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PRO FESSSIONAL

INSTRUCTIONS

COMBO™
a ToeOFF® Family Product



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

Single Patient Use

Because Professional Customization is Required - a
Prescription is also Required for the COMBO™ Orthosis.

The product must be fitted by or under the supervision of a
certified Prosthetist or Orthotist.

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CAREFULLY READ THESE INSTRUCTIONS BEFORE FITTING!

Intended use:

This product is intended for management of knee hyperextension in combination with footdrop. This product is intended **ONLY** to be used together with a ToeOFF (not for ToeOFF Short, Fantasy) or BlueROCKER. **No other combination is allowed.**

Indications:

Knee instability, hyperextension in combination with footdrop.

Contraindications:

- Total knee ligament loss
- Complete quadriceps insufficiency
- Patient height over 6'6" (2 meter)
- Patient weight over 330 pounds (150 kg)
- Severe loss of cognitive skills

NOTE:

When fitting is completed, no more than 10° of knee hyperextension should remain.



Thermoset Hybrid Compound

- Do not heat
- Relieve pressure areas by using foam

When Grinding/Cutting

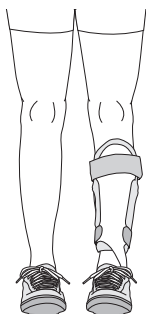
- Protect the eyes
- Cover the nose and mouth
- Do not grind/cut/drill into the lateral strut
- Do not overheat (max. 100°C/212°F) when grinding the composite

- 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.
- Both the ToeOFF/BlueROCKER and COMBO User Instructions supplied with each product should be given to and reviewed with the patient.
- It is vitally important that you discuss both User Instructions with the patient. Patient should 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 or any signs of damage to either brace.
- Changes, alterations, modifications or combinations 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.

COMBO Quick Reference Guide

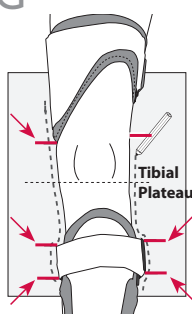
1 EVALUATE PATIENT

- Evaluate patient standing with ToeOFF/BlueROCKER.
- Observe patient's functional standing posture, particularly toe in/out position.



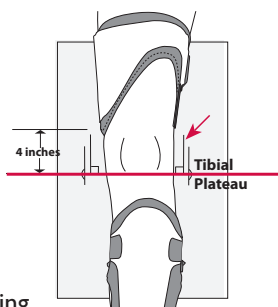
2 TRACE PATIENT'S LEG

- Patient should be supine. Be certain to duplicate standing and toe in/out posture observed in step one.
- Mark location of proximal area of Thigh Cuff and Wings on ToeOFF.



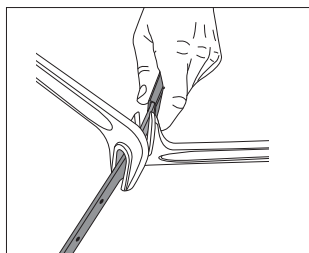
3 RECTIFY TRACING

- Proper joint alignment is important!
- Allow appropriate clearance between knee joint and the patient's knee.
- Position uprights on the tracing so the distal screw of the knee joint lines up with the tibial plateau line.



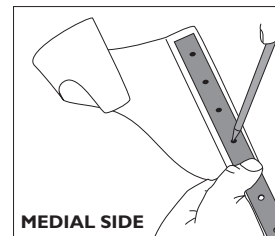
4 CONTOUR UPRIGHTS

- Be sure not to bend near holes closest to joint center.



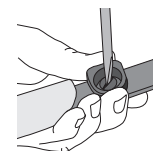
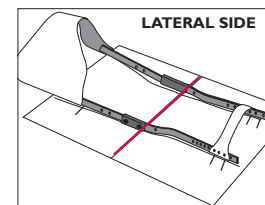
5 DRILL HOLES

- Align upright onto thigh cuff and mark hole location for distal and proximal holes. Drill two 4 mm holes using #18 bit.



