



Iceross Seal-In® X Locking TF and Icelock® 850 Hybrid



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Suspension is crucial

Locks & Liners

The success of the prosthesis is dependent on the fit between the residual limb and the socket. Suspension is crucial and using a prosthetic liner is key. Specifically, prosthetic liners have two main functions:

- Cushion the load between the socket and the residual limb
- Contribute to the suspension mechanism of the prosthesis.

Many choices of liner technology are available, mainly made from silicone or other elastomers: Locking liners, Cushion liners and Seal-In liners. From all the different suspension types the Locking liner has been a well-established method for more than 30 years and is well known and accepted by CPO's and users.

Each approach offers a variety of benefits and drawbacks. For example, the locking suspension technology provides a secure and simple connection between the liner and prosthesis. Donning and doffing are simpler and less cumbersome, providing 'noticeable feedback' especially for the patient population who needs reassuring that they are well-connected.

Vacuum suspension for locking liner users

Until now, choosing one over the other approach resulted in a trade-off between convenience and performance. A locking suspension system is known to allow for 'pistoning' (vertical movement of the residual limb inside the socket) while walking. When it comes to pistoning and rotational control, a vacuum suspension system like Seal-In is superior.^{1,2,3,4,5}

WHEN IT COMES TO PISTONING AND ROTATIONAL CONTROL, A VACUUM SUSPENSION SYSTEM LIKE SEAL-IN IS SUPERIOR.^{1,2,3,4,5}

Hybrid Suspension System

Iceross Seal-In X Locking TF with Icelock 850 Hybrid is a hybrid suspension system (A), combining both a locking suspension using a strap (B), and Seal-In suspension with movable seal rings (C) into one solution.

The Quick Connect feature is designed for ease and convenience, allowing users to don the socket while seated and release it from the liner with a simple push of a button.

The residual limb is guided into the socket by pulling the strap and the latch secures the residual limb in place sealing the socket to enable vacuum suspension.



UNITY®

ÖSSUR HAS DEVELOPED
A FORM OF ELEVATED
VACUUM SUSPENSION,
CALLED UNITY



A



B



C



Iceross Seal-In X Locking TF and Icelock 850 Hybrid

Seal-In Suspension

The benefit of using Seal-In liners compared to other kinds of suspension systems is supported in:

- Secure suspension²
- Reduced pistoning^{1,2,3,4,5}
- Improved rotational control³

Overview

With Seal-In, the suspension is achieved through the function of a seal ring creating an airtight connection between the liner and the inner socket wall, that reliably suspends the liner and the residual limb inside the socket and therefore to the prosthetic leg.

By incorporating a silicone liner suspension system with a Seal-In feature, the users experience improved suspension at the interface between the prosthetic socket and the residual limb. The enhancing function ensures that the user is more satisfied compared to other suspension systems. Patients using a Seal-In suspension subjectively report improvements in suspension due to reduced pistoning and improved rotational control.^{1,2,3,4,5}

The Benefits

Secure suspension

Secure suspension decreases residual limb movement within the prosthetic socket by firmly attaching the prosthesis to the residual limb. Inappropriate suspension can result in deterioration of the prosthetic socket fitting which can cause pain and skin ulcers.²



SECURE SUSPENSION²

Reduced pistoning

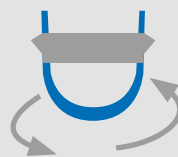
Improper fit and residual limb volume loss leads to increased pistoning. This is minimized by a good suspension system that secures the socket to the amputee's residual limb. With the use of a Seal-In liner, pistoning within the socket is reduced compared to a locking liner suspension^{1,3}, results showing up to 71% less⁵. Even when compared to a suction suspension system pistoning decreased^{2,4}, reducing the displacement between liner and socket in the different stages of gait.⁵



**REDUCED PISTONING
UP TO 71% WITH SEAL-IN⁵**

Improved rotational control

Rotation inside the socket can cause skin irritation. Good suspension reduces rotation of the residual limb. Study results show that rotational control improved with the Seal-In liner in comparison to a silicone liner with a shuttle lock and a PU liner.³



**IMPROVED ROTATIONAL
CONTROL WITH SEAL-IN³**

Elevated Vacuum Suspension

Adding an elevated vacuum system to a prosthesis with a Seal-In liner leads to:

- Improved transitions in body positions⁵
- Improved balance and stability⁶
- Reduced risk of falls^{6,7}
- Improved gait symmetry^{8,9}
- Reduced volume fluctuations^{8,10,11}

Overview

Elevated vacuum technology is proven to have significant advantages towards conventional socket suspension systems. With elevated vacuum, air is actively pulled out of the socket by the vacuum system. This results in a hypobaric pressure between 10 to 22 inHg, (inch per mercury) depending on the system applied. In combination with a Seal-In liner (and without a sleeve), range-of-motion is not restricted. Vacuum can then be released quickly and easily at the push of a button.

The combination of a liner and a vacuum pump, intended for vacuum assisted prosthetic suspension, generates a negative pressure inside the prosthetic socket, resulting in a secure and reliable liner suspension.

