

WILLOWWOOD ONE® TRANSFEMORAL SYSTEM

Prosthetist Instructions



WHAT'S IN THE BOX (FOR VACUUM SYSTEM)*

Alpha SmartTemp® Liner or Alpha Duo® Liner

One Gel Sock

One Seal

LimbLogic® Vacuum Pump

(includes Poron Filter, Sealing Gaskets, and instructions)

WillowWood One System Instruction Manual

WillowWood One System Patient Instructions

Fabrication Order Form

Pre-Paid Shipping Label

**Components for suction system sold separately*

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1. INTRODUCTION

PATIENT CRITERIA

The patient criteria for using the WillowWood One System in a transfemoral application are as follows:

Indicators

Patients who meet the following criteria should be considered for this system:

- Patients who are transfemoral amputees.
- Patients who comment about lack of suspension or feeling insecure in their current prosthesis.
- Patients who desire improved linkage from higher prosthetic socket trim lines.
- Patients with active lifestyles who could benefit from limb volume stabilization and a temperature-controlled prosthetic environment.
- Patients who comment about excessive sweating on the residual limb.
- Patients who potentially would benefit from better limb health.
- Patients who exhibit high cognitive function and are “in tune” with prosthetic fit.
- Patients with reasonable hand dexterity.
- Community ambulators.
- Patients who are technologically savvy, are willing to incorporate electronic devices into their lifestyle, and do not mind using prosthetic components with batteries that must be charged.
- Patients with redundant tissue.

Contraindicators

Patients with any of the following conditions may not be considered for this system:

- Patients who are transtibial amputees.
- Patients with a residual limb length less than 7 inches (178 mm) or a femoral length less than 6 inches (155 mm).
- Patients with bulbous residual limbs.
- Patients with deep scarring or deep invaginations could be a concern due to lack of contact from an OTS gel interface. These patients might be better served by a custom fabricated gel interface.
- Patients with open wounds.
- Patients who lack the ability to don and doff a gel interface or the ability to properly don and doff the system.
- Patients who have poor residual limb hygiene or who are unwilling or unable to comply with the cleaning and disinfecting instructions for the liner.
- For the vacuum version: Patients who lack the cognitive ability to understand the donning and doffing technique of the system as well as an understanding the function of the vacuum system.

ALPHA SMARTTEMP LINER

The Phase Change Materials (PCMs) in the liner work by storing body heat and preventing a rise in temperature until they can no longer store any more body heat. Once they have stored all the body heat they can, they become saturated, and the temperature in the liner will begin to behave like any other prosthetic liner. Please instruct your patient that, in order to receive the benefits of the PCMs in the liner again, this stored body heat needs to be discharged from the socket and liner as follows:

- Remove the liner from the limb.
- Place the liner in a cold or air-conditioned environment for a few hours.
- The release of heat from the liner may be expedited by submerging the liner in a cold basin of water for an extended period of time. Simply running the liner under cold water for a brief time will not completely discharge the stored heat energy.

Note: the conditions required to discharge the stored body heat will vary depending on how much energy has been stored in the PCMs and the environment used to discharge the PCMs.



Alpha products can melt or burn if exposed to high temperatures or flame. Do not expose your Alpha product to these conditions.



This Alpha product is intended for use on a single patient. Use of the product with multiple patients could lead to cross contamination between patients.



Warning: To avoid danger of suffocation, keep this product away from babies or children.



Warning: WillowWood One Transfemoral System components have been designed and tested for use only with other WillowWood One Transfemoral System components. Use with other sealing systems may result in loss of suspension resulting in injury

2. INITIAL DONNING

Do not apply any type of lotion, powder, or lubricant to the residual limb or to the liner, as these products could damage the liner. The residual limb should be clean, dry, and free of soap residue.

Refer to the liner size chart, available at www.willowwoodco.com, for guidance in selecting the correct liner size. The size of the liner also determines the size of the One Seal and One Gel Sock.

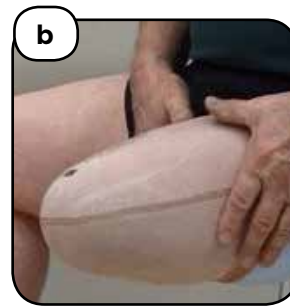
Note: in a later step, the liner and the One Gel Sock will be trimmed to the appropriate length for the definitive prosthesis. For now, leave the liner full length, and trim only enough off of the One Gel Sock to permit it to be rolled on completely.