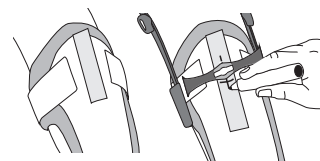
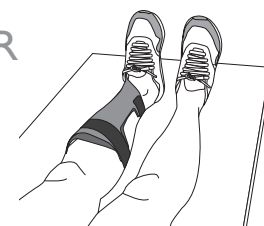
6 ASSEMBLE

- Slide on Joint Covers, Thigh strap and D-ring.
- Attach Thigh cuff, tibial connector and mount Popliteal Buckles.
- Loctite All Screws!



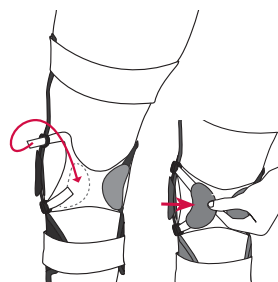
7 TIBIAL CONNECTOR

- With patient lying down, place tape on ToeOFF/BlueROCKER.
- Place COMBO on patient.
- Replicate patient's standing toe in/out posture and mark location for Thumb Screw.
- Drill 5mm (#9 Bit) hole and taper inside, using counter sink drill bit. Loctite screw and let set for 15 minutes.



8 FINISH BRACE

- Attach Popliteal Interface and adjust straps with knee slightly bent.



**LOCTITE
ALL SCREWS**

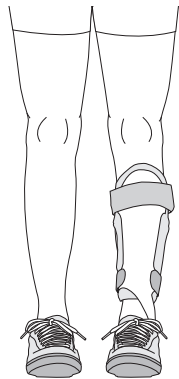
TOOLS & PARTS

Tools Required:

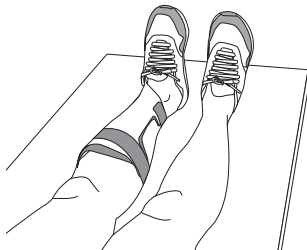
- Drill
- Drill Bit Size 9 (13/64) and 18 (1 1/64) drill bits
- Flat Head Screwdriver
- Screwdriver, Flat Head, Phillips Head
- Bending Irons
- Awl
- T-Square

Item #	Description	Qty.	Components
28780 0000	Joints with Uprights	1	Set of joints w/uprights 4 Screws (M4X5)
28782 0011 28782 0012 28782 0013	Knee Control Component with Popliteal Interface	1 2 4 4 1 1 1	Popliteal Pad w/4 buckles Joint covers Screws (M3X6, DIN965) Square nuts (M3, DIN562) Buckle for prox. thigh cuff Thigh strap Calf strap with slot
28781 1011-1014 28781 2011-2014	Thigh Cuff (Left) Thigh Cuff (Right)	1	Thigh Cuff
28783 0011 28783 0012 28783 0013	Thigh Cuff SoftKIT Set of 2	2 2 3	SoftKIT Interface pads Microfix for SM/MED Microfix for LG/XL
28784 0011 28784 0012 28784 0013	Tibia Connector	1 1 1 2 4 1 1	Loctite or equivalent (red) Thumb screw Tibia connector Teflon washers (16-5X0.5) Screws (M4X5) ToeOFF screw M5X8 BlueROCKER screw M5X10

I PREPARE PATIENT FOR FITTING

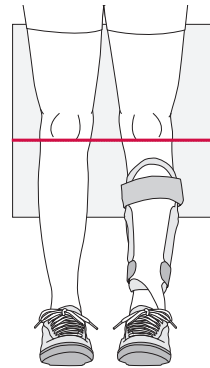


Evaluate patient's functional leg position and relative toe in/out while standing, always duplicate that position when fabricating COMBO.

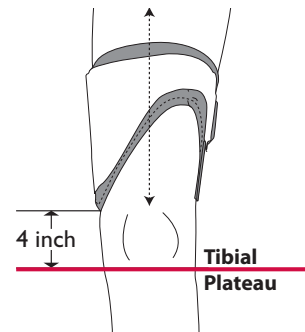


- Have patient in Supine position with shoes and appropriate ToeOFF® or BlueROCKER™ on.
- Make sure legs are parallel and be sure to duplicate patient's natural toe in/out position.

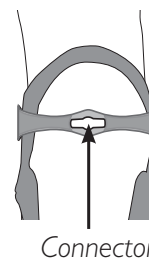
2 SIZE SELECTION



- Place tracing paper under the patient's leg. If using the tracing paper provided from Allard USA, line up the tibial plateau with the line marked on the paper "tibial plateau".
- Otherwise draw a horizontal line at level of Tibial Plateau.
- Take circumferential and M-L measurements, at knee center and 8 inches (20 cm) above mid-patella.

