Instructions for ordering Custom ToeOFF® / BlueROCKER®

Please read these instructions carefully before ordering!

- All pages of the order form should be completed, including the measurement form.
- This is a NON CE-MARKED product. The manufacturer complies with the requirements MDR 2017/745 Annex I Chapter II Requirements regarding Design & Manufacture, applicable for manufacturing. The following requirements are met by the manufacturer:
  MDR 2017/745 Annex I Chapter II; 10.1 with exception of c) and e); 10.4.1. a; 10.5 & 14.7. For design and remaining requirements in MDR 2017/745 Annex I it is referred to the Health & Medical Institution which prescribed the product. For Custom ToeOFF® and Custom BlueROCKER® we guarantee that the product has been produced according to GMP (Good Manufacturing Practice).
- It is recommended to apply the same careful patient selection, fitting and adjustments as for a regular ToeOFF® or BlueROCKER®.
- To optimize the performance and durability of the ordered product, we strongly recommend that you send a 10 second video or photo of the patient walking towards and away from camera with knees visible and wearing shoes that will be worn with the brace.
- Allard INT/UK/USA and Camp Scandinavia reserve the right to refuse orders for custom composite AFOs that exceed parameters to fabricate a device that might compromise safety for the wearer.
- This form must be submitted through https://submit.allardsupport.com
- By submitting this form you certify that personal data has been processed in compliance with HIPAA (USA) and GDPR (EU) 2016/679. The data will be processed only to the extent necessary to deliver ordered products according to the Data Privacy Regulation GDPR (EU) 2016/679.

Intended Use

Custom ToeOFF® and Custom BlueROCKER® is intended to support a foot when the ability to actively dorsiflex is reduced or completely lost. Custom BlueROCKER® is intended when extra stability is needed to support the ankle joint and when the patient needs bilateral dorsiflex assist.

Ordering Custom ToeOFF®/BlueROCKER®

Before ordering custom product(s), we strongly recommend that the patient first trials our standard ToeOFF®/BlueROCKER® product(s) when possible. When testing standard product(s), you´ll get a baseline for the type of product strength you are looking for, and from that point you can choose more or less stability in the M-L (frontal) or A-P(sagittal) planes (Section 8).

The Custom ToeOFF®/BlueROCKER® can be made from a scan, a cast (pos/neg), from measurement, or as a standard ToeOFF®/BlueROCKER® with changed properties (Section 2). It is important that our recommendations regarding alignment, casting and scanning are followed for the finished product to work and fit optimally. Ordering with measurements cannot be done if the patient has foot deformities, severe varus/valgus ankle position, or if there is pressure from the strut in a ToeOFF®/BlueROCKER®.

Alignment

When a standard ToeOFF®/BlueROCKER® is correctly fitted in a shoe with the corresponding heel height, the standard alignment for the foot and lower leg is with the ankle in a neutral (0°) position in the frontal plane (I mage 1) and the anterior shank to vertical at approx. 8-10° in the sagittal plane (Images 2 & 3). The 2nd metatarsal should be in the line of progression or slightly (≤7°) externally rotated.

Image 1

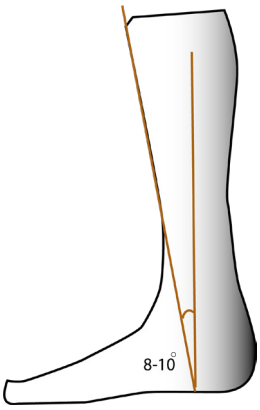


Image 2

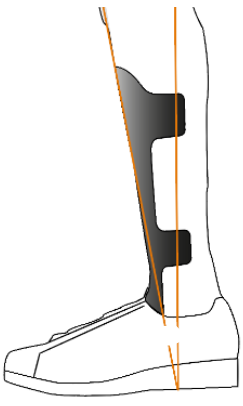


Image 3

In cases where the patient does not follow the standard alignment when standing or walking, it is important that the casting or scanning is done in a weight bearing position of the affected leg. Image 4 is an example where the patients right leg has standard alignment and the left leg has 7° of tibia varum.

