WillowWood One® Transtibial System

Socket Fabrication Instructions

CONTENTS

SECTION **PAGE**

WHAT'S IN THE BOX

The WillowWood One Transtibial Fabrication Kit includes the following items:

a. One Sleeve Dummy
b. 4-Hole Adapter
c. One Link Base
d. Screw Anchor
e. One Link Dummy
f. Screw
g. Poron Filter
h. Flange Bolt
i. One Link Nut
j. One Link Cap with O-Ring
k. Suction Pyramid
l. Stainless Steel M6x16 Flathead Cap Screws (4)
m. Foam Muffler

ADDITIONAL MATERIALS REQUIRED

Diagnostic socket

Orfitrans Extra Soft Silicone

Fabtech 60 Second Adhesive

ER Resin or PETG

Seamless one-piece PVA sheet (if using ER Resin)

Loctite® Threadlocker Blue 242® (or equivalent)

Standard fabrication supplies

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

PLASTER MODEL

Create a plaster model from the diagnostic socket. Be sure to keep the alignment of the diagnostic socket.

FLEXIBLE SOCKET

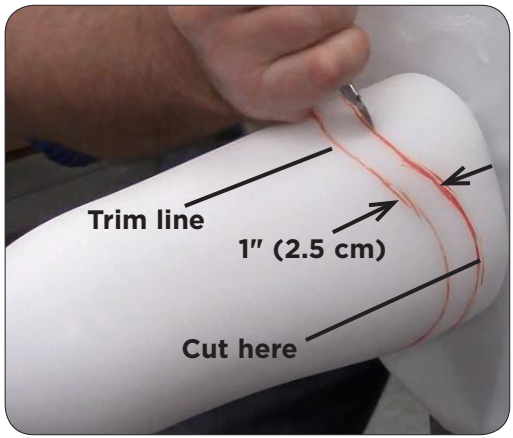
1. Vacuum-form the flexible socket:
   - Heat a sheet of Orfitrans Extra Soft thermoplastic for 16 minutes at 300° F (150° C), flipping the sheet halfway though. (Time and temperature may vary depending on your oven.)
   - Use talcum powder to lubricate heat-resistant gloves and thermoplastic.
   - Avoid creating a texture on the thermoplastic with the gloves or other fabrication aids.
   - Allow the thermoplastic to cool completely under vacuum.

2. Draw the trim line onto the flexible socket.

3. Draw a second line approximately 1" (2.5 cm) above the trim line that was just drawn. Cut at that line and discard the excess material.

   Make sure the surface of the flexible socket is smooth, with no glove prints.

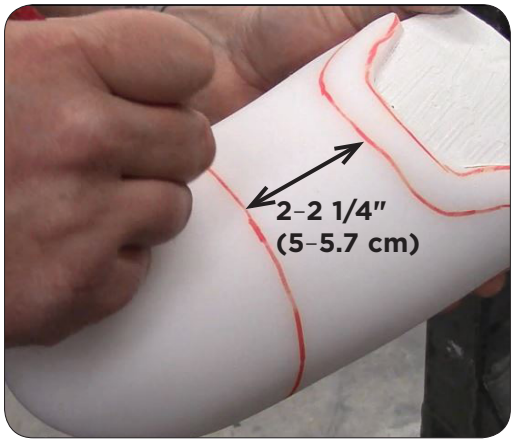
   Confirm that the thickness of the flexible socket is 3/16–1/4" (4.5–6 mm).



4. Make a mark on the flexible socket approximately 2–2 1/4" (5-5.7 cm) from the most distal trim line of the posterior shelf.

   Transfer this mark around the entire circumference, perpendicular to the limb axis.

   DO NOT CUT. This line will be used to indicate the placement of the Seal Dummy.