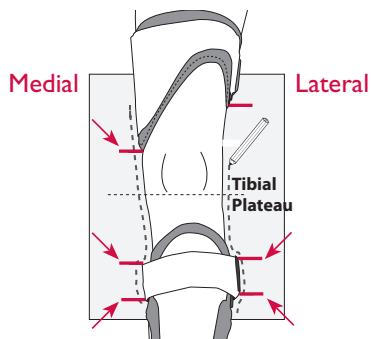


- Choose appropriate Thigh Cuff size. Make sure you have a snug fit.
- Thigh Cuff must be at least 4" (10cm) above Tibial Plateau.

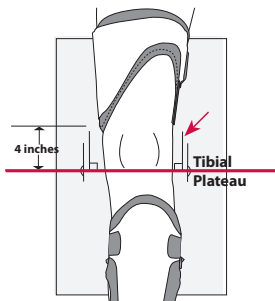


- Choose appropriate Tibial Connector size. In most cases it will be the same size as the ToeOFF/BlueROCKER.
- The Tibial Connector is marked with a sticker on the "lateral" side. Make sure the orientation is correct.

3 TRACE PATIENT'S LEG



- Mark the wings of the ToeOFF/BlueROCKER.
- Mark the lower edges of the Thigh Cuff on the tracing.



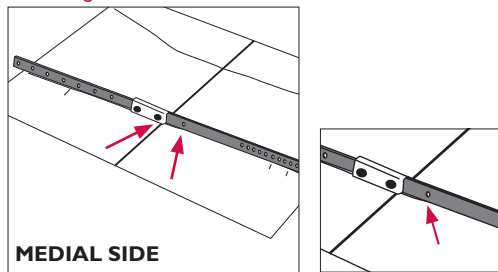
PROPER JOINT ALIGNMENT IS IMPORTANT!

- Rectify tracing. Using a T-square, make a medial and lateral perpendicular vertical line to the Tibial Plateau line. Be sure to keep the appropriate clearance for the knee joints both medially and laterally. These lines will act as a guide to maintain joint alignment.

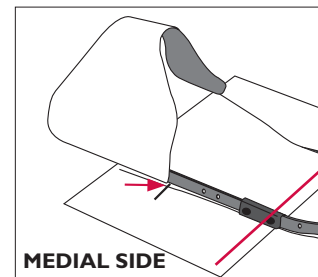
4 ASSEMBLING & CONTOURING

NOTE: The uprights with the closer spaced holes are the distal uprights (should point toward the ToeOFF/BlueROCKER).

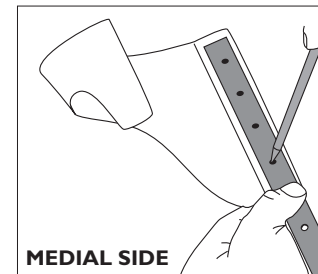
IMPORTANT: Unlike most custom KAFO's you have fabricated, COMBO incorporates a dual axis joint. The COMBO joint distal screw must be positioned at the level of the Tibial Plateau. This allows the proximal COMBO joint to find true knee center as the knee is flexing.



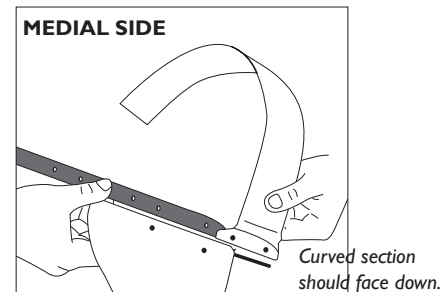
- Position medial upright on tracing so that the tapered holes that are closest to the joints are facing the leg.
- Position the joint so the distal screw lines up with the tibial plateau line.



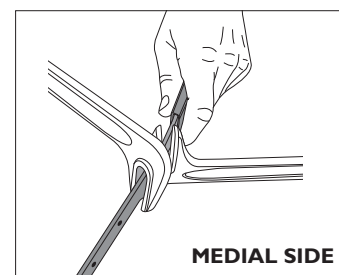
- Align thigh cuff with line on tracing that indicates lower level of thigh cuff.



