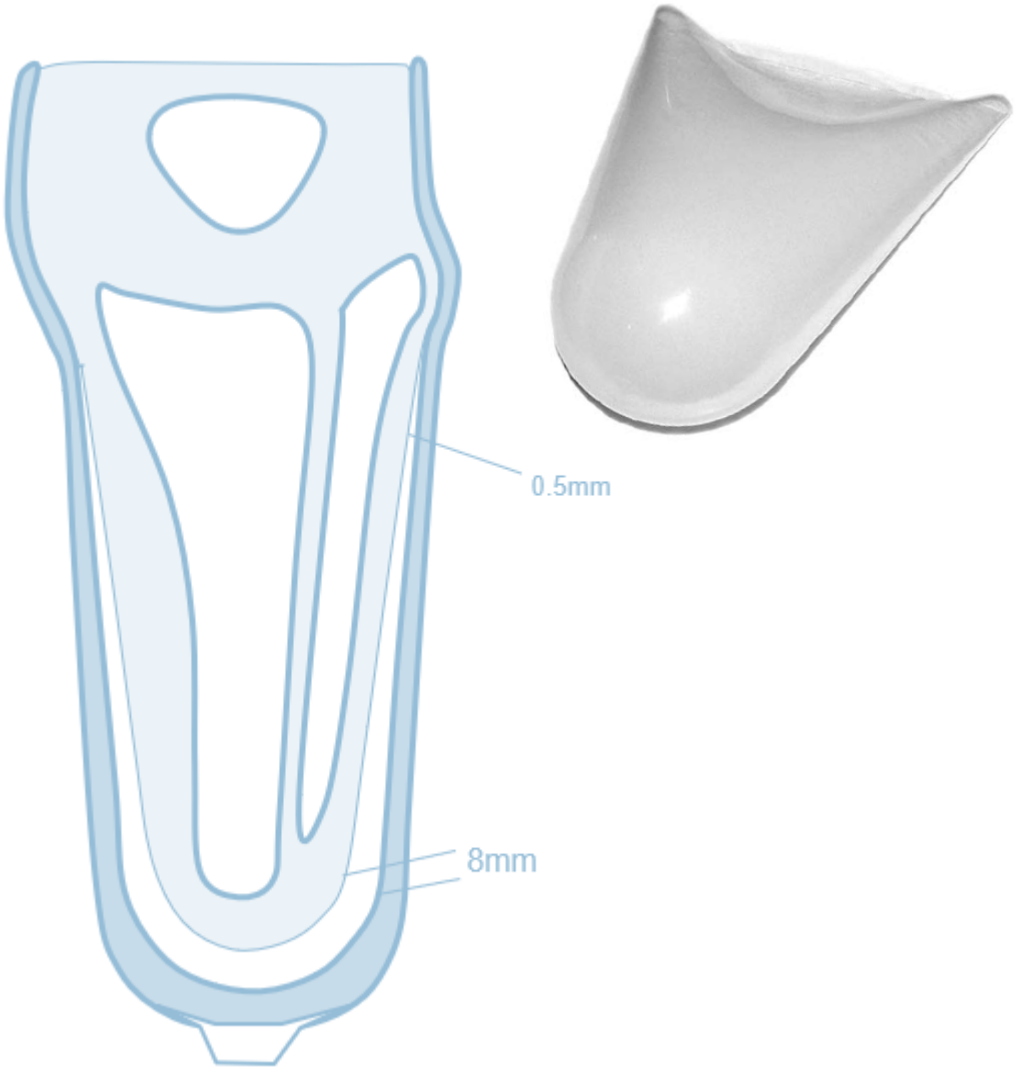
Measurement 4cm up from distal end = 24cm > Select liner size 23.5

Liner Selection Assessment

Liner Selection Assessment

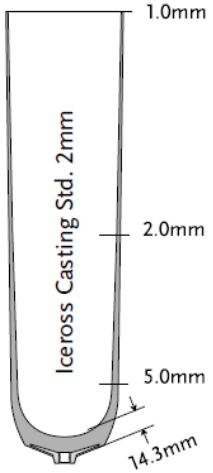
Recommended casting methods

Iceross Distal Cup



- When fitting **conical limbs** the Iceross Distal Cup assists fitting TSB sockets
- Modifies the overall profile of limb to “cylindrical” shape
- Soft DermoGel silicone assists in adding distal cushioning
- Size and fit Iceross liner over the Distal Cup

