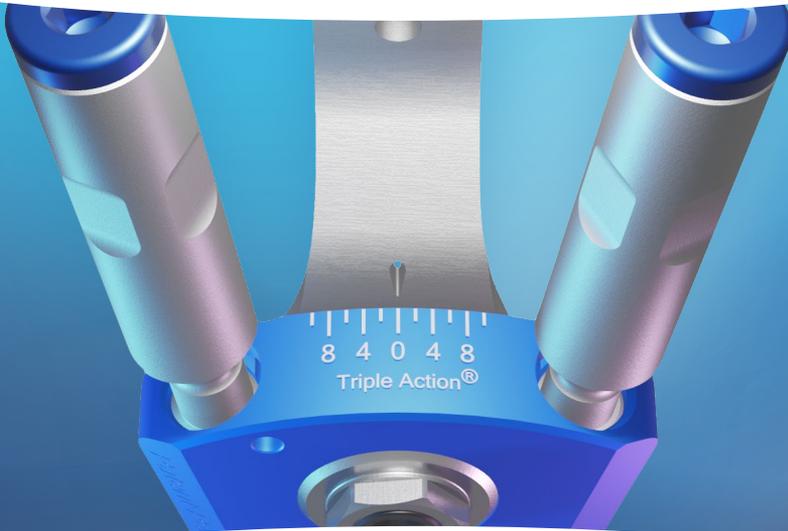


TRIPLE ACTION[®]

Pediatric Ankle Joint
(13mm Systems)

PRODUCT MANUAL



 **BECKER**



F 800-521-2192 | 248-588-7480
P 800-923-2537 | 248-588-2960
BeckerOrthopedic.com | f t in

Patent #10,500,081
©2020 Becker Orthopedic Appliance Co.
All rights reserved.
Revision 07/01/20

EC **REP**
Acorn Regulatory Consultancy Services Limited
Knockmorris Cahir Co. Tipperary Ireland, Postcode: E21 R766
P 012 4626 8456
F 012 4626 8648



TRIPLE ACTION[®]

Pediatric Ankle Joint
(13mm Systems)

TRIPLE ACTION[®] *DIFFERENCE*

The Pediatric Triple Action ankle joint offers unique features and exceptional performance for the orthotic treatment of complex and combined

biomechanical deficits in Cerebral Palsy, Spina Bifida and other pathologic neuromuscular conditions. Triple Action[®] has been shown to systematically influence the gait cycle in biomechanical studies.

The defining feature of Triple Action orthotics is the **independent** action of plantarflexion resistance, dorsiflexion resistance and alignment. The component's high stiffness, long-life springs and alignment feature can be tuned to optimize the phases of the gait cycle. This **adjustability** gives the clinician an effective tool to help balance support for the ankle and knee.

The Triple Action[®] ankle joint delivers features for all stages of pediatric orthotic management; as a static progressive orthotic adjunct to Botox[®] treatment, post-surgical immobilization following heel cord release or mobilization of the spastic ankle for active ambulation.

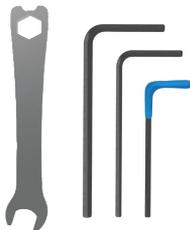


Models

GAIT PHASE WHERE ABNORMALITIES OCCUR					
Booster Configuration	Early Stance Phase	Late Stance Phase	Leg	Side	Order No.
 <p>None</p>	NORMAL		Either		3C76-A0*
 <p>PF</p>	ABNORMAL	NORMAL	Right	Lateral	3C76-A1*
			Left	Medial	
			Left	Lateral	3C76-A2*
			Right	Medial	
 <p>DF</p>	NORMAL	ABNORMAL	Right	Lateral	3C76-A2*
			Left	Medial	
			Left	Lateral	3C76-A1*
			Right	Medial	
 <p>PF & DF</p>	ABNORMAL		Either		3C76-A3

*Only available direct from Becker Orthopedic in some countries

Note: Right lateral component shown



Adjustment Wrenches
(included)

*The Booster Spring Unit cannot be removed from the Triple Action component housing. Doing so will destroy the Booster and void the product warranty.

