

Instructions for how to order ToeOFF®/BlueROCKER® Custom and SELECT Custom AFOs. Carefully read these instructions before use!

Custom AFO Descriptions:

The table below defines the difference between ToeOFF®/BlueROCKER® Custom and SELECT Custom AFOs. See page 7 for warranty information.

ToeOFF®/BlueROCKER® Custom

Properties are within the design parameters of standard ToeOFF®/BlueROCKER® as indicated below:

- Heel height: 5-25mm
- Ant./Post. stiffness increase or decrease (max 2 steps)
- Medial/Lateral stiffness increase or decrease (max 2 steps)
- No change of strut position
- Toe height always 15 mm

SELECT Custom AFO / SELECT Custom AFO Rigid

Properties are outside the design parameters of standard ToeOFF®/BlueROCKER® as indicated below:

- Heel height more than 25mm
 - Off-load for high instep
 - Change of Strut position
 - You can choose different stiffness for heel and toe
 - Off-load for 5th Metatarsal (change position of strut)
 - Change of toe height and heel height (5/5mm or 10/10mm)
- NOTE: How product functions is responsibility of fitting practitioner

IntendedUse: ToeOFF® and BlueROCKER® are intended to support a foot with impaired ability to actively dorsiflex. They are also intended to assist when the ability perform push off is reduced.

Indications: 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.

Contraindications: ToeOFF® and BlueROCKER® should not be used by patients with leg ulcers or in cases where moderate to severe edema is present, or where moderate to severe foot deformities are evident. ToeOFF® and BlueROCKER® should not be used when severe spasticity is present. The definition for spasticity is described in the Allard AFO Professional Instructions.

Special precautions should always be taken for patients with reduced sensation in the lower extremities.

Daily monitoring of skin condition is advised.

- Send a 10 sec video of the patient walking towards and away from camera with knees visible and wearing shoes that will be used with the brace.
- This form must be submitted through <https://submit.allardsupport.com>.
 - Basic Information (page 4 of this document). This page must always be filled out completely.
 - Special Characteristics (page 5 of this document).
 - Measurement Order Form (page 6 of this document): Complete and email this ONLY if you are ordering by measurements.
- The same demands for patient selection, fitting and adjustments should be followed as for a regular ToeOFF® or BlueROCKER®. Read the instructions in the Allard AFO Professional Instructions.
- Allard reserves the right to modify the warranty period or refuse orders for custom carbon composite AFOs that exceed parameters to fabricate a device that might compromise safety for the wearer.

***Contact customer support for more information about warranty terms, email: customs@allardusa.com**

By submitting this form you are certifying that personal data has been processed in compliance with GDPR (EU) 2016/679.

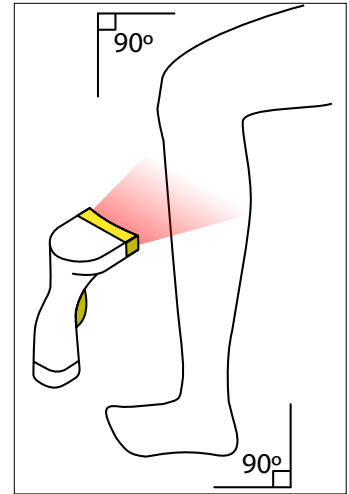
The data will be processed only to the extent necessary to deliver ordered products. Due to the Data Privacy Regulation GDPR (EU) 2016/679) this form must be submitted through <https://submit.allardsupport.com>.

Instructions for how to send in a Scan, Cast or Measurements

How to Scan

Put the foot in neutral on a "block" with the arch of the foot visible. If the patient is wearing corrective orthotic (varus/valgus) to correct a malformation, scan with the orthotic in position. Scan the foot and leg in neutral (foot and knee in 90° flexion) or with desired heel height. It is important that the patient does NOT move during the scanning, as this can affect the final result. If possible include the knee in the scan. Surfaces that will need relief should be clearly marked with landmarks (center point included).

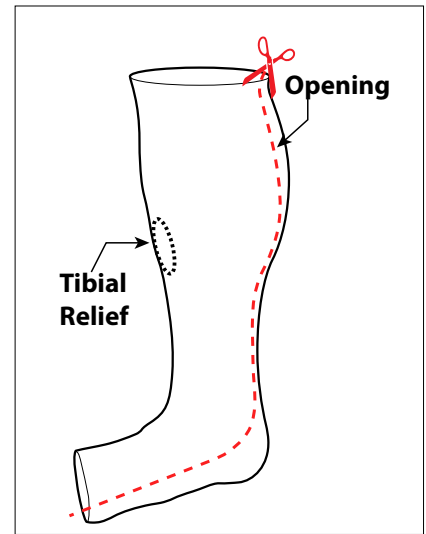
Align the scanned foot both anterior and medial/lateral. Position the foot so it is visible from the front. Please be sure to export your files as .cxp .obj .stl .vsrf .ply .cln .ssn or vorum spectra scan.



