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YPSILON™ ToeOFF® BLUEROCKER™

CLINICAL MANUAL

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CE

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INTRODUCTION

The Composite AFO's described in this Clinical Manual are **not** off-the-shelf orthoses. They require individual customization to each user, following the guidelines in this Clinical Manual.

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:

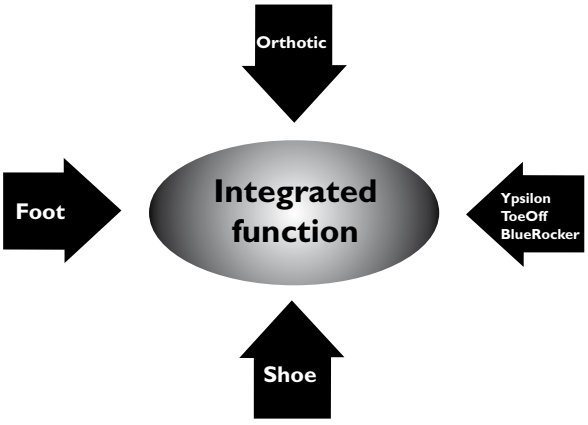
A. allow normal functional biomechanics to occur during the gait cycle
B. help prevent "foot slap" at initial contact
C. provide M-L and A-P stability at mid-stance
D. help propel the limb at terminal stance
E. pick the toes up for clearance during swing phase
F. control unstable proximal structures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

In between pre- and post-fitting assessment, 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. On top of all that, fitting and alignment considerations will impact outcomes. Finally patient comfort issues will need to be addressed. The folllowing sections of this manual will cover these issues.



INDICATIONS & CONTRAINDICATIONS

Intended use and Indications
ToeOFF, Ypsilon and BlueRocker are intended to support a foot when the ability to actively dorsiflex is reduced or completely lost due to conditions such as Stroke, Multiple sclerosis, Post polio syndrome, Muscular dystrophy, Spinal cord injuries, Traumatic brain injuries, Guillian-Barre syndrome, Charcot-Marie-Tooth, Myelomeningocele or Cerebral palsy. ToeOFF and BlueRocker are preferred when footdrop is combined with ankle instability. These two orthoses can also be used for partial foot amputations, most proximal level is Chopart.

Contraindications
ToeOFF, Ypsilon and BlueRocker should not be used by patients with leg ulcers or in cases where moderate to severe edema is present, or where moderate or severe foot deformities are evident. ToeOFF and Ypsilon should not be used when severe spasticity is present.

Limitations
Genu-recurvatum that can not be orthotically managed. Special precautions should always be taken for patients with reduced feeling in the lower extremities. Daily monitoring of skin condition is advised.

Note I
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 this instruction as well as risks associated with the unique attributes of the patient or the patient's caregiver circumstances.

Note II
Additional usage has been reported where clinical professionals have used these orthoses as part of the treatment of the following soft tissue injuries: Posterior tibial tendon dysfunction, Achilles tendonitis and Shin splints. Additional usage has also been reported where these orthoses have been used as a complement in treatment after Triple arthrodesis surgery.

Camp Scandinavia does not have any clinical evidence for the additional usage and they are not included in the stated intended use.

APPLICATIONS

Ypsilon
- Partial footdrop
- Weak dorsi-flexors
- No or mild spasticity
- Stable ankle
- Sensory Nerve Injury

ToeOFF
- Complete footdrop
- Mild proximal deficit
- Limb proprioception deficit
- Mild to moderate spasticity
- Partial foot amputations

BlueRocker
- Complete footdrop
- Weakness or impairment in multiple leg muscle groups
- Impaired balance
- Moderate proximal deficits
- Moderate spasticity
- Partial foot amputations
- Limb proprioception deficit

PATIENT ASSESSMENT

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

Intake information

In addition to usual intake information, obtain and record the information noted below. This will be important in determining the correct model and size.

