

Adult 2.0 Ankle Joint (19mm Systems)

# **IFU** INSTRUCTION FOR USE







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EC REP

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





Adult 2.0 Ankle Joint (19mm Systems)

The patented Adult 2.0 Triple Action ankle joint offers unique features and exceptional performance for the orthotic treatment of neuromotor deficits. It has been shown to systematically influence gait in biomechanical studies.

#### **Features**

- Independent adjustment of:
  - · Ankle alignment
  - Plantarflexion/dorsiflexion range of motion
  - · Plantarflexion spring stiffness
- Independent ankle alignment range of ±10°
- (5) high stiffness spring options included with booster spring models
- Compatible with unilateral or bilateral orthotic designs

#### Indications

- Lower limb functional deficits as a result of:
  - Stroke
  - Cerebral palsy
  - Multiple sclerosis
  - Spina bifida
  - · Spinal cord injury
  - · Charcot-Marie-Tooth
  - · Other neuromotor deficits

#### Contraindications

- Patient weight greater than 110 kg (240 lb)





## Models

GAIT PHASE WHERE ABNORMALITIES OCCUR Early Stance Phase Late Stance **Booster** Order No. Side Leg Configuration Phase None Right Lateral 3A76-A1\* Left Medial NORMAL Left Lateral 3A76-A0\* Right Medial PF Right Lateral 3A76-A3 Left Medial **ABNORMAL** NORMAL Left Lateral 3A76-A2 Right Medial None Right Lateral 3A76-A1\* Medial Left NORMAL **ABNORMAL** Left Lateral 3A76-A0\* Right Medial PF Right Lateral 3A76-A3 Medial Left **ABNORMAL** Left Lateral 3A76-A2 Right Medial

\*Only available direct from Becker Orthopedic in some countries Note: Right lateral component shown



## **Options & Accessories**

#### Stirrup Options



Medial Stirrup (Models 3A76-MEDR-1 & 3A76-MEDL-1)



Y Stirrup (Model 3A76-YR-1 & Model 3A76-YL-1)



Universal Rivet Stirrup (Model 3A76-R-1)



Fabrication Tool Kit (Model 3A00-FTK)

The fabrication tool kit includes fabrication dummies, alignment axis, attachment hardware and wrenches.



Camber Axis Triple Action Companion Joint (Model 751-ATA)

Thermoplastic unilateral AFO's require Camber Axis Triple Action Companion Joint, or other free motion ankle joint.



## **Adjustment**

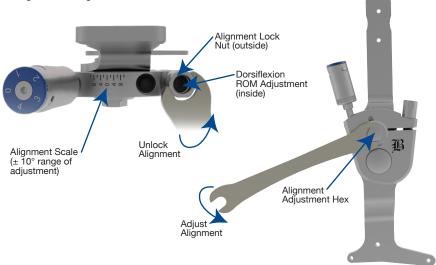
Triple Action ankle alignment, range of motion, and plantarflexion spring stiffness are independently adjustable. Ankle alignment rotates the component body about the pivot bearing to change the ankle angle without altering range of motion or resistance to ankle motion. Dorsiflexion and plantarflexion range of motion settings change the relative dorsiflexion and plantarflexion range of motion irrespective of the ankle alignment setting. Plantarflexion spring stiffness is adjusted by changing the spring configuration.

#### **Adjusting Ankle Alignment**

The ankle alignment setting changes the ankle angle of the orthosis without changing the available range of motion of the stirrup. In the open kinetic chain, this adjustment changes the ankle alignment toward plantarflexion and dorsiflexion. In the closed kinetic chain this adjustment alters the shank angle. The springs are not compressed during this adjustment, and the stirrup position remains fixed with respect to the component body. When the ankle alignment setting is at 0 degrees, the ankle angle in the AFO is equal to the ankle angle of the mold as fabricated. Ankle alignment with respect to this reference position is read directly in degrees from the scale on top of the component body. Ankle angle is adjustable over a 20° range.

#### To adjust alignment:

- Loosen the alignment lock nut on top of the component body (Note that the alignment lock nut also unlocks the dorsiflexion ROM setting).
- 2. Adjust alignment by rotating the hex on the front of the component body with the combination wrench.
- 3. Tighten the alignment lock nut.





#### **Adjusting Dorsiflexion Range of Motion**

The dorsiflexion range of motion adjustment changes the stirrup range of motion between its neutral position (at the alignment ankle angle) and the dorsiflexion motion limiting stop.