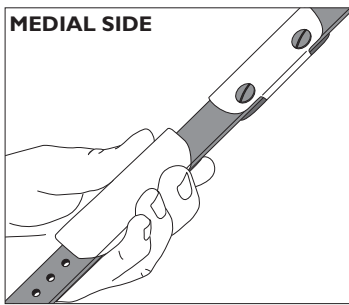
- Grasp thigh cuff and upright together, mark position for proximal and distal holes to attach upright to thigh cuff.
- Drill two 4mm holes using the #18 (11/64) drill bit.



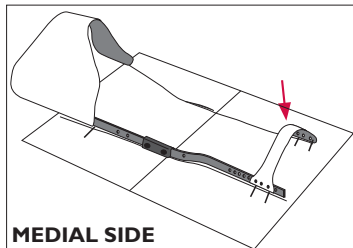
- Slide the thigh cuff strap over the top of the upright.
- Be certain thigh cuff strap is in desired position on upright. Use an awl to puncture holes through the strap where the screws will be located. Thread in the screw to sandwich the upright between the strap and the thigh cuff. Do not over-tighten the screws initially.



- Contour the medial upright to match the tracing. Avoid bending uprights back and forth as this can damage the uprights.
- **IMPORTANT:** Avoid contouring at level of holes closest to joint (holes for the Popliteal Interface buckles).

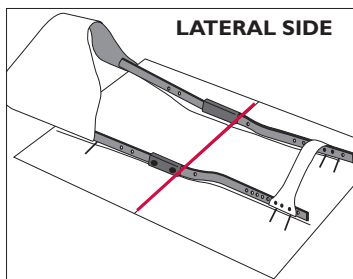


- Slide the joint cover onto the medial upright.



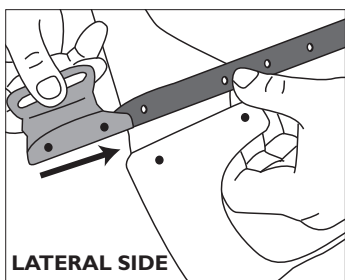
- Compare the contoured upright to the tracing to confirm appropriate alignment.
- Attach Tibial Connector on the medial side spaced evenly between the marks on the tracing that represent the proximal and distal marks of the ToeOFF/BlueROCKER wings.

Repeat same steps for Lateral Upright.



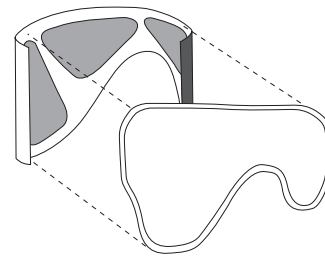
- Align upright on tracing so the distal screw of the knee joint lines up with the Tibial Plateau line, this allows the proximal COMBO joint to find true knee center as the knee flexes.

IMPORTANT: Make sure joints are squared to each other.



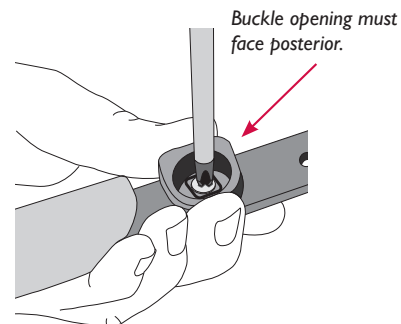
- The D-Ring can be placed on the medial or lateral side, depending on the patient's upper extremity deficit. Slide chafe over upright with straight end of chafe facing up.
- Use an awl to puncture holes for screws. Position thigh cuff on upright and secure chafe between upright and thigh cuff (do not over-tighten the screws initially).

5 THIGH CUFF INTERFACE



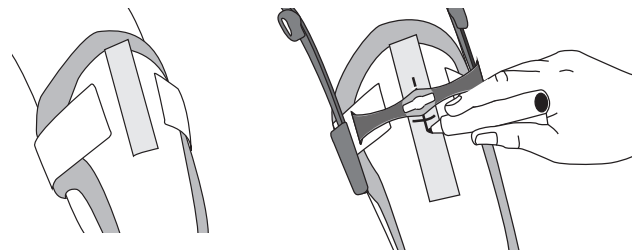
- Mount MicroFIX pieces onto inside of thigh cuff.
- Attach interface.

