

These documents have been provided by

WorryFreeDME

Compliance Documentation Pack

Custom Molded Gauntlet - Precasting Packet

To be completed by physician:

Biomechanical Evaluation Form (Medical Record Information)

- Documents medical necessity

Document of Medical Necessity

- Justifies qualification for use of AFO
 Details reason for prefabricated versus custom device
 Justifies level of fitting (off-the-shelf versus custom-fitted)
 Justifies code(s) selected

Prescription

- Description of the items
 Patient Name
 Physician's printed name
 Diagnosis
 Physician's signature (no stamps allowed)
 Date (no stamps allowed)
 Indication if right and / or left limb affected

To be given to Patient:

Proof of Delivery

- Patient Printed Name
 Date of delivery
 Item Description
 Item Code(s)
 Patient Signature
 Patient Address

DMEPOS Supplier Standards

To be completed by Supplier / Physician:

Dispensing Chart Notes

- Type of orthosis
 Describes method of fitting
 Documents patient satisfaction

* Confirms delivery of Supplier Standards

The OHI Family of Brands





Created by:

The American College of
FOOT & ANKLE ORTHOPEDICS
& MEDICINE

Biomechanical Evaluation Form

Patient Name:	
Chief Complaint:	
History of problem:	
Nature of discomfort/pain	
Location (anatomic)	
Duration	
Onset	
Course	
Aggravating and/or alleviating factors	

Left	Stance Evaluation:	Right	Normative values:	Treatments and response
	Angle of gait:->			
	Base of gait:->			
	Foot appearance			
	Tibial influence		0°-2° varus or valgus	
	Relaxed calcaneal stance position (RCSP)		0°	
	Neutral calcaneal stance position (NCSP)		0°	
	Non-Weight Bearing Evaluation:			
	Limb length:->		Equal	
	Hip sagittal plane-			
	Knee extended		Flexion 120°/extension 20-30°	
	Knee flexed		Flexion 45-60°/extension 20-30°	
	Hip transverse plane-			
	Knee extended		45° each direction	
	Knee flexed		45° each direction	
	Hip frontal plane		45° each direction	
	Knee sagittal plane		Flexion 120°/extension 0-10°	
	Knee recurvatum		Absent	
	Ankle sagittal plane-			
	Knee extended		Dorsiflexion 10°/plantarflexion 40-70°	
	Knee flexed		Dorsiflexion 10°/plantarflexion 40-70°	
	Subtalar joint-			
	Inversion		20°	
	Eversion		10°	
	Subtalar joint axis location			
	Midtarsal joint		0°	
	1 st ray range of motion		Dorsal & plantar excursion 5mm	
	1 st MTPJ range of motion		Dorsal 65° or >unloaded/20-40° loaded	
	Lesser MTPJ's			
	Other comments:			
	Muscle testing (extrinsics):			
	Invertors		5/5: normal strength	
	Evertors		5/5: normal strength	
	Dorsiflexors		5/5: normal strength	
	Plantarflexors		5/5: normal strength	
	Neurological testing:			
	Romberg->		Balance intact	
	Patellar reflex		2+ normal	
	Achilles reflex		2+ normal	
	Babinski		No hallux extension	
	Clonus		Absent	
	Protective sensation		Present	
	Gait Evaluation -			
	Gait pattern			
	Comment on head/shoulders, spine, pelvis, sagittal/transverse/frontal plane, postural, etc.			
	Footgear (size/width, wear pattern(s))->			
	Existing orthoses/type->			
	Weight->			
	Height->			
	Biomechanical assessment:			
	Treatment plan:			
Enter assistant name		Enter date of exam		
Signature of assistant		Signature of physician		

Save in patient's chart



Document of Medical Necessity: Custom Molded Gauntlet

Patient Name: _____

HICN: _____

Prognosis: Good

Duration of usage: 12 Months

I certify that Mr. / Ms. _____ qualifies for and will benefit from an ankle foot orthosis used during ambulation based on meeting all of the following criteria. The patient is:

- Ambulatory, and
- Has weakness or deformity of the foot and ankle, and
- Requires stabilization for medical reasons, and
- Has the potential to benefit functionally

The patient's medical record contains sufficient documentation of the patients medical condition to substantiate the necessity for the type and quantity of the items ordered.

