

allard^{INT}



kiddieGAIT™
kiddieROCKER™



YPSILON™



ToeOFF®



BLUEROCKER™

PRO

INSTRUCTIONS
ENGLISH

FESIONAL

KiddieGAIT™, KiddieROCKER™, ToeOFF®, Ypsilon™ and BlueROCKER™ are covered by multiple patents.

www.allardint.com

Carefully read this instruction booklet before fitting!



Thermoset Hybrid Compound

- Do not heat
- Relieve pressure areas by using foam

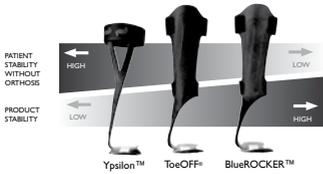
When Grinding/Cutting

- Protect the eyes
- Cover the nose and mouth
- Do not grind/cut/drill into structural sections such as the carbon skeleton or the lateral strut
- Do not overheat (max. 100°C/212°F) when grinding the composite

- Single Patient Use Only.
- The product must be fitted by or under the supervision of a Certified Orthotist-Prosthetist, Certified Orthotist or equivalent medical professional.
- Special precautions should always be taken for patients with impaired vision, cognitive disability and/or with reduced sensitivity in the lower extremities.
- The fitter should always inform the patient about the fact that the orthosis may alter the patient's ability for some activities such as driving a car.
- The User Instructions supplied with the product should be given to and reviewed with the patient.
- It is vitally important that you discuss the User Instructions with the patient. Patient shall be instructed to monitor product and skin condition on a daily basis. Patient must be informed to discontinue use immediately and report to you any signs of damage, signs of wear or any changes in performance of the device. It is equally important that patient discontinue use immediately and report back any changes in skin condition.
- Changes, alterations or modifications to the product not described in these instructions are done under the responsibility of the person doing them.
- Disposal: The product shall be disposed of in accordance with relevant national and local laws and regulations. If the product may have been exposed to infectious substances or bacteria the product should be destroyed according to relevant national and local laws and regulations covering disposal of contaminated materials.

Indications and Contraindications	4
Introduction	5
Patient Assessment	6

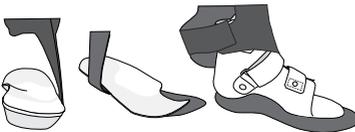
1 Product Selection. Decide stability, based on patient needs. Page 7-8.



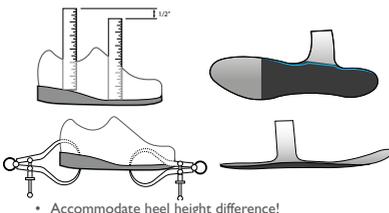
2 Size Selection Correct Application, based on the following: Page 9-10.

- Foot length
- Activity level
- Body type
- Spasticity
- Deficit type

3 Foot Biomechanics Orthotic shell, custom orthotics, UCBL, or SMO Page 11.



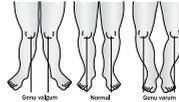
4 Shoe Selection & Heel Height Page 12.



- Accommodate heel height difference!

5 Proper Alignment Page 13.

- With the patient standing safely in parallel bars, check their alignment with either a plumb line or square.
- Make accommodation on plantar surface of the product using crepe or cork.



6 Proximal Control Page 14.

- Add as little as 1/8" (3.2mm) heel wedge
- *can be addressed in Step 4



7 Patient Comfort Page 15.

- Slide footplate forward or back in the shoe to distribute the pressure evenly across the tibia.



8 Patient Education Page 16.

DO's

- Use hand support ON Sit-to-Stand
- Wear SOCKS
- Use SoftKIT or ComfortKIT
- Use interface on footplate
- Inspect brace on a daily basis
- Check SKIN on a daily basis
- Wear recommended footwear

DON'Ts

- Stairs - Ball of Foot
- SQUATS - not at all

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Indications & Contraindications ToeOFF[®] Family of Products

Intended Use

Ypsilon, ToeOFF and BlueROCKER are intended to support a foot with impaired ability to actively dorsiflex. They are also intended to assist when the ability to perform push off is reduced. KiddieGAIT and KiddieROCKER are intended to support the foot/ankle complex in a more functional posture while allowing more normal ROM during the developmental years.

Indications

Ypsilon, ToeOFF and BlueROCKER are designed to manage footdrop in conditions such as Stroke, Multiple Sclerosis, Post Polio Syndrome, Muscular Dystrophy, Spinal Cord Injuries, Traumatic Brain Injuries, Guillian-Barre Syndrome, Charcot-Marie-Tooth, Myelomeningocele, Neuropathy or Cerebral Palsy.

ToeOFF and BlueROCKER are designed to support gait in conditions such as Posterior Tibialis Tendon Dysfunction (PTTD) and toe amputations. BlueROCKER can also be used for partial foot amputations, most proximal level is Chopart.

KiddieGAIT and KiddieROCKER are designed to support footdrop, gait deviations secondary to proprioceptive deficit (either unstable or low-tone gait), toe-walking with no midfoot collapse, low tone crouch gait in conditions such as Spina Bifida, Cerebral Palsy, Muscular Dystrophy and Myelomeningocele.

