

allard|^U_S^A

PRO FESSIONAL

INSTRUCTIONS

kiddieGAIT™



Manufactured by:
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Because Professional Customization is Required - a Prescription
is also Required for the ToeOFF Family of Orthoses.

www.allardusa.com

INDICATIONS AND CONTRAINDICATIONS

Indications

Footdrop, Gait deviation secondary to proprioceptive deficit (Either unstable or low-tone gait), Toe-walker with no midfoot collapse, Low Tone Crouch Gait, Spina Bifida, Cerebral Palsy, Muscular Dystrophy, Myelomeningocele.

Contraindications

Lacking ROM towards dorsiflexion (need at least 5° dorsiflexion past neutral). Very rigid foot structure. Quadriceps spasticity, Fixed postural Genu Valgum or Genu Varum. Fixed postural Pes Valgus or Pes Varus.

Limitations

Knee Hyperextension (if not managed)

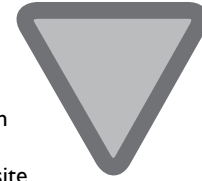
THERMOSET HYBRID COMPOUND

Thermoset Hybrid Compound

- Do not heat

When Grinding/Cutting

- Protect the eyes
- Cover the nose and mouth
- Do not grind/cut into Carbon Fiber or Kevlar
- Do not overheat the composite



NOTE:

Professionals selecting and/or fitting these orthosis should exercise due professional judgment throughout the selection, fitting, and appropriate education of the patient or caregiver, to minimize the potential risk associated with each individual patient. These risks may include the contraindications identified in this instruction as well as risks associated with the unique attributes of the patient or the patient's caregiver circumstances.

PATIENT ASSESSMENT & SELECTION OF INTERFACE/ORTHOTIC INTERVENTION

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Be attentive that the child's physiological conditions can change rapidly. We recommend early follow-up: initially at two weeks and then routinely. Be aware of how growth, changes in tone, and different treatment methods, such as operations and Botox can affect the child's conditions.

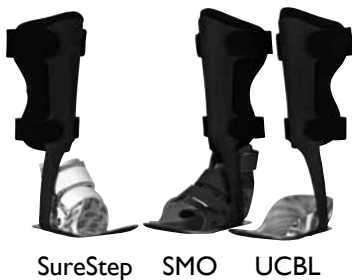
Make anatomical and gait assessment to determine function, stability, and deficits in both open and closed chain.

Footdrop Only (no supination/pronation, spasticity, rotational deformity or instability, proprioceptive dysfunction, or ankle instability):

There should always be an interface between the footplate and the foot. Use a firm prefab or custom foot orthotic device to cover the footplate. If only one side is involved, be sure to manage the opposite foot so as to not create a LLD.

Complex Involvement (more than pure footdrop):

KiddieGAIT should always be combined with an additional orthotic intervention, designed to control the position of the foot. To achieve gait as close to normal as possible, it is important that the foot position is as close to neutral as possible when non-weight bearing, and allowed to go into controlled pronation during weight bearing. The most common foot related problems like pronation, supination, pes varus, pes valgus should be corrected with this additional orthotic device. When spasticity is present, it is generally recommended that this orthotic include a deep heel cup to further encourage the heel-to-toe gait.



SureStep SMO UCBL

GUIDELINES FOR FOOT ORTHOTIC INTERVENTION

Spasticity, Rotational Deformity, and/or Rotational Instability:	FIRM PREFAB	CUSTOM	UCBL	TOTAL CONTACT SMO
Mild	X	X		
Mild w/Proprioceptive Dysfunction				X
Moderate			X	
Moderate w/Proprioceptive Dysfunction				X
Severe				X

Low Tone (Hypotonia) & Pronation: Consider a Flexible Compressive SMO (such as SureStep™)

2 SIZE SELECTION

Measurements shown to the right are for the orthosis only. Take into consideration the larger the size, the more support. Depending on above assessment findings, you may want to upsize or downsize to meet specific patient needs.