-Patient height and weight
-Body type (thin? stocky? obese?)
-Proximal deficits
-Activity level
-Foot length

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 subtalor neutral to determine if the foot has a tendency towards pronation, or supination. Also rule out Hallux Rigidus. Then 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 exisitng 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?

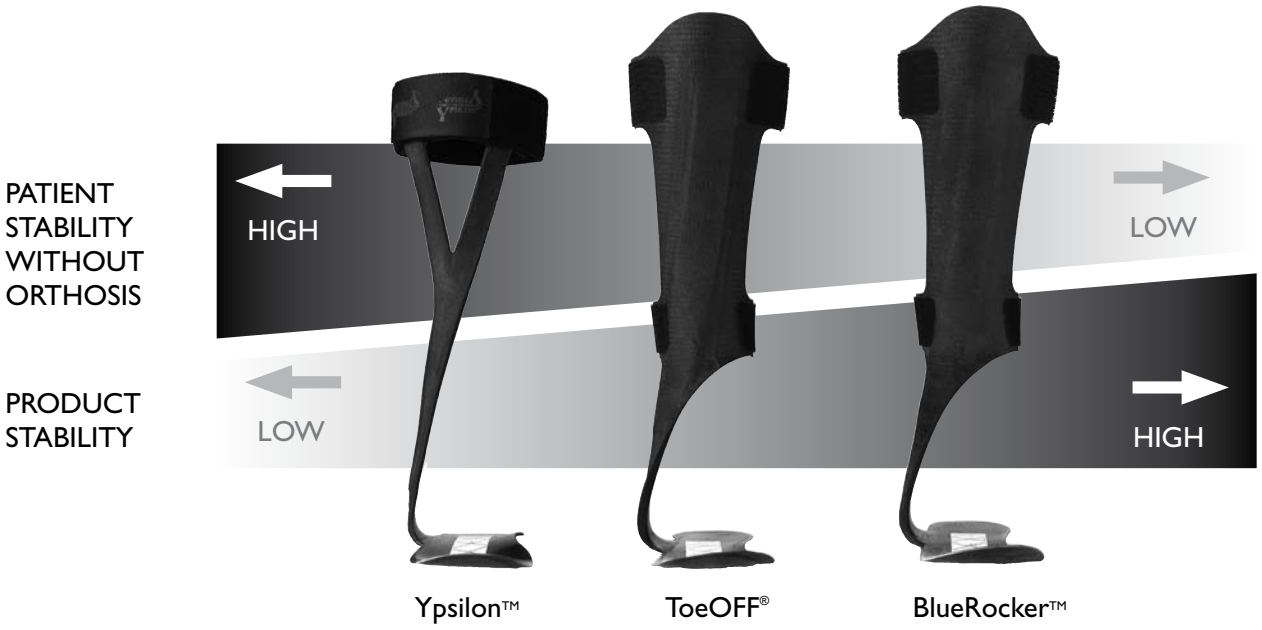
Gait capacity

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 19 for objective documentation protocols.

STEP 1 PRODUCT SELECTION

Ypsilon, ToeOFF and BlueRocker 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

- **Three point fixation/force principle.**
  Plantarflexion control while allowing natural 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. Allows more medial, lateral and rotational ankle movement.
- **Proximal ends of the "Y" provide the tibia fixation.**
  Tibia crest clearance.

ToeOFF

- **Moderate four point fixation/ force principle.**
  Lower leg stabilization and control and mild to moderate proximal anatomy control.
- **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