Contraindications

Ypsilon, ToeOFF or BlueROCKER should not be used when patients present with:

- Foot and/or leg ulcers
- Moderate to severe edema
- Moderate to severe foot deformities
- Severe proximal deficits (e.g.: quadriceps spasticity, genu valgum or varum, genu recurvatum)
- Severe spasticity

Contraindications

KiddieGAIT and KiddieROCKER should not be used when patients present with:

- 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

When Genu-recurvatum cannot be orthotically managed (such as with insoles or wedges), COMBO (a knee orthosis attachment for ToeOFF and BlueROCKER) may be a suitable solution. Further information on COMBO is available at www.allardusa.com.

Note

Professionals selecting and/or fitting and customizing these orthoses 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 these instructions as well as risks associated with the unique attributes of the patient or the patient's caregiver circumstances.

The composite AFO's described in these instructions are **not** off-the-shelf orthoses. They require individual customization to each user, following the guidelines in these instructions.

Depending on the device that is chosen, the engineering, design, and materials used in these devices provide a prefabricated shell that is ready for trained orthotists to utilize their expertise to fabricate a device that will:

- A. allow normal functional biomechanics to occur during the gait cycle
- B. help prevent "foot slap" at initial contact
- C. provide M-L and A-P stability at mid-stance
- D. help propel the limb at terminal stance
- E. pick the toes up for clearance during swing phase
- F. control unstable proximal structures
- G. optimize patient comfort while optimizing the integrity and durability of the orthosis

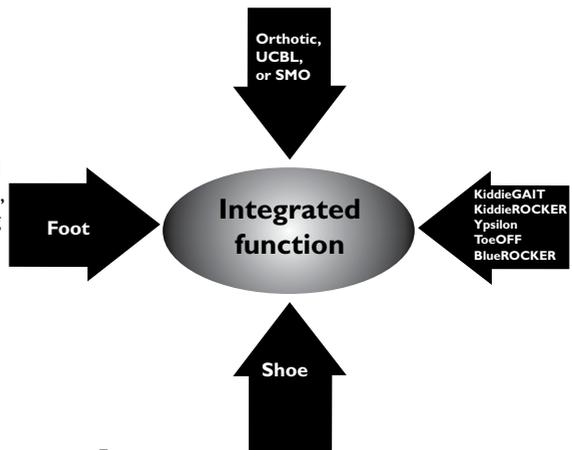
In other words, the orthotist's skill is required to provide as close to "normal" gait pattern as possible. The goal is not only to improve symmetry and function during gait, but also to prevent potential detrimental effects on the proximal joints and soft tissue structures in the biomechanical chain.

This manual starts and ends with patient assessment. Knowing both the functional deficits and biomechanics of each patient is critical to individually customize each orthosis for both fit and function following these instructions.

In-between pre- and post-fitting assessments, several steps are detailed to achieve the goals of optimizing function, comfort, and compliance while also optimizing the durability of the orthosis.



The customization of the orthosis to each user is a complex task of integrating four separate components into a single integrated functional unit. To do this, the correct model and size must be used, fit in the correct shoe, with the correct foot orthotic device. Fitting and alignment considerations will impact outcomes. Equally important, patient comfort issues will need to be addressed. The following sections of these instructions will cover these issues.



PATIENT ASSESSMENT

To obtain the best result using the most appropriate orthosis, it is important to follow the instructions in this booklet.

Intake Information

In addition to standard patient information, obtain and document the information used to determine the correct model, size, and modifications required to meet the prescription criteria and specific patient anomalies.

KiddieGAIT/KiddieROCKER

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 assessments to determine function, stability, and deficits in both open and closed chain.

Open Chain Biomechanical Assessment

- During this assessment, check for calcaneal ROM and whether calcaneal inversion "locks up" the foot and calcaneal eversion "unlocks" the foot.
- Given adequate ROM, check subtalar neutral to determine if the foot has a tendency towards pronation or supination.
- Rule out Hallux Rigidus (Hallux Rigidus can be managed with a foot orthotic on top of the ToeOFF footplate.)
- Check for callus formation and correlate callus findings to biomechanical assessment.
- Document all findings.

Barefoot Walking

This step is necessary to verify the open chain findings.

- Does the closed chain calcaneal ROM relate to the open chain findings?
- Does the mid-foot retain or lose its structural integrity as expected?
- Does the heel come off the ground as expected during the gait cycle or does it stay in contact too long?
- Are there any obvious proximal (knee or hip) deficits or compensations?

Document all findings.

Gait Assessment with Shoes (and existing device)

This step will provide information relative to the amount of support existing shoes (and AFO if used) provide during gait.

- Has heel lift timing been affected by footwear?
- Are proximal deficits or compensations the same, less or more?
- Is one limb in single limb stance for a shorter time than the other, giving the appearance of a limp?

Gait Capacity

Gather objective data on gait capacity while walking either with shoes and existing AFO, or just in shoes, after fitting the new orthosis to quantify functional outcomes. See page 18 for objective documentation protocols.