The goal of this therapy: (indicate all that apply)

- Improve mobility
- Improve lower extremity stability
- Decrease pain
- Facilitate soft tissue healing
- Facilitate immobilization, healing and treatment of an injury

Necessity of Ankle Foot Orthotic molded to patient model:

A custom (vs. prefabricated) ankle foot orthosis has been prescribed based on the following criteria which are specific to the condition of this patient. (indicate all that apply)

- The patient could not be fit with a prefabricated AFO
- The condition necessitating the orthosis is expected to be permanent or of longstanding duration (more than 6 months)
- There is need to control the ankle or foot in more than one plane
- The patient has a documented neurological, circulatory, or orthopedic condition that requires custom fabrication over a model to prevent tissue injury
- The patient has a healing fracture that lacks normal anatomical integrity or anthropometric proportions

I hereby certify that the ankle foot orthotic described above is a rigid or semi-rigid device which is used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body. It is designed to provide support and counterforce on the limb or body part that is being braced. In my opinion, the custom molded ankle foot orthosis is both reasonable and necessary in reference to accepted standards of medical practice in the treatment of the patient condition and rehabilitation.

Signature of Prescribing Physician: _____

Type I NPI: _____

Date: ____/____/____

Printed Name of Prescribing Physician _____

Phone: _____

The OHI Family of Brands



WorryFreeDME

Rx: Custom Molded Gauntlet

Doctor Name: _____

Patient Name: _____

Prognosis: Good Duration of usage: 12 Months

Product Brand and Model: _____

Product Information (Check brand and model, circle base code and addition(s)):

- Arizona Brace® Standard, Tall, AZ Sporty™, AZ Breeze™, Moore Balance Brace™**
 - R L **L1940** Plastic orthosis, custom molded from a model of the patient, custom fabricated, includes casting and cast preparation.
 - R L **L2330** Addition to lower extremity, lacer molded to patient model
 - R L **L2820** Addition to lower extremity orthosis, soft interface for mold plastic below knee section
- Arizona Brace® - Articulated**
 - R L **L1970** A semi-rigid molded plastic orthosis to hold the foot in neutral position (dorsi-plantar flexion), controls foot position, custom molded from a model of the patient, custom fabricated, includes casting and cast preparation.
 - R L **L2330** Addition to lower extremity, lacer molded to patient model
 - R L **L2820** Addition to lower extremity orthosis, soft interface for mold plastic below knee section
 - If Dorsiflex assist, ADD:**
 - R L **L2210** Addition to lower extremity, dorsiflexion assist (plantar flexion resist), (two per brace)
- AZ Slim™**
 - R L **L1904** AFO molded ankle gauntlet
 - R L **L2330** Addition to lower extremity, lacer molded to patient model
 - R L **L2820** Addition to lower extremity orthosis, soft interface for plastic below knee section
- Arizona Brace® - Extended, Unweighting**
 - R L **L1960** Plastic orthosis, custom molded from a model of the patient, custom fabricated, includes casting and cast preparation.
 - R L **L2330** Addition to lower extremity, lacer molded to patient model
 - R L **L2820** Addition to lower extremity orthosis, soft interface for mold plastic below knee section
- Arizona Mezzo™**
 - R L **L1907** Ankle orthosis, supramalleolar, with straps, with or without pads, custom fabricated
 - R L **L2330** Addition to lower extremity, lacer molded to patient model
- Arizona Mezzo™ - Partial Foot**
 - R L **L1907** Ankle orthosis, supramalleolar, with straps, with or without pads, custom fabricated
 - R L **L2330** Addition to lower extremity, lacer molded to patient model
 - R L **L5000** Partial foot, shoe insert, with longitudinal arch, toe filler

DX: (indicate all that apply) - Corresponds to Biomechanical Examination Form

Adult Acquired Flatfoot (PTTD)

