DDA™ (Dynamic Dorsi Assist) AFO Application Instructions

1) Make reference to attached standard PRAFO® Orthosis initial fitting instructions for proper positioning, adjustment of Inversion/Eversion and rotation bar adjustment. (Note: Fitting Instructions - A. “Proper sizing the height to patient’s leg(s)” does not apply to the DDA™. The DDA™ AFO has a floating calf section).

2) After securing all straps as indicated in the fitting instructions, secure the lower leg strap as shown in (Figure 1) below. (Figure 2) shows all of the strapping on the foot and calf secured properly. At this point, make sure that the heel is against the bottom of the foot plate and away from the heel connecting bar.

Figure 1

Figure 2

3) Once the leg has been positioned properly and the strapping secured, proceed with fastening the two dorsiflexion assist straps as shown in (Figure 3, 4 and 5) below. The dorsi assist straps should be tightened enough to create a moderate pull or stretch of the calf musculature. Do not over tighten straps; better results are achieved when providing a moderate tension/stretch over a longer period of time.

Figure 3

Figure 4

Figure 5

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4) To reproduce the specific tightness of the dorsiflexion assist straps, the straps can be marked with a pen at the point where it passes through the chafe/buckle, see Figure 6. Make sure tension of strap is maintained over time as there is typically a need to re tighten straps to maintain adequate tension. The tension can be assessed by pushing on the strap as shown in Figure 7.

Figure 6

Figure 7

5) See Figure 8 for proper fit of the DDA™ AFO. Note that elastic dorsi assist straps are maintaining the foot in a neutral position as related to the leg. Care should be taken to make sure foot is not pulled outward or inward unless your healthcare professional has instructed you otherwise. See Figure 9 for appropriate orientation for fitting posterior strap.

Figure 8

Figure 9

6) Recommended wearing schedule
   - As requested by ordering physician
   - In general to tolerance (determined by patients ability to wear without causing pressure, swelling or irritation.)
   - With patients having compromised sensation, at risk for skin breakdown or disruption of soft tissue surface – check position of device and skin after 1 hour of wear – if no concerns, increase wearing time by 2 hour increments, not to exceed 6 hours of wear without removal for 30 minutes to 1 hour, then reapply.

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Articulated AFO, PRAFO® and RAPO™ Orthoses Applications - Indications - Fitting Wearing, Caring and Patient Instructions

*• Clinically proven for effective ambulation**
• Fully adjustable in length and height
• Compatible with all liner variations that we offer if applicable
*• Proven superior integrity of the superstructure***
• Anatomical Concepts Inc. recommends patients be fit by a medical professional

Applications and Indications –

- **All AFO variations**
- Early Intervention for the evolving rehab patient
  - CVA,TBI,SCI, CP and Diabetic neuropathy
    - Promotes safe and stable ambulation
    - Offloads vulnerable soft tissue
    - Maintains foot and ankle position to offset joint contracture
    - Used as an interim AFO for gait tuning and sensory feed back
    - Controls spasticity and or increased tone

- **Articulated AFO variations**
- Facilitation of functional knee and ankle joint position
  - Allows for optimal Dorsi/Plantarflexion ankle positioning to provide adequate clearance during swing phase and knee stability in stance phase (see D1 under Fitting Instructions).
  - Allows for optimal Inv/Eversion ankle and foot positioning to provide or promote accommodation and positioning respectively. (See E1 under Fitting Instructions).
  - Allows for optimal Ab/Adduction ankle and foot positioning to provide or promote accommodation and positioning respectively. (See E1 under Fitting Instructions).
  - Assists Dorsiflexion while resisting plantarflexion (Dynamic Dorsi Assist (DDA) variation).

- Post musculoskeletal injury of the foot and ankle (Heavy duty version recommended for management of these or similar patient populations)
  - Post TAL immobilization
  - Post Botox or serial casting
  - Stable fractures of the foot and ankle
  - Tendon or ligamentous tear/rupture

*Lin R, et al (2009) Evaluation of the Pressure Relief Ankle Foot Orthosis in Individuals With Hemiparesis Using Three-Dimensional Gait Analysis, *Journal of Prosthetics and Orthotics*, *21-3*, pp. 132-137

***DeToro W, (2001) Plantarflexion Resistance of Selected Ankle-Foot Orthoses: A Pilot Study of Commonly Prescribed Prefabricated and Custom-Molded Alternatives: J Prosthet Orthot:13;39-44*

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Wear and Care Instructions –

