

Academy Tech Tips

Harmony E2 Test Socket and Definitive Socket Fabrication

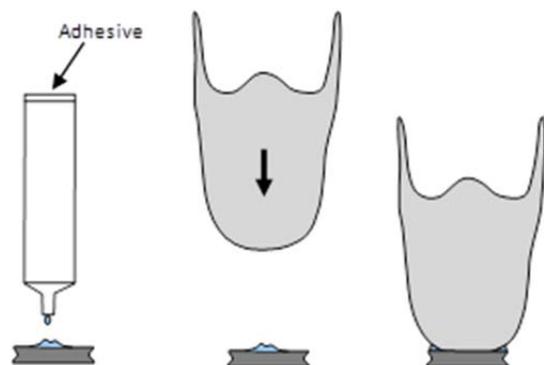


Figure : Test socket applied to 5R2 Lamination Disk

To get the best possible fitting with the Harmony E2 it's important to set up the test socket correctly. Before making the definitive.

This Tech tip will describe how to assemble the leg and attach it to the test socket. We describe the top-down approach here, but feel free to use the bottom-up approach if it's what your lab is used to.

Before you start, note the tilt of the socket as the patient stands on it, drawing alignment lines in the sagittal and coronal planes

1. Attach a 5R2 Lamination Disk to the bottom of the socket (Figure 1, above). Keep in mind your patient's unique alignment when attaching the adapter. In general you want to glue the adapter in a position where the pyramid adjustment screws will be in their neutral positions.

Set the adapter on the table so the writing on the plate is facing distally and the four-hole pattern is oriented correctly. Place FabTech 60 Second epoxy on the 5R2 Lamination Disk, and then set the roughened-up socket onto the 5R2 Lamination Disk and allow the epoxy to set.

2. If a gap exists between the adapter and the socket, use 50 mm (2") fiberglass casting tape to fill the gap. Continue by **tightly** wrapping the fiberglass casting tape around the adapter 5R2 and distal end of the socket as shown in the drawing. Wrap a minimum of 75–125 mm (3–5") up from the bottom of the socket to secure the adapter to the socket (Figure 2). If possible, leave a

minimum of 65 mm (2.5") of the socket exposed between the posterior trim lines and top of the fiberglass wrap for sealing purposes.

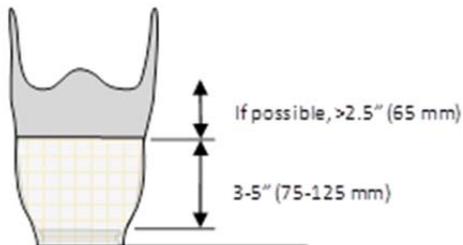


Figure 2

3. If you were unable to leave at least 65 mm (2.5") of the socket free of fiberglass tape, tightly wrap clear pressure sensitive tape (616F22) over the fiberglass before it cures. This will extend the surface onto which the sealing sleeve can seal. While the clear pressure sensitive tape provides an imperfect sealing surface, it is considerably better than the fiberglass casting tape alone.

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4. Drill a 6mm hole through the center hole of the 5R2 plate up into and through the socket (Figure 3).
5. Apply 636W111 Sil Poxy to the Tygon tubing and insert tubing into the hole.
6. After Sil Poxy has set, trim tubing flush on the inside of the socket and close to flush on the distal portion of the socket/plate.