Invert the liner so that the logo is on the inside, and place the distal end of the inverted liner against the distal end of the limb. Orientation of the logo (anterior, posterior, medial, or lateral) does not matter.

Carefully roll the liner up onto the residual limb. Make sure that there are no wrinkles or air pockets between the liner and the limb.

DO NOT PULL the liner onto the limb. Pulling the liner may stretch the gel, causing pulling on the skin and resulting in an uncomfortable fit.



Invert the One Gel Sock so that the silicone side is facing out. Place the distal end of the inverted sock against the end of the limb.

Carefully roll the sock up onto the limb so that the silicone side is against the liner. Make sure that there are no wrinkles or air pockets between the One Gel Sock and the liner.

3. SHAPE CAPTURE AND MODIFICATION

Note: refer to the OMEGA® User's Guide and the OMEGA® Scanner 3D User's Guide for additional information.

Note: measure the residual limb length and circumference at 2" (50 mm) intervals.

METHODS

Choose one of the following shape-capture methods according to patient criteria and residual limb assessment:

- OMEGA System
 - a. TF by Measurements
 - b. Scan and merge for NML, Quad, or IC socket designs using existing or new templates
 - c. Scan and merge for sub-ischial socket designs using templates LLVS 1, 2, or 3

Notes:

- *Templates are included with the OMEGA software to assist in shape design and configuration. The software allows users to utilize the provided templates or add their own templates for reference.*
- *Because the residual limb tissue is held firmly in place by the liner and the One Gel Sock, the patient may remain seated for the scanning process if desired.*
- Traditional casting (using a proximal brim system or freehand)

Note: If you will be applying a plaster cast, you may use hand casting or proximal brim methods.

MODIFICATION

Reduce the shape globally by 4-6% depending on the residual limb anatomy.

The amount of global reduction should be adjusted based on physical examinations and complementary measurements of the patient.

To facilitate diagnostic fitting and recognizing a correctly fitting socket, pay attention to these areas when modifying:

- Lateral wall shape
- Medial wall flare
- Adductor channel shape
- Distal compression

When you are done modifying, fabricate a conventional diagnostic socket.

4. STATIC TEST SOCKET EVALUATION

Have the patient don the liner, the One Gel Sock, and the diagnostic socket. Fold the top edge of the liner down onto the proximal edge of the socket.

Add a distal air expulsion hole if necessary for donning the socket.



TIPS FOR ASSESSING THE STATIC DIAGNOSTIC FIT

- For lateral contact under load/weight bearing:
 - Assess amount of contact
 - Adduct socket if necessary to further evaluate contact
 - Assess the necessity of an elongated sub-trochanteric depression
 - Distal contact should be achieved without overloading the distal femur, with minimal effort when donning, without elongating the tissues
- Analyze total contact:
 - Observe the Gel Sock weave
 - Look for signs of liner blanching
 - Use gel pads and contact indicators (Play-Doh, soft clay, gel fit etc.)
 - Observe proximal tissue containment
 - Assess overall comfort and support
- Confirm that the folding of the liner over the proximal edge is not masking any contact issues.
- Mark the socket to indicate any areas of discomfort or improper fit, then modify the socket accordingly.
- Maintain Total Surface Weight Bearing.

Mark alignment lines for the dynamic fitting assessment, then make any adjustments to the socket that are necessary.

Use this opportunity to position the side-mount pump (if applicable) in different places on the socket, to gauge the patient's reaction as to where the optimal final location should be.

5. DYNAMIC TEST SOCKET EVALUATION

ASSEMBLY

1. Add a 3-prong adapter or LimbLogic 4-Hole Adapter to the socket with FabTech 60 Adhesive. *Note: This might not be the final adapter that is used for the definitive socket.*
2. Reinforce the distal socket and distal attachment component with fiberglass for gait analysis.
3. Attach the LimbLogic pump to the socket (if applicable).

a. Distal Mount pump:

- Attach the pump with **one Sealing Gasket** to the 4-Hole Adapter.

b. Side Mount pump:

- Drill a 9/32" (7 mm) hole in the distal third of the socket wall.
- Place the **Diagnostic Gasket** on the Side Mount Pump as shown here, with the hole in the gasket centered over the filter on the pump. The "tail" near the top of the gasket is used to create better balance when attaching it to the pump.



Note: do not use black Sealing Gaskets with the diagnostic socket. A black Sealing Gasket is only required for the definitive socket.

- Apply pressure to the gasket in the area around the hole. This should cause the gasket to adhere to the circular recess surrounding the filter. If it does not completely seal, try repositioning the gasket.



