



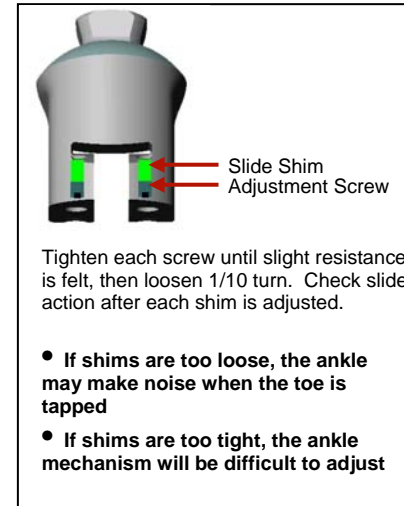
Runway® HX Foot Module

Instructions for Use

R-720-092 Runway HX, Prosthetist Instruction, Rev. B

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Important Information



- ✓ The ankle mechanism may loosen after a short break-in period. If the ankle makes a clicking noise when tapping the toe or heel of the foot, the ankle shims must be adjusted to provide optimal function.
- ✓ To adjust the ankle shims, remove the foot shell, and use a hex wrench (included) to tighten screws located on the underside of the composite slide receiver.¹
- ✓ The Runway foot module is not designed to be worn in sand or other dirty environments. If the ankle mechanism becomes dirty, it should be cleaned with Acetone, WD-40, or other suitable solvent.

- ✓ To provide optimal function and ease of adjustment, the ankle should be lubricated with white lithium grease after cleaning.

Bench Alignment

Sagittal Plane:

- Introduce the appropriate socket flexion and heel height, according to the amputee's requirements.
- Position the weight line, taken from the center of the socket at the patellar tendon level, so that it falls along the anterior edge of the pylon.

Coronal Plane:

- Introduce the appropriate socket adduction / abduction, according to the amputee's requirements.

¹ For Runways shipped before 07/02/08, use a 1/8" hex wrench. For those shipped on or after 07/02/08, use a 4mm hex wrench.

- Position the weight line, taken from the center of the socket at the patellar tendon level, so that it falls through the midline of the foot module in a neutral M-L position.
- Set toe-out at 3-5 degrees.

Static Alignment

- Fit the spectra sock and anatomical foot cover onto the foot module and place into shoe to ensure that the weight line falls along the anterior edge of the pylon.
- Establish the correct height of the prosthesis by having the amputee stand with feet approximately 4" apart, and equal weight bilaterally.
- Check socket flexion, ankle adjustment, load line position and toe-out.
- Correct as necessary.

Dynamic Alignment

Gait:

- The function of the foot may be optimized by modifying the alignment of the socket relative to the foot and by altering heel stiffness. The heel stores energy at heel strike and progressively releases it at midstance. Careful attention to alignment will ensure optimal energy return, and improve control of the prosthesis.
- As the amputee walks, check for smoothness of gait and even ground contact at all times.
- Optimize the alignment by progressively moving the weight line anteriorly over the foot to increase heel stiffness and observing the heel to toe function.
- The heel is too soft if the foot comes to foot flat too early or the amputee feels like they are sinking or trying to climb up over the toe. The toe will feel too stiff and the knee may hyperextend. Shift the socket anteriorly and/or use foam wedges (provided) to stiffen the heel, and soften the toe.
- The heel is too hard if the amputee's gait exhibits rapid heel to toe movement and they have difficulty in controlling the prosthesis. The toe may feel sluggish with minimal energy return and the knee may buckle.

Shift the socket posteriorly, or remove heel-stiffening foam to alleviate this problem.

- Use Loctite T-242 (not provided), and torque pyramid adjustment screws to 3.7 inch/pounds or to the manufacturer's recommendations.
- Freedom Innovations foot modules are manufactured to fit industry standard pyramids and receivers. It is the prosthetist's responsibility to choose and fabricate properly fitting connectors.

Verifying Foot Module Category:

- If the foot module provides minimal heel deflection, and exhibits a "flat spot" before rolling on to the toe, the foot module is too stiff, and should be replaced with a softer foot module.
- If the foot module provides excess heel deflection with stiffening bumpers properly installed, and exhibits a "flat spot" before rolling on to the toe, the foot module is too soft, and should be replaced with a stiffer foot module.

Warnings and Contraindications

No specific warnings and/or contraindications are specified for this device, although they should be used for the assembled prosthesis. These include, but are not limited to:

- ✓ Discontinue use, and consult your physician or prosthetist if the prosthesis causes pain, or injures you in any way.
- ✓ Do not attempt to adjust or service the prosthesis, except as advised by your prosthetist.
- ✓ Inform your prosthetist if you lose or gain a significant amount of weight.
- ✓ Have the prosthesis serviced at the regular intervals specified by the prosthetist.
- ✓ The Runway foot module is designed to be worn in a shoe. The foot shell and/or protective covering will wear in an accelerated manner if the prosthesis is worn without shoes.
- ✓ Freedom Innovations' feet are manufactured and tested for a particular weight and activity level. Use by an amputee other than the one for whom

they were originally manufactured may be dangerous to the amputee, and shall void any written or implied warranty.