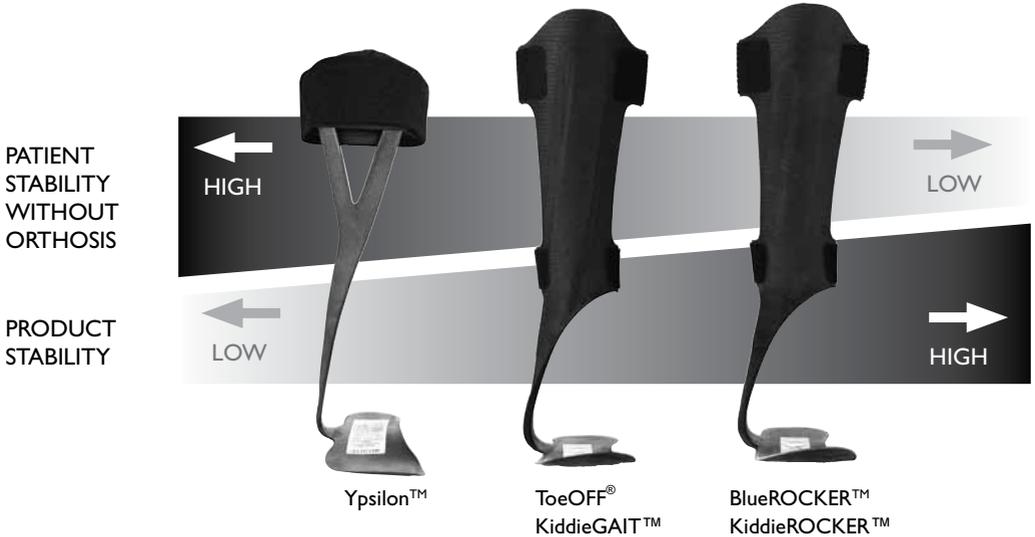


STEP 1

PRODUCT SELECTION

Ypsilon, ToeOFF, BlueROCKER, KiddieGAIT and KiddieROCKER are products that look very similar. However, they meet very different user needs. To determine which product is most suited for a specific patient, follow the steps given in this manual very closely.

The following scale correlates product rigidity to patient stability, when not wearing an orthosis.



Understand the orthotic principle engineered into each orthosis.

Ypsilon

For less involved cases of footdrop

Allows more medial, lateral and rotational ankle movements.

Long strut (leverage arm)

Allows orthosis to adapt to and move with the lower leg. Less resistance to ground reaction forces.

Strut extends lateral to instep.
Greater instep clearance.

Proximal ends of the "Y" provide the tibia fixation.

Tibia crest clearance.

ToeOFF KiddieGAIT

For moderate involved cases of footdrop

Mild to severe footdrop together with mild to moderate ankle instability.

Full coverage, anatomically shaped anterior tibia shell
Tibia stabilization and control.

Short strut "wraps" over instep.
Medial-lateral and rotation control of the foot and ankle complex.

BlueROCKER KiddieROCKER

For more involved cases of footdrop

Footdrop with multiple involvement, severe ankle instability and/or proximal weakness/deficits.

Full coverage, anatomically shaped anterior tibia shell
Tibia stabilization and control.

Short strut "wraps" over instep.
Medial-lateral and rotation control of the foot and ankle complex.

KiddieGAIT™ KiddieROCKER™

SELECTION OF INTERFACE/ORTHOTIC INTERVENTION

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

There should always be an interface added 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 leg length discrepancy.

Complex Involvement (more than footdrop):

KiddieGAIT and KiddieROCKER 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 in open chain, and allowed to go into controlled pronation during closed chain. 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.



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

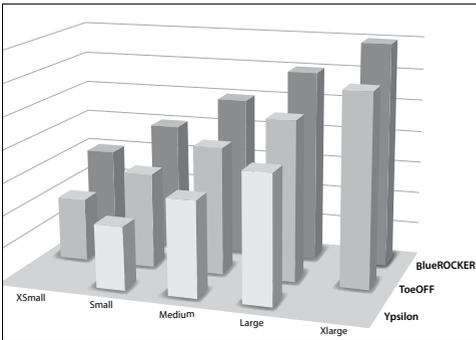
Low Tone (Hypotonia) & Pronation: Consider a Flexible Compressive SMO (such as SureStep™)

Consider Specific Patient Needs

The ToeOFF Family Products are all calibrated in their dynamics with Ypsilon being least rigid up to BlueROCKER/KiddieROCKER being the most rigid. For each version the dynamics are also calibrated from size XS, which is least rigid, to XL, which is most rigid. Flexibility increases as sizes decrease for appropriate response to lesser loads. Factor the dynamic response into the size selection. When making the choice of product and size, read pages 7-10 of these instructions for guidance. Take into consideration different aspects like spasticity, stability, balance, need for support, activity, lifestyle, body type and other factors. This should always be done on an individual basis with the fitter taking into consideration the unique situation and needs for the individual patient.