Iceross Direct Socket Casting Liners



I-09DCXX

Provides good final socket fit for use with Direct Socket system or Icecast casting when a socket for a 3mm standard profile liner is being made

User profile

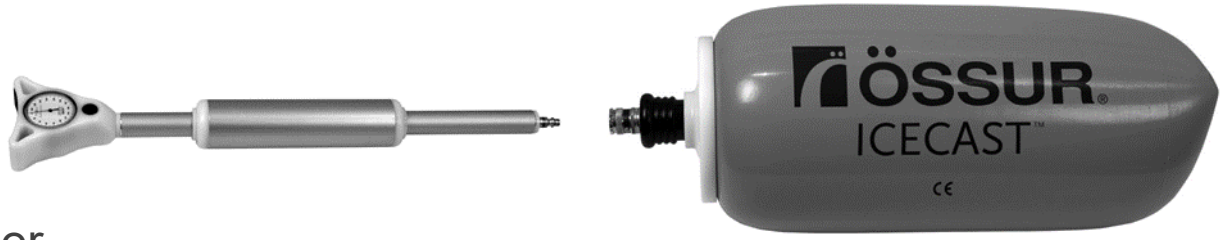
- Transtibial
- Sizes 18-34
- Casting only
- Locking

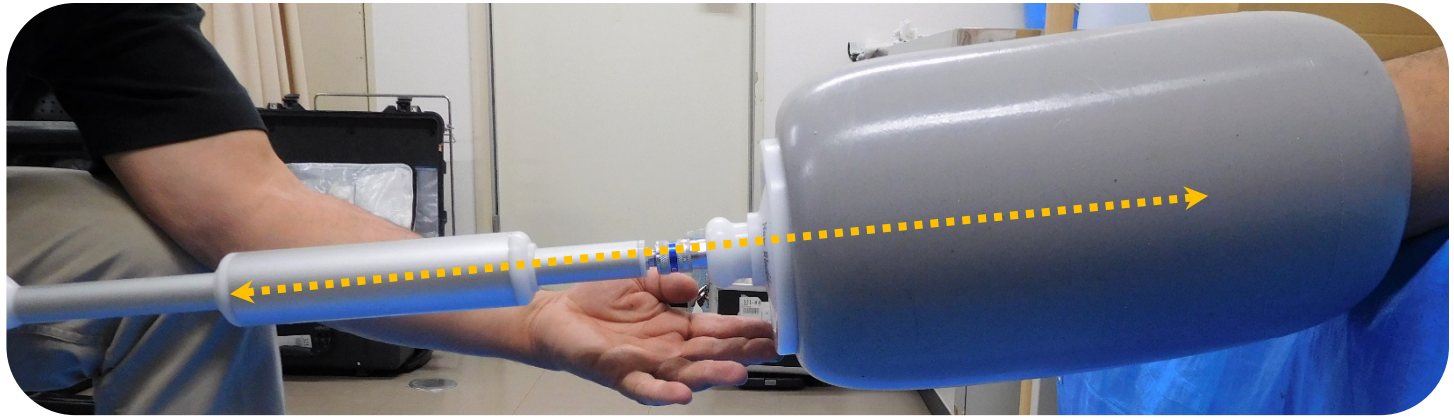
Key features:

- 2mm profile
- Full length matrix
- High durometer silicone

Casting with Icecast

- When using Icecast, the corresponding size of 2mm casting liner must be used.
  - Protect liner with clingfilm wrap
  - Mark MPT and measure length
  - Wrap with plaster bandage
  - Wrap cast in clingfilm to protect Icecast bladder





Modifications:
No volumetric reductions will be required.
Only modifications required are for the lock dummies.

Direct Socket Compatible

- Compatible with Direct Sockets
  - When made using the 2mm casting liners
- Direct Sockets can be easily retrofitted with the 562 hybrid lock and the Seal-In X Locking Liner

Seal-In X Locking: Hand Cast - Method

Seal-In X Locking liner (without Seal ring).