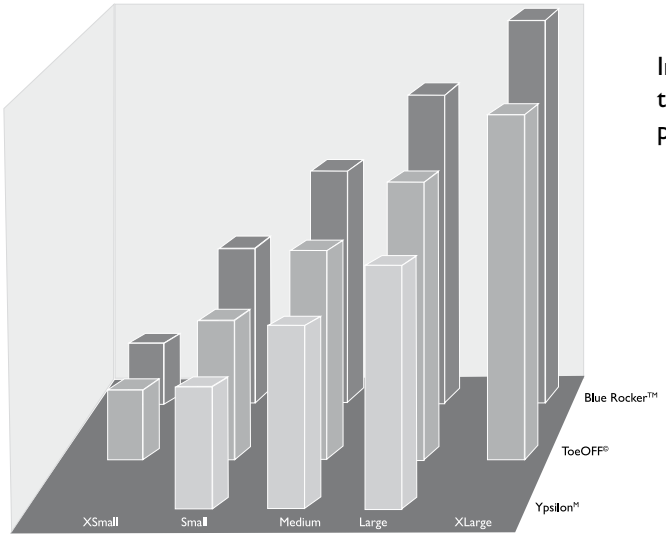
- **Four point fixation/force principle.**
  Rigid four point lower leg stabilization and control.
- **Full coverage, anatomically shaped anterior tibia shell.**
  Tibia stabilization and control.
- **Short strut "wraps" over instep.**
  Maximum medial-lateral and rotation control of the foot and ankle complex.
- **Maximum stability in A-P and M-L directions.**
  Superior stability for users who cannot find stance stability.

SIZE SELECTION STEP 2

Consider specific patient needs

The Ypsilon, ToeOFF and BlueRocker are all gradated in their dynamics with Ypsilon being less rigid up to BlueRocker being the most rigid. For each version the dynamics are also gradated from size XSmall being less rigid to the XLarge being the most rigid. Flexibility increases as sizes decrease for appropriate response to lesser loads. Factor the dynamic response into the size selection. For example, if a size medium would be appropriate according to the sizing guide, but the patient is unusually heavy for that shoe size, you may want to select a size larger and shorten the footplate to accommodate the shoe, and the tibia height if necessary to accommodate patient leg length.

Product Rigidity Graph



Patient Activity Level

If the patient is very active, particularly if lifestyle demands excessive dorsiflexion (travel up-down stairs frequently, occupation requires frequent driving, etc.) optimum flexibility may be a benefit. By the sizing guide, a size large may seem appropriate but the size medium offers more flexibility. For issues of product integrity, it may be more appropriate to select a size medium.

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

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

Initial Foot Length Sizing Table

This sizing table 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 pages 9 and 10.

	TOEOFF, FANTASY, BLUEROCKER		YPSILON		TOEOFF SHORT	
Size	**Height**	**Footplate Length**	**Height**	**Footplate Length**	**Height**	**Footplate Length**
XS	14” (360mm)	8 1/4” (210mm)	N/A	N/A	N/A	N/A
S	15” (380mm)	9” (230mm)	13” (330mm)	9” (230mm)	11 5/8” (295mm)	8 1/2” (215mm)
M	16” (405mm)	9 5/8” (245mm)	13 3/8” (340mm)	9 5/8” (245mm)	12 5/8” (320mm)	9 1/4” (235mm)
L	17” (430mm)	10 5/8” (270mm)	13 3/4” (350mm)	10 5/8” (270mm)	13 3/8” (340mm)	10” (255mm)
XL	17” (430mm)	11 1/4” (285mm)	N/A	N/A	N/A	N/A

Spasticity

The orthosis cannot control spasticity. However, the lightweight and energy rebounding capability may still offer significant benefits to the wearer that presents with this condition. The Ypsilon should only be used in cases of very minor spacticity. The ToeOFF can be used if there is mild spasticity as defined in the paragraph below and then only if a tone reduction foot orthotic is used on top of the ToeOFF footplate. The BlueRocker may be used in situations of moderate spasticity assuming that a tone reduction foot orthotic is used on top of the BlueRocker footplate.

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

***Minimal**: Allows patient to land on a stable calcaneous 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 calcaneous is able to evert at initial contact and invert before pre-swing.*

***Moderate**: Causes the calcaneous 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 calcaneuos 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 the 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 persists throughout swing phase also.*

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.