For example, based on footplate length in the sizing guide on page 19, a size medium may be determined to “fit” the patient. However, assessment of the patient’s individual situation and needs, can lead to the decision to use a size larger or smaller to better meet those needs.

Product Rigidity Graph Ypsilon, ToeOFF and BlueROCKER



Proximal Instabilities

As a general rule, the greater the proximal instability the more control is needed from the orthotic device. Examples include:

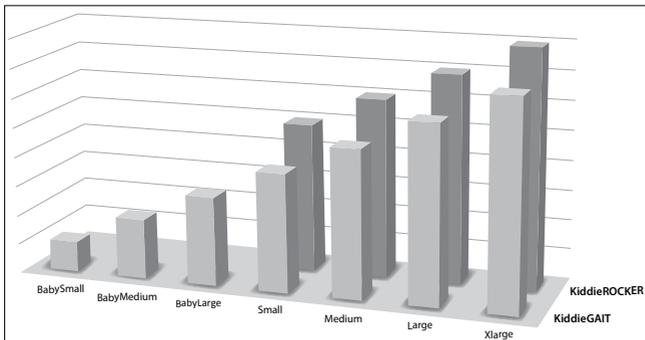
- excessive knee flexion secondary to weak M.Quadriceps to weak M.Soleus
- delayed knee extension secondary to weak M.Soleus
- knee hyperextension secondary to weak M. Gastrocnemius

In these cases, start with the ToeOFF/KiddieGAIT and move up to the BlueROCKER/KiddieROCKER and/or up one size for additional proximal control.

Initial Foot Length Sizing Table

The sizing table on page 19 is only a guide based on foot length and tibia height. Optimum size may be one size smaller or larger, depending on the criteria discussed above and on page 10.

Product Rigidity Graph KiddieGAIT and KiddieROCKER



Spasticity

The orthoses cannot fully control spasticity. However, the lightweight and energy reflecting capability may still offer significant benefits to the wearer that presents with this condition.

Ypsilon, ToeOFF and KiddieGAIT are preferred orthoses in cases of mild spasticity as defined in the paragraph below and then only if a tone reduction foot orthotic, UCBL, or SMO is used on top of the footplate.

BlueROCKER and KiddieROCKER are preferred orthoses in situations of moderate spasticity assuming that a tone reduction foot orthotic, UCBL, or SMO is used on top of the footplate.

The following is a guide for the functional assessment of degree of spasticity:¹

Mild: Allows patient to land on a stable calcaneus without excessive supination of the forefoot and then shift the body weight over the heads of the metatarsals, although during swing phase the foot assumes a varus or supinated posture. In other words, the calcaneus is able to evert at initial contact and invert before pre-swing.

Moderate: Causes the calcaneus to assume a position of varus with excessive supination at initial contact; however, during midstance, some pronation occurs and body weight can again be transferred normally across the forefoot. In other words, the calcaneus is able to pass through neutral into some degree of inversion during mid-stance.

Severe: Characterized by the foot and ankle being held in a position of equinus through stance so that body weight remains on the lateral aspect of the forefoot with little or no weight bearing through the heel or medial metatarsal heads. This varus position also persists throughout swing phase.

Flaccidity

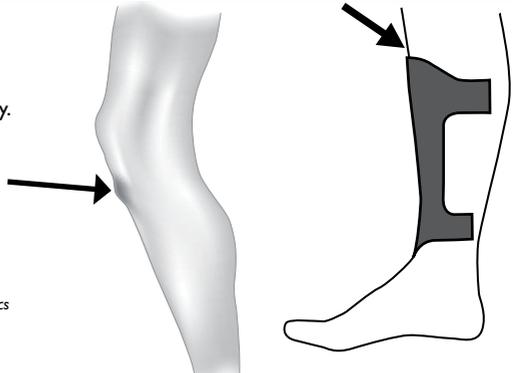
These individuals often become much more active with their new found "freedom" wearing this kind of orthosis. Patient instructions relative to stride length and toe walking up stairs are very important so these patients don't "ride" the orthosis into too much dorsiflexion. Increased flexibility in the orthosis may reduce the stress applied to it. It is recommended to consider a size smaller than indicated by the sizing guide and lengthen the footplate (as explained on page 13) to optimize the integrity of the orthosis.

Dorsiflexion Assist

The longer the footplate length, the greater the dorsiflexion assist. To reduce toe lift, select a smaller size. To increase toe lift, select a larger size. To increase dorsiflexion assist select the next larger size orthosis. This will provide less flexibility in the orthosis and increase the lever arm length of the footplate. To decrease the amount of dorsiflexion assist, select the next smaller size orthosis to provide greater flexibility in the orthosis and a shorter lever arm of the footplate.

Height Adjustment

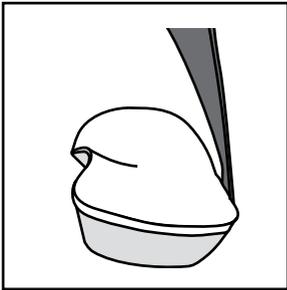
The upper section of the anterior shell can easily be trimmed down if it is interfering with Tibial Tuberosity. Trim with scissors and grind to a smooth surface.