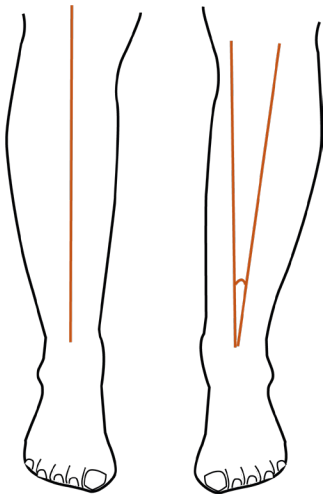


Image 4, Right leg: Straight 0°, Left leg: Tibia varum 7°

If the patient has a varus/valgus malposition, we recommend the patient wear custom made insoles. Scan with the insoles in position. (Section 2)

Draw the plumb lines on the anterior and lateral aspects of the cast, or by setting landmarks along the plumb lines in the scanning procedure. The plumb line should be marked all the way to the toes, to show the rotation of the foot relative to the lower leg. (Image 5).

If it is not possible to mark the plumb line in the scanning system used, this must be stated in the form with sagital and frontal alignment degree (section 7).

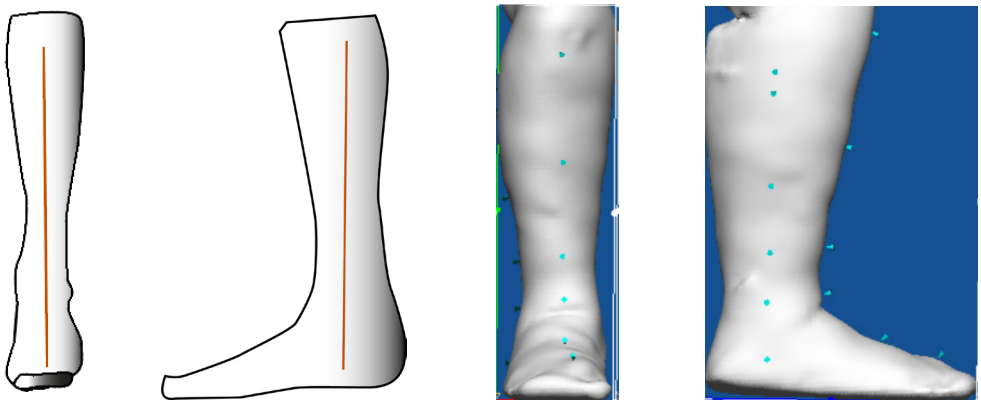


Image 5

We only accept casts/scans with plumb lines.
(If you cannot mark your scan, fill in the alignment degrees in section 7)

Scanning

Make sure the scan is covering the foot and lower leg, including the tuberosity of the tibia. The plantar surface of the foot is not necessary to cover, as long as the contour of the foot and heel is captured (Image 6 & 7). The scanning should be done with the required heel height (Section 6).

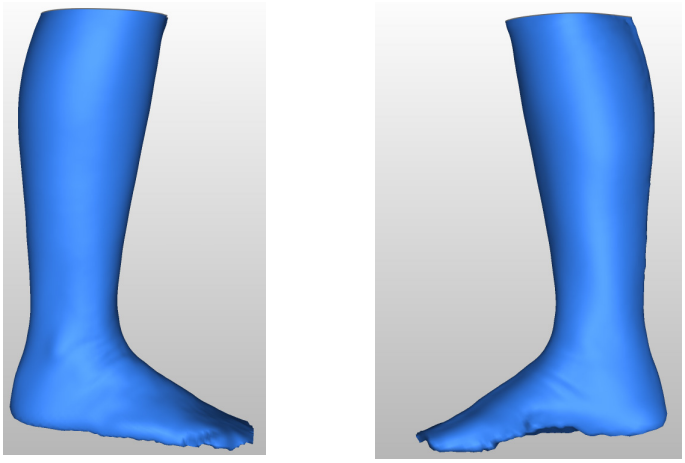


Image 6 & 7

The scanning **should only capture one leg** and be clear of surrounding objects and disturbances (Image 8 and 9).