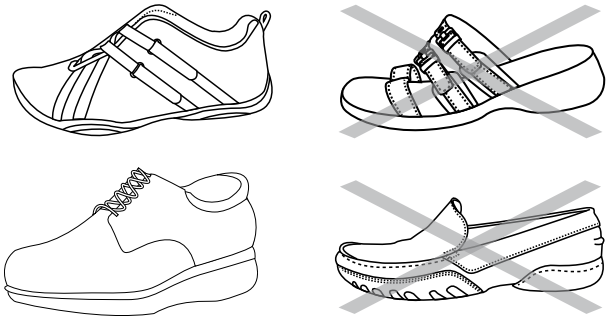
ToeOFF FAMILY PRODUCT SELECTOR GUIDE

CONDITION	Ypsilon	ToeOFF	ToeOFF + 1 size	Blue Rocker	Custom AFO	KAFO
Footdrop						
Mild	●					
Complete		●	●	●		
ML Stability						
Stable	●	●	●	●		
Unstable		●	●	●		
Weight						
Thin-avg.	●	●	●	●		
+ 40 lbs.			●	●		
+ 80 lbs.				●		
ROM						
Normal	●	●	●	●		
Hyper/hypo			●	●		
Proximal deficit						
None	●	●	●	●		
Mild		●	●	●		
Moderate			●	●		
Severe						●
Spasticity						
None	●	●	●	●		
Mild		●	●	●		
Moderate			●	●		
Severe					●	
Deformity/Edema						
None	●	●	●	●		
Mild		●	●	●		
Moderate					●	
Severe					●	
Muscle deficit						
Balanced	●	●	●	●		
Unbalanced				●		
Partial foot amp.						
Toe		●				
Transmet			●	●		
Lisfrank				●		
Chopart				●		
Activity level						
Household	●	●	●	●		
Community	●	●	●	●		
Active*		●	●	●		

** Consider downsizing 1 size*

Note: The information shown in this table is available in an easy-to-use slide chart and we will be pleased to send you one at no charge upon request.

STEP 3 SHOE SELECTION & HEEL HEIGHT



Lateral Views

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:

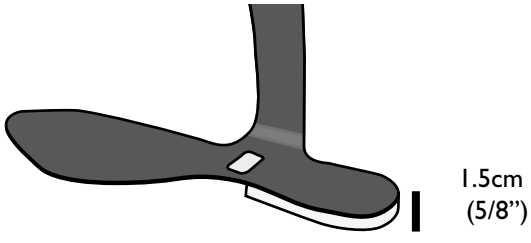
- Firm heel counter, for proper control of the rear foot.
- The foot and the orthosis should be secured by the shoe.
- Rocker-type sole at toe end for smoother transition from 2nd to 3rd rocker.
- Laced, for easier donning and doffing, and to allow adjustable compressive support at mid-foot.
- Rubber sole, to minimize the chance of slipping on wet surfaces.
- Removable insole, to allow space for the footplate with modifications.
- 1.5 cm (5/8 inches) toe-to-heel height differential, as a starting point to control the knee extension moment.
- Avoid pressure from the upper leather on the upper side of the foot, especially when using BlueRocker.

ACCOMODATE BRACE TO SHOE

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

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.

2) Laminate ¼" 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.



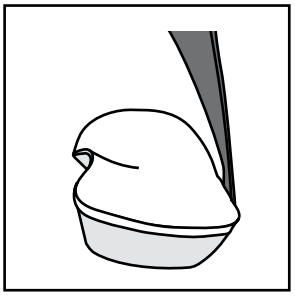
Heel height

These orthoses are fabricated to accommodate ap-prox- imately 1.5 cm (5/8") heel height. If the shoe has a higher or lower heel, add appropriate heel wedge or reduce the heel height accordingly. To assure optimum gait pattern, be certain to modify both shoes in the same manner to keep the pelvis level.

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 or destructive hyperextension moments at the knee.

CUSTOMIZE TO FOOT STEP 4

To optimize gait and maximize product durability, the foot should be corrected to allow the calcaneous to move through neutral during the gait cycle. Maintaining the foot in "subtalor neutral" is not necessary. It is important to allow the calcaneous 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. At a very minimum, we recommend a relatively firm prefabricated orthotic shell be used on top of the footplate.