References:

¹Shamp et al., "The Neurophysiological Ankle-Foot Orthosis", *Clinical Prosthetics and Orthotics*, 10 (1), pp. 15 - 23 ²Shamp, "Neurophysiologic Orthotic Designs in the Treatment of Central Nervous System Disorder", *Journal of Prosthetics and Orthotics*, Vol. 2, Num. 1, pp. 14-32.

To optimize gait and maximize product durability, the foot should be corrected to allow the calcaneus to move through neutral during the gait cycle. Maintaining the foot in "subtalar neutral" is not necessary. It is important to allow the calcaneus to move through neutral from inversion during swing to eversion during stance. Orthotic correction of the foot is very important with this family of devices. Over-pronation for example, can lead to excessive ankle dorsiflexion and internal tibial rotation which could combine to place undue stress on the lateral upright. There should always be an interface between the footplate and the foot.

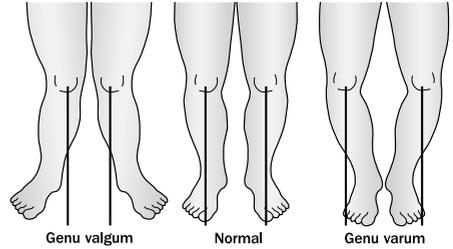


Pronation

If no other foot deformities exist, post the medial aspect of the calcaneus on top of the footplate to decelerate the pronation moment. If there are additional foot biomechanical abnormalities, an alternative may be to custom mold a corrective foot orthosis and use contact cement to adhere it into position onto the top of the footplate.

NOTE

If the patient has been in a posterior designed device for some time, be aware of the potential for mid-foot hyper-mobility. Because ankle dorsiflexion is biomechanically linked to calcaneal eversion, and posterior devices limit calcaneal eversion, very often the dorsiflexion will occur at the midfoot instead of the ankle, causing hyper-mobility at the midfoot. In these cases, it would be appropriate to consider a biomechanical orthotic that provides some heel lift and midfoot support to normalize foot structures.



Frontal Plane Alignment

- With the patient standing safely in parallel bars, check their alignment with either a plumb line or square.
- Make accommodation on plantar surface of foot orthotics and/or footplate using crepe or cork.
For KiddieGAIT/KiddieROCKER see page 8.

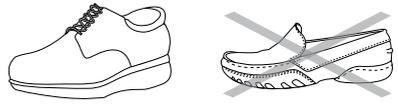


Supination

If no other foot deformities exist, post (wedge) the anterior lateral aspect of the orthotic shell to accelerate pronation. Be aware of forefoot involvement, and check for forefoot valgus along with a plantar-flexed Hallux. If these or additional foot deformities exist, custom mold a corrective device with forefoot lateral posting and a first ray cut-out and use contact cement to adhere it into position onto the top of the footplate.

Important

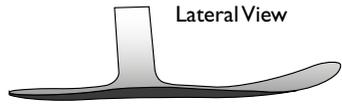
If using inlays, shoe inserts, or other foot supports; make appropriate adaptations for the opposite foot to keep the pelvis level.



- Firm heel counter, for proper control of the rear foot.
- The foot and the orthosis should be secured by the shoe.
- Rocker-type sole at toe end for smoother transition from 2nd to 3rd rocker.
- Use shoes that allows for 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 with modifications.
- Avoid pressure from the upper leather on the upper side of the foot.

Shoe Selection

Proper footwear is critically important to the overall success of the new orthosis. Think of shoes as acting as the "exoskeletal" device for the "endoskeletal" orthosis. As such, shoes should be well constructed to include:



Accommodate Brace to Shoe

Always accommodate brace to shoe - consider in cases of extreme stress, e.g., footdrop one side and trans-tibial amputation other side.

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.

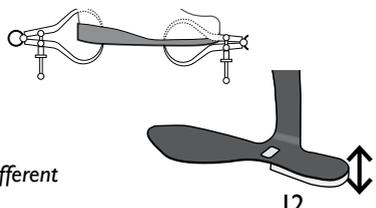
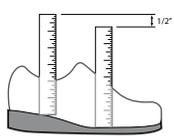
When necessary, fill in the void following Step A and B.

Step A. Measure the heel rise of the shoe from the inside of the shoe.

Step B. Glue crepe, cork, or other high durometer material to the plantar surface to make up the difference. Example: Heel measurement equals 3/4" (19 mm), then subtract the ball measurement of 1/4" (6.3 mm), which makes the heel rise of the shoe 1/2" (12.7 mm). If using a size Large brace, which has a 5/8" (16 mm) heel rise built into the product, add 1/8" (3.2 mm) to the plantar surface. It is recommended to start with a thicker material and grind it down, tapering the anterior section down to zero and the apex being under the heel.

Heel Height

To maintain the proper tibial shank angle, the heel rise that is set in each product varies and is listed under the product name on page 19. The brace should be matched up to the heel rise in the patient's shoe. However, in the ToeOFF/BlueROCKER Custom there is no set heel rise, it can vary depending what was written on the order form.