#### To Zero Dorsiflexion ROM:

- Loosen the alignment lock nut on top of the component body.
- While holding the nut with the combination wrench, turn the DF ROM adjustment screw fully clockwise using the 4mm adjustment wrench.
- Tighten the alignment lock nut.

#### To Increase Dorsiflexion ROM:

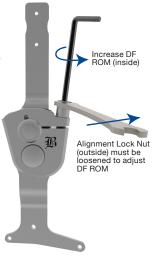
- Loosen the alignment lock nut on top of the component body.
- Turn the adjustment screw counter clockwise to increase DF ROM 3° per full turn while holding the alignment lock nut.



· Tighten the alignment lock nut.

#### Notes:

- The maximum DF ROM setting is 12° (4 turns of the adjustment screw).
- Count the number of turns to keep track of the setting.
- If the alignment setting changes during this adjustment, return alignment to the desired setting before tightening the alignment lock nut.



Adjusting Dorsiflexion ROM

#### Staged Dorsiflexion Resistance

The dorsiflexion resist function uses two springs installed in the anterior channels of the component body. The middle spring is the "2nd rocker spring" and the anterior-most spring is the "terminal stance spring." The 2nd rocker spring is lower stiffness and its range of motion (ROM) is not adjustable. The terminal stance spring is high stiffness, it's ROM is adjustable and determines the overall ROM of the component in dorsiflexion. Adjusting the dorsiflexion ROM setting between 0° and 6° applies high active resistance to dorsiflexion using both the 2nd rocker and terminal stance springs. If the dorsiflexion ROM setting is adjusted between 6° and 12°, the 2nd rocker spring acts alone through the first 6° of stirrup articulation before the terminal stance spring is encountered. When the terminal stance spring is encountered, the stiffness and resistance to dorsiflexion increase rapidly to the end of ROM. The stirrup angle at which terminal stance spring is encountered is adjusted by the dorsiflexion ROM setting. This patent-pending Triple Action feature is called "Staged Resistance."



#### **Adjusting Plantarflexion Range of Motion**

The plantarflexion range of motion adjustment changes the stirrup range of motion between its neutral position (at the alignment ankle angle) and the plantarflexion motion limiting stop.

#### To Zero Plantarflexion ROM:

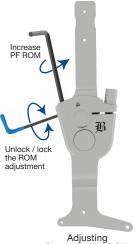
- Unlock the ROM Adjustment using the 1.5mm hex wrench to loosen the ROM Lock Set Screw.
- Turn the ROM adjustment screw fully clockwise using the 4mm adjustment wrench.

#### To Increase Plantarflexion ROM:

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

#### To Lock Plantarflexion ROM:

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



Adjusting Plantarflexion ROM Figure 1

#### Notes:

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

# Adjusting Plantarflexion ROM with the PF Booster Spring

Rotate the booster to adjust the PF ROM setting.

#### To Zero Plantarflexion ROM



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



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



Figure 3. Loosen the ROM Dial screw using the 2mm adjustment wrench and zero the PF ROM setting by turning the blue ROM dial. The plantarflexion channel side of the component body serves as a reference for this adjustment.



## Adjusting Plantarflexion ROM with the PF Booster Spring Cont.

#### To Adjust Plantarflexion ROM with the PF Booster:

- Loosen the ROM Lock Set Screw to unlock the adjustment (Figure 1).
- Turn the Booster counter clockwise to increase PF ROM 5° per turn.
- Lock the booster by torquing the ROM Lock Set Screw to 0.5 Nm (Figure 1).

#### Notes:

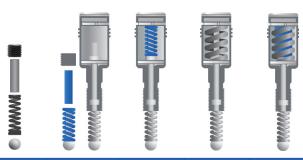
- The maximum PF ROM setting is 10° (2 turns of the Booster).
- The PF ROM is read directly from the blue PF ROM Dial.



#### **Adjusting Plantarflexion Spring Stiffness**

The stiffness of plantarflexion spring configurations 0 and 1 are suitable for the management of mild swing phase gait deficits. If higher plantarflexion stiffness is needed, the Triple Action with plantarflexion Booster Spring may be required. With the Booster Spring, the Triple Action component's plantarflexion resist can be configured with four different stiffness options.

#### **Spring Configurations**



PF Spring Configuration			2		4
Booster Required	No	No	Yes	Yes	Yes
Bottom Spring	Long ROM	Standard	Standard	Standard	Standard
Top Spring	None	None	Standard	High	High & Standard
Stiffness	X0.5 (low)	X1 (low)	X2 (moderate)	X4 (high)	X5 (very high)
Max. ROM	18°	10°	10°	10°	10°



#### **Configuring the PF Booster Spring**

The stiffness of plantarflexion spring configuration 1 is about 3 times higher than a conventional metal ankle joint.