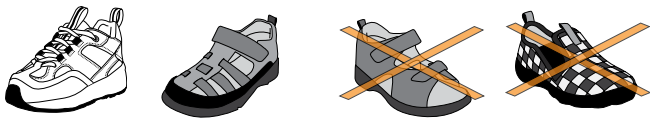
Size	Height	Footplate Length
Small*	220mm 8 5/8"	160mm 6 1/4"
Medium*	257mm 10 1/8"	180mm 7 1/16"
Large*	295mm 11 5/8"	200mm 7 7/8"

*Specify left or right

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SHOE SELECTION AND ACCOMMODATION

A. Well constructed rocker toe shoe

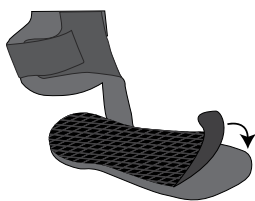


- Firm heel counter, for proper control of the rear foot.
- Wide toe box (to assure free movement of the phalanges) and wide midfoot to accommodate the orthotic intervention chosen to position the foot.
- The foot and the orthosis should be secured by the shoe. Note: If child was previously wearing a plastic AFO, depending on the orthotic intervention selected, it probably will be necessary to change to a smaller size to assure the shoe will provide appropriate support to the orthosis (remember, the shoe is an integral component of the orthosis).
- Rocker-type sole at toe end for smoother transition from 2nd to 3rd rocker.
- Laced, for easier donning and doffing, and to allow adjustable compressive support at mid-foot.
- Rubber sole, to minimize the chance of slipping on wet surfaces.
- Removable insole, to allow space for the footplate modifications and orthotic interventions.
- Approximately 3/8" toe-to-heel height differential, as a starting point to control the knee extension moment.

B. Only when necessary, accommodate brace to shoe: consider in cases of extreme stress, e.g., footdrop one side and trans-tibial amputation other side, or if patient has delaminated a previous KiddieGAIT.

B-1. Observe the void in front of and behind the center of the strut as it is joined to the bottom of the footplate. Depending on the patient's shoes and gait pattern, the motion allowed by this void may allow undue stress to that juncture.

B-2. Laminate 1/4" cork or EVA cork to the bottom of the footplate in the area of the strut – footplate juncture. Grind off excess on the bottom lateral aspect so that cork remains in front of and behind the center of the juncture, filling in the voids. The bottom medial aspect may be further contoured to accommodate to the built-in arch in the shoe.

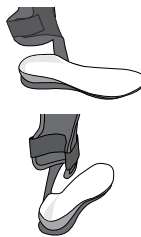


KiddieGAIT & Plastic Orthotic Intervention

Plastic has a tendency to “chew away” at carbon composites. When using KiddieGAIT in conjunction with a plastic orthotic intervention, cover the top of the footplate with a non-skid interface (use barge cement to attach).

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PREFAB OR CUSTOM ORTHOTIC



• If the footplate does not fill the shoe, either add leather or rubber to extend the length of the toe end or heel end of the footplate, or attach a foot orthotic interface to the footplate of sufficient length to fill the shoe. This is very important to assure the brace will maintain proper alignment during gait, and will not shift in the shoe.

Supination/Pronation Control

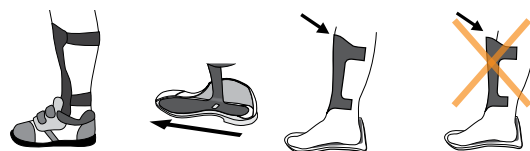
- Manage supination/pronation, etc. with a semi-rigid pre-fab or custom orthotic device. This orthotic device should fill the inside of the shoe and be attached to the footplate (2-sided tape is often sufficient) to prevent any shifting in the shoe.
- Do the same adjustments on both feet to avoid creating a LLD.

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PROPER ALIGNMENT AND INSTEP CLEARANCE

Tibia Alignment for ToeOFF and BlueRocker

Assure even pressure distribution along the tibial crest. Before fitting into shoe, apply SMO or place other orthotic intervention onto footplate. Place patient's foot onto the foot bed. Shift the footplate forward or backward to locate ideal location to achieve even pressure distribution of the anterior plate along the full length of the tibia. For example, distal pressure can often be relieved by shifting the footplate forward. Mark foot position on footplate and trim as necessary. Then, to prevent the footplate from shifting in the shoe, either add leather or rubber to extend the length of the toe end or heel end of the footplate.