The Benefits

Improved transitions in body positions

Using an elevated vacuum socket system significantly improves ambulation and transfers, like sitting and standing.⁵

Improved balance and stability

Individuals with lower limb amputation are at increased risk of falling compared to age-matched peers. With the use of an elevated vacuum system, balance and stability can be improved. Significantly better results have been reported from the Berg Balance Scale and Four Square Step Test (objective measures that assesses balance and fall risk in adults).⁶



**IMPROVED BALANCE AND
STABILITY WITH ELEVATED
VACUUM SYSTEM⁶**

Reduced risk of falls

A reduced risk of falls was also concluded with the results of significantly less time needed in the Timed Up and Go-test, that evaluates ambulation, transfers and turns, and the risk of having ≥ 1 fall and the risk of recurrent falls (≥ 2 falls) reduces as well, within trans-tibial amputees, when using an elevated vacuum suspension compared to a regular socket.⁷



REDUCED RISK OF FALLS^{6,7}

Improved gait symmetry

In addition to improved balance and reduced risk of falls, multiple studies that performed gait analysis found that a vacuum assisted socket system improves gait symmetry. In more detail, an increase in symmetry is achieved in step length and stance duration as compared with suction sockets.^{8,9}

Reduced volume fluctuations

A vacuum condition inside the socket maintains a better fit. Instead of volume loss, a socket tightly held by vacuum leads to reduced volume fluctuation, resulting in reduction of pistoning in the tibia bone and more symmetrical step length and stance duration.⁸ The combination of reduced pistoning and maintenance of volume is thought to account for the more symmetrical gait observed with the vacuum.^{8,10,11}



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Combining the benefits of both

Iceross Seal-In X Locking TF & Icelock 850 Hybrid bring the benefits of the advanced vacuum suspension of the Seal-In system to transfemoral amputees of all activity levels who prefer or rely on locking suspension.

Users can now pull their residual limb with liner into the socket using the strap with Quick Connect. This allows for donning the prosthesis while seated. Featuring the same moveable seal rings characteristic of all Iceross Seal-In X liners, users can enjoy the benefits of locking suspension while experiencing vacuum suspension benefits such as reduced pistoning and improved rotation control. Paired with the Unity elevated vacuum system, users gain the added clinical benefits of reduced volume fluctuations, improved gait symmetry, better balance, and reduced risk of falls.

The hybrid suspension portfolio now features a TT and a TF Iceross Seal-In X Locking liner, and two Icelock options:

- Icelock 562 Hybrid combining a pin-locking suspension with vacuum suspension
- Icelock 850 Hybrid combining a strap-locking suspension with vacuum suspension

Conclusion

Seal-In X Locking TF & Icelock 850 Hybrid successfully integrate the advantages of elevated vacuum suspension of the Seal-In system for transfemoral amputees of all activity levels who prefer or rely on locking suspension.

By combining the benefits of locking suspension with the enhanced control of a vacuum system, users benefit from reduced pistoning and improved rotational control. When paired with Unity, these advantages are further amplified, offering additional clinical benefits such as reduced volume fluctuations, improved gait symmetry, better balance, and a reduced risk of falls.



Icelock 850 Hybrid
for Direct Socket

Icelock 850 Hybrid
for 4-Hole Socket

Icelock 850 Hybrid
for Laminated Socket



1. A. Eshraghi, N. A. Abu Osman, M. Karimi, H. Gholizadeh, E. Soodmand, and W. A. B. W. Abas, "Gait Biomechanics of Individuals with Transtibial Amputation: Effect of Suspension System," PLoS ONE, vol. 9, no. 5, May 2014.
2. S. Brunelli, A. S. Delussu, F. Paradisi, R. Pellegrini, and M. Trallesi, "A comparison between the suction suspension system and the hypobaric Iceross Seal-In® X5 in transtibial amputees," Prosthet. Orthot. Int., vol. 37, no. 6, pp. 436–444, Dec. 2013.
3. S. Ali, N. A. Abu Osman, M. M. Naqshbandi, A. Eshraghi, M. Kamyab, and H. Gholizadeh, "Qualitative study of prosthetic suspension systems on transtibial amputees' satisfaction and perceived problems with their prosthetic devices.," Arch. Phys. Med. Rehabil., vol. 93, no. 11, pp. 1919–23, Nov. 2012.
4. H. Gholizadeh, N. A. Abu Osman, A. Eshraghi, S. Ali, and E. S. Yahyavi, "Satisfaction and Problems Experienced With Transfemoral Suspension Systems: A Comparison Between Common Suction Socket and Seal-In Liner," Arch. Phys. Med. Rehabil., vol. 94, no. 8, pp. 1584–1589, Aug. 2013.
5. H. Gholizadeh, N. A. A. Osman, M. Kamyab, A. Eshraghi, W. A. B. W. Abas, and M. N. Azam, "Transtibial prosthetic socket pistoning: Static evaluation of Seal-In® X5 and Dermo® Liner using motion analysis system," Clin. Biomech., vol. 27, no. 1, pp. 34–39, Jan. 2012.
6. Samitier, C. B., Guirao, L., Costea, M., Camos, J. M. & Pleguezuelos, E. The benefits of using a vacuum-assisted socket system to improve balance and gait in elderly transtibial amputees. Prosthet. Orthot. Int. 40, 83–88 (2016).
7. Rosenblatt, N. J. & Ehrhardt, T. The effect of vacuum assisted socket suspension on prospective, community-based falls by users of lower limb prostheses. Gait Posture 55, 100–103 (2017).
8. Board, W. J., Street, G. M. & Caspers, C. A comparison of trans-tibial amputee suction and vacuum socket conditions. Prosthet. Orthot. Int. 25, 202–209 (2001).
9. Gholizadeh, H., Lemaire, E. D. & Sinitski, E. H. Transtibial amputee gait during slope walking with the unity suspension system. 65, 205–212 (2018).
10. Goswami, J., Lynn, R., Street, G. & Harlander, M. Walking in a vacuum-assisted socket shifts the stump fluid balance. Prosthet. Orthot. Int. 27, 107–113 (2003).
11. Rosenblatt, N. J., Ehrhardt, T., Fergus, R., Bauer, A. & Caldwell, R. Effects of Vacuum-Assisted Socket Suspension on Energetic Costs of Walking, Functional Mobility, and Prosthesis-Related Quality of Life. 29, 65–72 (2017).