

Kintrol™ Instructions for Use

Product Number: VS4

Introduction

The Kintrol™ foot/ankle combines hydraulics and fiberglass to provide K2 ambulators an exceptionally normal walking gait – regardless of surface angle or speed. The result is rock solid stability and the confidence for users to choose their own path.

- Articulated ankle movement provides 12 degrees of motion, with adaption to slopes for improved stability and overall comfort.
- An innovative Dorsi-Assist Spring assists toe clearance to prevent stumbles and falls.
- Precision controls are easily accessible, making the set-up fast and efficient.
- The design uniquely delivers gait simulating biological norms on both slopes and level ground for superior stability.

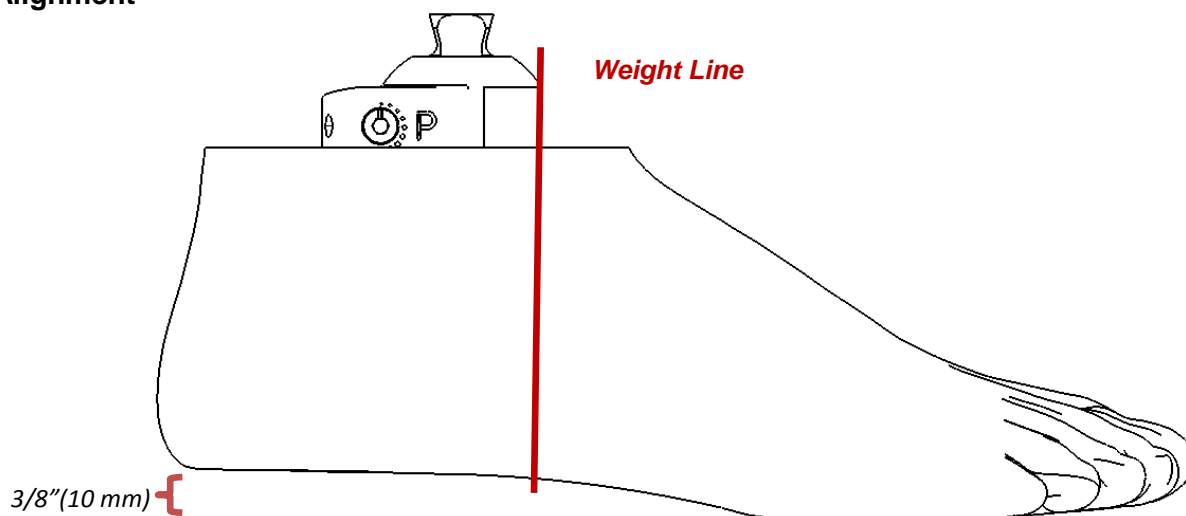
Patient Selection

The Kintrol™ is intended for use by transtibial and transfemoral K2 level ambulators. It is recommended for unilateral use. Caution should be used when fitting bilateral patients due to the added movement of the ankle. Kintrol™ has a weight limit of 300 lbs (136 kg).

Assembly

The Kintrol™ foot/ankle is pre-assembled and consists of a foot module, ankle unit, Spectra™ sock, and foot shell. After dynamic alignment, torque pyramid adjustment screws to the manufacturer's specifications. Secure pyramid adjustment screws with a thread locking adhesive (i.e., Loctite 242).