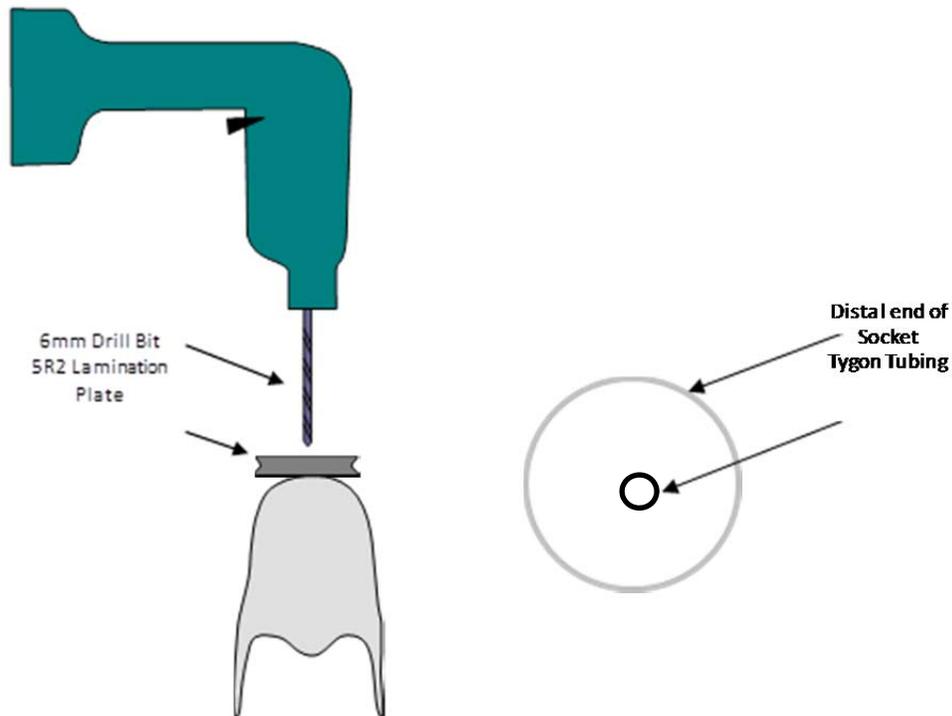


Figure 3

4R153 Adapter Plate Set up

7. Screw the 501Z61=M12x1.5 Locking Screw into the lateral adapter plate and tighten to 3 Nm.
8. Press the PE solid rod into the proximal TPU insert.
9. Slide the TPU insert with PE solid rod into the adapter plate and fasten adapter plate to the 5R2 Lamination Disk. As shown in the IFU.

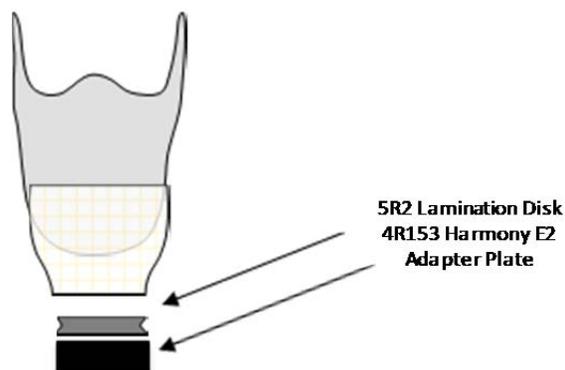


Figure 4

Definitive Socket Set Up

1. Place prosthesis into a vertical alignment jig. Cover the distal 6mm hole with flexible tape before filling socket with plaster.
2. Place a temporary collar around the proximal end of the socket to extend it proximally ~10 cm (4”).
3. Pour plaster into the test socket ~5 cm (2”) above the medial-lateral trim lines. Embed an anchoring post/adaptor in the plaster.
4. Remove the positive mold from the test socket and jig and smooth it if necessary.
5. Mount the mold on a vacuum platen so that there is space between the platen and mold. This will allow the plastic to be pulled under the mold and minimize the risk of having wrinkles in the PETG inner wall of the socket.
6. Pull 3 mm (1/8”) PETG plastic over the positive mold using a vacuum table. This PETG forms the inner wall of the socket and reduces the chances of air leaking into the socket through laminations that may not have been fully impregnated with resin. This is an important step to prevent vacuum leaks.
7. Use a knife to remove the PETG that extends above the mold. Sand the remaining plastic with 60 grit sandpaper. Clean the plastic with isopropyl alcohol.
NOTE: Do not use acetone or thinner because they will degrade the plastic.
8. Slide a full length of fiberglass braid over the mold. Twist it at the distal end of the mold, and reflect it back over the mold so one layer covers the entire mold and two layers cover the bottom 1/4–1/2 of the mold.
9. Pull a PVA bag over the lay-up. Pour resin into the top of the bag and apply a vacuum at the bottom of the bag. Work the resin through the laminations by sliding a string **down** the PVA bag. Tape the top of the PVA bag to pinch any excess resin away from the distal end of the socket
10. Place the mold back into the vertical jig and attach the 5R2 Lamination Disk to mold using FabTech 60 composite adhesive.
11. Sand and clean the outside of the socket using 60 grit sandpaper and isopropyl alcohol.
12. Place 5R2 Lamination Disk dummy on distal end of plate, lay-up mold and laminate.

NOTE: To save time and additional steps, now is a good time to make a protective slip cover. We recommend a slip cover for all Harmony systems to protect the sealing sleeve.

13. Follow Distal Air Channel and 4R153 instructions listed above.