

WILLOWWOOD ONE® TRANSTIBIAL SYSTEM

Prosthetist Instructions



WHAT'S IN THE BOX

Vacuum Kit

- Alpha Duo® Liner (D990-194X*)
- One Sleeve (ONE-SLEEVE-TT-XX*)
- LimbLogic® Distal Lamination Kit (LLV-ONE-D)
- LimbLogic Fob (LLV-21200)
- One System Instructions (ONE-IN1)
 - Prosthetist Instructions
 - User Instructions (to be provided to the patient)
 - Order Form
 - Return Shipping Label

Suction Kit

- Alpha Duo Liner (D990-194X*)
- One Sleeve (ONE-SLEEVE-TT-XX*)
- One Fabrication Kit (ONE-TT-FABKIT-XX*)
- One System Instructions with Fabrication (ONE-IN2)
 - Prosthetist Instructions
 - User Instructions (to be provided to the patient)
 - Socket Fabrication Instructions
 - Order Form

* Value of X depends on size ordered.

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



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

INDICATIONS/CONTRAINDICATIONS

Indications

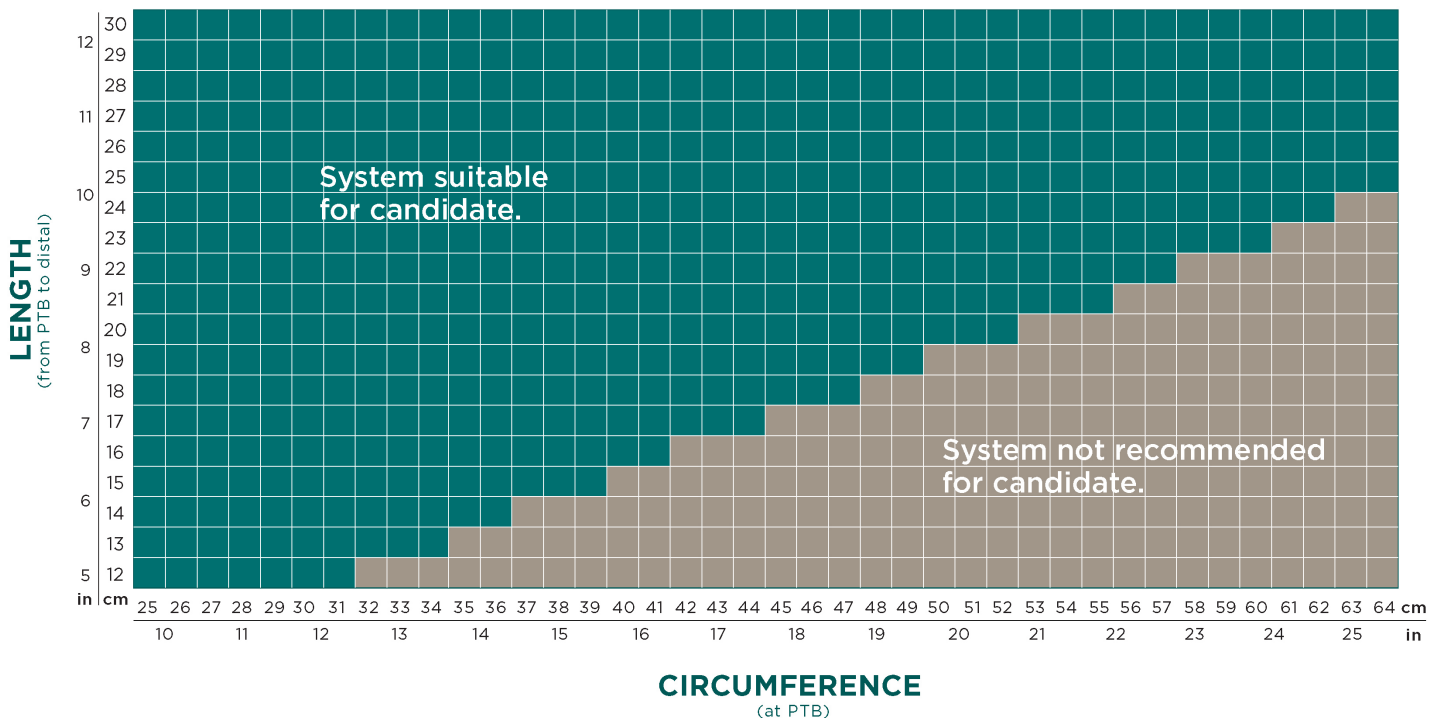
Patients who meet the following criteria should be considered for this system:

- Patients who are transtibial amputees.
- Patients who comment about lack of suspension or feeling insecure in their current prosthesis.
- 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 with redundant tissue.

Contraindications

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

- Patients who are transfemoral amputees.
- Patients with a residual limb length less than 5 inches.
- Patients with bulbous residual limbs.
- 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.
- Patients with a combination of limb length and limb circumference that is unsuitable according to the chart below.



QUICK-START GUIDE

1. Initial Donning

- Have the patient don the **Alpha Duo Liner** and the **One Gel Sock**

2. Shape Capture and Modification

- Capture the shape over the liner and the sock
- Reduce the positive model 5-7%

3. Diagnostic Socket

- Create a diagnostic socket
- Apply the **One Sleeve** on the exterior of the diagnostic socket
- Evaluate and modify the diagnostic socket

4. Definitive Socket

• For ONE-TTVD-XX-XX*

- Fill out the **Definitive Socket Order Form**.
- Use the **Pre-Paid Shipping Label** to ship the order form and diagnostic socket to WillowWood.
- WillowWood will ship you the completed flexible socket and laminated socket.