Options & Accessories

Lateral Stirrup
(Model 3C76-LAT-1)



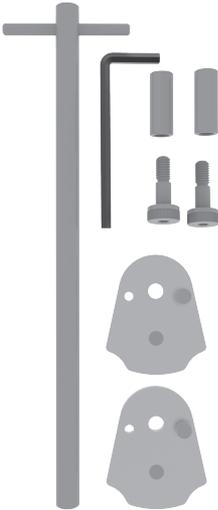
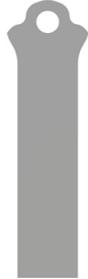
Medial Stirrup
(Models 3C76-MEDR-1 &
3C76-MEDL-1)



Y Stirrup
(Model 3C76-YLNG-1)



Universal Rivet Stirrup
(Model 3C76-R-1)



Fabrication Tool Kit
(Model 3C00-FTK)

Fabrication Tool Kit -
Includes Fabrication
Dummy, Alignment Axis,
Alignment Bushing, M6
Shoulder Screw and
Fabrication Wrench (4mm).

**Tamarack Flexure
Joint® Medium**
(Model 740-M)

Unilateral AFO's require
medium size Tamarack
Flexure Joint, or other free
motion ankle joint.



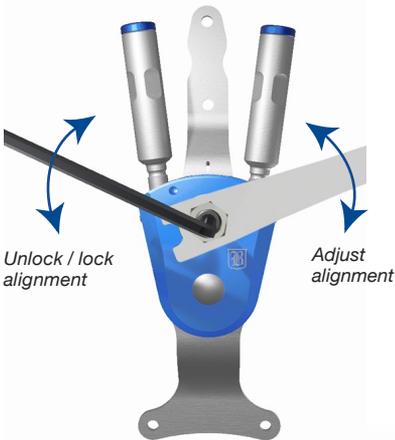
Adjustment

Alignment, range of motion, and resist are independently adjustable. The alignment adjustment determines the null angle of the stirrup and rotates the upper bar around the pivot bushing. Alignment is adjusted by turning the hex on the front of the component body. The screw inside the hex locks the alignment adjustment.

Range of motion settings are adjusted by turning the adjustment screws on top of the component body. There are motion limiter pins inside the springs to establish the 0° ROM position as a reference for this adjustment. Resist is adjusted by changing spring configurations. Two spring configurations are available.

Adjusting Alignment

*Loosen the alignment lock
(inside the hex) 1/2 to 3/4 turn to
unlock the alignment adjustment*



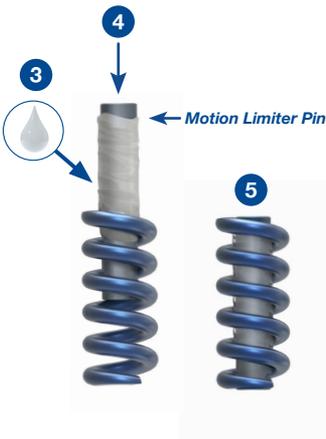
The recommended
tightening torque for
the alignment lock is:
7Nm (62 in-lb)



*The alignment adjustment
range is $\pm 10^\circ$*

Spring Installation

1. Remove the adjustment screw, resist spring and motion limiter pin from the channel
2. **Do not** remove the ball bearing
3. Grease the motion limiter pin
4. Insert the motion limiter pin into the spring
5. Wipe excess grease from the outside of the spring
6. Install the spring with the motion limiter pin into the channel and tighten the adjustment screw until resistance is felt.
7. Adjust range of motion as necessary



Adjusting Range of Motion

The range of motion adjustment changes the stirrup range of motion between its neutral position and the motion limiting stop.

To Zero ROM:

- Turn the ROM Adjustment using the 1.5mm hex wrench to loosen the ROM Lock Set Screw.
- Turn the ROM adjustment screw fully clockwise using the 4mm adjustment wrench.

To Increase ROM:

- Turn the adjustment screw counter clockwise to increase ROM by 5° per full turn.

To Lock ROM:

- Lock the adjustment screw by torquing the ROM Lock Set Screw to 0.5 Nm (Figure 1).



Figure 1

Notes:

- The maximum ROM setting is 10° (2 turns of the adjustment screw).
- Count the number of turns to keep track of the setting.
- The ROM adjustment screw is pre-coated with an antimigration patch and does not require thread locking adhesive for the first five adjustments.

Adjusting Range of Motion with the Booster Spring Option

With the Booster Spring models, rotate the booster to adjust the ROM setting.

To Zero ROM



Figure 1. Unlock / lock the ROM Adjustment using the 1.5mm hex wrench to loosen / tighten the ROM Lock Set Screw.



Figure 2. Adjust the ROM setting to 0° by turning the Booster fully clockwise with the adjustment wrench.