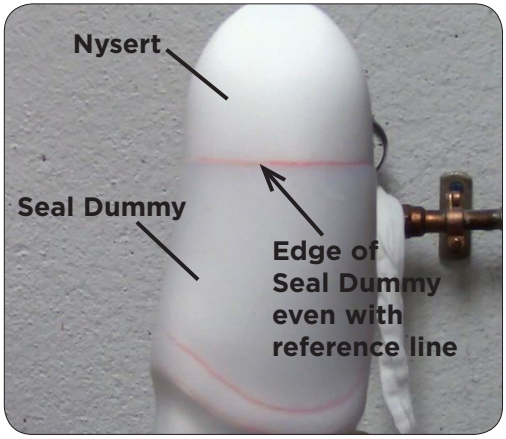
FIRST LAMINATION

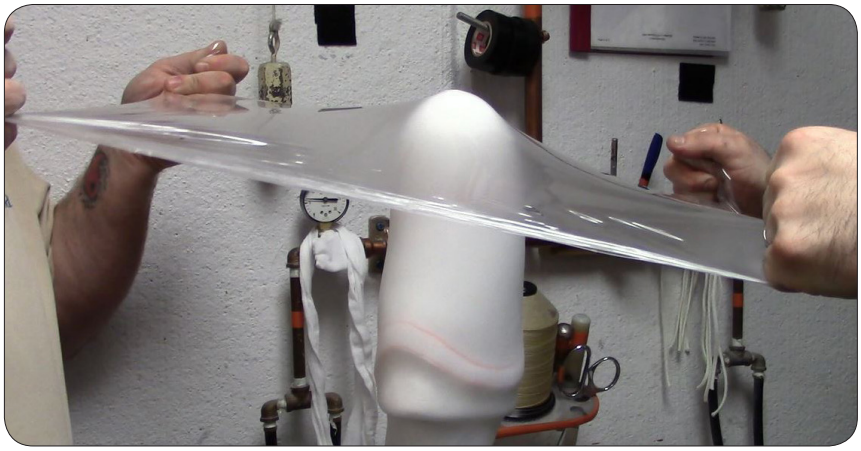
Follow the procedure listed below for the lamination method you are using:

- If you are using **ER Resin**, follow the procedure below.
- If you are using **PETG**, follow the procedure on page 6.

If you are using ER Resin:

1. Place the model with the flexible socket in a lamination fixture.
2. Apply a Nysert to the model. Twist the Nysert at the distal end of the model and reflect the rest of the Nysert back down onto the model. Smooth the Nysert at distal end of the model.
3. Prepare a **seamless** one-piece PVA sheet.
4. Apply the Seal Dummy, matching the edge of the Seal Dummy to the line drawn around the flexible socket earlier.
5. Lightly apply talcum powder to the Seal Dummy.
6. Apply the PVA sheet and add vacuum.



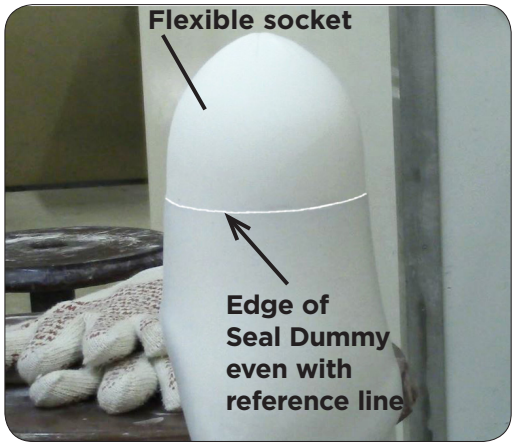


7. Proceed with the first lamination, using standard practices.
8. Allow to cure. Proceed to page 7.

FIRST LAMINATION

If you are using PETG (Vivak):

1. Place the model with the flexible socket in a vacuum stand.
2. Apply the Seal Dummy directly to the flexible socket (no Nysert), matching the edge of the Seal Dummy to the line drawn around the flexible socket earlier.



