



Iceross Seal-In® X5 Transtibial users



Life Without Limitations®



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ES- Atención: Los productos y componentes Össur están diseñados y probados según ISO 10328. La compatibilidad y conformidad con este estándar se obtiene sólo si los productos y componentes Össur se utilizan con otros componentes recomendados o autorizados por Össur componentes Össur o autorizados. Si en cualquier momento se detecta un desplazamiento o desgaste del producto en una parte estructural de una prótesis, se debe prescribir al paciente el cese inmediato del uso del dispositivo y que consulte a su especialista clínico.

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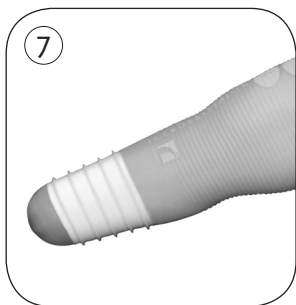
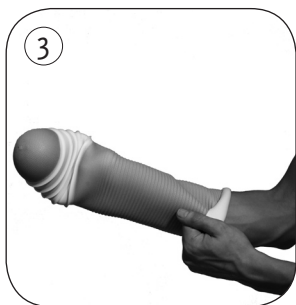
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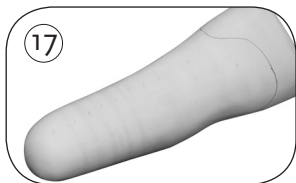
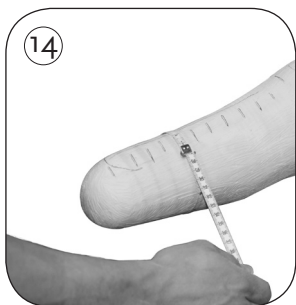
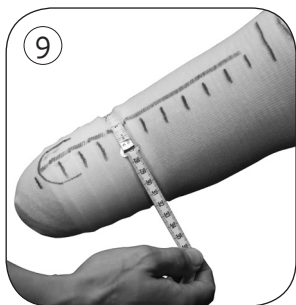
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INTRODUCTION

The Iceross Seal-In® X5 liner provides a transtibial user with a convenient method of guaranteeing secure suspension. The choice of advanced silicone and textile material offers excellent protection of soft tissues and optimal range of motion of the knee.

The incorporation of 5 serial Seals along the length of the liner has shown to prevent air leaks from occurring and also assists greatly in improved proprioception and control of the prosthesis.

Correct selection of the liner will depend on residual limb condition, the amount of soft tissue and activity/impact level of the user.

The successful fitting of the Transtibial prosthesis is dependent on the fit of the hard socket. Appropriate socket design is fundamental for comfort, control and suspension to be achieved. The following hand casting instructions are intended as a recommendation to help create a well fitting socket accommodating the Iceross Seal-In Liner.

The Iceross Seal-In® X5 liner is recommended for use with a Total Surface Bearing (TSB) design and to be used both with thermoplastic and acrylic lamination socket designs.

The Iceross Seal-In Liner is to be used with Icelock Expulsion Valve 551 (L-551000) for suspension. The 551 valve is specifically designed to maintain suspension when using Seal-In Liner. A knee sleeve is not required to maintain suspension.

In the case of extreme residual limb shapes, Iceross Distal Cup® (I-3000xx) may be required to be used beneath the liner.

Please read the following hand casting and rectification instructions carefully before proceeding.

EQUIPMENT (Figure 1)

- 2 x 15cm Plaster of Paris bandages (non elastic)
- Plastic Film
- Tape Measure
- Water
- Indelible pencil
- Single ply casting sock

PATIENT ASSESSMENT

Carry out full assessment of the amputee taking care to assess the following:

- Hand strength and dexterity is sufficient to roll the liner onto their residual limb.
- A degree of user cognitive ability is required to correctly and safely use the liner on a daily basis.

Inspect residual limb. Knowledge of anatomical landmarks, scarring and sensitive areas will aid in socket fitting.

- Residual Limb is of sufficient length to allow up to 3 Seals to be housed fully within the socket.
- The residual limb needs to be stable, with less than 3 ply sock daily fluctuation.

Collect relevant prosthetic history and standard measurements.