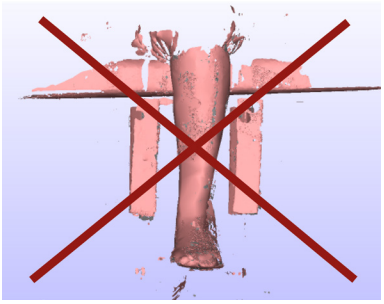


Image 8

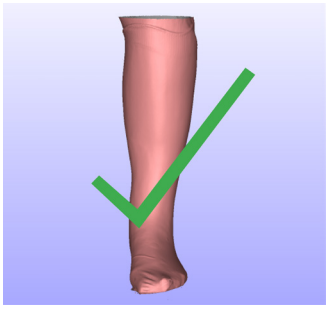


Image 9

There are several scanning systems on the market, with different handling and accuracy. Follow the recommendations from the manufacturer of your equipment for the best result. The scan should be prepared in millimeters (mm). The client must check that the scanner delivers a scan in the correct scale. The measurement form (page 7) should always be filled in to give us an idea that the scan is scaled correctly. If the patient has any areas that require relief, this should be marked on the scan and mentioned on the form.

We accept the following file formats:

.obj .ply .stl .vsrf .cxpxp .cln .ssn Vorum Spectra scan.

The Cast (Positive or Negative)

Make sure the cast is covering the whole foot and lower leg, including the tuberosity of the tibia.
The negative cast must be made with synthetic casting or STS-sock and MUST have a medial or posterior opening (so the shape of the tibial crest and the area for the strut is captured). The opening should be closed with staples as shown in Image 10 below, to avoid overlapping or enlarging of the cast. The casting should be done with the required heel height. (Section 6)

You are looking from medial side.

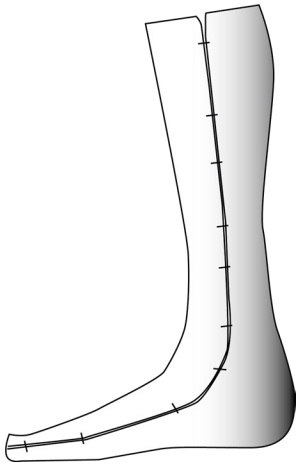
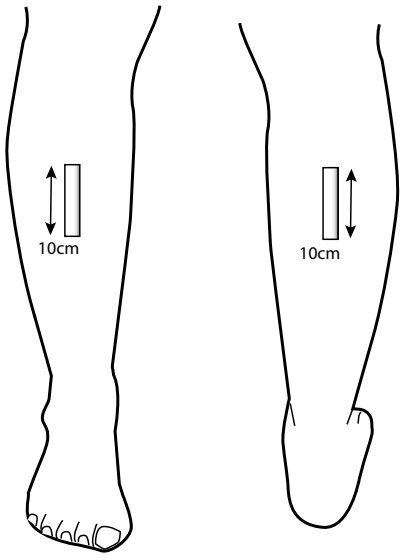


Image 10

The scanning for fabrication of the AFO will be done on the outside of the negative cast, therefore it is very important that the cast has a smooth surface.
If the patient has areas that need pressure relief, the boundaries and the apex(es) should be marked on the cast and specified on the form. (Section 7).

