#### **Compliance Documentation Pack**

Custom Molded Gountlet - 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













# Created by: The American College of FOOT & ANKLE ORTHOPEDICS MEDICINE

#### **Biomechanical Evaluation Form**

	Ч
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:→	<b>_</b>		
	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:		0	
	Limb length:→		Equal	
	Hip sagittal plane-		Lquai	
	Knee extended		Flexion 120°/extension 20-30°	
	Knee flexed		Flexion 45-60°/extension 20-30°	
	Hip transverse plane-		TIGNOTI 45-00 / EXTERISION 20-30	
	Knee extended		45° each direction	
	Knee extended 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-		Description of 10°/plantage and 20°	
	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 <sup>st</sup> ray range of motion		Dorsal & plantar excursion 5mm	
	1st 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→			
Biomechanica	al assessment:			
Treatment pla				
Enter assistant			Enter date of exam	
Signature of as			Signature of physician	
orginature or as	SSISTAIN		oignature of physician	
			1	

Save in patient's chart

#### **Document of Medical Necessity: Custom Molded Gauntlet**

Patient Name:		HICN:	
Prognosis: Good	<b>Duration of usage:</b> 12 Montl	hs	
I certify that Mr. / Ms	S	qualifies for and w	ill benefit from
an ankle foot orthosis	s used during ambulation base	d on meeting all of the following criteria	. The patient is:
<ul> <li>Ambulatory, and</li> </ul>			
<ul> <li>Has weakness or</li> </ul>	deformity of the foot and ankle, a	and	
<ul> <li>Requires stabiliza</li> </ul>	ation for medical reasons, and		
<ul> <li>Has the potential</li> </ul>	to benefit functionally		
-	l record contains sufficient doc ntity of the items ordered.	cumentation of the patients medical cond	lition to substantiate the necessity
The goal of this thera	apy: (indicate all that apply)		
☐ Improve mobility	I		
☐ Improve lower ex	xtremity stability		
□ Decrease pain			
☐ Facilitate soft tis	ssue healing		
☐ Facilitate immob	pilization, healing and treatment o	of an injury	
Necessity of Ankle Fo	oot Orthotic molded to patient r	nodel:	
A custom (vs. prefabric of this patient. (indicate		en prescribed based on the following criteria	a which are specific to the condition
☐ The patient could	d not be fit with a prefabricated A	AFO	
$\square$ The condition ne	ecessitating the orthosis is expec	ted to be permanent or of longstanding dura	ation (more than 6 months)
$\hfill\Box$ There is need to	control the ankle or foot in more	than one plane	
☐ The patient has a model to preve		llatory, or orthopedic condition that requires	custom fabrication over
$\square$ The patient has	a healing fracture that lacks norn	mal anatomical integrity or anthropometric p	proportions
or restricting or eliminating	g motion in a diseased or injured part o custom molded ankle foot orthosis is bo	id or semi-rigid device which is used for the purpose of the body. It is designed to provide support and co th reasonable and necessary in reference to accepte	unterforce on the limb or body part that is bei
Signature of Prescribing I	Physician:	Type I NPI:	Date://
Printed Name of Prescrib	oing Physician	Phone:	