6 MOUNT BUCKLES



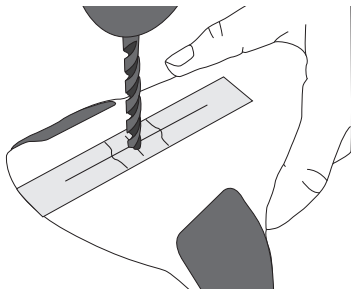
- Detach the buckles from the strapping.
- The buckles must be attached with the opening for the buckles to the posterior.
- Using enclosed screws and nuts, attach the buckles to the uprights at location of the holes immediately above and below each joint. Loctite every screw.

7 TIBIAL CONNECTOR



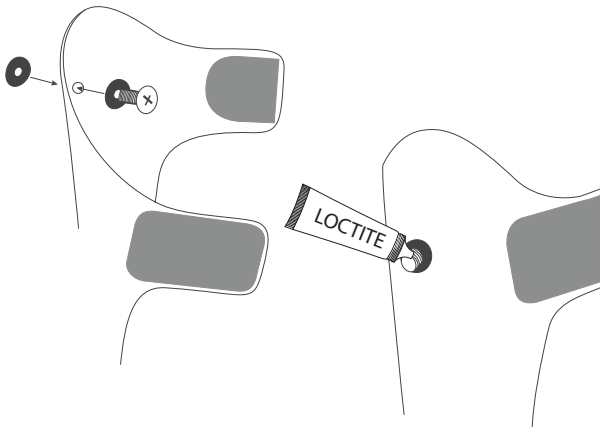
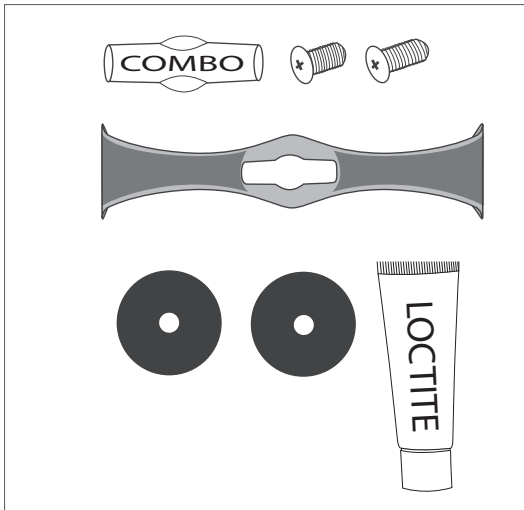
- Have patient in supine position with ToeOFF/BlueROCKER on.
- Legs should be in a straight position from hip to foot, with foot in walking position and pelvis parallel to the table.
- Add a strip of masking tape to the front of the ToeOFF/BlueROCKER.
- Put the COMBO back on patient's leg.
- Position Tibial Connector over the wings of the ToeOFF/BlueROCKER.
- Mark position for Thumbscrew.

NOTE: MAKE SURE TO LOCTITE EVERY SCREW.



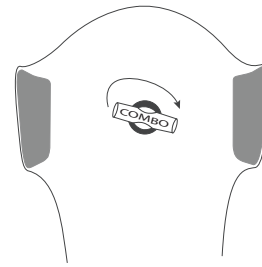
- Drill 5mm (#9, 13/64, drill bit) hole at marked position, countersink the hole (inside).

8 CONNECTOR

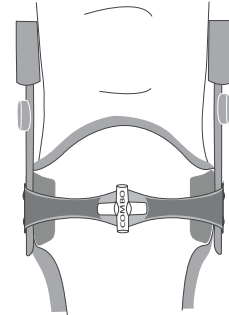


- Attach washer and screw. Choose length of screw depending on the thickness of the shin plate. As a guide, use the shorter screw for a ToeOFF and the longer screw for a BlueROCKER.

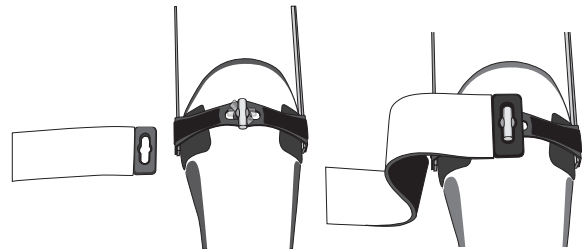
IMPORTANT:
PUT LOCTITE ONTO THE SCREW AND LET THE LOCTITE SET FOR AT LEAST 15 MINUTES BEFORE TURNING THE SCREW. REMIND THE PATIENT THAT THE LOCTITE TAKES 24 HOURS TO FULLY CURE.