- **Articulated AFO's –**
    - **Product Codes: 652SKG, 653SKG, 654SKG, 655SKG, 682SKG, 752SKT**
  - With arch support, foam lining and open toe shoe
    - *Primarily worn when most time is spent upright, ambulating and patient not at risk for skin breakdown.*
    - *Can be worn during waking hours while recumbent, properly positioned and secured.*
  - With terry cloth liner and open toe shoe
    - *Primarily worn during ambulation and while recumbent (without shoe)*
    - *When patient at risk for skin breakdown*
  - With terry cloth liner and no open toe shoe
    - *For household ambulation and recumbent positions*

- **PRAFO® and RAPO™ Orthoses –**
    - **Product Codes: 650SKG, 650RTBS, 550SKG, 450RKG**
  - For household ambulation and recumbent positions

- **Recommend wearing schedule –**
  - As requested by ordering physician
  - In general to tolerance (determined by patients ability to wear without causing pressure, swelling or irritation).
  - With patients having compromised sensation, at risk for skin breakdown or disruption of soft tissue surface - check skin after 1 hour of wear - if no concerns increase wearing time by 2 hour increments not to exceed 6 hours of wear without removal for 30 minutes to 1 hour, then reapply.

- **General –**
  - When unable to achieve a 90° position at the ankle (See C3 under Fitting Instructions)
    - *Use articulated system to accommodate position*
  - Allows for future adjustment to accommodate improved ankle position.
  - When spasticity or abnormal tone is present
    - *Use Dynamic Dorsi Assist (DDA) Articulated AFO*
      - *Allows for push through during episodes of increased or varying spasticity or tone.*
  - When sensation is absent or diminished, increasing risk factor for breakdown
    - Use articulated system to accommodate position
      - *Allows for future adjustment to accommodate improved ankle position.*
  - Care should be taken when the surface area of the superstructure or straps comes in contact with areas with compromised or open soft tissue. These areas should be bridged and or relieved in most all cases to eliminate further soft tissue compromise.
      - *Seek further assistance from your local orthotist to customize the system to meet the needs of you and your patient.*

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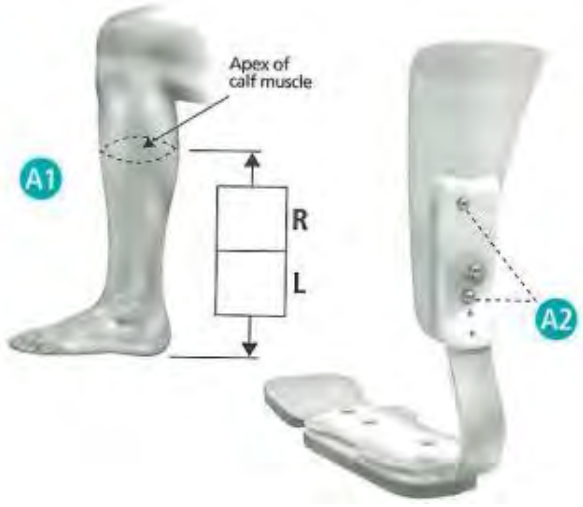
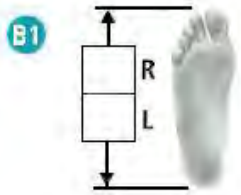
Fitting Instructions –



A. Properly sizing the height to patient leg(s)

1. Measure from the plantar surface of the heel to the posterior apex of the patient's calf. As depicted in A1.

2. Lengthen or shorten the AFO height as needed so the proximal edge of the calf segment equals the measurement taken in step 1. This may require removing the screws in the calf segment, recontouring the metal heel-connecting bar and reassembling the calf to the metal heel-connecting bar. As depicted in #A2.
   Note: To shorten the overall height, it will require cutting the length of the heel-connecting bar and adding additional holes.



B. Properly sizing of the foot length to patient foot (feet)

1. Measure the distance from the posterior aspect of the heel to the distal aspect of the longest toe. This measurement should be determined with the patient in a standing position, if the patient's condition permits such. As depicted in #B1.
2. Loosen the (2) distal screws found on the walking base and slide the toe extension proximally or distally as needed to equal the measurement taken in step 1. As depicted in #B2.
3. If necessary, the polypropylene toe extension can be trimmed, just beyond the distal end of the toes, in a manner normally employed by those trained in the art of thermoplastic Orthotics.