- You should be able to turn the pump upside down without the gasket falling off. If the gasket falls off, it was not properly attached to the pump.



- With the gasket attached, place the pump over the drilled hole in the diagnostic socket. Make sure that the air path is not obstructed.
- Apply pressure to compress the gasket slightly against the socket. Secure the pump to the socket with tape.

Adjust the vacuum settings as desired.

5. Conduct an airtight seal test.
6. Add a distal release valve or hole (optional) to aid in doffing the socket.
7. Assemble the knee unit and do a bench alignment.

DONNING



Have the patient don the liner as shown before. Leave the liner long enough to reflect over the proximal edge of the socket.

Next, do an initial trim on the One Gel Sock so that the proximal edge is 2"-3" (or 50 mm - 75 mm) below the perineum, in order to expose enough of the liner to seal against the One Seal. (If you have already established the trim line, the proximal edge of the seal should be about 1" below the medial socket wall.)

Have the patient don the One Seal with the sealing fins on the outside surface and toward the distal end, as shown here.

Note: this is not the method of donning the seal for the definitive prosthesis; this is for fitting only, because the Removable Brim has not been made yet.

For a socket with a Side Mount vacuum pump:

The next step is to check the length of the One Seal to see if it needs additional trimming. Have the patient don the socket, and check to see whether the fins on the One Seal are **distal** or **proximal** to the air evacuation hole for the side mount pump.



If the fins are **distal** to the hole, then the full-length One Seal is too long to be used in the dynamic diagnostic fitting process.

To decide what to do next, determine how much would need to be trimmed from the seal in order for the fins to be **proximal** to the hole:

If the fins are **proximal** to the hole, then the length of the One Seal is fine, and the patient can wear the seal "as is" for the dynamic fitting.

If the length of the trimmed One Seal would be longer than 6":

Cut the One Seal and use it in the fitting.

Be sure to trim the end that has the wave pattern. Do NOT trim the end with the fins.

If the length of the trimmed One Seal would be less than 6":

DO NOT cut the One Seal, because then the seal will be too short to reflect onto the Removable Brim in the definite prosthesis at the time of delivery.

Instead, set the One Seal aside until it is needed later. Create a seal by reflecting the liner over the socket trim line.

If the One Seal will be worn for the dynamic fitting:



The **One Seal** must have at least 1" of contact with the liner, so trim the **One Gel Sock** as needed to create that contact (effectively 2"- 3", or 50 mm - 75 mm below perineum level).

You may also trim the liner at this point in time, since you will not need to reflect the liner to create a seal in the definitive socket.



Don the socket. For a socket with a Side Mount vacuum pump, the fins should now be proximal to the vacuum hole.



Make sure that the One Seal doesn't fold over on itself.

Tip: if the socket cannot be donned without the One Seal folding over on itself, spray alcohol on the fins only, then don the socket.

DYNAMIC EVALUATION

Determine the appropriate height and alignment for the prosthesis. Activate the vacuum system as desired, if applicable (refer to the LimbLogic Instructions for details).

Be sure to identify the following on the test socket:

- Alignment lines (sagittal and coronal planes)
- Side Mount Pump position (if applicable)
- Proximal trim lines
- Expulsion Valve position
- Distal adapter required for definitive socket

6. THE DEFINITIVE SOCKET

After determining the alignment, send the diagnostic socket to WillowWood or to a technician who has been certified by WillowWood for fabrication of the Removable Brim and definitive socket.

After the definitive socket has been fabricated, confirm that the following items on the socket are correct:

- Side Mount Lamination Plate position (if applicable)
- Expulsion Valve position
- Trim lines

7. DELIVERING THE DEFINITIVE PROSTHESIS

ASSEMBLY (VACUUM VERSION ONLY)

- For a **Distal Mount** pump: using the M6 flathead screws, attach the pump and the desired 4-hole component to the socket with **one sealing gasket** between the pump and the socket. For a definitive prosthesis, apply Loctite 242 Removable Threadlocker (or equivalent) to the screws, and tighten the screws to **9 ft-lbs (12 Nm)**.

- For a **Side Mount** pump:
 - Confirm that the Adhesive Seal has been applied to the Side Mount Lamination Plate as shown.

Adhesive Seal



- Attach the pump and **one sealing gasket** to the Side Mount Lamination Plate on the socket using the M4x10 socket head cap screws. For a definitive prosthesis, apply Loctite 242 Removable Threadlocker (or equivalent) to the screws, and tighten the screws to **22 in-lbs (2.5 Nm)**.
- Note: Do not over tighten the cap screws, as stripping the mounting plate threads requires a re-fabrication of the definitive socket.