Pronation

If no other foot deformities exist, post the medial aspect of the calcaneous 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 rubber 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.

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 plantarflexed 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 rubber cement to adhere it into position onto the top of the footplate.

Accommodation of other foot orthotics

Use rubber cement to adhere metatarsal pads, arch supports, pads for posting, etc. to the top of the footplate. If the patient already has a custom molded foot orthotic, it also can be adhered to the top of the footplate using rubber cement.

Important

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

STEP 5 PROPER ALIGNMENT

Thermoset Hybrid Compound
- Do not heat
- Relieve pressure point using foam padding
- Do not drill into material

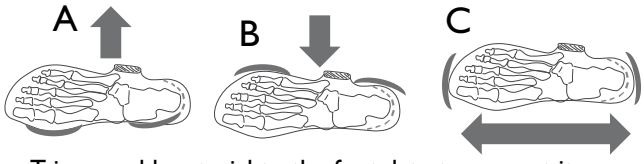
When Grinding/Cutting
- Protect the eyes
- Cover the nose and mouth
- Do not grid/cut into Carbon or Kevlar
- Do not overheat the composite

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.

Tibia Alignment for Ypsilon™:

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.

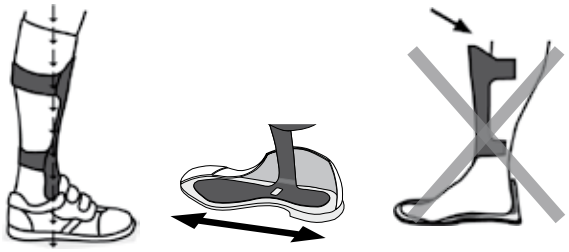
a) Shift the footplate laterally to keep 5th MTP free from pressure.
b) Shift the footplate medially if too far from 5th MTP.
c) Shift the footplate forward or backwards to correct position and to avoid contact with tibia crest.

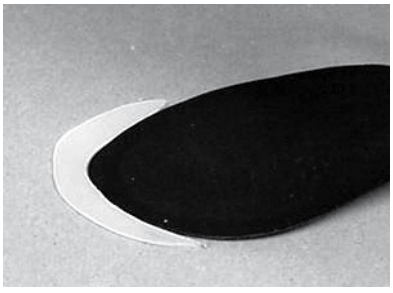


Trim or add material to the footplate to prevent it from sliding in the shoe and losing proper alignment.

Tibia Alignment for ToeOFF® and BlueRocker™

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, using a marking pencil to trace that end of the foot. Follow instructions below for "Changing footplate length". Then, add leather or rubber to extend the length at the heel and to prevent the footplate from shifting in the shoe.





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.

PROXIMAL CONTROL

STEP 6

To encourage more knee extension

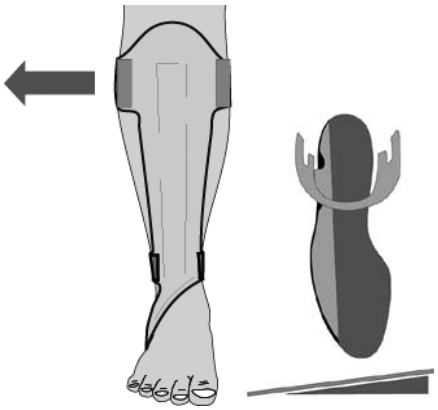
The anterior design of theToeOFF® family of products will influence the knee extension moment. To encourage even more extension and minimize the flexion forces, decrease heel height. This shifts the proximal section of the anterior shell backward to encourage knee extension earlier in the gait cycle.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

To encourge more knee flexion

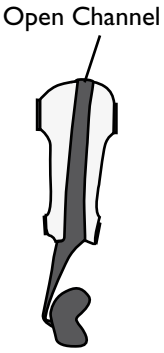
To encourage more knee flexion and delay the extension moment, increase heel height or add wedging underneath the heel portion of the footplate. This shifts the proximal section of the anterior shell forward to encourage more knee flexion. Start with as little as 1/16" wedge and gradually continue to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

To influence towards knee valgum

To apply an influence towards increased valgum forces, wedge the bottom of the footplate on the lateral side.