- Flat foot [pes planus] (acquired)
 - right (M21.41) left (M21.42)
- Spontaneous rupture of other tendons, ankle and foot
 - right (M66.871) left (M66.872)
- Disorder of ligament, ankle
 - right (M24.271) left (M24.272)
- Disorder of ligament, foot
 - right (M24.274) left (M24.275)
- Other acquired deformities of foot
 - right (M21.6X1) left (M21.6X2)

Amputation

- Acquired absence of great toe
 - right (Z89.411) left (Z89.412)
- Acquired absence of other toe(s)
 - right (Z89.421) left (Z89.422)
- Acquired absence of foot
 - right (Z89.431) left (Z89.432)

Foot Drop

- Foot Drop, acquired
 - right (M21.371) left (M21.372)

Hemiplegia

- affecting right dominant side (I69.951)
- affecting left dominant side (I69.952)
- affecting right non-dominant side (I69.953)
- affecting left non-dominant side (I69.954)

Lateral Ankle Instability

- Other specific joint derangements of ankle, not elsewhere classified
 - right (M24.871) left (M24.872)

DJD of Ankle and Rearfoot

- Primary osteoarthritis, ankle and foot
 - right (M19.071) left (M19.072)
- Pain in ankle and joints of foot
 - right (M25.571) left (M25.572)
- Pain in lower leg
 - right (M79.661) left (M79.662)
- Pain in foot
 - right (M79.671) left (M79.672)
- Other specified congenital deformities of feet (Q66.89)

Other

Foot Risk / Imbalance

- Muscle weakness, generalized (M62.81)
- Ataxic gait (R26.0)
- Difficulty in walking (R26.2)
- Unsteadiness on feet (R26.81)
- Other abnormalities of gait and mobility (R26.89)
- Condition is bilateral

Therapeutic Objective(s): (indicate all that apply)

- Improve mobility
- Improve lower extremity stability
- Decrease pain
- Facilitate soft tissue healing
- Facilitate immobilization, healing and treatment of an injury

Signature of Prescribing Physician: _____ Type I NPI: _____ Order Date: ____/____/____

(Must be current with CMS)

Prescribing Physician Printed Name: _____

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Dispense Date: _____
Work Order #: _____

Gauntlet AFO Collection



Arizona Brace®

- Standard (5" above ankle) Tall (9" above ankle)
Color: Sand Black White Brown Pink
Closure: Laces Velcro Speed Laces Boot Hook



Arizona Brace®

- Unweighting (Proximal ht. 1" below fibular head)
 Extended (Proximal ht. 1" below fibular head)
Color: Sand Black White Brown Pink
Closure: Laces Velcro Speed Laces Boot Hook



Arizona Brace® - Articulated

- Standard Tall Extended
Color: Sand Black White Brown Pink
Closure: Laces Velcro Speed Laces Boot Hook
Hinge: Tamarack Tamarack Dorsi - Assist



AZ Sporty™ (5" above ankle)

- Color:** Sand Black White Brown Pink
Closure: Laces Velcro Speed Laces Boot Hook



AZ Breeze™

- Color:** Sand Black
Closure: Laces Velcro Speed Laces Boot Hook



AZ Slim™ (5" above ankle)

- Color:** Sand Black White Brown Pink
Closure: Laces Velcro Speed Laces Boot Hook



Moore Balance Brace™

- Color:** Sand Black
Closure: Laces Velcro



Arizona Mezzo™

- Standard Partial Foot
Color: Sand Black White Brown
Closure: Laces

Additional Charge options: Foot plate to end of toes (Our standard trim length is proximal to met heads) Removable, multi density insole

Patient Information: Patient Name: _____ Height: _____ Weight: _____
 Right Foot Left Foot Bilateral

Shipping and Billing Information: Bill to my account: Arizona SafeStep Langer Account # _____

Practitioner: _____ Email: _____
Provide email to receive an email alert once this order has been shipped.