### **Rx: Custom Molded Gauntlet**

Doctor Name:	Patien	it Nan	ne:	
Prognosis: Good Duration of usage: 12 Mo	nths <b>Product Brand</b>	and	Model	:
Product Information (Check brand and mode	el, cirlcle base code and addition(s)	)):		
Arizona Brace® Standard, Tall, AZ Sporty™, AZ  R L L1940 Plastic orthosis, custom molocustom fabricated, includes casting  R L L2330 Addition to lower extremity, land land land land land land land land	ded from a model of the patient, and cast preparation.  acer molded to patient model rthosis, soft interface for mold  nosis to hold the foot in neutral position sition, custom molded from a model udes casting and cast preparation. acer molded to patient model rthosis, soft interface for mold  dorsiflexion assist see)	R R R R	L L Arizona L L rizona L	Brace® - Extended, Unweighting L1960 Plastic orthosis, custom molded from a model of the patient, custom fabricated, includes casting and cast preparation. L2330 Addition to lower extremity, lacer molded to patient model L2820 Addition to lower extremity orthosis, soft interface for mold plastic below knee section Mezzo™ L1907 Ankle orthosis, supramalleolar, with straps, with or without pads, custom fabricated L2330 Addition to lower extremity, lacer molded to patient model Mezzo™ - Partial Foot L1907 Ankle orthosis, supramalleolar, with straps, with or without pads, custom fabricated L2330 Addition to lower extremity, lacer molded to patient model L2330 Addition to lower extremity, lacer molded to patient model L5000 Partial foot, shoe insert, with longitudinal arch, toe filler
DX: (indicate all that apply) - Corresponds to Back Adult Acquired Flatfoot (PTTD)  Flat foot [pes planus] (acquired)	Amputation  Acquired absence of great toe	9.422) 9.432) 21.372) 951) 952) de (I69.9 nkle, no	.953) 954) ot	DJD of Ankle and Rearfoot  Primary osteoarthritis, ankle and foot
Improve mobility	Improve lower extremity stab	oility		Decrease pain
Facilitate soft tissue healing	Facilitate immobilization, heali	•	d treatn	
Signature of Prescribing Physician:  Prescribing Physician Printed Name:	Type I NP	l:(Must	be current	with CMS) Order Date:/
	<ul> <li>The OHI Family of F</li> </ul>	Rran	ıds –	















Arizona AFO (877) 780-8382 Langer Biomechanics (800) 645-5520 SafeStep (866) 712-7837

Ship to address: 4825 East Ingram St. Mesa, AZ 85205 Fax: 480.222.1599

Dispense Date:	
Work Order #:	

#### **Gauntlet AFO Collection**

	Arizona Brace®		<b>6 6</b>	Arizona	Brace®
	Standard (5" ab		☐ Ui	nweighting (Proximal ht. 1" below fibular head)	
18	Color: Sand	☐ Black ☐ White ☐ Brown ☐ Pink	<b>3</b>	☐ Ex	tended (Proximal ht. 1" below fibular head)
	Closure: Laces	☐ Velcro ☐ Speed Laces ☐ Boot Hook	3	Color:	☐ Sand ☐ Black ☐ White ☐ Brown ☐ Pink
				Closure:	Laces Velcro Speed Laces Boot Hook
	Arizona Brace® - A	rrticulated	The same of the sa		Sporty™
		Tall Extended		•	bove ankle)
O		Black  White  Brown  Pink		Color:	Sand Black White Brown Pink
		Velcro ☐ Speed Laces ☐ Boot Hook  □ Tamarack Dorsi - Assist		Closure:	☐ Laces ☐ Velcro ☐ Speed Laces ☐ Boot Hook
		Tallialack Doloi - Assist			Disas TM
000	☐ AZ Breeze™	1	TO TO	_	<b>Slim</b> ™ bove ankle)
	Color: Sand	-		Color:	Sand Black White Brown Pink
	Closure: Laces	Velcro Speed Laces Boot Hook	R	Closure:	Laces Velcro Speed Laces Boot Hook
	☐ Moore Balance	Brace™		Arizona	n Mezzo™
	Color: Sand	Black		☐ St	tandard   Partial Foot
	Closure: Laces	☐ Velcro		Color:	☐ Sand ☐ Black ☐ White ☐ Brown
				Closure:	Laces
Additional Char	<b>ge options:</b>	plate to end of toes (Our standard trim length is	proximal to met heads	Rem	novable, multi density insole
		,			•
Patient Inform		Name: It Foot               Left Foot			Height: Weight:
Obinaina and D	Ţ.		CofoCtors		A constant
Snipping and B	Billing Information:	Bill to my account: Arizona	Sarestep 🔲 L	anger	Account #
Practitioner:			Email: Prov	vide email to	receive an email alert once this order has been shipped.
Facility Name:					,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
Phone:			Fax:		
Ship to address:					
Manufacturing	g and shipping:				
MFG:	· · · · · · · · ·	Days (\$75.00) 🔲 7 Business Day	rs (\$50.00)		
Ship:	☐ Ground ☐	3 Day Air 🗌 2 Day Air 🗎 Overn	night $\square$ Othe	r:	
Special Instruc	tions: If you do not w	ant the dorsi-plantar angle of the ca	st set to our re	commend	lations, please choose:
	-	-			to Neutral Other
Domarko					
nemarks:					
		——— The OHI Fami	lv of Bran	ds —	