TRIMMING

Using the medial socket trim line as the defining length, cut the liner either horizontally or at an angle for the lateral wall contact.

Cutting the liner straight across allows the liner to be donned in any orientation. Cutting the liner at an angle is acceptable, as long as the patient is aware that the liner must be donned in the same orientation each time.

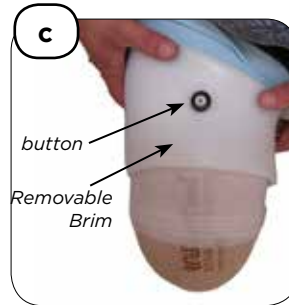
Trim the One Gel Sock to the length required for use in the definitive socket, maintaining maximum coverage of the residual limb for vacuum purposes.

DONNING

a Don the liner and the One Gel Sock.

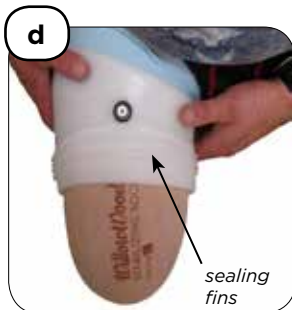


Orient the **One Seal** so that ridges are on the inside and the sealing fins are toward the bottom. Pull the One Seal onto the limb over the liner so that the One Seal extends about 1" to 1.5" above the top edge of the One Gel Sock, sealing against the exposed portion of the liner.

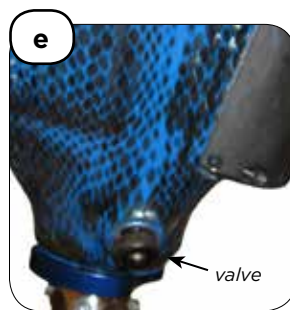


Have the patient don the **Removable Brim**, with the locking button facing anterior.

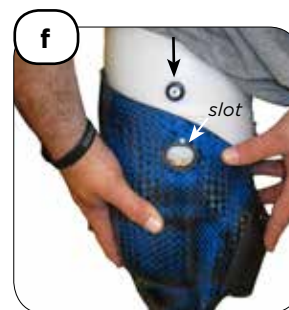
Tip: it may be helpful to place the brim a little lower than where you think it should be. Placing the brim as high on the limb as possible may make it hard to line up the buttons with the socket slots.



Fold the bottom of the One Seal up onto the Removable Brim, exposing the sealing fins. Make sure that the One Seal does not cover the buttons on the brim.



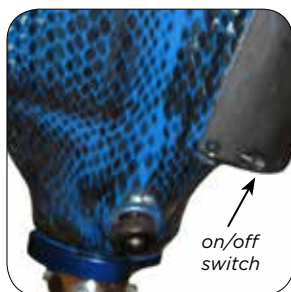
Loosen the Expulsion Valve.



Have the patient step into the socket so that the buttons on the Removable Brim snap into the slots on the socket.

Tip: before activating the vacuum system, you may want to remove the valve from the socket so that you can look through the hole to confirm that the limb is properly seated in the socket. Reinstall the valve before turning on the pump.

USING THE VACUUM SYSTEM (IF APPLICABLE)



Ask the patient to take a few steps on the prosthesis to ensure that the limb is fully seated in the socket.

Before turning on the vacuum pump, check the following:

- Alignment Buttons are snapped into place in the socket slots
- Residual limb is contacting the distal end of the socket
- Expulsion Valve has been tightened.

Failure to do this can result in residual limb tissue damage and poor socket fit.

With the patient standing in a full weight bearing position, press the on/off switch on the pump to activate the vacuum system. The pump will beep one time.

Pressing the on/off button again will turn off the system. The pump will beep either two or four times.

Refer to the LimbLogic Instructions for additional details.

FINAL STEPS

Assess the final alignment of the prosthesis.

Fully educate the patient on how to don and doff all of the components of the WillowWood One System, how to operate and charge the LimbLogic pump, and how to clean and disinfect the liner.