Facility Name: _____

Phone: _____ Fax: _____

Ship to address: _____

Manufacturing and shipping:

- MFG: 3 Business Days (\$75.00) 7 Business Days (\$50.00)
 Ship: Ground 3 Day Air 2 Day Air Overnight Other: _____

Special Instructions: If you do not want the dorsi-plantar angle of the cast set to our recommendations, please choose:
 Leave cast exactly as is Correct Ankle Varus / Valgus Correct Forefoot to Neutral Other _____

Remarks: _____

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WorryFreeDME

Proof of Delivery: Custom Molded Gauntlet

Supplier Name: _____

HICN: _____

Product Information (Check brand and model, circle base code and addition(s)):

Arizona Brace® Standard, Tall, AZ Sporty™, AZ Breeze™, Moore Balance Brace™

- R L **L1940** Plastic orthosis, custom molded from a model of the patient, custom fabricated, includes casting and cast preparation.
- R L **L2330** Addition to lower extremity, lacer molded to patient model
- R L **L2820** Addition to lower extremity orthosis, soft interface for mold plastic below knee section

Arizona Brace® - Articulated

- R L **L1970** A semi-rigid molded plastic orthosis to hold the foot in neutral position (dorsi-plantar flexion), controls foot position, custom molded from a model of the patient, custom fabricated, includes casting and cast preparation.
- R L **L2330** Addition to lower extremity, lacer molded to patient model
- R L **L2820** Addition to lower extremity orthosis, soft interface for mold plastic below knee section

If Dorsiflex assist, ADD:

- R L **L2210** Addition to lower extremity, dorsiflexion assist (plantar flexion resist), (two per brace)

AZ Slim™

- R L **L1904** AFO molded ankle gauntlet
- R L **L2330** Addition to lower extremity, lacer molded to patient model
- R L **L2820** Addition to lower extremity orthosis, soft interface for plastic below knee section

Arizona Brace® - Extended, Unweighting

- R L **L1960** Plastic orthosis, custom molded from a model of the patient, custom fabricated, includes casting and cast preparation.
- R L **L2330** Addition to lower extremity, lacer molded to patient model
- R L **L2820** Addition to lower extremity orthosis, soft interface for mold plastic below knee section

Arizona Mezzo™

- R L **L1907** Ankle orthosis, supramalleolar, with straps, with or without pads, custom fabricated
- R L **L2330** Addition to lower extremity, lacer molded to patient model

Arizona Mezzo™ - Partial Foot

- R L **L1907** Ankle orthosis, supramalleolar, with straps, with or without pads, custom fabricated
- R L **L2330** Addition to lower extremity, lacer molded to patient model
- R L **L5000** Partial foot, shoe insert, with longitudinal arch, toe filler

Instructions For Use:

You have been dispensed this custom molded ankle orthosis to immobilize your foot and ankle. An AFO often requires a period of adjustment. It is best to wear it for one hour more each day and to continue this for two weeks. It should only be removed as specifically instructed. If the brace feels too tight, you may be walking too much. Get off your feet, loosen any straps and elevate your foot until the tightness resolves. If your symptoms do not resolve, please contact our office immediately. Should the device crack or break, remove it and do not use it again until you contact our office. Straps, laces should be kept clean of

clothing fabric to insure the device is properly secured to your extremity. Applying a skin moisturizer and wearing knee high socks will prevent your skin from irritation.

Material failure warrantee coverage:

- Hardware, plastic and metal component are covered at no-charge for six months.
- All soft materials: material covers, Velcro straps and limb support pads, are covered at no - charge up to ninety days.

I have read the posted Complaint Resolution Policy and have been provided with a copy of the Medicare Supplier Standards. I certify that I have received the item(s) indicated. The supplier has reviewed the instructions for proper use and care and provided me with written instructions. I understand that failure to properly care for this item(s) will result in the warranty being voided. This could result in my responsibility for future repair or replacement costs if my insurance policy will not cover such costs. The supplier has instructed me to call the office if I have any difficulties or problems with the device.