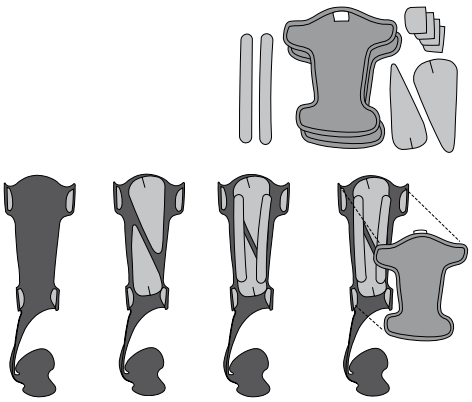


These orthoses should never be re-shaped by application of heat. Doing so will cause delamination and negatively alter the dynamics of the orthosis.



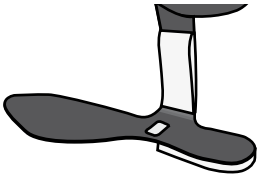
Pressure on the tibia

Patient Comfort
ToeOFF® and BlueRocker™ 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 pads to form the channel for tibia relief, self-adhesive Velcro, plus two terry cloth liners (an extra for laundering) to simplify and expedite the tibia padding process.
ComfortKIT™ and SoftSHELL™ are ready made options for easy, simple and quick padding.

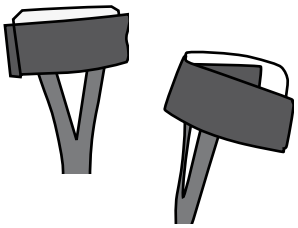


Pressure over instep for ToeOFF® and BlueRocker™

Add padding to the distal medial aspect of the lateral strut. 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 ToeOFF® and BlueRocker™

For mild pressure, add 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.



Pressure at calfband for Ypsilon™

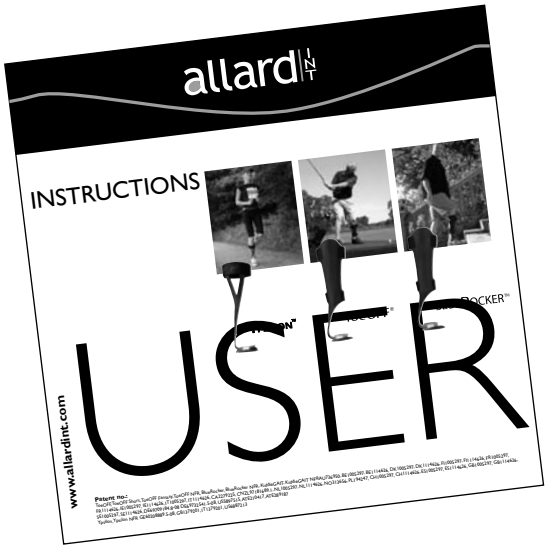
Angle the straps to fit the shape of the calf.
Add 3 mm soft foam padding to the strap.

Damage to shoe interior

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 rubber 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

STEP 8



Patient education is critically important to the overall success of any orthotic device, and the Ypsilon, ToeOFF and BlueRocker 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 and give to him or her to take home for continued reference.

User instructions are included with each product. It can also be down loaded from allardusa.com. Extra copies can be ordered from Allard USA.

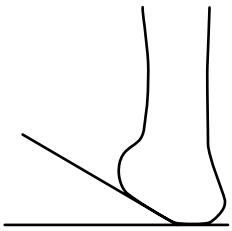
DIABETIC FOOT

Occasionally the orthosis may be indicated for use on a diabetic foot with footdrop secondary to neurological insult. 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.