Orthotic Design Considerations

For best results, Triple Action AFO designs must be rigid. AFOs that are too flexible will decrease the systematic influence of the Triple Action ankle joint on gait. Rigid thermoplastic polypropylene materials in 4mm (5/32 inches) thickness are recommended for Triple Action AFO fabrication. Ribs or stiffeners placed at the distal tibial section may also be used to stiffen the orthotic structure. It is recommended that anterior (ventral) tibial shell with full footplate AFO designs be used where dorsiflexion resist is greater than plantarflexion resist in order to manage knee flexion. Ankle foot orthoses may use one or two Triple Action components depending on patient weight and spasticity. However, if a single Triple Action is used, it is necessary to pair the Triple Action with a free motion companion joint. Becker Orthopedic recommends the medium size Tamarack Flexure Joint (Model 740-M or Model 740-M-BLK) as a companion joint in single Triple Action applications.

One Triple Action® or Two?

The decision whether to use one or two Triple Action ankle joints should consider

Patient weight: 25 kg (55 lb) to 50 kg (110 lb)

Spasticity: Low, Moderate, High

Calf circumference: 20 cm (8 in) to 40 cm (16 in)

Important: Two Triple Action components are recommended for Post-Op applications

Fabrication Options

Thermoplastic



Unilateral*

4mm (5/32") Polypropylene



Bilateral

4mm (5/32") Polypropylene

**Requires Companion Joint*

**Important: Unilateral AFOs require medium size Tamarack Flexure Joint®, or other free motion ankle joint.*

Disassembly for Fabrication

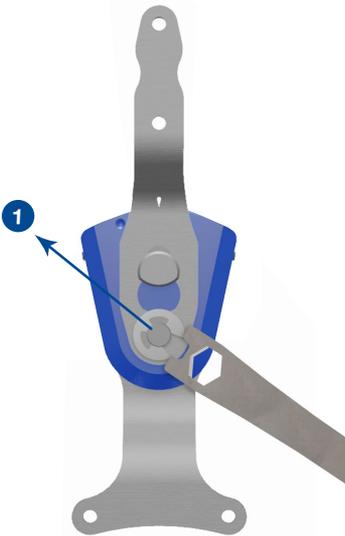
The upper bar and stirrup must be removed from the component body and attached to the Fabrication Dummy for fabrication.

To remove the bar and stirrup from the component body

1. Remove the Pivot Bushing E-Clip using the combination wrench
2. Remove the Pivot Bushing
3. Slide the upper bar toward the top of the component body and remove
4. Remove the stirrup

Prior to re-assembly, grease the pivot bushing, upper bar slot and stirrup head.

If the Pivot Bushing is difficult to remove from the component body, slightly loosen the adjustment screws.



Use the combination wrench to remove the Pivot Bushing E-Clip



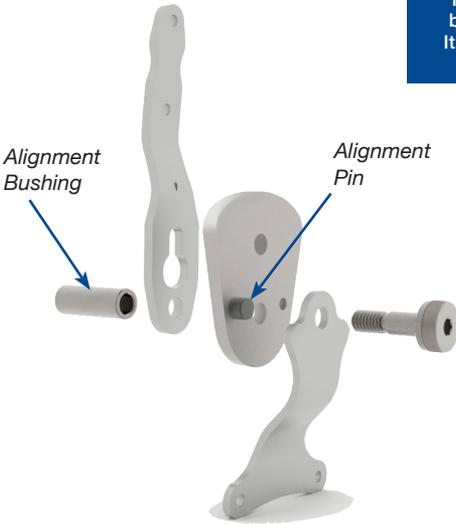
Apply threadlocker to bar attachment screws prior to final assembly.

Disassembling the Pediatric Triple Action®

Assembling the Fabrication Tool

The ankle angle of the negative mold should be corrected prior to filling. The Triple Action fabrication dummy holds the upper bar and stirrup in alignment. When fabricated in this way, the 0° alignment setting will correspond to the corrected ankle angle of the mold, and ensure $\pm 10^\circ$ adjustment range with respect to the corrected ankle angle of the AFO.

The stirrup head should be firmly seated against the Alignment Pin.



IMPORTANT: Don't bend or mar the stirrup head or upper bar where they contact the component body during fabrication.



Set the ankle axis in the negative cast using the Alignment Axis in the Fabrication Tool Kit, and fill the mold. Strip the mold and remove the Alignment Axis from the positive mold.



The Alignment Bushing fits into the Alignment Axis hole in the positive plaster mold.

Triple Action[®] Clinical Tuning Procedure

Through biomechanical research, Becker Orthopedic has developed an evidence-based Systematic Tuning Procedure to help simplify application of the Triple Action[®] ankle joint. This procedure is intended as a starting point to help you more quickly arrive at optimal component settings using Observational Gait Analysis.

Tuning Procedure

1. Bench Adjustment
2. Static Alignment
3. Swing Phase Alignment
4. Stance Phase Adjustment

Spring Selection

Before performing Bench Adjustment, the desired Triple Action springs must be installed. Refer to “Spring Installation” for additional information on spring installation.