Patient Signature _____

Date Delivered: ____ / ____ / ____

Printed Patient Name _____

Patient Address _____

Original in patient's chart, copy to patient

The codes contained herein are not the official position or endorsement of any organization or company. They are offered as a suggestion based upon input from previous customers. Each prescribing practitioner should contact his or her local carrier or Medicare office to verify billing codes, regulations and guidelines relevant to their geographic location.

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WorryFreeDME

CMS Medicare DMEPOS Supplier Standards

1. A supplier must be in compliance with all applicable Federal and State licensure and regulatory requirements and cannot contract with an individual or entity to provide licensed services.
2. A supplier must provide complete and accurate information on the DMEPOS supplier application. Any changes to this information must be reported to the National Supplier Clearinghouse within 30 days.
3. An authorized individual (one whose signature is binding) must sign the application for billing privileges.
4. A supplier must fill orders from its own inventory, or must contract with other companies for the purchase of items necessary to fill the order. A supplier may not contract with any entity that is currently excluded from the Medicare program, any State health care programs, or from any other Federal procurement or non-procurement programs.
5. A supplier must advise beneficiaries that they may rent or purchase inexpensive or routinely purchased durable medical equipment, and of the purchase option for capped rental equipment.
6. A supplier must notify beneficiaries of warranty coverage and honor all warranties under applicable State law, and repair or replace free of charge Medicare covered items that are under warranty.
7. A supplier must maintain a physical facility on an appropriate site. This standard requires that the location is accessible to the public and staffed during posted hours of business. The location must be at least 200 square feet and contain space for storing records.
8. A supplier must permit CMS, or its agents to conduct on-site inspections to ascertain the supplier's compliance with these standards. The supplier location must be accessible to beneficiaries during reasonable business hours, and must maintain a visible sign and posted hours of operation.
9. A supplier must maintain a primary business telephone listed under the name of the business in a local directory or a toll free number available through directory assistance. The exclusive use of a beeper, answering machine, answering service or cell phone during posted business hours is prohibited.
10. A supplier must have comprehensive liability insurance in the amount of at least \$300,000 that covers both the supplier's place of business and all customers and employees of the supplier. If the supplier manufactures its own items, this insurance must also cover product liability and completed operations.
11. A supplier must agree not to initiate telephone contact with beneficiaries, with a few exceptions allowed. This standard prohibits suppliers from contacting a Medicare beneficiary based on a physician's oral order unless an exception applies.
12. A supplier is responsible for delivery and must instruct beneficiaries on use of Medicare covered items, and maintain proof of delivery.
13. A supplier must answer questions and respond to complaints of beneficiaries, and maintain documentation of such contacts.
14. A supplier must maintain and replace at no charge or repair directly, or through a service contract with another company, Medicare covered items it has rented to beneficiaries.
15. A supplier must accept returns of substandard (less than full quality for the particular item) or unsuitable items (inappropriate for the beneficiary at the time it was fitted and rented or sold) from beneficiaries.
16. A supplier must disclose these supplier standards to each beneficiary to whom it supplies a Medicare covered item.
17. A supplier must disclose to the government any person having ownership, financial, or control interest in the supplier.
18. A supplier must not convey or reassign a supplier number i.e., the supplier may not sell or allow another entity to use its Medicare billing number.
19. A supplier must have a complaint resolution protocol established to address beneficiary complaints that relate to these standards. A record of these complaints must be maintained at the physical facility.
20. Complaint records must include: the name, address, telephone number and health insurance claim number of the beneficiary, a summary of the complaint, and any actions taken to resolve it.
21. A supplier must agree to furnish CMS any information required by the Medicare statute and implementing regulations.
22. All suppliers must be accredited by a CMS approved accreditation organization in order to receive and retain a supplier billing number. The accreditation must indicate the specific products and services, for which the supplier is accredited in order for the supplier to receive payment of those specific products and services (except for certain exempt pharmaceuticals). Implementation Date October 1, 2009
23. All suppliers must notify their accreditation organization when a new DMEPOS location is opened.
24. All supplier locations, whether owned or subcontracted, must meet the DMEPOS quality standards and be separately accredited in order to bill Medicare.
25. All suppliers must disclose upon enrollment all products and services, including the addition of new product lines for which they are seeking accreditation.
26. Must meet the surety bond requirements specified in 42 C.F.R. 424.57(c). Implementation date May 4, 2009
27. A supplier must obtain oxygen from a state-licensed oxygen supplier.
28. A supplier must maintain ordering and referring documentation consistent with provisions found in 42 C.F.R. 424.516(f).
29. DMEPOS suppliers are prohibited from sharing a practice location with certain other Medicare providers and suppliers.
30. DMEPOS suppliers must remain open to the public for a minimum of 30 hours per week with certain exceptions.