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APPROPRIATE FLEXION/EXTENSION & FLOOR REACTION ADJUSTMENT

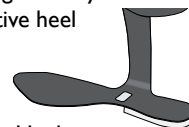
Knee Extension / Flexion Adjustment

KiddieGAIT is fabricated to accommodate approximately 9mm (3/8") size small, 10mm (13/32") size medium, and 11mm (7/16") heel height. If the shoe has a significantly higher or lower heel, add or reduce the effective heel height.

To encourage:

Knee Extension (minimize flexion) – Decrease Heel Height

Knee Flexion (delay extension) – Increase Heel Height



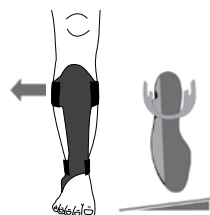
Valgum/Varum Adjustment

To influence towards:

Knee Valgum - wedge the bottom of the footplate on the lateral side.

To influence towards:

Knee Varum - wedge the bottom of the footplate on the medial side.



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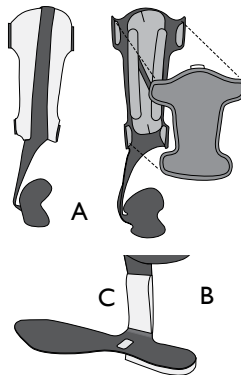
PATIENT COMFORT

A. The orthosis should always have padding on the inside before delivery to the patient. If pressure on the tibial crest, always pad both laterally and medially, leaving an open channel for tibia crest relief.

B. SoftKIT™ is a ready made option for easy, simple and quick padding. SoftSHELL™ is another ready made option that not only is a soft interface, but also gives the KiddieGAIT a fun pattern front.

C. Pressure Over Instep. See Instruction No. 5. If pressure remains:

- Shape and adhere padding to the distal medial aspect of the lateral strut to shift the foot medially, or
- Shift foot orthotic slightly medial and attach to footplate.



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CAREGIVER INSTRUCTION

Give to and review with the caregiver the Caregiver Instructions supplied with the product.

STRAP REMOVAL: Emphasize to the caregiver the “Strap Removal” instructions. The straps **MUST** be pulled from front to back to remove. The wings that hold the straps are made flexible for patient comfort and to accommodate varying calf sizes. If wings are pulled forward repeatedly, the carbon composite will crack and cause the wings to fracture.

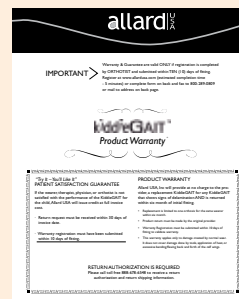
Especially point out and review with the Caregiver the “skin monitoring” and “Caring for the Orthosis” sections in the Caregiver Manual.

VALIDATION YOU HAVE PROVIDED INSTRUCTIONS:

Have the caregiver sign the back of the Caregiver Instructions, make a copy for the patient’s records, and give original to caregiver. An extra copy is included with the product for the caregiver to give to the day attendant if child is in an “out of the home” day program.



WARRANTY REGISTRATION & CLINICAL MANUAL



WARRANTY REGISTRATION: Warranty is valid only when warranty registration is completed by ORTHOTIST (not patient) and submitted within 10 days of fitting.

More detailed information about fitting is available on the ToeOFF® Family CD-Rom, at www.allardusa.com and www.toeoff.com. Please read the ToeOFF® Clinical Manual for complete instructions.

Patent no.:

ToeOFF, ToeOFF Short, ToeOFF Fantasy, ToeOFF NFR, BlueRocker, BlueRocker NFR, KiddieGAIT, KiddieGAIT NFR: AU736950, BE1005297, BE1114626, DK1005297, DK1114626, FI1005297, FI1114626, FR1005297, FR1114626, IE1005297, IE1114626, IT1005297, IT1114626, CA2279225, CNZL97181689.1, NL1005297, NL1114626, NO313656, PL194247, CH1005297, CH1114626, ES1005297, ES1114626, GB1005297, GB1114626, SE1005297, SE1114626, DE69709184.8-08 DE69732541.5-08, US5897515, ATE210417, ATE289187