Negative Cast-must be formed from fiberglass/synthetic casting or STS-sock and **MUST** have a posterior or medial opening (so the natural shape of the tibial crest is captured).

To be consistent with scanning instructions: Do the casting with the foot and leg in neutral (foot and knee in 90° flexion) or with desired heel height (see pictures page 2). Try to get the cast as smooth as possible. If the patient is wearing corrective orthotics (varus/valgus) to correct a malformation, it is beneficial to cast with the orthotics on the patient. Cast the foot in neutral or with desired heel height. If any surfaces need relief, mark these clearly with a colored marker. Draw a plumb line on the anterior and lateral aspects of the cast. These lines will represent the patient's varus/valgus angle, as well as the dorsi/plantarflexion angle of the leg. Send the cast together with the order form. The scanning for fabrication of the AFO will be outside the cast.

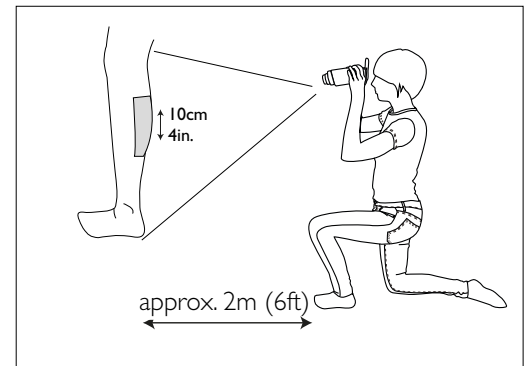
Negative casts MUST have a POSTERIOR or medial opening.



Measurement (Two photos required)

When ordering a product from measurements, both circumferential and M-L measurements in mm (not inches) should be taken with the patient sitting and the foot and knee in 90° flexion. Ordering with measurements cannot be done if the patient has foot deformities, severe varus/valgus position in ankle, or if there is pressure from the strut in a standard ToeOFF®/BlueROCKER®. Please have your patient try a standard ToeOFF®/BlueROCKER® before ordering an Allard Custom AFO from measurements.

Please send two photos of the patient. First, with the patient standing, mark the anterior part of the patient's leg with a plumb line and take a photo (jpg). Then place a strip of tape that measures exactly 10 cm/4 inch on the posterior aspect of the calf (it should be placed vertically as it is for scaling). Take a digital photo from approximately 2 meters (6 feet) away and try to be at the same height as the leg (you will probably need to kneel down).



Order form

From the information given in the order form an orthosis will be manufactured where foot length,width, heel height, stiffness and stability are comparable to a standard ToeOFF®/BlueROCKER®, unless otherwise noted on the second page of the order form.

Reference data

Make sure that the patient's foot length and length of lower leg (knee center to floor) is filled out on the order form. If the patient has an irregular shaped leg, please send a few photos (anterior, lateral and medial view) together with the order form.

*Date: _____ *Purchase order No: _____
 *Company: _____ *Orthotist: _____
 *Phone: _____ *E-mail: _____
 *Address: _____

*This order is made from: Scan Cast - Fiberglass (negative)
 Measurement Standard ToeOFF®/BlueROCKER®
 Scan/cast includes a corrective varus/valgus control orthotic: YES NO
(Make sure you remove the orthotics before sending cast for fabrication).
 Objective for ordering a custom as opposed to a standard ToeOFF® or BlueROCKER®: _____

*Order No: (same as on cast and file): _____
 *Diagnosis: _____
 Patient is currently using: ToeOFF® _____ size BlueROCKER® _____ size Custom S/N _____
 *Height: _____ *Weight: _____ (kg) *Foot length: _____ (mm) *Lower leg height: _____ (knee center to floor)
 *Plantar/dorsiflexion: Neutral (90°) can be achieved with passive ankle motion? YES NO
 10° Dorsiflexion can be achieved with passive ankle motion? YES NO
With 10° dorsiflexion in ankle, patient will better use the dynamics in the brace, but it is not a demand for ordering the brace.
 *Partial foot amputation: YES NO What level _____
 *Activity level: Short distances indoor with assistance
 Short distances indoor and outdoor without assistance
 Manage daily activities without problems
 Walk longer distances without problems
 High activity, sports on a daily basis

