



Adjustable ROM Ankle Joint

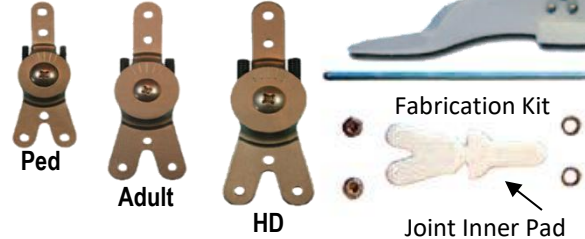
Instructions For Use



The Meridian Ankle Joints require that the completed orthosis maintains proper ankle joint alignment, and square Joints to promote proper function and operation. Follow the fabrication instructions for best results. Weight limit is: ped= 50kg / 110lb, adult= 90kg / 200lb, HD= 136kg / 300lb. Joint range is 30 degrees in Dorsi-Flexion / 30 degrees in Plantar-Flexion for total of 60 degrees of fine tune adjustment range.

Meridian Ankle Joint		
P/N	Description	Unit
MAJ-100P	Pediatric	Set
MAJ-100A	Adult	Set
MAJ-100HD	Heavy Duty	Set

Fabrication Kit		
P/N	Description	Unit
MAJ-KIT-P	Pediatric	Kit
MAJ-KIT-A	Adult	Kit
MAJ-KIT-HD	Heavy Duty	Kit



Fabrication:

- Identify and mark with an indelible pencil, the desired ankle joint axis placement height and location for medial and lateral malleolus on negative cast
- ⚠ **NOTE:** Joints must be parallel, and the uprights have minimal ability for contouring (max 100cm / 4" radius). Excess contouring will lead to cracking, as they are not very malleable. There will be gapping of the struts to the cast.
- At ankle joint marks, drill an appropriate hole for the threaded rod to be placed into the cast impression
- Apply petroleum jelly to threaded rod, place the rod through the holes at the ankle joint axis, and seal the rod to the cast
- Prepare plaster model by filling, removing plaster wrap, and modifying as usual.
- Ensure that there is proper clearance for ankle joint in your modification before proceeding to next step
- Disassemble Meridian Ankle Joints; thread proximal joint onto threaded rod (minor contouring can be done, but with large smooth radius – sharp bends can crack upright and void warranty!)
- Apply distal joint over proximal joint, apply washer and thread on provided hex nuts to fasten the joints onto the mold (minor contouring can be done, but with large smooth radius – sharp bends can crack upright and void warranty!)
- Fill in the gap for the upper and lower struts with plaster (there will be gapping depending on anatomy shape)
- Remove excess rod protruding from the hex nuts, but keep enough to allow for rod removal after pulling plastic!
- Ensure joint squareness to each other, then vacuum form plastic on positive model as usual
- After plastic has cooled, expose the rod so the hex nuts can be removed, then completely remove the threaded rod
- Mark, then cut, and finish AFO as usual, then cut ankle joint trim on AFO to allow proper clearance for ROM
- Drill holes for 8-32 attachment screws using 5/32" drill bit
- Clean and reassemble Meridian Ankle joints, then attach to AFO with screws provided; Loctite and torque to 7-8Nm
- Apply inner joint pads, or can apply filler foam padding of your choice to the inner faces of Meridian Ankle Joints
- Adjust anterior and posterior set screws for desired amount of range of motion with included hex wrench

Environment:

Store at room temperature, and avoid extremely hot, cold, or moist storage environments Storage Temperature Range: between temperatures of -10°C to 50°C [14°F and 122°F]

Do not store in wet or very hot environment.

Allowable environmental conditions

Use – relative humidity: 0 % to 90 %, non-condensing

Storage/transportation – relative humidity: 20 % to 90 %, non-condensing

Splash - Fresh water, rain, salt water, urine, dust, sand, particles of foam cosmetics

cleaning required after contact with salt-laden air, salt water, chlorinated water, urine, sand

Unallowable environmental conditions

Storage/transportation: high vibrations, impacts

Cleaning agents containing solvents

CE Conformity

This product meets the requirements Council EU 2017/1745 (MDR) for medical products. This product has been classified as a class I product according to the classification criteria outlined in appendix IX of the guidelines. Please keep this manual in safe place for future use.



Warranty covers defects in workmanship for the given warranty period. Signs of abuse, lack of biannual inspection, improper installation are examples of areas not covered by warranty.

Useful Life

Service life of the product is covered by the warranty period. Not to be used on another wearer other than original intended wearer.

*** Never use Red Loctite, ONLY Blue Loctite on any adjustment screws or fasteners!**

⚠ Note: Do not apply a wet lubricant to the joint! This will attract dirt and can soil the wearers socks/shoes. Use a dry lubricant if necessary. Not for wet environments, or high activity usage. Use appropriately for given situational needs
Warranty period: 6 months. Damaged uprights due to excessive contouring is not covered under warranty.