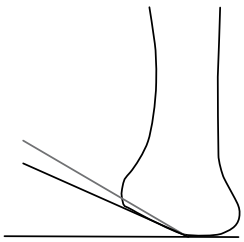
For footdrop conditions, compliance to the protocols in this manual are mandatory. In addition, it is mandatory that a custom foot orthotic be created to allow maximum pressure distribution on the plantar surfaces. This may necessitate a therapeutic depth shoe, depending on the thickness of the orthotic. All other fitting guidelines must be stringently adhered to. Be aware of the upward curvature of the toe section of the footplate. Be certain there is not any pressure on the dorsal surface of the toes or forefoot.

Forefoot Amputations

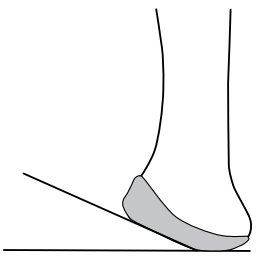
It is generally acceptable to use a carbon fiber footplate if the amputation is at the level of the toes or distal metatarsals. If the transmetatarsal amputation was at the mid or proximal metatarsal level, or more proximally up to Lisfranc or Chopart amputations, the additional lever arm provided by 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 silicone interface between the residual foot and the filler prosthesis is generally recommended.



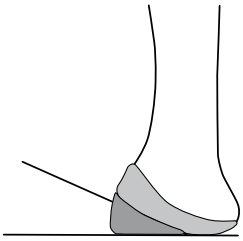
1. Do a closed chain assessment of the sagittal plane ROM of the ankle. Normal sagittal plane calcaneal angle should be in the range of 40°.



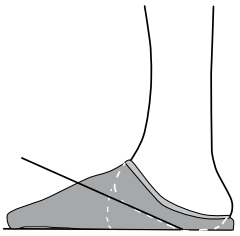
2. Position and cast the residual foot at maximum dorsiflexion less 10°, or at 40°, whichever is greater. This allows the ankle a functional ROM during gait. Be aware that an acquired limb length discrepancy may exist if the angle is less than 40°.



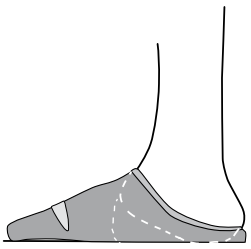
3. Mount the socket on a wedge that will maintain the functional ROM casting angle.



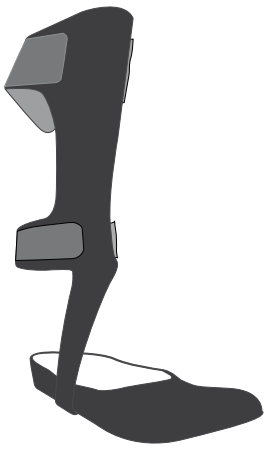
4. Fabricate the socket to optimize pressure distribution. The rear foot part of the socket should allow the calcaneous to move through neutral up to 20° of inversion during swing and up to 10° of eversion during stance. Post as you would for a biomechanical foot orthotic for over pronation or excessive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



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



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.



7. Adhere the completed device on a BlueRocker, assuring proper alignment of the foot to the pre-tibial 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 in patient education.

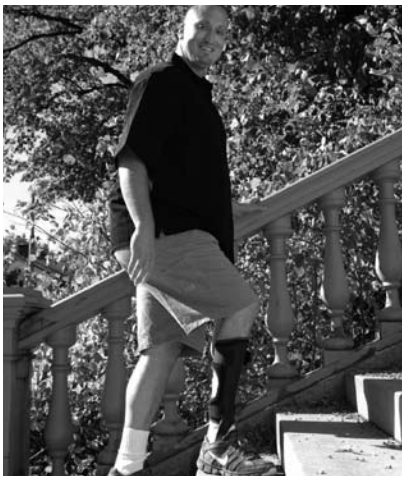
Observe differences between gait with orthosis and previous gait.

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.

Is the patient complying with instructions relative to stride length?
Re-instruct if stride length is too long.

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



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

OBJECTIVE DATA COLLECTION

Objective data can be collected with a 10 m (30') runway and a stopwatch. Ten meter (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 (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 their orthosis.

Maj 2010

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