There are four spring configurations available for the Pediatric Triple Action ankle joint. Each of these options offers unique resist and range of motion capabilities for patient management.

Systematic Tuning Procedure for Triple Action Ankle Joints.

To view, please scan the QR Code ▶

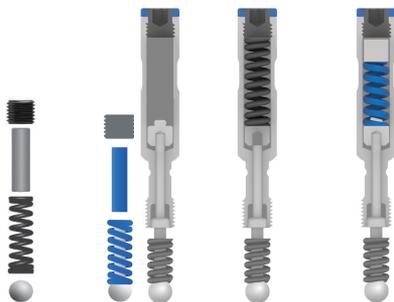


Triple Action Spring Configurations



**The Booster Spring Unit cannot be removed from the Triple Action component housing. Doing so will destroy the Booster and void the product warranty.*

**Internal bottom spring under booster is covered with a lifetime warranty for defects in materials and workmanship.*



PF Spring Configuration	1	2	3	4
Booster Required	No	No	Yes	Yes
Bottom Spring	Standard	High	High	High
Top Spring	None	None	Long ROM	High
Stiffness	X0.2 (low)	X1 (low)	X1.5 (moderate)	X2 (high)
Max. ROM	15°	10°	18°	10°

Spring Selection (Continued)

The Standard and High Resist Springs are suitable for the management of mild biomechanical deficits in larger patients or smaller patients with more severe deficits. To expand applications to heavier patients with higher spasticity, the Booster Spring option may be installed or two components may be used.

Gait Type*	Pattern	Orthotic Design	Mild to Moderate	Moderate to Severe
<p>Gait Type 1: Hemiparesis with drop foot in swing phase secondary to dorsiflexion insufficiency. No significant triceps surae contracture.</p>		Posterior (dorsal) tibial shell. Sulcus length footplate.		
<p>Gait Type 2: Hemiparesis with dropfoot and true equinus secondary to triceps surae contracture, with or without genu recurvatum.</p>		Posterior (dorsal) tibial shell. Sulcus length footplate.		
<p>Gait Type 3: Hemiparesis with true equinus. Jump gait with contracture or spasticity of gastrosoleus. Spastic co-contraction of quadriceps and hamstrings.</p>		Anterior (ventral) tibial shell. Full length footplate.		
<p>Gait Type 4: Hemiparesis gait type 3 plus hip flexor/adductor spasticity.</p>		Anterior (ventral) tibial shell. Full length footplate.		
<p>Crouch Gait: Diplegia with excessive dorsiflexion, knee and hip flexion.</p>		Anterior (ventral) tibial shell. Full length footplate.		

*Gait Type from "Classification of gait patterns in spastic hemiplegia and spastic diplegia: a basis for a management algorithm". Rodda et al. 2001.

Triple Action[®] Clinical Tuning Procedure

Bench Adjustment

Prior to fitting the orthosis, bench adjust the components as follows:

1. Lock plantarflexion (PF) ROM at 0°
2. Lock dorsiflexion (DF) ROM at 0°
3. Set the alignment to 0°



Adjust the alignment setting to 0°. Refer to "Adjusting Alignment" for additional information.

Lock both ROM settings by turning the adjustment screws fully clockwise. Refer to "Adjusting Range of Motion" for additional information.

Static Alignment (PF and DF ROM at 0°)

Don the orthosis and shoes to the patient and perform static alignment with the patient standing. Adjust the ankle angle with the ROM settings locked at 0° to tune the shank to vertical angle, and move the weight line over the midfoot. The knee should be slightly flexed. A typical starting point for the shank to vertical angle is 11°. This is measured at the tibial crest with the orthosis and shoe donned. Optimize the patient's sense of standing balance and stability. If there is insufficient dorsiflexion ROM to make the adjustment due to a gastrosoleus contracture, a lift may be required under the heel of the AFO to incline the shank.



Swing Phase Alignment (PF and DF ROM at 0°)

With the ROM settings still locked at 0°, use the alignment setting to adjust toe clearance in mid swing and foot position at initial contact. Observe the foot to floor angle while making this adjustment. Note that increasing dorsiflexion alignment may reduce knee extension at terminal swing if there is gastrocnemius tone or contracture. Also observe step length symmetry while making this adjustment.



Toe Clearance (left) and Foot to Floor Angle (right)

Early Stance Phase Adjustment (DF ROM at 0°)

Adjust plantarflexion ROM to activate the ankle in 1st rocker and early stance to stabilize the knee. Begin by increasing the plantarflexion (PF) ROM setting by 1 to 2-turns (5 to 10°) of the adjustment screw.