Alignment



Bench Alignment

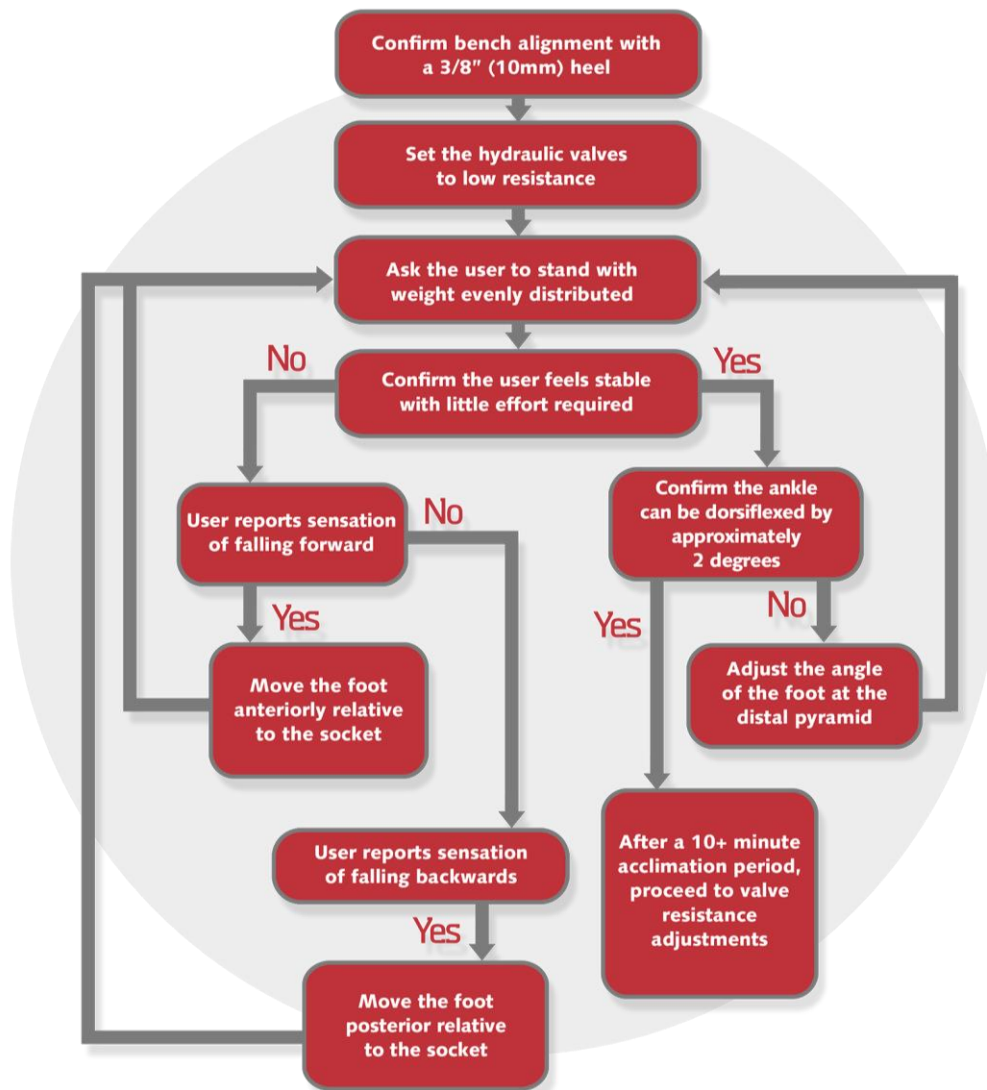
With a 3/8" (10mm) lift under the heel or the foot placed in the desired shoe with the pyramid level to the floor, use a plum bob or laser to confirm that the weight line falls through the anterior aspect of the pylon and pyramid.

Static Alignment

To complete the static alignment, stand the patient in a set of parallel bars. The patient should be able to stand comfortably without feeling as if the knee is flexing or hyperextending. If the knee is flexing, slide the foot anteriorly. If the knee is hyperextending, slide the foot posteriorly.

Tip! Angular adjustment of the pyramid will impact the ratio of the 12 degrees of movement. Plantarflexing at the pyramid will decrease the dorsiflexion range of motion provided by the ankle. Dorsiflexing at the pyramid will increase the plantar flexion range of motion.

Ensure that the range of dorsiflexion and plantarflexion motion is maintained during static alignment. Check when flexion is properly accommodated that the system still has 2° dorsiflexion and 10° plantarflexion.



Dynamic Alignment Once a stable static alignment is achieved, begin walking the patient in the parallel bars to optimize alignment and function on level ground.

Using your patient's feedback, adjust the hydraulic valves carefully to balance the comfort provided by the ankle damper and the energy return provided by the foot

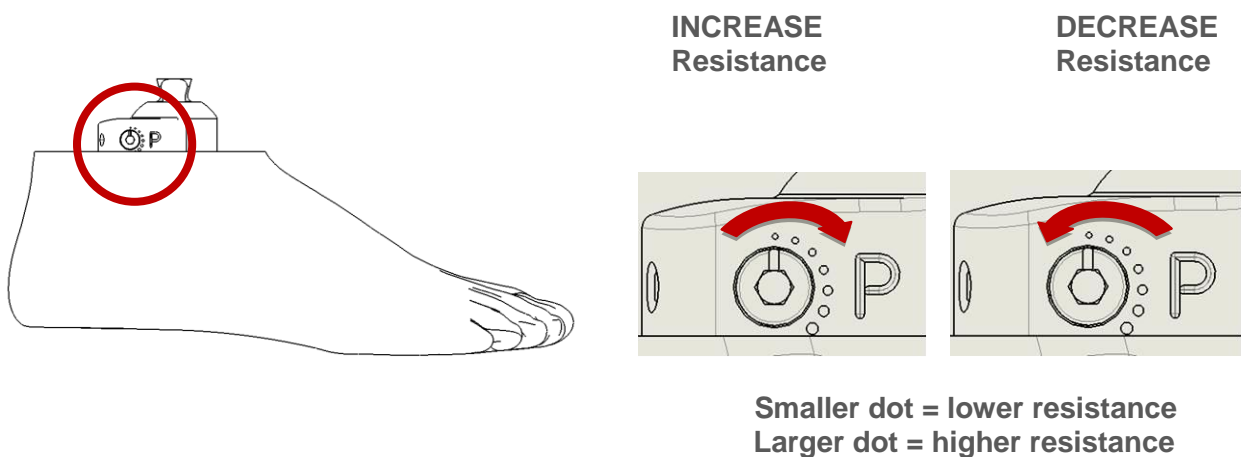
module. (Higher resistances will allow the keel to be loaded more, providing more energy return. Lower resistances will allow more ankle motion and comfort while sitting and ambulating on slopes and uneven terrain.)