The OHI Family of Brands





Dispensing Chart Notes: Custom Molded Gauntlet

Patient Name: _____

HICN: _____

Product Information (Check brand and model, circle base code and addition(s)):

Arizona Brace® Standard, Tall, AZ Sporty™, AZ Breeze™, Moore Balance Brace™

- R L **L1940** Plastic orthosis, custom molded from a model of the patient, custom fabricated, includes casting and cast preparation.
- R L **L2330** Addition to lower extremity, lacer molded to patient model
- R L **L2820** Addition to lower extremity orthosis, soft interface for mold plastic below knee section

Arizona Brace® - Articulated

- R L **L1970** A semi-rigid molded plastic orthosis to hold the foot in neutral position (dorsi-plantar flexion), controls foot position, custom molded from a model of the patient, custom fabricated, includes casting and cast preparation.
- R L **L2330** Addition to lower extremity, lacer molded to patient model
- R L **L2820** Addition to lower extremity orthosis, soft interface for mold plastic below knee section
If Dorsiflex assist, ADD:
- R L **L2210** Addition to lower extremity, dorsiflexion assist (plantar flexion resist), (two per brace)

AZ Slim™

- R L **L1904** AFO molded ankle gauntlet
- R L **L2330** Addition to lower extremity, lacer molded to patient model
- R L **L2820** Addition to lower extremity orthosis, soft interface for plastic below knee section

Arizona Brace® - Extended, Unweighting

- R L **L1960** Plastic orthosis, custom molded from a model of the patient, custom fabricated, includes casting and cast preparation.
- R L **L2330** Addition to lower extremity, lacer molded to patient model
- R L **L2820** Addition to lower extremity orthosis, soft interface for mold plastic below knee section

Arizona Mezzo™

- R L **L1907** Ankle orthosis, supramalleolar, with straps, with or without pads, custom fabricated
- R L **L2330** Addition to lower extremity, lacer molded to patient model

Arizona Mezzo™ - Partial Foot

- R L **L1907** Ankle orthosis, supramalleolar, with straps, with or without pads, custom fabricated
- R L **L2330** Addition to lower extremity, lacer molded to patient model
- R L **L5000** Partial foot, shoe insert, with longitudinal arch, toe filler

S) A custom molded gauntlet was dispensed and fit at this visit. Patient is ambulatory. Due to the patient's condition and related symptoms this device is medically necessary as part of the overall treatment. It is anticipated that the patient will benefit functionally with the use of this device. The custom device is utilized in an attempt to avoid the need for surgery and because a prefabricated device is inappropriate.

O) Upon gait analysis, the device appeared to be fitting well and the patient states that the device is comfortable.

A) Good fit. The patient was able to apply properly and ambulate without distress. The function of this device is to restrict and limit motion and provide stabilization in the ankle joint.

P) The goals and function of this device were explained in detail to the patient. The patient was shown how to properly apply, wear, and care for the device. It was explained that the device will fit and function best in a lace-up shoe with a firm heel counter and a wide base of support. When the device was dispensed, it was suitable for the patient's condition and not substandard. No guarantees were given. Precautions were reviewed. Written instructions, warranty information and a copy of DMEPOS Supplier Standards were provided. All questions were answered.

Additional Notes: _____

Supplier Signature: _____

Dispensing Date: _____

Print Supplier Name: _____

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