#### **Proof of Delivery: Custom Molded Gauntlet**

Supplier Name:	HICN:
Product Information (Check brand and model, cirlcle base code and ad Arizona Brace® Standard, Tall, AZ Sporty™, AZ Breeze™, Moore Balance	· · · · · · · · · · · · · · · · · · ·
<ul> <li>R L L1940 Plastic orthosis, custom molded from a model of the procustom fabricated, includes casting and cast preparation.</li> <li>R L L2330 Addition to lower extremity, lacer molded to patient model.</li> <li>R L L2820 Addition to lower extremity orthosis, soft interface for replastic below knee section.</li> </ul>	a model of the patient, custom fabricated, includes casting and cast preparation.  B. J. 2330 Addition to lower extremity Jacer.
☐ Arizona Brace® - Articulated	interface for mold plastic below knee section
<ul> <li>R L L1970 A semi-rigid molded plastic orthosis to hold the foot in net position (dorsi-plantar flexion), controls foot position, custom m from a model of the patient, custom fabricated, includes casting cast preparation.</li> <li>R L L2330 Addition to lower extremity, lacer molded to patient model.</li> </ul>	nolded R L L1907 Ankle orthosis, supramalleolar, with ng and straps, with or without pads, custom fabricated R L L2330 Addition to lower extremity, lacer
<ul> <li>R L L2820 Addition to lower extremity orthosis, soft interface for r plastic below knee section</li> <li>If Dorsiflex assist, ADD:</li> <li>R L L2210 Addition to lower extremity, dorsiflexion assist (plantar flexion resist), (two per brace)</li> </ul>	mold ☐ Arizona Mezzo <sup>™ -</sup> 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 L1904 AFO molded ankle gauntlet R L L2330 Addition to lower extremity, lacer molded to patient mo R L L2820 Addition to lower extremity orthosis, soft interface for public below knee section	R L <b>L5000</b> Partial foot, shoe insert, with longitudinal arch, toe filler odel
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 co- indicated. The supplier has reviewed the instructions for proper use and care and p for this item(s) will result in the warranty being voided. This could result in my resp cover such costs. The supplier has instructed me to call the office if I have any diff	rovided me with written instructions. I understand that failure to properly care onsibility for future repair or replacement costs if my insurance policy will not
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.













#### **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
- 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.













### **Dispensing Chart Notes: Custom Molded Gauntlet**

Patient Name: HICN:					
Product Information (Check brand and model, cirlcle base code and addition(s)):					
Arizona Brace® Standard, Tall, AZ Sporty™, AZ Breeze™, Moore Balance B  R L L1940 Plastic orthosis, custom molded from a model of the patie custom fabricated, includes casting and cast preparation.  R L L2330 Addition to lower extremity, lacer molded to patient mode R L L2820 Addition to lower extremity orthosis, soft interface for mol 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 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 moleplastic 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, lacer molded to patient model R L L2820 Addition to lower extremity, lacer molded to patient model R L L2820 Addition to lower extremity, lacer molded to patient model R L L2820 Addition to lower extremity orthosis, soft interface for plastic below knees extremity orthosis.	atient, atient, atient, and Brace® - Extended, Unweighting a model of the patient, 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 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 L2330 Addition to lower extremity, lacer molded to patient model  R L L2300 Partial foot, shoe insert, with longitudinal arch, toe filler				
S) A custom molded gauntlet was dispensed and fit at this visit. Patient is aml device is medically necessary as part of the overall treatment. It is anticipal device. The custom device is utilized in an attempt to avoid the need for sure to sure the custom device appeared to be fitting well and the patient A) Good fit. The patient was able to apply properly and ambulate without condition and provide stabilization in the ankle joint.  P) The goals and function of this device were explained in detail to the patient the device. It was explained that the device will fit and function best in a late When the device was dispensed, it was suitable for the patient's condition reviewed. Written instructions, warranty information and a copy of DMEPOS Additional Notes:  Supplier Signature:  Print Supplier Name:	cipated that the patient will benefit functionally with the use of this surgery and because a prefabricated device is inappropriate. Itient states that the device is comfortable.  In the distress of the function of this device is to restrict and limit motion and the patient was shown how to properly apply, wear, and care for a lace-up shoe with a firm heel counter and a wide base of support, on and not substandard. No guarantees were given. Precautions were POS Supplier Standards were provided. All questions were answered.  Dispensing Date:  Dispensing Date:				