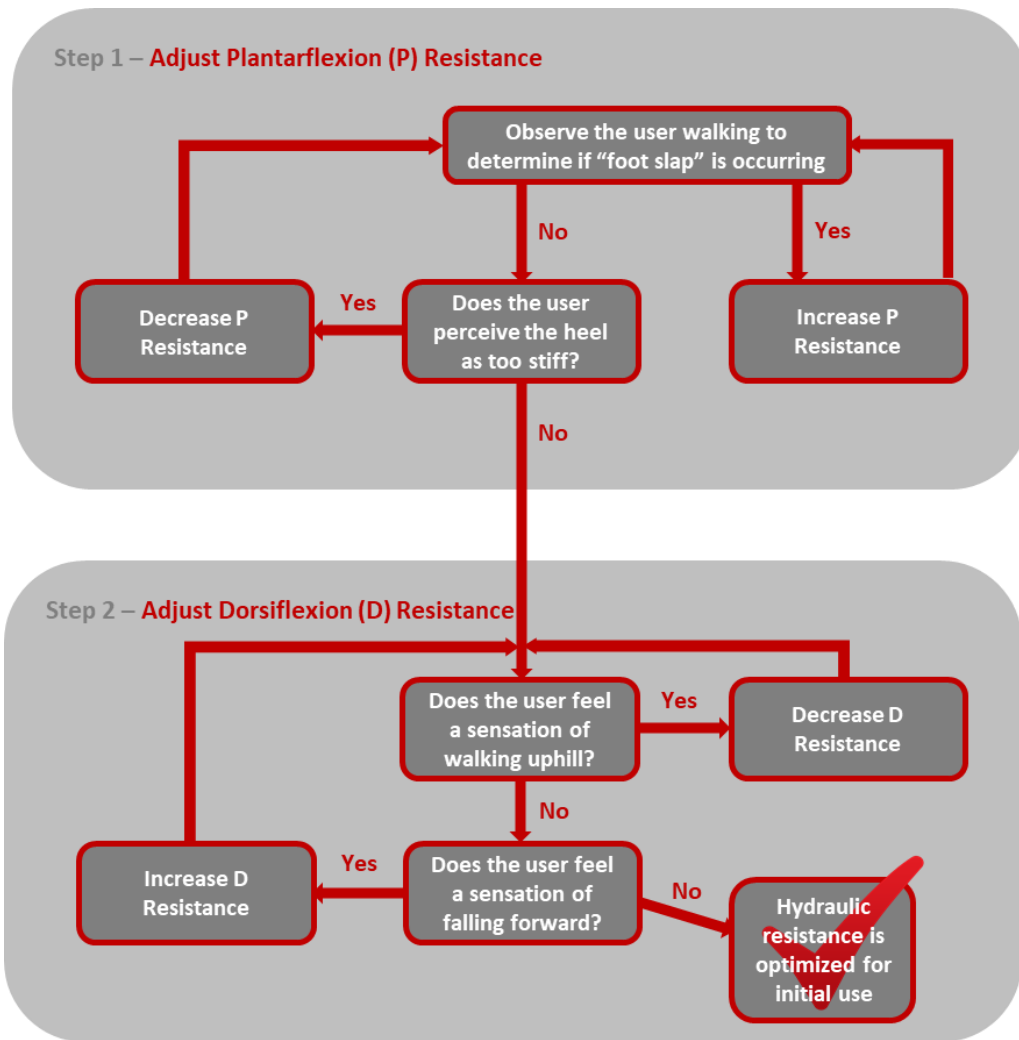
Due to the posterior placement of the Kintrol's ankle pivot point, changes to the plantarflexion and dorsiflexion resistance settings will be most noticeable to the patient when they are walking on slopes, not level ground. Adjustments of the resistances are best done on a gradual slope as a final step in dynamic alignment.