Once the orthosis is customized to this initial pair of shoes, instruct the patient that every pair of shoes to be worn should be brought in and checked by the orthotist to make sure the shoe is properly constructed and has the appropriate toe-to-heel height differential. Failure to do so could lead to unstable gait, destructive hyperextension moments at the knee or delamination.

See heights for the different products on page 19.

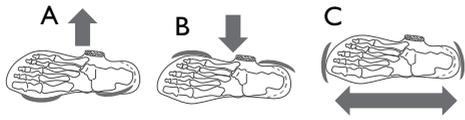
STEP 5 PROPER ALIGNMENT

Alignment of the orthosis to the tibia could be compared to the importance of the anatomical alignment of a prosthetic leg. This alignment affects both comfort and gait pattern. It also controls the critical alignment of the lateral strut to appropriate structures at the mid-foot. Having proper alignment will therefore optimize gait outcomes and serve to increase product durability.

Strut Alignment

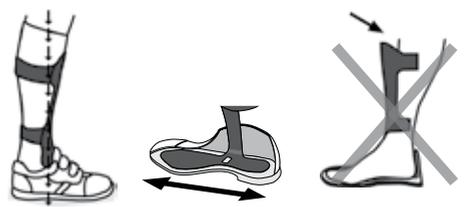
The strut should be located just posterior to the 5th metatarsal head and extend upward without touching the tibia. Shift the footplate forward or backward to achieve this proper alignment.

- a) Shift the footplate laterally to keep 5th MTP free from pressure.
- b) Shift the footplate medially if too far from 5th MTP.
- c) Shift the footplate forward or backwards to correct position and to avoid contact with tibia crest.



Tibia Alignment

Assure even pressure distribution along the tibial crest. To determine neutral position (ankle at 90°) a plumb-line should drop just behind the knee axis and hit the floor at the cuboid bone. Have patient stand on footplate (without shoe) and shift the footplate forward or backward to locate ideal alignment of the orthosis for even pressure distribution from top to bottom of the anterior shell. If optimum tibia plate alignment results in the footplate extending beyond the toes or the heel, use a marking pencil to trace that end of the foot. Follow instructions below for "Changing Footplate Length".



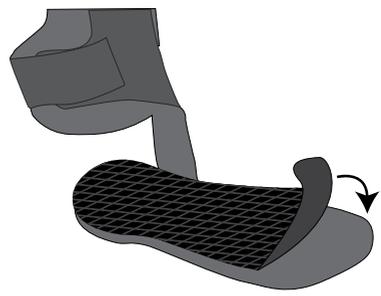
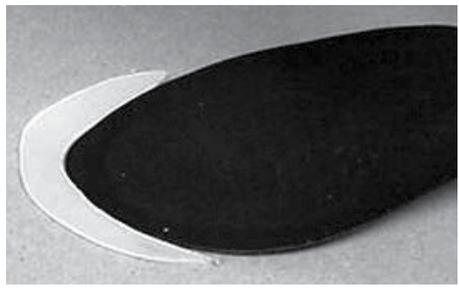
Changing Footplate Length

To shorten the footplate, cut or grind off excess length. Be certain to buff the edges to eliminate sharp edges. To eliminate any remaining rough edges it may be necessary to cover the footplate with soft leather.

To lengthen the footplate, cut a crescent shape out of 1.5 mm (1/16") plastic so the concave side fits the contours of the footplate and the convex side fits the margin of the inside of the shoe. Cover the entire surface with shoe leather using contact cement to hold the components in place. This is very important to prevent the footplate from shifting in the shoe.

Plastic Orthotic, SMO, UCBL Intervention

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



To encourage more knee extension

The anterior design of the ToeOFF family of products will influence the knee extension moment. To encourage even more extension and minimize the flexion forces, decrease heel height. This shifts the proximal section of the anterior shell backward to encourage knee extension earlier in the gait cycle. Start with as little as 1/16" (1.6 mm) decrease and gradually continue to decrease as necessary. Make appropriate adaptations for the opposite foot to keep the pelvis level.

To encourage more knee flexion

To encourage more knee flexion and delay the extension moment, increase heel height or add wedging underneath the heel portion of the footplate. This shifts the proximal section of the anterior shell forward to encourage more knee flexion. Start with as little as 1/16" (1.6 mm) wedge and gradually continue to increase as necessary. Make appropriate adaptations for the opposite foot to keep the pelvis level.

Remember that these changes may affect shoe selection!

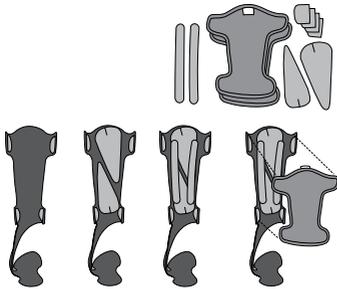
These orthoses should never be re-shaped by application of heat. Doing so will cause delamination and negatively alter the dynamics of the orthosis.

Open Channel



Pressure on tibia

ToeOFF, BlueROCKER and KiddieGAIT/KiddieROCKER should always have padding on the inside of the anterior shell before delivery to the patient. Pad both laterally and medially, leaving an open channel for tibial crest relief.