Be sure to deliver all of the following items to the patient:

- Alpha SmartTemp or Duo Liner
- One Gel Sock
- One Seal
- One WillowWood One System Patient Instructions
- For vacuum version:
 - LimbLogic Fob
 - LimbLogic Charger
 - LimbLogic Patient Instructions and Quick-Start Guide

8. TROUBLESHOOTING

Problem	Probable Cause	Solution
New liner user is sweating excessively.	Body has not yet adjusted to the closed environment of the liner.	The perspiration should subside after several weeks of liner use. Also, some patients have found that it helps to apply moderate amounts of unscented alum-based antiperspirant to the residual limb before putting on the liner. Always follow label directions, and never use anti-perspirant if there are open sores on the residual limb. Note: non-alum-based products may damage the liner.
Long-time liner wearer suddenly starts sweating.	Air is getting between the liner and the residual limb, possibly due to residual limb shrinkage.	Check the fit of the liner and socket. Tighten up the socket or change to a liner of a different size, style, or thickness.
	There is a hole in the liner.	Replace the liner.
Heavy sweating on hot days or while active.	Liner is saturated with body heat.	Discharge the body heat in a cool environment.
Skin irritation all over the residual limb.	Poor hygiene.	Review proper cleaning, rinsing, and disinfecting procedures.
	Use of a harsh or irritating lotion, cream, powder, or soap.	Check to see whether the patient has recently changed to a different cleaning product, or has started using any lotions, creams, or powders containing hydrocarbon oils or animal fats or oils. (For some amputees, antibacterial soap has caused skin irritations.)
	The liner or the socket is loose, possibly due to residual limb shrinkage.	Tighten up the socket or change to a liner of a different size, style, or thickness to eliminate the looseness. To confirm that this is not an allergic reaction, perform a "patch test": apply a piece of liner material somewhere else on the body and look for a reaction.
Skin irritation along the top edge of the liner.	The liner is being pulled onto the limb instead of being rolled onto the limb, or the liner is too tight.	Review proper donning procedure.
Open wounds and non-intact skin.	Could be caused by a number of issues, including socket fit and specific patient variables.	Address the specific cause of the situation, and apply a bandage or other appropriate covering to prevent direct contact between the wound and the liner.
System leaks.	Debris in Expulsion Valve.	Flush valve with tap water.
	One Seal fins torn.	Replace One Seal.
	Sealing surface between liner and One Seal is too small.	Ensure that One Seal length is correct. Review proper One Seal placement.
	O-ring on Expulsion Valve is compromised.	Replace valve.
	Holes in One Seal.	Replace One Seal.
	Pump screws loose or missing,	Refer to instructions for screw installation.
	Side Mount pump not properly seated on Lamination Plate.	Refer to instructions for attaching Side Mount pump.
Abrasion on outer surface of liner.	No ShearBan dots on Locking Button T-nuts.	Replace ShearBan dots.
	Rough edges on Removable Brim.	Smooth trim lines.

9. WARRANTY

Important Note: For the safety of you and your patients, WillowWood will not resell any returned Alpha Liners that may possibly have been worn.

Warranty

Alpha Liner, One Seal, and One Gel Sock

The warranty is 12 months from the date of invoice against defects in material and workmanship. There is no warranty, expressed or implied, for damage caused by abuse, mishandling or accident. The warranty is void if the fitting and routine care instructions are not followed. For your protection and ours, please thoroughly clean all used products prior to return.

One Socket

The warranty for the One Socket is 2 months from the date of invoice.

LimbLogic

Refer to the LimbLogic Prosthetist Instructions for details on the LimbLogic warranty.

Warranty Disclaimer

WillowWood warrants that each product manufactured will, at the time of delivery, be of workmanlike quality and substantially free of defects. WillowWood makes no other warranty, implied or expressed, and makes no warranty of merchantability or fitness for a particular purpose. This warranty shall terminate immediately upon an action to combine our products with other materials or in any manner change the nature of our products. The sole remedy is replacement of the products or credit for the products. If a replacement product is provided to a customer, the warranty period will be the number of days remaining on the original warranty. WillowWood's liability shall not exceed the purchase price of the product. WillowWood is not responsible for any indirect, incidental or consequential damage.

Retention of Rights

WillowWood retains all intellectual property rights reflected in its physical products, regardless of the transfer of the physical products to another party or parties.

Returns

WillowWood will handle all One System returns. If you wish to return a One System product, follow these simple steps:

A. Be prepared to provide the following information:

- Account # or company name
- Purchase order # and/or serial #
- Quantity to be returned
- Reason for return

B. Please call Customer Care at 1.800.848.4930 to get a Return Merchandise Authorization (RMA) number. This must be done before the product is returned.

C. When packing the product, place the RMA number prominently on the outside and inside of the package containing the product being returned.

By following these steps you will guarantee that your return will be processed expeditiously and credited accurately.

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