

RIDGEFLEX pediatric

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 should be utilized to form the cavity for Free Motion or Dorsiflexion Assist Joints.

NOTICE: Using the Dorsiflexion Assist Joints to form the joint cavities is NOT recommended.



RIDGEFLEX pediatric
PRFD-200
RIDGEFLEX EXTREME ANKLE JOINT
DORSIFLEXION ASSIST



ST&G USA CORPORATION
stngco.com
PRFD-200

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 dummy placement. The RidgeFlex joints will compensate to a bind free single joint axis.

Note: If the cast is dry, 2 sided tape or spray adhesive can be utilized to mount the fabrication dummy. Apply tape or spray directly to the cast, apply nylon hose, then apply tape or spray onto the fabrication dummy and mount the dummy onto the cast. This will simplify removal of the cut plastic from the cast.

Important! If there is moisture, the tape will not adequately adhere to the cast and the dummy will float during the plastic pulling stage. You can try the spray adhesive first, but check to be sure fabrication dummy does not move. If the dummy does not stay put, it would be advised to apply with included nails.



Fig. 1 RidgeFlex Molding Dummy and included nails

CE Conformity
This product meets the requirements Council EU 2017/1745 (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 use.

Useful Life
Service life of the product is covered by the warranty period.

Disposal
The device and its packaging must be disposed of in accordance with respective national/local environmental regulations.

PRFD-200 IFU REV B (5-1-25)

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PRFD-200

RIDGEFLEX EXTREME ANKLE JOINT - DORSIFLEXION ASSIST

3. Pull thin nylon vacuum forming hose over mold and dummy, being sure not to pull the nylon too tight and bridge the dummy. (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.

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. Trimming plastic for RidgeFlex Joint:

Dorsi-Flexion Joint – refer to included trimline reference and dimensions supplied with the joint.

Standard Joint – refer to the included trimline reference and dimensions supplied with the joint.

Important! The plastic should encompass as much of the joint as possible to provide the most return. Please reference the trimline reference material for that specific joint.

10. Make holes for attachment screws where the dimple was indicated using a 9/32" drill bit.

11. 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.

Environment:

Store at room temperature, and avoid extremely hot, cold, or moist storage environments Storage Temperature Range: between temperatures of -10°C to 50°C [14°F and 122°F] Do not store in wet or very hot environment.

Allowable environmental conditions

Use – relative humidity: 0 % to 90 %, non-condensing

Storage/transportation – relative humidity: 20 % to 90 %, non-condensing

Splash - Fresh water, rain, salt water, urine, dust, sand, particles of foam cosmetics

cleaning required after contact with salt-laden air, salt water, chlorinated water, urine, sand

Unallowable environmental conditions

Storage/transportation: high vibrations, impacts

Cleaning agents containing solvents

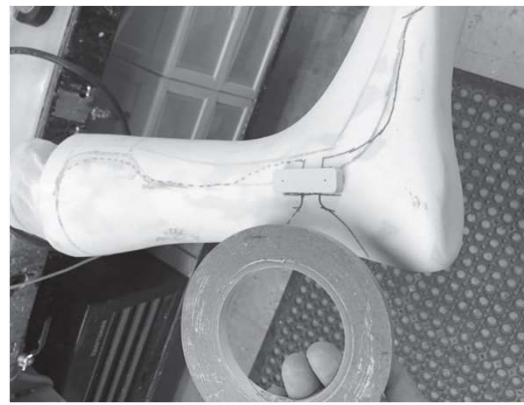


Fig. 2 Mount dummy to cast (see note above)



Fig. 3 Pull plastic over cast and dummy



Fig. 4 Note the hole in the dummy through the plastic.

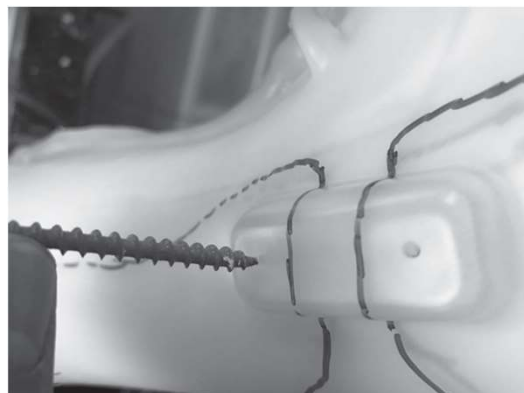


Fig. 5 Indicating hole with a dimple.