

Instructions for use



NOTE: Not recommended trim line shown! Refer to next page diagram

FABRICATION INSTRUCTIONS

An optimized cavity will promote the fit and function of the RidgeFlex Joints and it is recommended to always fabricate using the RidgeFlex Molding Dummies. Cutting the articulation area of the AFO plastic should be done according to the recommended trim lines, but the width of the cut, for the most part, is not too critical. The Molding Dummy must be utilized to form the cavity for Free Motion or Dorsiflexion Assist Joints.

⚠ NOTICE: Using the Ridgeflex Joints to form the joint cavities is NOT recommended!



Mold and Dummy Prep for Vacuum Forming

1. The rectified mold should be ready to pull to incorporate the needed support and to provide adequate clearances.
2. Determine joint locations and attach molding dummies. Position the molding dummies so the mid-point is located on or near the desired axis of joint motion. Install using nails provided (trim length if needed). Either mechanical (line of progression) or anatomical joint alignment can be chosen for joint placement. The RidgeFlex joints will compensate to a bind free single joint axis.

⚠ Note: If the cast is dry, spray adhesive can be utilized to mount the fabrication dummy. Apply tape directly to the cast, (apply nylon hose— if necessary, and apply a 2nd application of spray over 1st nylon). Mount the dummy over the tape, and apply nylon hose. This will simplify removal of the cut plastic from the cast. This was done on this demonstration.

⚠ Important! If there is moisture, spray adhesive will not adequately adhere to the cast and the dummy will float during the plastic pulling stage, and it would be advised to apply with included nails.

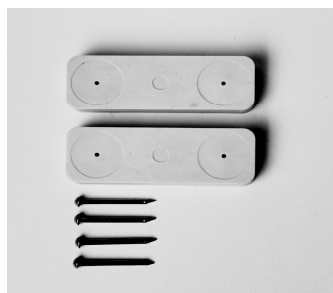


Fig. 1 RidgeFlex Molding Dummy and included nails



Fig. 2 Mount dummy to cast (see note above)



Fig. 3 Pull plastic over cast and dummy

3. Pull thin nylon vacuum forming hose over mold and then apply the dummy with nails provided. (Fig. 2 Molding dummies can be positioned wherever you prefer to locate the joint axis.)

4. Vacuum form or laminate to form the orthosis shell. (Fig. 3)

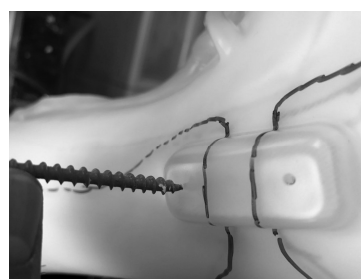
5. Allow thermoplastic to cool and harden. Now is a good time to indicate the mounting hole location in the plastic. (Fig. 4)

Indicate the center of the nail head and dimple the plastic with a sharp object (a screw point was used in this case Fig. 5).

Remove the AFO shell from the mold in one piece. An ideal, well formed cavity is formed tightly to securely anchor the joint.



Fig. 4 Note the hole in the dummy through the plastic and trim line



NOTE: This is not the recommended trim line!

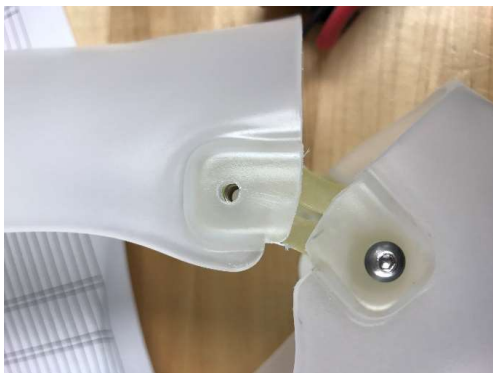
Fig. 5 Indicating hole with a dimple.

6. Rough cut AFO for removal from mold – Do not cut through ankle at this time, or damage to the dummy will occur.

7. Remove AFO from mold.

8. After removal of the fabrication dummy, cut to separate the foot section from the calf section. Optimal cavity formation promotes superior coverage surrounding the joint body giving it maximum support, anchorage in the orthosis, and the ability of the RidgeFlex Joint to provide the best rotational control.

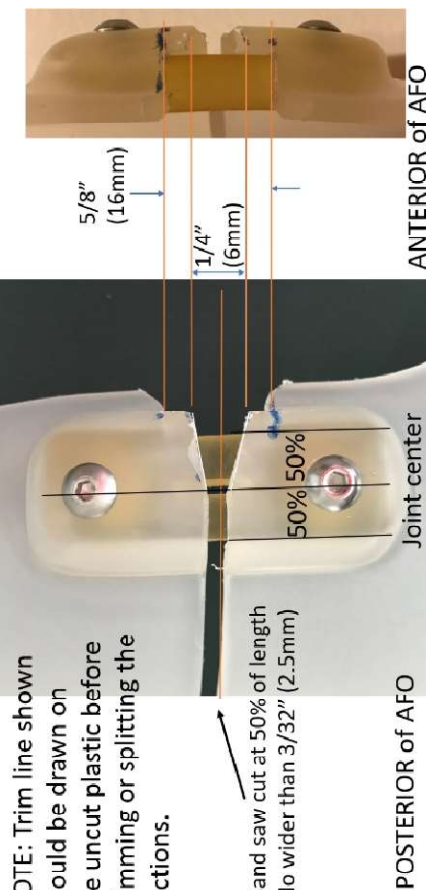
9. Drill out the hole that was indicated, using a 9/32" drill bit.



NOTE: Dorsi-flexion joint shown. Cavity can fit either joints

10. Install the joints into the cavities with the screws supplied. The anchor nut comes pre-bonded to the RidgeFlex joint for easy installation. Use a thread locker to prevent the hardware from loosening. Loctite® 242 removable is recommended. Cover exposed interior of joint with included adhesive cover.

Maximum Dorsi-Flexion Joint Return Open Anterior, closed lateral wall
(Recommended for DF joint)



NOTE: Trim line shown should be drawn on the uncut plastic before trimming or splitting the sections.

Band saw cut at 50% of length No wider than 3/32" (2.5mm)

Temperature Range:

- Between 0°C to 54°C (32°F to 130°F).
- Avoid constant and continuous exposure to UV rays
- Rinse with clean water if exposed to salty, chlorinated, or otherwise potentially corrosive liquids.

**Storage:**

- Store at room temperature; avoid wet, very hot, or extremely cold environments, and excessive UV exposure.

Warranty:

- 6 months, provided it is used as intended without modification, and only for the original intended user.
- Do not reuse on another prosthesis.

Conformity:

- This product meets the requirements Council EU 2017/745 (MDR) for medical products. This product has been classified as a class I product according to the classification criteria outlined in appendix IX of the guidelines. Please keep this manual in safe place for future reference.

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Specifications subject to change.

Made in the U.S.A