• For ONE-TTSU-XX-XX*

- Follow the **WillowWood One Transtibial Socket Fabrication Instructions** to fabricate a flexible socket and a laminated socket.
- Attach the Suction Pyramid.



5. Assembly and Final Donning

- Assemble the **One Sleeve** to the flexible socket
- Insert the flexible socket into the laminated socket
- Install the **One Link**
- Don the prosthesis

Be sure to review and share the User Instructions with the patient. Storing the One Sleeve correctly is crucial for maintaining system performance.

Visit
willowwoodco.com
for videos on fabrication
and One Sleeve
assembly!



6. LimbLogic System (for ONE-TTVD-XX-XX*)

- Follow the LimbLogic Prosthetist Instructions to attach the LimbLogic pump to the socket, charge the battery, and adjust system settings.
- Review and share the LimbLogic Patient Instructions with the patient.



* Value of X depends on size ordered.

INITIAL DONNING

1. Invert the **Alpha Duo Liner** so that the logo is on the inside. Place the end of the liner against the end of the limb. The position of the logo does not matter. The logo can face to the front, to the back, or to the side.
2. Carefully roll the liner up onto the 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 discomfort.
3. Invert the **One Gel Sock** so that the silicone side is facing out. Place the end of the inverted sock against the end of the liner.
4. 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.

SHAPE CAPTURE AND MODIFICATION

Capture the shape of the limb over the liner and One Gel Sock using the OMEGA® System or hand casting, according to patient criteria and residual limb assessment.

Reduce the positive model 5-7% to obtain Total Surface Weight Bearing. (Amount may vary depending on casting technique, limb length and tissue type.) Include a slight patella bar if desired and a posterior shelf. Do NOT build up the model anywhere.

DIAGNOSTIC SOCKET

Fabricate a conventional diagnostic socket.

Apply the One Sleeve on the exterior of the socket as you would for a typical suspension sleeve.

Conduct static and diagnostic fittings, and modify the socket to correct any areas of discomfort or proper fit:

- Observe the weave of the One Gel Sock. Uneven spacing of the weave indicates uneven pressures in the socket.
- Check to see if the socket is tight around the edges of the patella when the leg is at full extension.
- The socket fits correctly if:
 - the limb contacts the distal end of the socket without adding socks over the One Gel Sock.
 - adding one single-ply sock over the One Gel Sock prevents the limb from contacting the distal end of the socket under full weight bearing.

DEFINITIVE SOCKET

After determining the alignment, fabricate a socket according the WillowWood One Transtibial System Fabrication Instructions.

ASSEMBLY AND FINAL DONNING

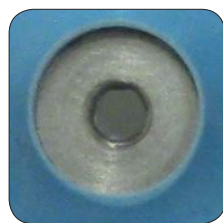
1. Locate anterior on the One Sleeve.
2. For ease of assembly, mist the outside of the flexible socket and the inside of the sleeve with alcohol.

3. While the flexible socket and sleeve are still damp, slide the sleeve onto the flexible socket:

- The larger end of the sleeve should be toward the top, and the smaller end with the sealing fins should be toward the bottom.
- The distal edge of the sleeve should be about 2" (5 cm) below the posterior trim line of the socket.



4. Insert the flexible socket with the One Sleeve on it into the laminated socket. Align the hole on the flexible socket with the One Link hole on the laminated socket. Lightly mist the One Sleeve fins or the inside of the socket with alcohol if necessary.



5. Insert the flange bolt through the flexible socket and One Link hole.
Apply Loctite® Threadlocker Blue 242® (or equivalent) to the flange bolt.



6. Using a 7 mm socket, install the One Link Nut onto the flange bolt. Tighten to 25 in lb.

Do not over-tighten.

Sand down the flange bolt if necessary so that it is flush with the One Link Nut.



7. Screw on the One Link Cap with O-Ring.



8. Fold the large end of the sleeve down onto the socket to expose the open end of the socket.



9. Have the patient step into the socket and pull the sleeve up onto the residual limb.



10. If there is a LimbLogic pump on the socket, have the patient stand up into a full weight-bearing position, then press the on/off switch to turn on the LimbLogic pump. Refer to the LimbLogic instructions for more details.

TRIMMING

One Sleeve

The silicone portion at the proximal end of the One Sleeve may be trimmed if necessary. Do not trim the portion of the sleeve that is covered by fabric.

One Gel Sock

Trim the One Gel Sock to follow the contours of the socket, approximately 1" above the socket trim line.



POSSIBLE ISSUES

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.
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.
	Hole in the liner.	Replace liner.
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 top edge of 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.	Sleeve fins torn.	Replace sleeve.
	Holes in sleeve.	Replace sleeve.
	Pump screws loose or missing,	Refer to instructions for screw installation.
	Loose One Link Cap with O-Ring.	Tighten One Link Cap with O-Ring.

Warranty

Alpha Liner 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 Sleeve

The warranty is 3 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.

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:

1. Be prepared to provide the following information:
 - Account # or company name
 - Purchase order # and/or serial #
 - Quantity to be returned
 - Reason for return
2. 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.
3. 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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