C. Donning

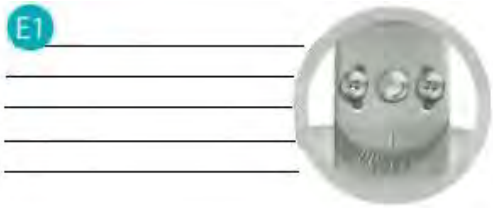
1. Patient should be sitting or supine.
2. The patient's hip and knee should both be flexed to approximately 60˚ to relax the extensor muscles.
3. Grasp the patient gently by the toes of the involved extremity trying to dorsiflex the foot to a neutral position. As depicted in #C3.
4. While maintaining the patient's extremity in this position, place the (fully opened) AFO against the extremity, calf in contact with the calf segment and the foot in contact with the foot plate. As depicted in #C4.
5. Secure the patient's extremity into the AFO following the sequence of the strap adjustments.
   - Secure the middle Velcro® strap first. As depicted in #C5.
   - Re-evaluate the positioning of the posterior heel and secure all of the remaining dorsal straps and the calf strap.

D. Adjustment of Dorsi/plantarflexion angle

1. Loosen the (2) screws on the sagittal hinge (take precautions not to totally remove the screws from the self-locking nuts). As depicted in #E1.
2. Rotate the foot in relation to the calf to the desired angle.
3. Maintain the foot in the desired angle and tighten the (2) sagittal hinge screws.

E. Adjustment of Inversion/Eversion and or Adduction/Abduction angle(s)

1. Follow similar instructions referred to in D except you will be adjusting the coronal hinge. As depicted in #E1.



F. Adjustment of optional rotation bar

1. Pivot the bar medially/laterally to offset Internal/external rotation of the hip. As depicted in #F1.
2. The bar can be recontoured to maximize the desired rotational control. As depicted in #F2.

G. Final evaluation of fitting process

1. Carefully inspect the position of the patient's heel to insure there is not contact with the superstructure.
2. If contact is present, first try refitting the AFO. If there is still contact, add additional padding under the calf liner.
   Note: use a full calf section pad, starting with 1/8" to ¼" thick Aliplast or equivalent.
3. If this does not solve the heel contact, you may call provider service at 800.837.3888.

ACI's orthoses are designed and engineered as prefabricated products to be trimmed, bent, or otherwise modified by a licensed health professional or expert, such as, but not only limited to an orthotist, podiatrist, or prosthetist, for custom fitting to the patient.
OUR WARRANTY IS IMMEDIATELY VOID IN ITS ENTIRETY IF THE PRODUCT IS NOT CUSTOM-FITTED BY A LICENSED MEDICAL PROFESSIONAL TRAINED TO FIT ORTHOTIC DEVICES AS DESCRIBED AND ILLUSTRATED IN ACI'S INSTRUCTIONS.

Patents

5,908,398	7,112,181	6,464,659	7,122,016
6,302,858	7,662,119	5,944,679	

European Patent EP 0 931 525

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PATIENT INSTRUCTIONS

To APPLY orthoses:

1) Patient should be sitting or supine.

2) The patient's hip and knee should both be flexed to approximately 60° to relax the extensor muscles.

3) Grasp the patient gently by the toes of the involved extremity trying to dorsiflex the foot to a neutral position. (As depicted in C3)

4) While maintaining the patient's extremity in this position place the (fully opened) orthosis against the extremity, calf in contact with the calf segment and the foot in contact with the foot plate. (As depicted in C4)

5) Secure the patient's extremity into the orthosis following the sequence of strap adjustments.
   - Secure the middle VELCRO® strap first. (As depicted in C5)
   - Re-evaluate the positioning of the posterior heel and secure all of the remaining dorsal straps and calf strap.

- Notify your Orthotist, Therapist, Doctor or Nurse immediately if you should develop any pressure points or discoloration of skin while wearing the orthosis.

- A notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

- The CDC recommends treatment with Lysol Disinfecting Sprays/Wipes for MRSA and most other common staph infections.

- We recommend if these infections occur to remove the liner system and wipe down the plastic and aluminum frame real good with the wipes. Let it dry before reapplying the liner system after the liner is cleaned, of course. The liner should be sprayed with a light mist of Lysol covering as much of the front and back surface area inclusive of the straps as possible. Let dry for 10 minutes or so. Then machine wash liner (See Washing Instructions for liners below).

- Check all screws on the orthosis on a regular basis especially the walking base. Apply removable Thread locker to screw threads to prevent them from loosening.

- The material is non-allergenic, flame resistant and machine washable.

- Washing instructions: Use a delicate cycle or hand wash. For best results, wash at a temperature below 150 degrees. Dry on a cool-low setting or air dry.

- Washing of the liner will eventually reduce its thickness and eventually its effectiveness.

EC REP
EMERGO EUROPE
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VARIETY OF REPLACEMENT LINERS AVAILABLE

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