Booster spring stiffness may be increased up to 18 times that of a conventional component. Spring stiffness increases linearly with configuration number. The maximum active ROM for all plantarflexion spring options is 10 degrees.

#### To change the booster spring configuration:

- 1. Increase the plantarflexion ROM setting to 15° by turning the booster counter clockwise to decrease booster spring compression (Figure 4).
- 2. Remove the plantarflexion booster ROM dial screw and plantarflexion ROM Dial (Figure 5).
- 3. Remove the Keeper Plate and install the desired spring configuration (Figure 6).



Figure 4. Adjust the Booster to 15° ROM.



Figure 5. Remove the ROM Dial Screw and PF ROM dial.



Figure 6. Remove the Keeper Plate and install the desired spring configuration.



# Orthotic Design Considerations

For best results, Triple Action AFOs must be rigid. AFOs that are too flexible will decrease the systematic influence of the Triple Action ankle joint on gait. Rigid carbon/epoxy laminated orthoses are recommended for Adult Triple Action AFOs. Ribs or stiffeners may also be included to help stiffen the structure. If single upright designs are used, attention should be given to enhancing torsional stiffness of the tibial section.

The Triple Action component may also be used in single, or double upright polymer AFOs. Polymer AFOs should be made of polypropylene homopolymer in a sheet thickness of 4.8mm (3/16 inches). If a single Triple Action component is used in a polymer AFO, a medial free motion companion joint with high torsional stiffness must be paired with the Triple Action. Becker Orthopedic recommends the Camber Axis Triple Action Companion Joint, Model 751-ATA, for use in single upright polymer AFOs using the Adult Triple Action ankle joint, Model 3A76. Depending on spasticity, a single Triple Action component placed on the lateral or medial side may be suitable for the management of patients up to 100kg (220 lbs).

Anterior (ventral) AFO designs (Figure 7) with full length footplates are recommended when dorsiflexion resist function predominates, such as in sub-acute stroke or TBI management/rehabilitation, or where there is a quadriceps or plantarflexor insufficiency. Posterior (dorsal) AFO designs (Figure 8) with sulcus or full-length footplates are recommended when there is high plantarflexion spasticity, or knee extension in the early stance phase of gait, such as in extensor synergy in chronic stroke.



Figure 7. Anterior (ventral) design.

Figure 8. Posterior (dorsal) design.

#### **Fabrication Options**

#### **Thermoplastic**





Unilateral\* 5mm (3/16") Polypropylene





Bilateral 5mm (3/16") Polypropylene

#### Composite



Unilateral
Wet Lamination like Becker BCO
Shadow™, Max™ or PrePreg





Bilateral Wet Lamination like Becker BCO Lite™, Shadow™, Max™ or PrePreg

\*Important: Thermoplastic unilateral AFOs require Camber Axis Triple Action® Companion Joint, or other free motion ankle joint



# Triple Action<sup>®</sup> 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 allow clinicians to 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
  - Early Stance Phase Adjustment
  - Late Stance Phase Adjustment

Systematic Tuning Procedure for Triple Action Ankle Joints.

To view, please scan the QR Code ▶



#### **Spring Selection**

Before performing Bench Adjustment, the desired Triple Action plantarflexion spring configuration must be installed (refer to Adjusting PF Spring Stiffness).

The Adult Triple Action ankle joint with spring configuration 1 in the plantarflexion channel is suitable for the management of patients with mild swing and stance phase gait deficits under 100 kg (220 lbs). For patients with higher spasticity or greater weight the booster spring is recommended. In general, higher stiffness springs should be used to manage higher spasticity patients.

The plantarflexion booster spring expands applications of the Triple Action to patients with a broad range of neuromusculoskeletal deficits. All plantarflexion spring options have 10° ROM and stiffness increases linearly with PF spring configuration number.

#### **Bench Adjustment**

After the desired PF spring configuration has been installed and prior to fitting the orthosis, bench adjust the component as follows:

- Adjust the plantarflexion ROM setting to 0°.
- 2. Adjust the dorsiflexion ROM setting to 0°.
- 3. Set the ankle alignment to 0°.



#### 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 for knee stability. The knee should be slightly flexed to place the weight line over the midfoot and improve the patient's sense of standing balance and stability. Avoid aligning the ankle to the patient's maximum ROM in dorsiflexion when making this adjustment. If there is insufficient dorsiflexion ROM to make this adjustment due to a gastrosoleus contracture, a heel lift or shoe modification may be necessary.