3. Heat 1/8" (3 mm) PETG at 320° F (160° C) for 3 minutes, then flip and heat for 2 minutes.
4. Pull the PETG onto the model and cut the excess as soon as possible.

5. Once cooled, sand the outer surface of the PETG by hand for better adhesion.
6. Apply putty and tape to the proximal cut to keep resin out.
7. Proceed with the first lamination, using standard practices.
8. Allow to cure. Proceed to page 7.

DISTAL ADAPTER

1. Remove the outer PVA bag and roughly sand the entire model to improve the bonding of the remaining components. **Be careful not to sand through the lamination into the plaster model.**

2. Place the model back in the transfer fixture.

3. Cover the center hole in the 4-Hole Adapter (LLV-01041) with masking tape.

4. Attach the adapter to the socket using Fabtech 60 Second Adhesive.

5. Once the adhesive has set, remove the socket from the transfer fixture.

Edges are smooth against the socket.

ONE LINK

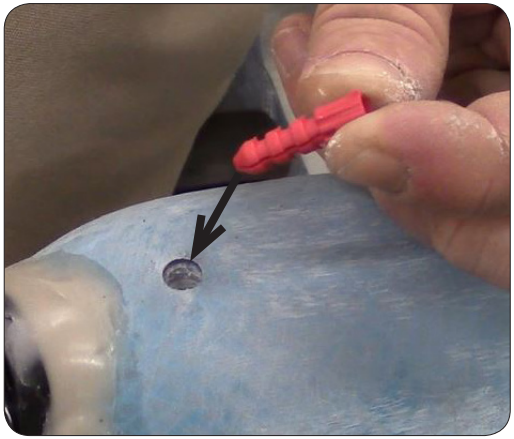
1. Decide where to place the One Link.

    - WillowWood recommends medial placement. **Posterior placement is not recommended.**
    - Must be placed distal to the Seal Dummy line.
    - The One Link must be able to sit flat against the surface of the socket.
    - Mark the desired location on the socket.

Example of an acceptable placement of the One Link.

2. At the location selected in the previous step, drill a 9/32" (7.1 mm) hole deep enough to accommodate the screw anchor. Clean the edges of the hole.

3. Insert the screw anchor into the hole.

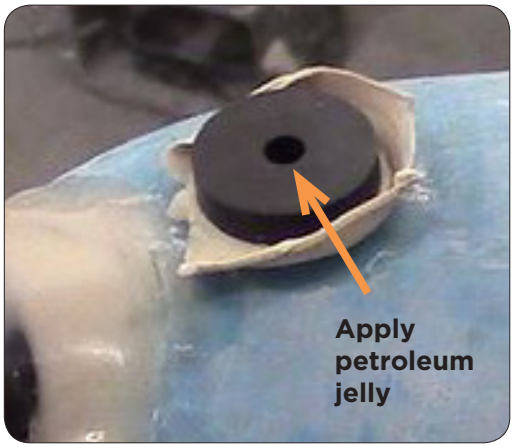


4. Adhere the One Link Base into the hole using Fabtech 60 Second Adhesive. The One Link Base will be snug in the hole.
5. Wipe off excess adhesive.

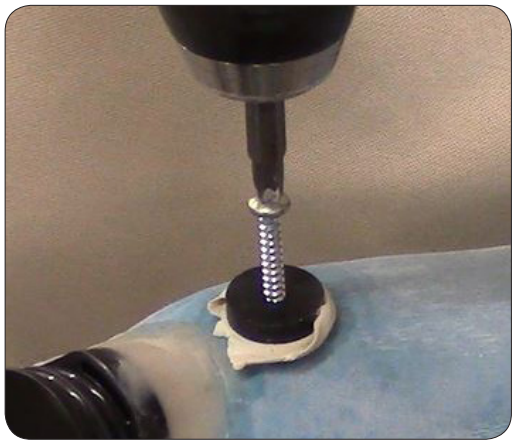
6. Apply putty to the One Link Dummy.