Product Fabricated from Measurements

If the lower part (the footplate and strut) of the standard ToeOFF®/BlueROCKER® fits the patient, but the upper part (anterior shell) is too wide or too narrow we can produce a custom-made product from measurements. Together with the measurement form, a photo of the patient's leg must be included. Take the photo of the foot, lower leg and the knee. Please do not send photographs of the whole patient. The photo must reflect the alignment of the leg when standing/walking and be sharp and clear. Attach a 10cm long tape onto the calf or shin to be used in scaling the photo. (See image below)



BASIC INFORMATION

1

Date: _____ Purchase order No: _____

Company: _____ Orthotist/Prescriber: _____

Phone: _____ E-mail: _____

Address: _____

2

This order is based on:

☐ Scan ☐ Cast ☐ Standard ToeOFF® or BlueROCKER® **with changed properties** ☐ Measurement (last page) ☐ Reorder, exactly the same (no changes)

Scan/cast includes a corrective varus/valgus control insole; ☐ Yes ☐ No
(Make sure you remove the orthotics before sending cast for fabrication).

State the reason why a custom product is ordered instead of a standard product, include any additional information or instructions for fabrication here.

_____

_____

3

Patient ID (As recorded on cast and file): _____

Diagnosis: _____

Patient is currently using:

ToeOFF® size: _____ BlueROCKER® size: _____ Custom S/N: _____

Other product: _____ ☐ None

Height: _____ (m) Weight: _____ (kg)

Affected side: ☐ Left ☐ Right ☐ Bilateral

Plantar/dorsiflexion: Can normal ROM in the ankle(s) be achieved with passive ankle motion?

☐ Yes ☐ No ⇨ Describe contracture: _____

Partial foot amputation: ☐ No ☐ Yes, at level: _____

Spasticity : ☐ No ☐ Yes ☐ Mild ☐ Moderate ☐ Severe*
**Severe spasticity is a contraindication for ToeOFF® and BlueROCKER®*

Crouch gait: ☐ No ☐ Yes

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

4

Product & Accessories ordering

Custom ToeOFF®: ☐ Left ☐ Right ☐ Bilateral

Custom BlueROCKER®: ☐ Left ☐ Right ☐ Bilateral

Accessories: ☐ SoftKIT™ ☐ ComfortKIT™ ☐ No accessory

PRODUCT SPECIFIC INFORMATION

5

Depending on what foot plate length you decide, you must choose foot plate width from the same size interval.

Length

Size	Standard Length	Available Custom foot plate length	Custom Foot plate length (5mm interval)	Standard width forefoot	Available Custom foot plate width	Custom foot plate width (5mm interval)
XXS	195mm	190-200mm		70mm	65-75mm	
XS	210mm	205-215mm		75mm	70-80mm	
S	230mm	220-235mm		80mm	75-85mm	
M	245mm	240-255mm		85mm	80-90mm	
L	270mm	260-275mm		95mm	90-100mm	
XL	285mm	280-295mm		100mm	95-105mm	
XXL	305mm	300-310mm		105mm	100-110mm	

Width at MTP

6

Heel height:

☐ 5mm ☐ 7mm (Equal to 2½ models) ☐ 10mm

☐ 15mm(Equal to original ToeOFF®/BlueROCKER® + 2.0 models) ☐ 20mm ☐ 25mm ☐ >25mm _____mm

(Additional cost)

7

Relief prominences and alignment preferences: *Should always be marked on scan/cast*

Tibia crest: ☐ Left _____mm ☐ Right _____mm

Other relief regions:

Width x length of relief region : ☐ Left leg____x____mm ☐ Right leg____ x_____mm

Height of relief region: ☐ Left leg_____mm ☐ Right leg_____mm

Off Load for base of the 5th metatarsal: ☐ Left leg_____mm ☐ Right leg_____mm

Off Load for high instep: ☐ Left leg_____mm ☐ Right leg_____mm

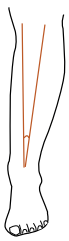
(Only possible to choose on Scan or Cast)

Standard alignment : ☐ Yes ☐ No If no, please state the requested alignment below

Frontal plane:

Left leg____degrees ☐ Varus ☐ Valgus

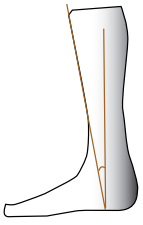
Right leg____degrees ☐ Varus Valgus



Sagittal Plane (the anterior shank to vertical):