CONTRAINDICATIONS FOR USE

Contraindications are:

1. Unstable limb volume
2. Extremely conical limbs
3. The most proximal Seal extends over the knee joint.
This may affect the user's ability to flex the knee. See the table below.

To assess the minimum recommended length, measure the residual limb length from mid patella tendon to the distal end, with knee in full extension. Compare the measurement to the table below:

Liner Sizes	Minimum Recommended Length
18 through 25	11 cm (4 1/4 inches)
26,5 through 36	13 cm (5 inches)

NOTE: Low posterior trimlines of the hard socket can affect suspension and should be assessed on individual basis.

NOTE: For shorter residual limbs contact your technical sales representative.

LINER SIZING (Figure 2)

To determine the correct ICEROSS size:

1. Measure the circumference of the residual limb at 4cm from the distal end with the tissue hanging down.
2. Choose the Liner size, as measured or if between sizes choose the closest size below measurement.

EXAMPLE: If the residual limb measures 24.5cm at the indicated location, choose Iceross size 23.5

Selecting the correct size is very important. If the liner is too tight, this may cause pistoning and/or numbness and blistering. If the liner is too loose, increased perspiration and/or move the limb inside the liner may occur. Perspiration and movement can lead to blisters and rashes. A Seal-In Liner that is too tight may also produce excessive ring tension to the residual limb from the Seals. If any of the above symptoms or any other indication of improper fit are noted, the user should be instructed to contact his/her physician or prosthetist immediately.

DONNING AN ICEROSS SEAL-IN LINER

1. To don the liner use the Clean and Simple Lubricant Spray (S-610250).
2. Before donning a new liner wash it with lukewarm water, and dry it with a lint free cloth.
3. Grip the top of the liner and slide it over the hand until the inner surface is fully exposed. **(Figure 3)**
4. Turn the liner inside out by gripping the distal end from the inside as shown in the illustration. **(Figure 4)**
5. Spray Clean and Simple lubricant into the inverted liner for easier roll on. **(Figure 5)**
6. After exposing as much of the distal end of the liner as possible, position the liner against the residual limb and with light compression roll upward onto the limb. Ensure that all the air is expelled from beneath the liner. **(Figure 6)**
7. Roll the liner all the way up the limb, taking care not to damage it with fingernails. Do not tug or pull.
8. Ensure the Seals are perpendicular to the long axis of the residual limb sit horizontally around their full circumference.

NOTE: Be very careful that the inside of the liner is clean, dry and free from any foreign objects that can cause skin irritation.

NOTE: Inverting the Iceross Seal-In® X5 liner several times will soften the liner and facilitate easier rolling.

PREPARATION FOR CASTING (Figure 7 & 8)

Apply single layer of plastic film firmly over Iceross. Ensure all areas are covered.

Apply wet casting sock over plastic film; hold firmly in place with straps or tape if necessary.

Identify and mark the following:

- Patella
- Fibula head
- Crest of Tibia
- Other bony areas that may contact socket wall
- Neuroma
- Sensitive areas

CASTING

Casting Technique (Figure 9 & 10)

1. Measure the limb circumference at 2cm intervals from MPT to the distal end.
2. Cast Limb in relaxed extension (10-15 degrees).
3. Tighten cast material around the circumference working hands from anterior to posterior.
4. Mould plaster from anterior to posterior defining the bony prominences and capturing residual limb shape. Gently mould the plaster thoroughly around the Seals.
5. Pinch any excess casting material together along the posterior midline. As the casting material begins to set tighten the AP dimension along the length of the cast to maintain snug contact.

MODIFICATION

1. Strip cast. (Figure 11)
2. Ensure all marks transfer to positive. (Figure 12)
3. Remove any ridges present over the area of the Seals and the ridge of accumulated material in the posterior of the socket. (Figure 13)
4. Compare measurements with recorded measures taken over the liner, and calculate appropriate reduction. (Figure 14)
5. 4% reduction from measure at level of MPT. (Figure 15)
6. Grade the reduction to 0% at a level that corresponds to the lowest measurement.
7. Build-ups should be kept to a minimum. Build-ups over 5mm may affect suspension.
8. Medial and lateral supracondylar areas may be formed to increase medial/lateral stability.
9. Smooth cast

Ensure the AP dimension along the length of the Seals is maintained close to the measurements to prevent suspension failure during active knee flexion.