SoftKIT™

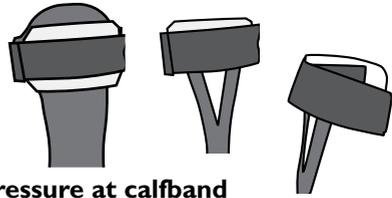
SoftKIT is a pre-packaged kit, consisting of two pre-cut vertical neoprene pads (not included in the KiddieGAIT/KiddieROCKER SoftKIT) to form the channel for tibia relief, self-adhesive Velcro, plus two fabric pads (an extra for laundering) to simplify and expedite the tibia padding process.

ComfortKIT™ and SoftSHELL™ are additional options for easy, simple and quick padding.



Pressure over instep

Add padding to the distal medial aspect of the lateral strut, see page 11, instructions for supination, or if necessary shift orthotic medially. This will shift the foot medially to relieve pressure from the distal section of the anterior plate. For Ypsilon - also review alignment on page 13.



Pressure at calfband

For mild pressure, angle the strap slightly to fit the shape of the calf, or add 1/8" (3 mm) soft foam padding to the strap. The pad should be slightly wider than the width of the strap. If discomfort persists or is moderate to severe, check alignment as described on page 13.



Apply Ypsilon™ Pad

- Flex the padded plastic interface and attach to the Ypsilon cover to allow approximately a 5mm (3/16") gap between the center of the tibia pad and the brace.
- Adjust the position of the pad (slightly medial or lateral of center) to re-distribute any uncomfortable pressure.
- Instruct the patient how to re-position the Ypsilon padding after washing.



Damage to shoe interior

There should always be an interface between the footplate and the foot. The thinness of the orthosis allows it to be worn in "normal" shoes without increasing shoe size. Some brands of shoes, however, provide minimal, if any, reinforcement where the upper joins the sole. The orthosis' thin carbon composite may cause damage to these shoes. Either cover the footplate with thin shoe leather or use contact cement to adhere a protective covering around the peripheral edge of the orthosis footplate to prevent this damage. The lateral strut may also damage the top border of the shoe. Use moleskin or other thin padding material to prevent this damage.



Patient education is critically important to the overall success of any orthotic device, and the ToeOFF Family Products are no exceptions. Great skill and care on the part of the orthotist can be over-ridden by patient non-compliance. "User Instructions" are included with each orthosis. Review these instructions with the patient or caregiver and give them to him or her to take home for continued reference.

Do's

- Use hand support ON Sit-to-Stand
- Wear SOCKS
- Use SoftKIT or ComfortKIT
- Use interface on footplate
- Inspect brace on a daily basis
- Check SKIN on a daily basis
- Wear recommended footwear

Don'ts

- Stairs - Ball of Foot
- SQUATS - not at all

Make sure patient signs the USER Instruction, make a copy for your patient file, & return original to patient!

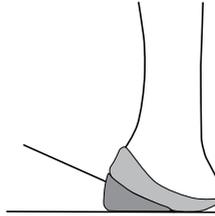
DIABETIC FOOT

Occasionally the orthosis may be indicated for use on a diabetic foot with footdrop secondary to neurological deficit. If used in these cases, significant precautions must be taken to insure that there is even pressure distribution over all plantar and proximal contact areas, and that any edge or ridge pressure is eliminated.

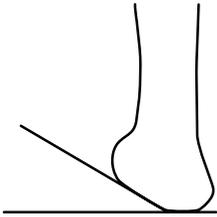
Partial Foot Amputations, using BlueROCKER

It is generally acceptable to use a carbon fiber footplate if the amputation is at the level of the toes or distal metatarsals. If the transmetatarsal amputation was at the mid or proximal metatarsal level, or more proximally up to Lisfranc or Chopart amputations, the additional lever arm provided by the anterior shell of these orthoses may help to normalize gait. If the orthosis is appropriate, a custom filler prosthesis should be integrated with a custom foot-bed for optimum pressure distribution. A Plastazote or similar interface between the residual foot and the filler prosthesis is generally recommended.

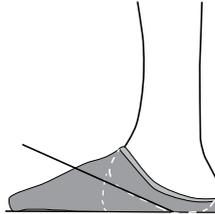
4. Fabricate the socket to optimize pressure distribution. The rear foot part of the socket should allow the calcaneus to move through neutral up to 20° of inversion during swing and up to 10° of eversion during stance. Post as you would for a biomechanical foot orthotic for over-pronation or excessive supination.



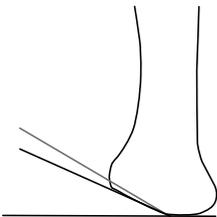
1. Do a closed chain assessment of the sagittal plane ROM of the ankle. Normal sagittal plane calcaneal angle should be in the range of 40°.



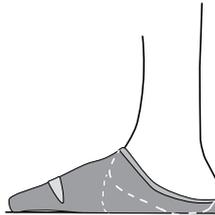
5. Integrate the socket and wedge into the partial foot, making it the same size (length and width) and arch height as the contralateral foot.