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

With the patient walking, and the ROM settings still locked at 0°, adjust the alignment setting to improve 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 and optimize for step length symmetry while making this adjustment.





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



#### Early Stance Phase Adjustment (DF ROM at 0°)

Increase plantarflexion ROM 5° to 10° (1 to 2 turns of the adjustment screw or booster spring) to activate the ankle in 1st rocker and early stance. Increasing PF ROM will decrease the pre-load resistance of the PF resist. Ensure that toe clearance and foot position at initial contact are maintained as PF ROM is increased.

- 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.

If plantarflexion ROM must be decreased to less than 5° to maintain ankle position during this adjustment, it may be necessary to increase the stiffness of the plantarflexion spring by changing the spring configuration to a higher number.



## 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 (3 to 6°) 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.



We recommend lubricating the pivot bearings regularly with a small drop of non-synthetic, light machine oil. Additionally, the component should be inspected every six months for worn or damaged parts and excessive play or wear. If detected, replace the worn or damaged parts.

To maximize the life of the product, the parts listed below should be replaced according to the following maintenance schedule:

#### **Replace Every 12 Months:**



Models 3A76-A0

#### Models 3A76-A0 and 3A76-A1

Order No.	Description	Periodicity	
3A76-A0-A1-12	12 month maintenance kit	Every 12 months	



#### Models 3A76-A2 3A76-A3

#### Models 3A76-A2 and 3A76-A3

Order No.		Description	Periodicity	
	3A76-A2-A3-12	12 month maintenance kit	Every 12 months	

At each scheduled maintenance, or patient follow-up appointment, it is highly recommended that the orthosis and the component(s) be inspected for proper function using the checklist below.

- Evaluate stirrup range-of-motion.
- · Verify component is actively resisting motion.
- Clean out any dust, or debris in the joint clevis.
- Inspect component and springs for visible wear and
- replace if necessary.
- Ensure all fasteners are properly tightened.

#### **Bearing Replacement Instructions**

- 1. To install new bearings, first remove old bearings (3A76-2 & 3A76-3) from joint body (3A76-1) and upper bar (3A76-11) using the bearing installation tool and an arbor press.
- 2. Install the new front bearing (3A76-3) into the joint body. The front bearing is identified as the bearing that does not have a notch in its flange.
- 3. To install the replacement bearing in the component body, carefully align the bearing with the hole through the joint body. Press the bearing into the counterbore using the bearing installation tool and an arbor press. Important: The bearing must be fully seated in the counterbore with its flange flush with the component body.
- 4. To install the bearing (3A76-2) in the upper bar (3A76-11), align the notch in the bearing flange with the pin in the upper bar counterbore. Carefully align the bearing with the hole through the upper bar before fully seating it using the bearing installation too and an arbor press. Ensure the bearing is fully seated in the upper bar.

#### **Bearing Reaming**

- 1. After the bearings (3A76-2 & 3A76-3) are pressed into the component body (3A76-1) and upper bar (3A76-11), they must be reamed.
- Place the upper bar (3A76-11) in position on the back of the component body (3A76-1) with the bearing inserted into the pivot hole through the component body and align the upper bar cam slot with the cam hole through the joint body.
- Firmly secure the upper bar to the component body using a clamp and ream the pivot bearings using a 0.472" reamer provided with the bearing installation tool kit.
- 4. Apply non-synthetic, light machine oil to the bearings and assemble the component per the assembly instructions.

For additional information, please refer to our bearing installation video by scanning the QR Code

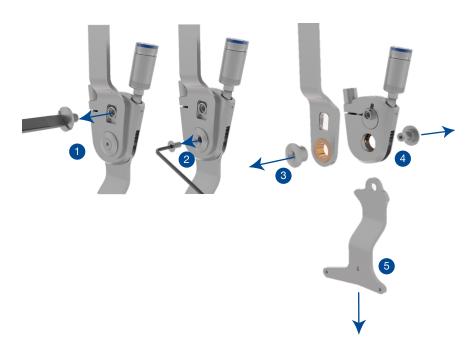




#### **Disassembly**

Use the following procedure to disassemble the component for fabrication and maintenance:

- 1. Remove the alignment bushing screw using a large slotted screwdriver.
- 2. Remove the pivot bushing screw using the Torx T20 wrench.
- 3. Remove the upper bar pivot bushing and upper bar.
- 4. Remove the front pivot bushing.
- 5. Remove the stirrup.