If no, this will be a SELECT Custom AFO

*From the information above a ToeOFF®/BlueROCKER® Custom, or SELECT Custom AFO/ SELECT Custom AFO Rigid will be fabricated where the foot length, foot width, heel height, A-P stiffness and M-L stiffness is equal to the standard product checked below:
 ToeOFF®: Left Right Bilateral
 BlueROCKER®: Left Right Bilateral
 Accessories: None SoftKIT Black SoftKIT Beige ComfortKIT
 T-Strap

ToeOFF®/BlueROCKER® Custom
CE-Registered product
Basic cost

SELECT Custom AFO / SELECT Custom AFO Rigid
Non CE-Registered product
Basic cost

***Footplate length:** _____ mm
(5mm interval from 190 - 310 mm)

***Heel height** (effective toe-lift is always 15mm)

As a standard ToeOFF®/BlueROCKER® (15mm)

Heel height: 5mm 10mm
 20mm 25mm

Footplate width: Equal to 1 sz smaller
 Equal to 1 sz larger

Compared to standard ToeOFF®/BlueROCKER®

Relief prominences:

Tibia crest: 3mm 5mm
 _____ mm

Other relief : _____ mm
(Only for order from scan or cast)

Off-load for high instep
i.e when there is a cavus/varus deformation.
(Only for order from scan or cast).

**Off-load at base of 5th metatarsal
(due to impingement)**

SELECT Custom AFO / SELECT Custom AFO Rigid
Non CE-Registered product
Additional Cost

Heel height > 25 mm _____ mm

Preset of Toe height and Heel height

- 5mm toe height & 5 mm heel height
- 10 mm toe height & 10 mm heel height

ToeOFF®/BlueROCKER® Custom
CE-Registered product
Additional Cost

Compared to standard ToeOFF®/BlueROCKER®

A-P Stiffness:

- Less stiff, compared to ~ 1 sz smaller
- Less stiff, compared to ~ 2 sz smaller
- More stiff, compared to ~ 1 sz larger
- More stiff, compared to ~ 2 sz larger

M-L Stiffness :

- Less stiff, compared to ~ 1 sz smaller
- Less stiff, compared to ~ 2 sz smaller
- More stiff, compared to ~ 1 sz larger
- More stiff, compared to ~ 2 sz larger

**I agree to get a Select Custom AFO or Select Custom AFO Rigid, if some of order parameters is outside
ToeOFF®/BlueROCKER® Custom**

Change of stiffness for heel / toe part

Compared to standard ToeOFF®/BlueROCKER®

- Standard toe - less stiff heel,
compared to ~ 1 sz smaller
- Standard toe - stiffer heel,
compared to ~ 1 sz larger
- Standard heel - less stiff toe,
compared to ~ 1 sz smaller
- Standard heel - stiffer toe,
compared to ~ 1 sz larger

**NOTE! It is not possible to combine the stiffness in A-P with a softer M-L.
NOTE! 2 x stiffness in M/L and A/P is not an option in size XSmall and Small.
NOTE! When a less rigid product is required we recommend we carefully
check that this does not effect spasticity, if present.**

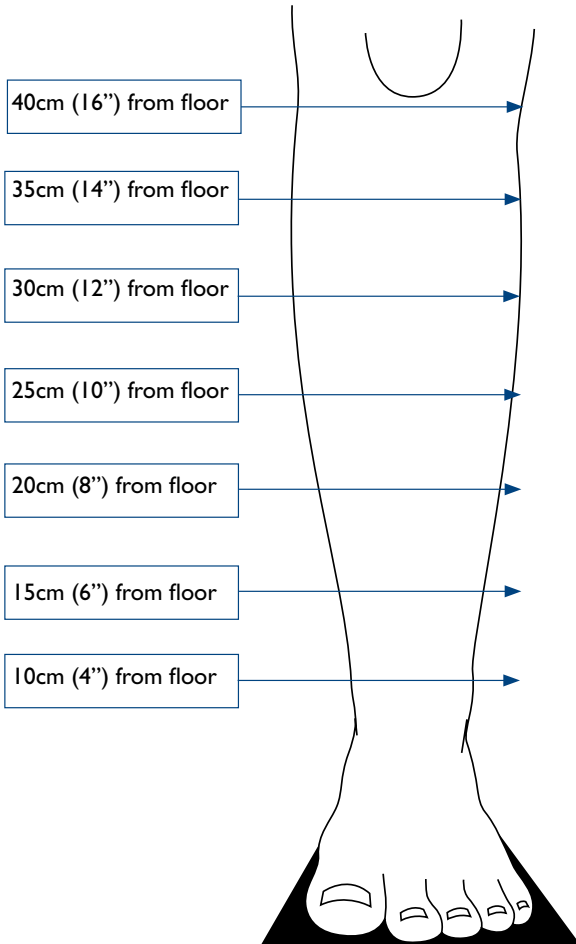
Only use this page if you are ordering a product from measurements. The information on pages 4 and 5 must also be completed and sent with the order.