- ✓ Notify your prosthetist immediately if the ankle slips from a high heel position to a lower position or if the ankle begins to make noise.
- ✓ The Runway foot module should not be used in water. If the foot is immersed in chlorinated or salt water, it should be rinsed with fresh water as soon as possible.

Maintenance and Disinfection

- Never attempt to loosen the bolts affixing the ankle / pyramid attachment.
- Freedom Innovations' foot modules should be inspected and serviced every six months, if necessary.
- The foot may be cleaned and/or disinfected with soap and warm water. If the foot is used in water, it is advisable to remove the foot shell to clean and disinfect the interior of the shell.
- If the foot is used in dirty environments, it is advisable to clean the ankle mechanism with WD-40 and compressed air. Lithium grease may be applied to the slide to provide optimal function.

Shim screw adjustment

- Tighten each shim screw individually until it affects slide movement, and then back off each screw 1/10 of a turn. Proper balancing of the shim screws is crucial to proper pin engagement.
- Improper shim screw adjustment can prevent full engagement of the adjustment pin. After adjusting the shim screws, it is advisable to check for full pin engagement in each adjustment hole.

Ankle Disassembly

Freedom Innovations does *not* recommend field disassembly of the Runway ankle. Return the foot to our Utah Service Center rather than attempting disassembly in the field.

The following product circumstances require return of the Runway to the Utah Service Center, without attempting field disassembly/reassembly:

- Slipping from a high heel position to a low heel position
- Can not alleviate noise issues through shim adjustment
- Damage to slide or screw threads
- Corrosion



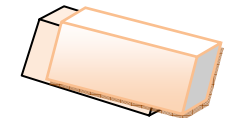
Altering Heel Stiffness:

- In most cases, stiffening the heel is best achieved by moving the weight line anteriorly or dorsiflexing the foot. However, the heel action may also be stiffened, reducing its deflection, by affixing the heel stiffening foam between the heel and toe portions of the foot module.
- During dynamic alignment, hold the heel stiffening foam in place by applying the double-sided adhesive strip between the contact surfaces of the foam and the heel component.
- After the proper hardness has been selected, remove the temporary adhesive strip, lightly scuff the area to be glued, clean the mating surface with a solvent and apply with a permanent adhesive such as Barge Cement (not provided). Do not glue the upper portion of the stiffening foam to the upper member of the foot, as this will affect foot performance and lead to eventual failure of the stiffening foam.

Optional Foam Stiffening Block

Locate optimal position with double-sided tape

Permanently mount with Barge or similar cement on bottom side



Ankle Adjustment Instructions

Warning:

Never attempt to adjust ankle while standing on the prosthesis. Heel height of the prosthesis should always be adjusted while sitting in a chair, preferably next to a hand rail or other suitable means of support.

Manual Adjustment:

Insert 3 mm hex wrench through the cosmetic/protective into the hex key port.

To increase heel height, turn the wrench clockwise.

To decrease heel height, turn the wrench counterclockwise.

Fourteen full turns will change the heel height by one inch.

Caution:

The wrench must be removed from the ankle before placing weight on the foot. Failure to remove the wrench could cause damage to the cosmetic/protective cover.

Evaluation of adjustment:

Improper adjustment of heel height will affect performance of the foot.

Heel too high:

If the heel height of the foot is set higher than that of the shoe, the toe of the foot will feel stiff while the heel will feel soft, causing hyperextension of the knee. To provide proper balance, decrease heel height until a smooth rollover is achieved.

Heel too low:

If the heel height of the foot is set lower than that of the shoe, the heel of the foot will feel stiff while the toe will feel soft, causing flexion of the knee. To provide proper balance, increase heel height until a smooth rollover is achieved.

Cosmetic Finishing Instructions

Step One:

Prepare footshell by sanding the proximal edges as illustrated below:



This will provide a greater surface area to adhere to the cosmetic shin foam, will ease transition lines, and allow the finishing material to stretch rather than tear when the heel height is adjusted by the amputee.

Step Two:

Bond finishing foam (Otto Bock 6R8 or equal) to footshell.

Step Three:

Shape the ankle with the foot set for 3/8" heel height.

Step Four:

Set the foot module to a high heel height, and ensure that the finishing foam does not wrinkle in the Achilles area.

Step Five:

Apply Shoe Goo™ sealant (available at shoe stores) over ankle transition, and smooth it with a wet finger. This step provides a transition material that will help to extend the life of the cover.



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