

allard^{USA}

PRO FESSIO

INSTRUCTIONS



YPSILON™



ToeOFF®



BLUEROCKER™

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

www.allardusa.com

INDICATIONS AND CONTRAINDICATIONS

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.

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

THERMOSET HYBRID COMPOUND

Thermoset Hybrid Compound

- Do not heat

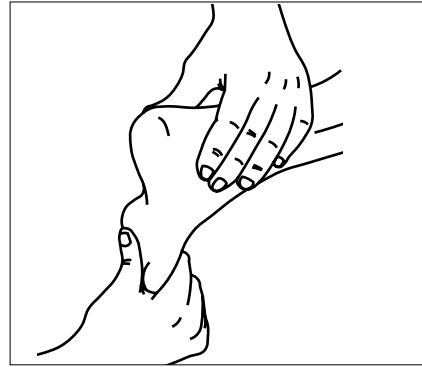
When Grinding/Cutting

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



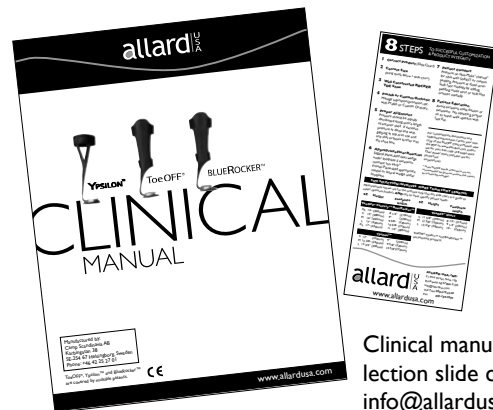
I

CORRECT PRODUCT



Before choosing product style or size, make a proper assessment of the affected foot to determine function and stability in both open and closed chain. Take into consideration the larger the size, the more rigidity. Guide for initial product selection:

- Stable ankle: Ypsilon™
- Ankle instability: ToeOFF®
- Ankle instability with quadriceps weakness: BlueRocker™
- More details are described in the ToeOFF® Clinical Manual



Clinical manual and product selection slide chart. Call or email info@allardusa.com for your free manual and slide chart.

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CORRECT SIZE

Size selection involves more than foot length. Use the sizing chart in the Clinical Manual and Slide Chart as a guide only. As the size increases, the level of dynamic support and the height of the orthosis increases. Consider sizing up to increase strength of the orthosis or down to increase flexibility to meet specific patient needs.

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SHOE SELECTION AND ACCOMMODATION



a) well constructed rocker toe shoe

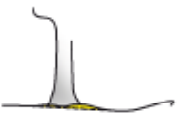
- Firm heel counter, for proper control of the rear foot.
- Rocker-type sole at toe end for smoother transition from 2nd to 3rd rocker.
- Laced, for easier donning and doffing, and to allow adjustable compressive support at mid-foot.
- Removable insole, to allow space for the footplate with modifications.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

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

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



Lateral Views



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

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PREFAB OR CUSTOM ORTHOTIC



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



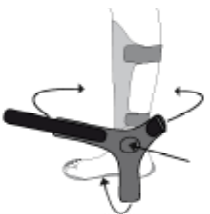
Supination/Pronation Control

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



Pes Valgus Control

- For severe pes valgus that cannot be controlled from ground up with foot orthotics, consider addition of the ToeOFF T-Strap (call for more information).
- T-Strap pulls the talocrual and subtalar joints laterally to position them back underneath the tibia.



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PROPER ALIGNMENT AND INSTEP CLEARANCE

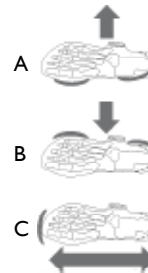
Tibia Alignment for ToeOFF and BlueRocker

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



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.

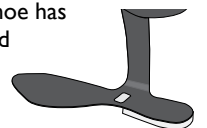
C. Shift the footplate forward or backwards to correct position and to avoid contact with tibia crest.

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APPROPRIATE FLEXION/EXTENSION & FLOOR REACTION ADJUSTMENT

Knee Extension / Flexion Adjustment

All three products (ToeOFF, Ypsilon and BlueRocker) are fabricated to accommodate approximately 1.5 cm (5/8 inch) heel height. If the shoe has a significantly higher or lower heel, add or reduce the effective heel height.



To encourage:

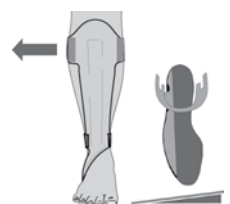
Knee Extension
(minimize flexion)
Decrease Heel Height

Knee Flexion
(delay extension)
Increase Heel Height

Valgum/Varum Adjustment

To influence towards:
Knee Valgum - wedge the bottom of the footplate on the lateral side.

To influence towards:
Knee Varum - wedge the bottom of the footplate on the medial side.



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PATIENT COMFORT

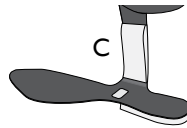
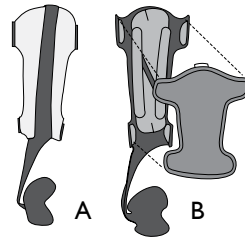
ToeOFF® and BlueRocker™

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

B. SoftKIT™, ComfortKIT™ and SoftSHELL™ are ready made options for easy, simple and quick padding.

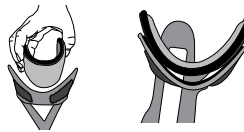
C. Pressure Over Instep. See Instruction No. 5. If pressure remains:

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



Ypsilon™

- There should be approximately a 3/16" gap between the center of the tibia pad and brace.
- Adjust the position of the tibia pad (slightly to the left or right) to re-distribute any uncomfortable pressure.



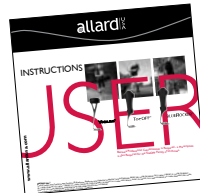
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PATIENT EDUCATION

Review User Instructions with the patient. Have the patient sign the back of the User Instructions, make a copy for the patient's records, and give original to patient to take home.

REMINDER:

Warranty registration must be completed and submitted by orthotist to validate warranty.



Patent no.:

ToeOFF, ToeOFF Short, ToeOFF Fantasy, ToeOFF NFR, BlueRocker, BlueRocker NFR, KiddieGAIT, KiddieGAIT NFR: AU736950, BE1005297, BE1114626, DK1005297, DK1114626, FI1005297, FI1114626, FR1005297, FR1114626, IE1005297, IE1114626, IT1005297, IT1114626, CA2279225, CNZL97181689.1, NL1005297, NL1114626, NO313656, PL194247, CH1005297, CH1114626, ES1005297, ES1114626, GB1005297, GB1114626, SE1005297, SE1114626, DE69709184.8-08 DE69732541.5-08, US5897515, ATE210417, ATE289187
Ypsilon, Ypsilon NFR: GE60208889.5-08, GB1379201, IT1379201, US6887213

WARRANTY REGISTRATION & CLINICAL MANUAL

Be aware that the orthosis may alter the patient's abilities for some activities, i.e. driving a car.

Give to and review with the patient the User Instructions supplied with the product.

Point out where discussed in User Instructions and remind patient the importance of routine checking of orthosis for any signs of damage.

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

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

Partial Foot Application

Visit www.allardusa.com, click on BlueRocker photo, click on "ToeOFF Family Clinical Manual", scroll to page 17. Or, call 888-678-6548 and request our Voice Over Power Point presentation for this topic.