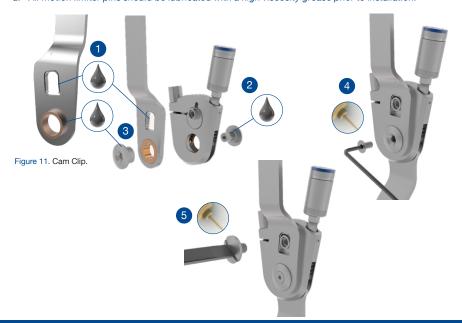
#### **Assembly**

The Adult Triple Action ankle joint requires minimal maintenance. The pivot bearings in the upper bar and component body should be lubricated on a monthly basis using a small drop of oil. The pivot screw and cam screw should be coated with medium strength thread locking adhesive prior to final assembly. Note that the bar attachment screws (not included) should also be coated with thread locking adhesive prior to final assembly.

- Install and lubricate the cam clip (Figure 11) with SAE 30W oil. Ensure that the cam clip is oriented correctly in the cam slot with the open end of the clip toward the pivot bearing.
- Lubricate the bearing shoulder of the male pivot bushing with SAE 30W oil. Insert the stirrup into the clevis and push the D-shaped mandrel of the pivot bushing into the stirrup D-hole.
- Lubricate the bearing shoulder of the female pivot bushing and the outer shoulder of the bearing that inserts into the component body with SAE 30W oil.
- 4. Apply medium strength thread locker to the pivot screw and torque to 4Nm.
- 5. Apply medium strength thread locker to the cam screw and install.

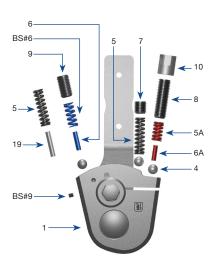
#### Notes:

a. All motion limiter pins should be lubricated with a high viscosity grease prior to installation.

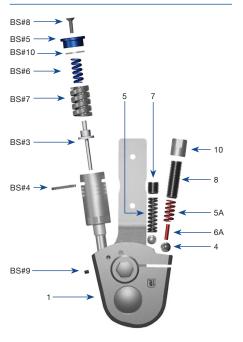


## **Triple Action Components**

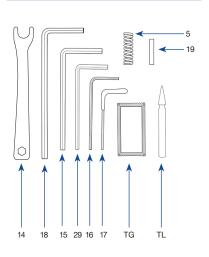
#### **Front View**



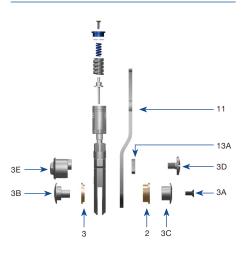
#### Front View



#### **Accessories**



#### **Side View**



## **Triple Action Part Numbers**

Reference #	Description	
1L	Joint Body - Left	
1R	Joint Body - Right	
2	Upper Bar Bearing	
3	Front Bearing	
3A	Pivot Screw	
3B	Male Pivot Bushing	
3C	Female Pivot Bushing	
3D	Cam Bushing Screw	
3E	Cam Bushing	
4	1/4" Ball Bearing	
5	2nd Rocker Spring - (Z970006)	
5A	Terminal Stance Spring (Red) - (Z970007)	
6	1st Rocker Pin (Blue) - (Z970055)	
6A	Terminal Stance Pin (Red) - (Z970009)	
7	2nd Rocker Set Screw	
8	Terminal Stance Set Screw	
9	1st Rocker Set Screw	
10	Alignment Lock Nut	
11L	Upper Bar - Left	
11R	Upper Bar - Right	
13A	Cam Clip - (Z970013)	
14	Combination Wrench	
15	4mm Hex Wrench	
16	2mm Hex Wrench	
17	1.5mm Hex Wrench	
18	T20 Torx Wrench	
19	1st Rocker Pin (1/8" x 3/4") - (Z970008)	
29	2.5mm Hex Wrench	
BS#3	Booster Spring Base and Pin Assembly	
BS#4	Booster Spring Keeper Plate	
BS#5	ROM Dial	
BS#6	Booster 600 Spring (Blue)	
BS#7	Booster 1800 Spring	
BS#8	Booster ROM Dial Screw	
BS#9	P ROM Lock Set Screw	
BS#10	0 Booster Spring Cup	
TG	Teflon Grease	
TL	Thread Lock	

- Notes:

   To order parts, please specify the original order number, right or left, medial or lateral, followed by the part number desired.
- Highlighted rows are included in Maintenance Kits





# Adult 2.0 Ankle Joint (19mm Systems)



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