7. Place the One Link Dummy on the One Link Base.

8. Apply petroleum jelly to the hole in the center of the One Link Dummy.



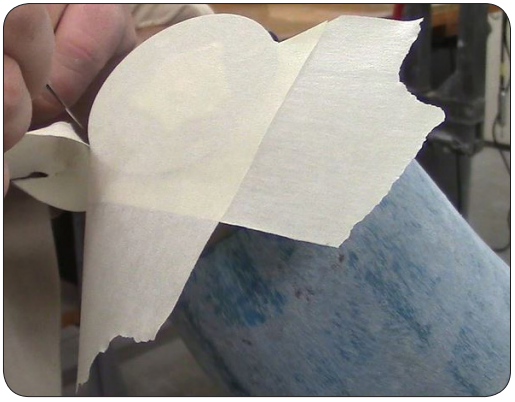
9. Secure the One Link Dummy with the screw.



10. Apply putty to the screw head.
11. Thoroughly clean excess putty from the One Link Base.

SECOND LAMINATION

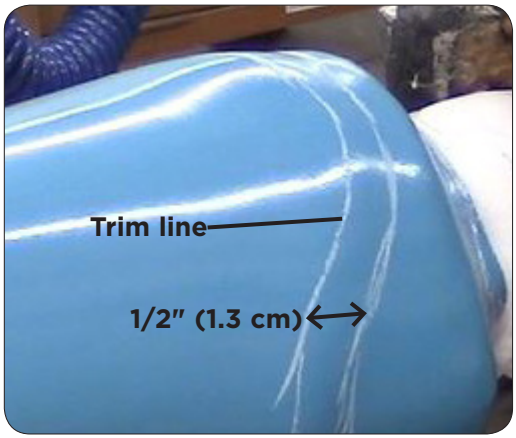
1. Apply 2 pieces of 3" (7.5 cm) wide masking tape to the bottom of the 4-Hole Adapter. Trim the excess.
2. Transfer the socket to a lamination stand.



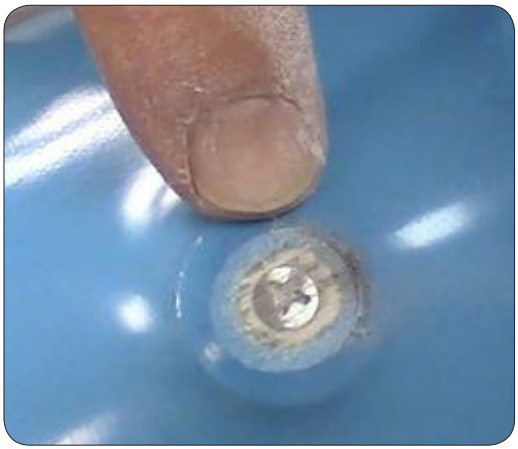
3. Secure the 4-Hole Adapter with 4 pieces of 1" (2.5 cm) wide carbon.
4. Proceed with the second lamination, using standard practices. Allow to cure.

SOCKET FINISHING

1. Draw the trim line on the laminated socket.
2. Draw a second line approximately 1/2" (1.3 cm) above the trim line that was just drawn.



3. Sand to expose the One Link screw. Remove the screw.



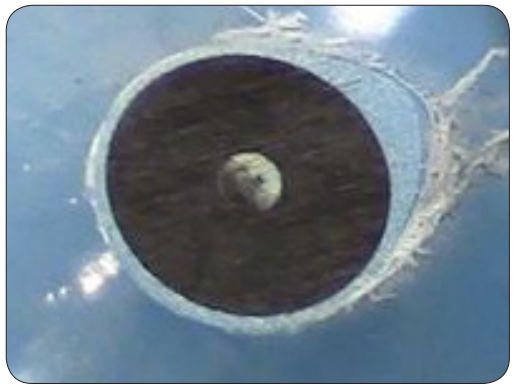
4. Drill a 3/16" (4.8 mm) hole in the center of the 4-Hole Adapter, through both the laminated socket and flexible socket, to create a vacuum port in the flexible socket.
5. Separate and remove the socket from the plaster model. I**f using PETG, be careful not to crack the PETG when removing the socket from the plaster.**

6. At this point there is a lip on the laminated socket that prevents the flexible socket from being removed. Sand the laminated socket to remove the lip.