NOTE: Volume is one of the most important features of the socket. Ensure all measurements are accurate.

PRESURE SENSITIVE AREAS

For pressure sensitive areas apply minimal relief to the following areas:

- Distal end of Tibia.
- Fibula head (distal and posterior).
- Posterior Wall.

Note: Reliefs should be localised and kept to a minimum of 4mm where the Seals are in contact with the socket wall. Greater than 5mm may affect suspension. Ensure any relief provided produces a smooth contour allowing full contact from the Seals.

Pressure pads (K-190xxx) can be used to provide relief to these sensitive areas, but should not pass over or under the level of the Seals as it may compromise suspension.

TRIMLINES (Figure 16 & 17)

Locate posterior wall at level defined during casting procedure.

Add plaster in area of medial and lateral hamstring if required.

The posterior wall should be shaped to provide a smooth „W“ shape dipping to ensure relief over the hamstring tendons.

Note: Maintaining the height of the posterior wall increases the overall weight-bearing area.

NOTE: Low posterior trimlines can affect suspension when one or more of the Seals extend out of the hard socket. It is recommended that no more than 2 Seals are exposed above the posterior wall of the socket.

SHORT RESIDUAL LIMBS

Minimum recommended length of residual limb is 11 to 13cm, depending on liner size. When using the Iceross Seal-In® X5 with shorter residual limbs, users may experience loss of suspension and discomfort when flexing the knee if the Seals extend over the knee cap.

DO NOT allow the Seals to extend higher than the mid patella in full extension.

TEST SOCKET FITTING

It is recommended that the socket fit is assessed with a dynamic check socket prior to fabrication of the final socket, Please note that when transferring a user from any other liner or suspension method it is normal that the residual limb will alter in volume and shape in the first weeks following fitting. To optimize the socket fitting it is recommended that a dynamic test socket is used for a period of two weeks, following this period any shape or volume changes should be corrected with socket adjustments prior to proceeding to a definitive socket manufacture.

The Iceross Seal-In® X5 liner is recommended for use with the Icelock Expulsion Valve 551 (L-551000). Refer to the Icelock Expulsion Valve Instructions For Use for installation procedure.

Evaluate the following aspects of the check socket. All aspects should be optimized prior to continuing:

Ease of Donning

- Lightly spray the Seals around their full circumference, and inside the hard socket for smoother entry with Clean and Simple lubricant.
- Align the prosthesis as instructed by the prosthetist and push into the hard socket expelling air.

Socket Volume:

- No air gaps are present over bony prominences when load is applied to the socket.
- Maximum contact by the Seals to the internal surface of the socket
- User reports comfortable socket pressures.

Trim-Lines:

- Intimate cosmetic fitting
- Full flexion possible whilst maintaining secure suspension from the Seals

- Appropriate relief for Hamstring Tendons Suspension:
- Minimal pistoning of the socket in relation to the Iceross Seal-In® X5 liner.
- Firm effective suspension
- Seals stay engaged to the socket wall through the full range of active flexion with resistance.

Control:

- Rotational stability
- Comfortable flexion and extension
- Medial and lateral stability

NOTE: If the user is having difficulty donning the prosthesis, more lubricant may be needed or the valve is blocked.

NOTE: If the user feels the skin of the residual limb is being stretched to one side after donning the prosthesis, the distribution of the lubricant is inadequate around the full circumference of the Seals.

DEFINITIVE SOCKET FITTING

The internal surface of the definitive socket should be as smooth as possible for all socket materials.

For Acrylic laminated sockets, a double layer of Dacron lay up material will provide a smooth internal finish to the socket.

Rough finishing will affect suspension and may affect the durability of the Seals.

Iceross Seal-In® X5 is covered by one or more of the following patents. Other U.S. and foreign patents pending. ® indicates trademark registration in U.S.A. and selected countries only.

- Canada: 2,288,935;
- China: ZLo1809540.2
- USA: 6,136,039; 6,485,776; 6,626,952; 7,001,563

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