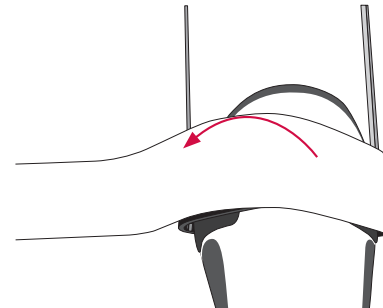
- Attach the Thumb Screw and turn until screw is horizontal to the leg.
- Make sure there is no play between the AFO and the Tibia Connector.



- Fit the brace onto patient in supine position.
- Place the Tibial Connector over the Thumb Screw. Turn Thumb Screw to vertical position.

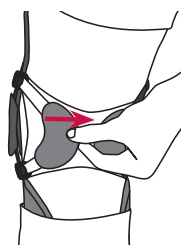
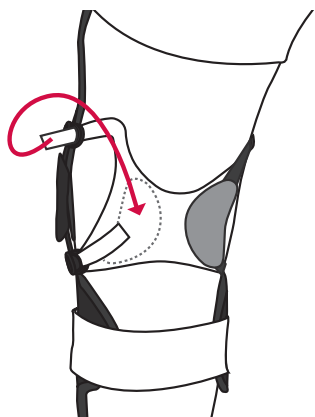


- Place rubber molded end of strap over the Thumb Screw.

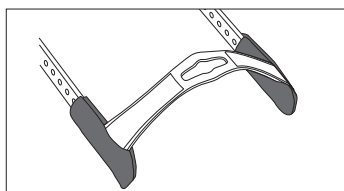
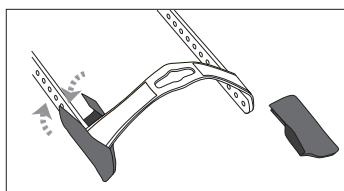


- Secure strap completely around the leg so that it overlaps the Thumb Screw.
- Do not use a strap under the Tibial Connector. Use the long strap that is provided to wrap completely around the ToeOFF/BlueROCKER and the Thumb Screw.

8 POPLITEAL INTERFACE



- Have patient supine or standing with the knee slightly flexed when adjusting the tension.
- Adjust thigh strap.
- Open the C-shaped Velcro tabs on the back of the Popliteal Interface.
- Pull the four straps through the buckles.
- Adjust the tension with the four straps.
- Make sure to pull in a straight line. Close the C-shaped Velcro on top of the four straps.
- Check that the patient does NOT show knee hyperextension exceeding 10° after final fitting.

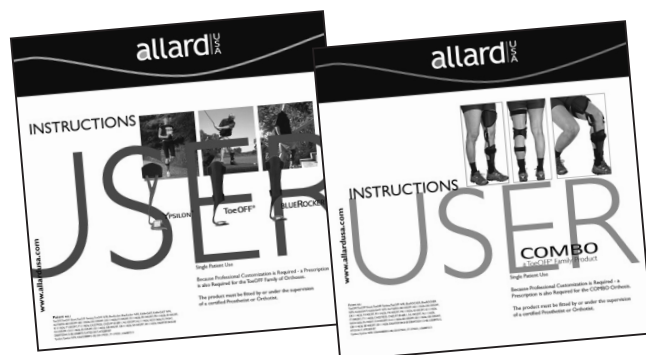


- Apply end covers to distal ends of uprights.

9 FINISH BRACE



- If needed, cut off extended upright parts.
- To avoid damage to cloth and soft tissue, make sure all parts are smooth. Make sure all screws are secured with Loctite (red).
- Instruct patient to only open the buckles on one side when donning and doffing.



10 USER INSTRUCTION & FOLLOW UP

- Instruct patient not to open the C-shaped Velcro tabs.
- Instruct patient to only open the buckles on one side when donning and doffing.
- Read through both the COMBO and ToeOFF/BlueROCKER User together with patient and inform patient about donning and doffing.
- Book appointment for follow up within one week!



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