Before removing lip.

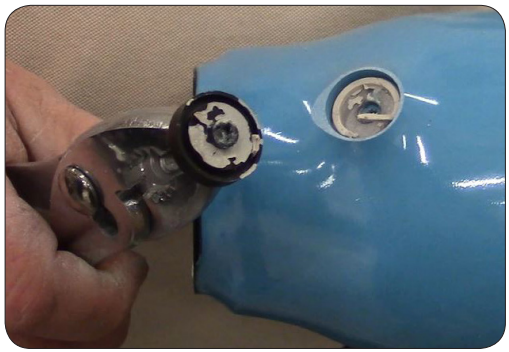
After removing lip.

7. Sand to expose the One Link Dummy.



8. Separate and remove the flexible socket from the laminated socket.

   Remove the Dummy.



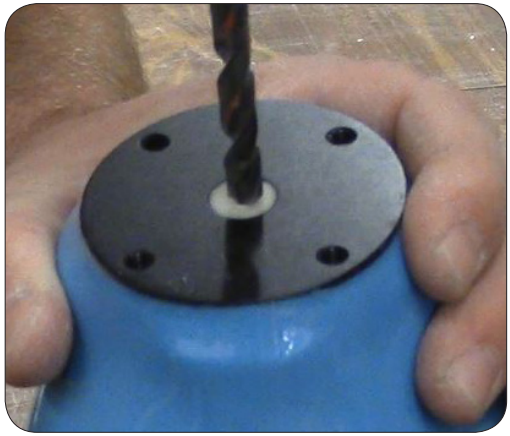
9. Trim and sand the flexible socket to the desired proximal trim line.
10. Place the flexible socket back into the laminated socket.
11. Trace the top edge of the flexible socket onto the laminated socket as shown at right.
12. Remove the flexible socket

13. Sand and polish the laminated socket edges so that the finished laminated socket is 1/8" (3 mm) higher than the flexible socket everywhere except in the posterior area, where the laminated socket should blend to match the flexible socket.

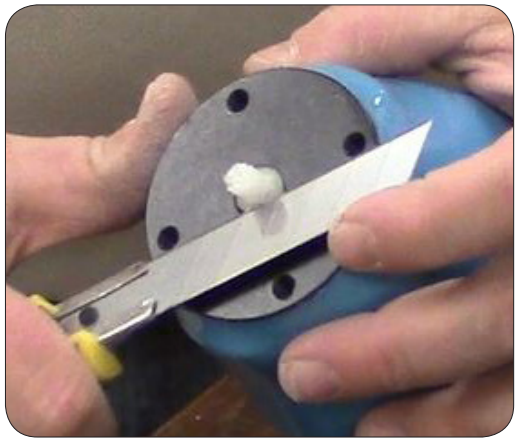
14. Remove the flexible socket.

15. Drill a 9/32" (7.1 mm) hole through the center of the 4-Hole Adapter on the laminated socket.

    DO NOT drill the 9/32" (7.1 mm) hole through the flexible socket.



16. Push the poron filter into the hole. Cut it flush with the socket.



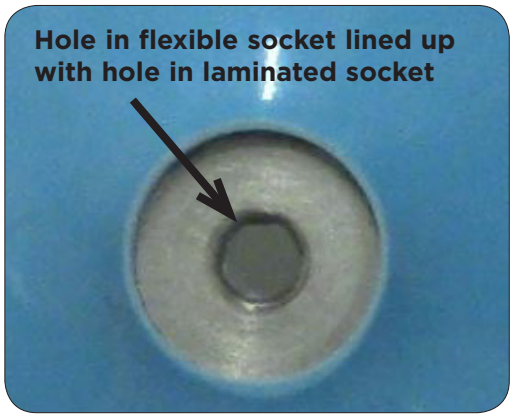
17. If you are ready to deliver the One System to the patient, proceed to Page 15 for instructions on applying the One Sleeve to the socket.