Left leg____degrees inclined

Right leg____degrees inclined



8 Specify if more or less stability is required in comparison to our standard ToeOFF® and BlueROCKER®. Please understand that added stiffness in one direction cannot be combined with reduced stiffness in the another direction (8:1). ***Note that you can only choose one option of either 8:1 or 8:2. There is an additional cost to each of these options.***

8:1

A-P Stiffness:

- ☐ Less stiff - ***remove one*** layer of fiber
- ☐ Less stiff - ***remove two*** layers of fiber
- ☐ More stiff - ***add one*** layer of fiber
- ☐ More stiff - ***add two*** layers of fiber

M-L Stiffness:

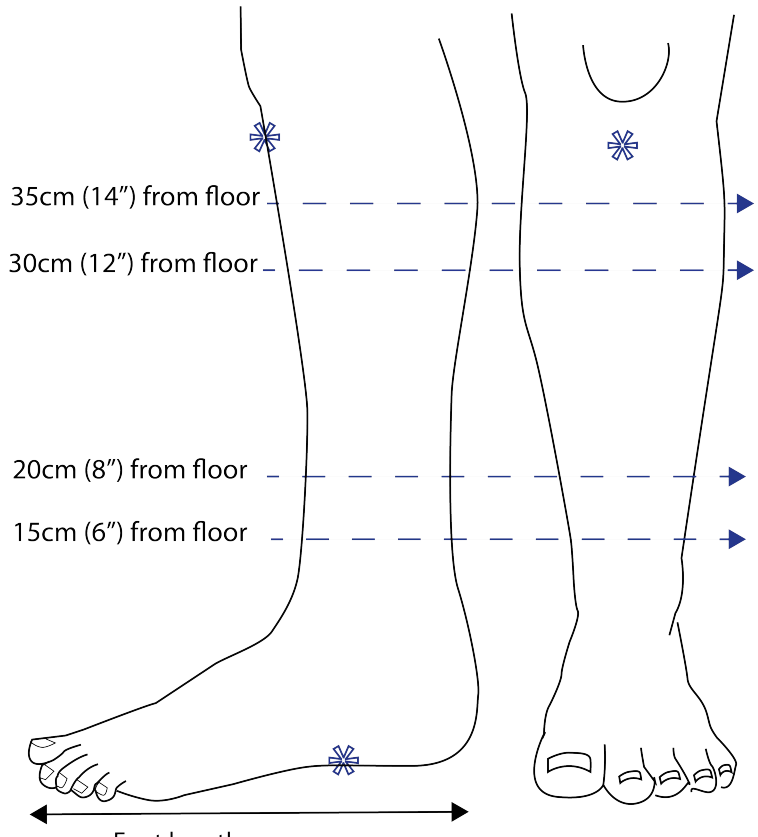
- ☐ Less stiff - ***remove one*** layer of fiber
- ☐ Less stiff - ***remove two*** layers of fiber
- ☐ More stiff - ***add one*** layer of fiber
- ☐ More stiff - ***add two*** layers of fiber

8:2

Different stiffness for heel/toe part. Only one option:

- ☐ Standard toe - ***less stiff*** heel - ***remove one*** layer of fiber
- ☐ Standard toe - ***stiffer*** heel - ***add one*** layer of fiber
- ☐ Standard heel - ***less stiff*** toe - ***remove one*** layer of fiber
- ☐ Standard heel - ***stiffer*** toe - ***add one*** layer of fiber

Measurement



LEFT LEG		RIGHT LEG	
M-L	CIRCUM-FERENCE	M-L	CIRCUM-FERENCE
mm	mm	mm	mm

Foot length =_____mm

Tuberosity-floor=_____mm

✱ Tuberosity of tibia &
Base of 5th metatarsal
should be marked on cast/scan

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