Start the dynamic alignment by setting the plantarflexion stiffness first to optimize the heel strike to mid-stance motion before proceeding on to adjust the dorsiflexion adjustment.

Adjust plantarflexion resistance to dampen heel strike. If a foot slap is noticed or heel strike is too abrupt, increase the "P" resistance. If the heel is too firm or the knee is buckling at heel strike, decrease "P" resistance.

Dorsiflexion "D" resistance is adjusted to control the advancement over the foot. If the patient feels they are walking "downhill", increase D resistance. If the effort to advance over the foot is challenging for the user, decrease "D" resistance.





Fitting Tips & Troubleshooting

The following fitting tips will help to optimize Kintrol's performance. If the proposed solutions do not result in a satisfactory outcome, please contact Freedom Innovations Technical Services for further support.

Foot too stiff / too soft

As a first step, weigh the patient to confirm current body weight and review the Kintrol specific category selection chart to assure the proper foot stiffness has been selected.

Heel is too soft

Symptoms:

- Sinking at heel strike, 'crushing' the heel
- Difficult to progress the step from heel strike to mid stance
- User feels they are walking up hill or forefoot feels too long

Solutions:

- Check A-P alignment; ensure foot is not positioned too far anterior
- Increase the plantar flexion 'P' resistance

- Change heel bumper to an increased category level

Heel is too stiff

Symptoms:

- Rapid knee flexion, instability
- Heel to toe progression too rapid
- Lack of energy return sensation

Solutions:

- Shift socket posteriorly in relation to the foot
- Decrease the plantar flexion 'P' resistance
- Change heel bumper to a decreased category level

Category 1	Blue
Category 2	Yellow
Category 3	Red
Category 4	Black

If the proposed solutions do not result in a satisfactory outcome, please contact Freedom Innovations Customer Service (+31 (0) 532030300).

Spectra™ Sock

A Spectra™ sock is provided to protect the foot shell and minimize noise. Spectra™ socks must be replaced at intervals appropriate to the user's activity level. Failure to inspect and replace the Spectra™ socks may prematurely wear the foot module and may void the warranty.

Foot Shell

When removing or installing the foot shell, follow instructions in the foot shell IFU (R-720-129) to prevent damage to the foot module.

Kintrol™ System

Sizes: 23-30 cm
 Average Build Height: 109 mm / 4.3 in
 User Weight Rating: 136 kg (300 lbs)
 Heel Height: 10 mm (3/8 in)
 Connector: Male pyramid
 Warranty: 24 months (shell 6 months)

Maintenance

- Inspect the foot module every six months. If the user is more active, more frequent inspection may be necessary. Service as necessary. Replace Spectra™ sock and/or foot shell if worn to prevent damage to the fiberglass components.
- The foot module may be cleaned and/or disinfected with soap and warm water.

Warnings

- Failure to adhere to the guidelines of the *Instructions for Use* will void the warranty.
- Advise users to practice driving with the Kintrol™ in a safe place to ensure they adjust to the plantar and dorsiflexion movement provided by the ankle.
 - Advise users to practice sitting and standing with the Kintrol™ in a safe place to ensure they adjust to the plantar and dorsiflexion movement provided by the ankle.

- Never use the foot module without a foot shell. Failure to comply may cause the user to fall, premature wear, loss of function, and/or product failure.
- Always use the foot module with a sock and with a shoe when outdoors. Failure to comply may cause premature wear, loss of function, and/or product failure.
- Never allow aggregates such as sand to remain in the foot shell. Upon exposure to aggregates, immediately disassemble foot module and rinse with water. The abrasive properties of aggregates will quickly wear the fiberglass components of the foot module.
- Freedom Innovations foot modules are manufactured to fit industry standard pyramids and receivers. It is the prosthetist's responsibility to select and/or fabricate properly fitting attachment components.
- Never attempt to loosen the set screws affixing the pyramid connector.
- Discontinue use and consult your prosthetist if any part of the prosthesis starts to make noise, or the foot loses its responsiveness.
- Inform your prosthetist if you lose or gain a significant amount of weight.
- Avoid use in water, as prolonged exposure to moisture may have a negative impact on the life of the product. After use in water, completely dry the product.
- Freedom Innovations foot products are manufactured and tested for a particular weight and activity impact level. Use by another user for whom it was not originally manufactured may cause injury and shall void any written or implied warranty.



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