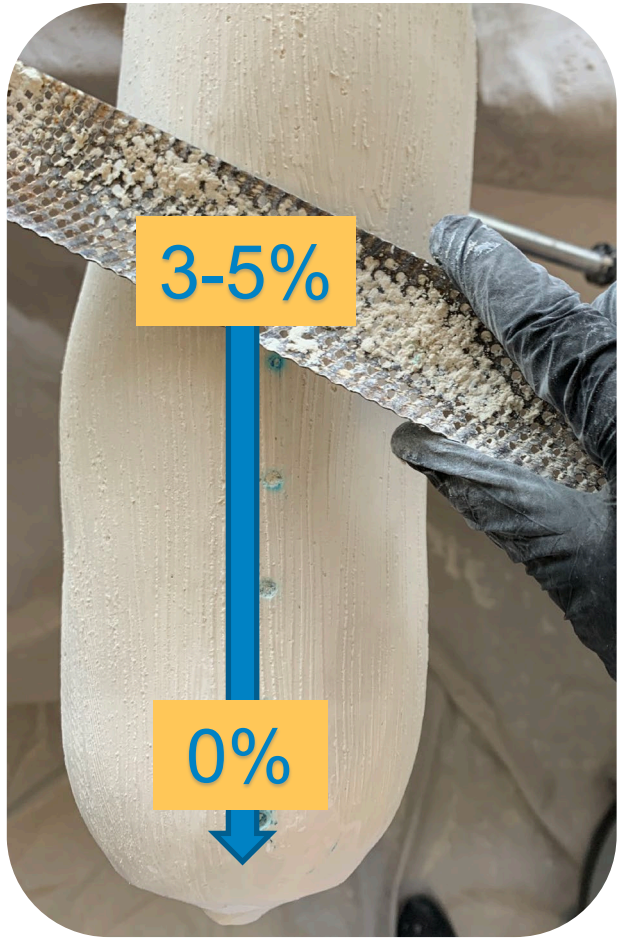
Casting:

- Measure circumferences, bony M-L and length
- 3-5° knee flexion
- Distal plaster cap to capture umbrella
- Neutral cast (Elastic & rigid)
- No triangulation or pinching of cast

Seal-In X Locking: Hand Cast – Modification Method

Modification:

- Correct bony M-L dimension
- Graduated volume reduction 3-5% proximally down to 0% distally
- Respect distal shape of umbrella
- Work around bony sensitive areas.
- Flatten the cast distally as required for socket adaptor dummies
- Attach dummies according to liner size



Seal-In X Locking: Evaluating the check socket

Ideal fit places the X-grip seal ring as high as possible on the limb with equal distribution of pressure around the seal. Seal should fully seat just below the posterior socket trim lines.

Seal-In X Locking: Evaluating the check socket

Socket Fabrication

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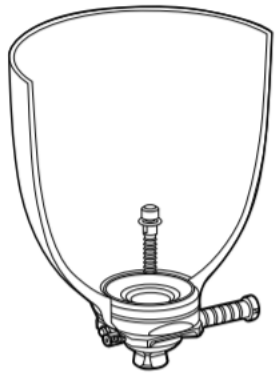


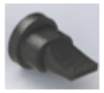
Instructions for Use

ICELOCK 562 HYBRID

MAINTENANCE, CLEANING AND STORAGE

Cleaning

- Cover the pin hole (e. g. tape or plasticine) in order to avoid dust falling into the lock,
- Clean the socket with low air pressure.
- Check the pin hole and remove any dust, dirt or similar contamination.
- If noise or leakage occurs, unscrew and remove the Unity barb (3mm hex key) and outlet port (8mm hex key). Use low air pressure to clean the air channels, clean or exchange the duckbill valves and assemble again correctly.

Part #	Part name	Items included
L-562300	Spare Part Kit	4x  2x  4x 

Compatibility

The hybrid lock must be used only with the Iceross Seal-In X Locking liner.

Warning

- Injury to the user can occur if the hybrid 562 lock is used with a Seal-In liner or Cushion liner

e.g. without an umbrella, the distal end of the limb will be drawn down into the void of the lock body.

Conclusion

The Iceross **Seal-In X Locking** liner is a solution for trans-tibial amputees, developed for **locking liner users** of all activity levels, providing superior function by **combining the benefits** of **locking** suspension with the benefits of **vacuum** and/or **elevated vacuum**.

References

[1] Board et al. (2001) A comparison of trans-tibial amputee suction and vacuum socket conditions. J Prosthet Orthot Int. England; 25(3): 202–209.

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

[3]Hoskins et al. (2014) Using vacuum-assisted suspension to manage residual limb wounds in persons with transtibial amputation: a case series. J Prosthet Orthot Int. 38(1): 68-74

[4] Kuntze, F AE., Neves, EB (2015) A comparison of vacuum and KBM prosthetic fitting for unilateral transtibial amputees using the Gait Profile Score. Gait Posture. 41(2):683-7.

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