*Order No: _____

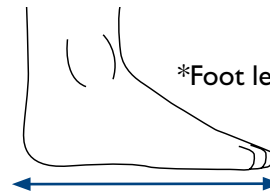
Side: Left Right

 Circumf.

 M-L

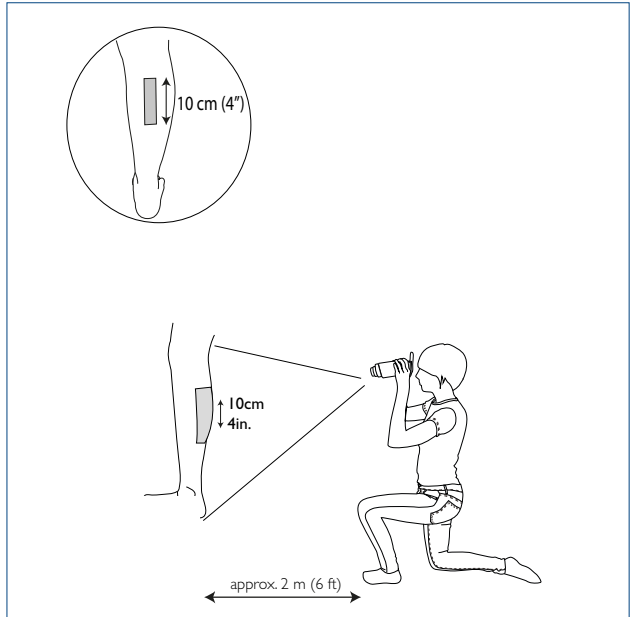


_____ mm	_____ mm
_____ mm	_____ mm
_____ mm	_____ mm
_____ mm	_____ mm
_____ mm	_____ mm
_____ mm	_____ mm
_____ mm	_____ mm



*Foot length = _____ mm

Place a strip of tape that measures exactly 10cm (4'') on the posterior aspect of the calf (it should be placed vertically and is used for scaling). Take a digital photo (jpg) from approximately 2m (6 ft.) distance and try to be at the same height as the leg (you will probably need to kneel down).



ALLARD CUSTOM AFO WARRANTY

Allard USA return policy for Allard AFO products assumes that fitting has been done correctly, adjustments have been carried out according to Professional Instructions supplied and Patient Instruction has been reviewed with patient. The Patient Instructions should be given to the patient or the caregiver to take home. Our return policy is that we grant warranty for defects in material and workmanship as indicated by specific product listed below.

- For all Allard AFOs, warranty registration must be submitted within 10 days of initial fitting to validate warranty.

All Allard Custom AFOs

Allard USA grants warranty for defects in material and workmanship and will provide at no charge to the provider a replacement Allard AFO Custom of equal value, provided the replacement does not require change in position of the strut or change in heel height (unless the change is required due to a fabrication error). There will be an additional charge if the replacement requires a change in properties not specified in the original order, for example changes in A-P and/or M-L stiffness. Replacement is limited to one orthosis for the same wearer that is returned within one year from date of initial fitting. Provider must inspect product and immediately call if AFO does not meet order requirements.

IMPORTANT

Warranty & Guarantee are valid ONLY if Warranty Registration is completed by ORTHOTIST and submitted within TEN (10) days of initial fitting:

1. Complete warranty registration online at www.allardusa.com, or
 2. Fax Warranty Registration Form to 888-952-2787, or
 3. Scan and e-mail to warranty@allardusa.com
- Product return must be made by the original provider. If the wearer does not have a record of the original provider or the original provider is no longer in business; the wearer should call Allard USA and ask for a Customer Service Specialist, who will help find a nearby facility that can help.
 - Replacement does not include fitting, modification or other provider costs.
 - This warranty does not cover change in function or damage done by tools, application of heat, or excessive bending/flexing back and forth of the calf wings.

All products returned must have a Return Authorization Number.

If you purchased the product from a distributor: Contact that company to obtain Return Authorization.

If you purchased the product from Allard USA: Call toll free 888-678-6548 to obtain Return Authorization.

For additional questions: Please contact Allard USA prior to returning any products.

Allard USA, Inc.

Toll Free: 888-678-6548

Email: warranty@allardusa.com

Warranty Fax: 888-952-2787

www.allardusa.com