    If you are simply assembling the flexible socket to the laminated socket for shipment or storage, which does not involve applying the One Sleeve, proceed to page 17.

ASSEMBLY WITH ONE SLEEVE

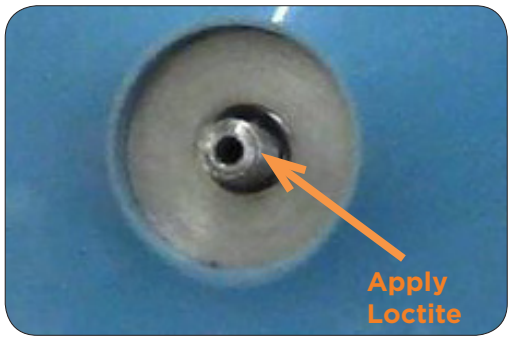
1. Locate anterior on the One Sleeve.
2. For ease of assembly, mist the outside of the flexible socket and the inside of the sleeve with alcohol.
3. While the flexible socket and sleeve are still damp, slide the sleeve onto the flexible socket:
   - The larger end of the sleeve should be toward the top, 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.

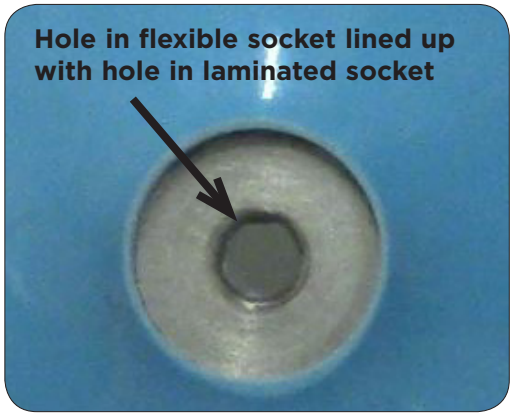
7. Screw on the One Link Cap with O-Ring.
8. Perform a vacuum test to confirm that the socket is airtight.

9. Fold the large end of the sleeve down onto the socket to expose the open end of the socket.
10. Have the patient step into the socket and pull the sleeve up onto the residual limb.

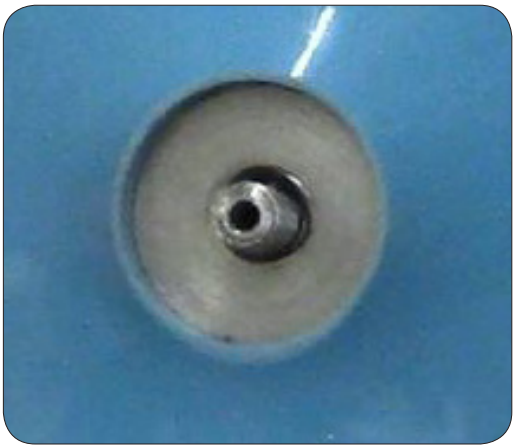
ASSEMBLY WITHOUT ONE SLEEVE

Use this method only when assembling the flexible socket to the laminated socket for shipment or storage. For delivery to the patient, refer to page 15.

1. Insert the flexible socket into the laminated socket, aligning the hole on the flexible socket with the One Link hole on the laminated socket.



2. Insert the flange bolt through the flexible socket and One Link hole.



3. Using a 7 mm socket, install the One Link Nut onto the flange bolt.

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

4. Screw on the One Link Cap with O-Ring.
5. Perform a vacuum test to confirm that the socket is airtight.

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.

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