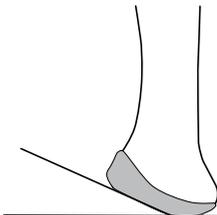
2. Position and cast the residual foot at maximum dorsiflexion less 10°, or at 40°, whichever is greater. When possible, this allows the ankle to be restored to functional ROM during ambulation. Be aware that an acquired limb length discrepancy may exist if the angle is less than 40°.



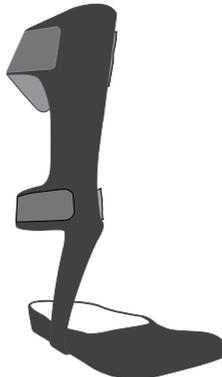
6. Add a break point anterior to the socket or at the shoe break point so that the filler prosthesis does not press into the socket during the propulsion phase of gait.



3. Mount the socket on a wedge that will maintain the functional ROM casting angle.



7. Adhere the completed device on a BlueROCKER, assuring proper alignment of the foot to the anterior shell. With equal pressure distribution along the entire length of the shell, mark the location of the partial foot on the footplate and adhere at that location.



POST-FITTING GAIT ASSESSMENT

Gait assessment after fitting is important to determine if desired outcomes have been achieved. It is also important to determine that beneficial influences are being exerted proximally. This is also the time to observe compliance to the instructions already given to the patient during patient education.

Observe differences between gait with orthosis and previous gait.

Has heel lift timing been normalized, or is heel lift still delayed?

If still delayed, consider heel lift with firmer midfoot support.

Have proximal deficits or compensations been normalized?

Adjustments in posting or lifts may be needed to influence frontal and/or sagittal plane deviations from normal.

Gather and document objective data in the same manner that initial objective data was obtained. Compare outcomes to the initial data and note variances.



OBJECTIVE DATA COLLECTION

Objective data can be collected with a 10 m (30') runway and a stopwatch. Ten meters (30') is the minimum length required for valid repeatable data.

Ask the patient to walk the distance up and back two or three times. Time each trial and count the number of steps taken to cover the 10 m (30') distance. Document the findings. Then calculate:

Velocity (meter (feet) per second)
= distance (10 m or 30') / time (seconds)

Cadence (steps per second)
= number of steps / time (seconds)

Stride length
= distance (10 m or 30') / number of steps

Single limb stance as a percentage of the gait cycle is not quantifiable using only these tools. Do note, however, the relative parity between single limb stance with the orthosis as compared to their previous condition. Generally one can observe that the appearance of a limp will diminish with the use of the orthosis.

Initial Foot Length Sizing Table

These sizing tables are only a guide. Optimum size may be one size smaller or larger, depending on the criteria discussed on pages 9 and 10.

Ypsilon

Size	Height	Footplate Length	Heel Height
S	13" (330mm)	9" (230mm)	3/8" (10mm)
M	13 3/8" (340mm)	9 5/8" (245mm)	3/8" (10mm)
L	13 3/4" (350mm)	10 5/8" (270mm)	7/16" (12mm)

ToeOFF, BlueROCKER

Size	Height	Footplate Length	Heel Height
XS	14" (360mm)	8 1/4" (210mm)	7/16" (12mm)
S	15" (380mm)	9" (230mm)	7/16" (12mm)
M	16" (405mm)	9 5/8" (245mm)	9/16" (15mm)
L	17" (430mm)	10 5/8" (270mm)	5/8" (16mm)
XL	17" (430mm)	11 1/4" (285mm)	5/8" (16mm)

ToeOFF Short

Size	Height	Footplate Length	Heel Height
S	11 5/8" (295mm)	8 1/2" (215mm)	1/4" (7mm)
M	12 5/8" (320mm)	9 1/4" (235mm)	1/4" (7mm)
L	13 3/8" (340mm)	10" (255mm)	1/4" (7mm)

KiddieGAIT, KiddieROCKER*

Size	Height	Footplate Length	Heel Height
BabySmall	6" (150mm)	4 1/4" (110mm)	1/4" (7mm)
BabyMedium	7" (180mm)	5" (125mm)	1/4" (7mm)
BabyLarge	7 3/4" (200mm)	5 1/2" (140mm)	5/16" (8mm)
*S	8 5/8" (220mm)	6 1/4" (160mm)	5/16" (8mm)
*M	10 1/8" (257mm)	7 1/16" (180mm)	3/8" (9mm)
*L	11 5/8" (295mm)	7 7/8" (200mm)	3/8" (9mm)
*XL	12 3/8" (315mm)	8 1/4" (210mm)	3/8" (9mm)

*KiddieROCKER is only available in sizes Small, Medium, Large and XLarge.

ToeOFF and BlueROCKER Custom are not included in the charts above as the height, foot plate length and heel height is based on the individual requirements.



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KiddieGAJT™, KiddieROCKER™, ToeOFF®, BlueROCKER™
Patent no: 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, ATE28918.©

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Patent no: Ypsilon: GE60208889.5-08, GB1379201, IT1379201, US6887213©

1202010 Camp Scandinavia January 2013©

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