- If toe clearance or foot to floor angle decreases → Decrease the PF ROM.
- If knee hyperextension in early stance increases → Decrease the PF ROM.
- If the knee flexes excessively in 1st rocker → Increase the PF ROM.



Late Stance Phase Adjustment

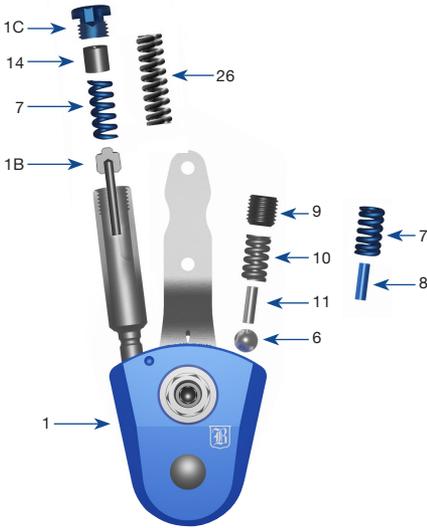
Adjust dorsiflexion ROM to activate the ankle in 2nd rocker and late stance to stabilize the knee. Begin by increasing the dorsiflexion (DF) ROM by 1 to 2-turns (5 to 10°) of the adjustment screw.

- If the knee flexes excessively after midstance → Decrease the DF ROM.
- If the knee hyperextends at the end of stance phase → Increase the DF ROM.

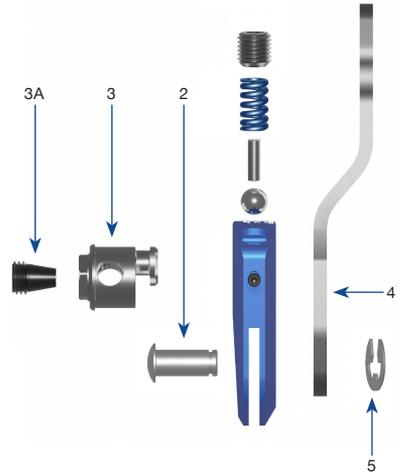


Triple Action Components

Front View



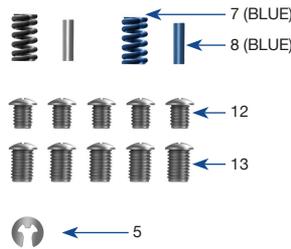
Side View



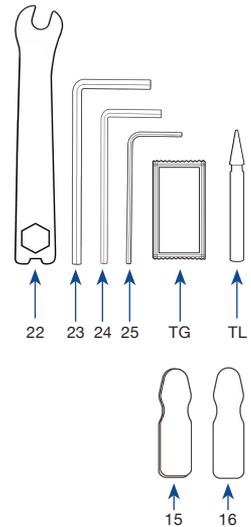
Top View



Small Parts



Accessories



Triple Action Part Numbers

Reference #	Description
1B	Booster Spring Base and Pin Assembly
1C	Booster Cap
2	Pivot Bushing
3	Cam Bushing
3A	Cam Bushing Screw
3B	Cam Bushing Locking Jaw
4	Upper Bar
5	HD Side Mount Ext. Retaining Ring (1/4")
6	1/4" Ball Bearing
7	High Torque Spring
8	High Torque Pin 3mm x 10mm
9	Set Screw M8 x 1 x 8mm Flat Point
10	Standard Torque Spring
11	Standard Torque Pin 1/8 x 7/16
12	Attachment Screw 6mm
13	Attachment Screw 8mm
14	Spring Spacer
15	Upper Bar Pelite Pad - 3mm
16	Upper Bar Shearban® Patch
22	Combination Wrench
23	4mm Hex Wrench
24	2.5mm Hex Wrench
25	1.5mm Hex Wrench
26	Long Rom Spring
TG	Teflon Grease
TL	Thread Lock

Note:

- To order parts, please specify the original order number, right or left, medial or lateral, followed by the part number desired.

TRIPLE ACTION[®]

Pediatric Ankle Joint (13mm Systems)



F 800-521-2192 | 248-588-7480
P 800-923-2537 | 248-588-2960
BeckerOrthopedic.com | **f** **t** **in**

Patent #10,500,081
©2020 Becker Orthopedic Appliance Co.
All rights reserved.
Revision 07/01/20



Acorn Regulatory Consultancy Services Limited
Knockmorris Cahir Co. Tipperary Ireland, Postcode: E21 R766
P 012 4626 8456
F 012 4626 8648

