The use of advanced composite materials in Prosthetics has been around for a number of years. Flexfoot, Springlite and others have pioneered the use of these materials with amazing results. However, the field of Orthotics has seen relatively little use of advanced composite materials until recently with the advent of the ToeOFF® (Camp International) and Walk-On™ (Otto Bock) AFO's. Unfortunately, these braces are only available in standard sizes and often require modification to adequately fit the patient, while other patients simply cannot use these off-the-shelf braces for a number of reasons.

Our desire is to provide practitioners with another option for their patients—composite braces that are designed and made specifically for each patient. Not to replace the use of pre-fab braces when they work, but to give practitioners and their patients a choice. When composite materials are used effectively, they can create dynamic, energy return braces or extremely rigid ones. Our materials include several types of Pre-Preg Carbon Fiber, as well as Pre-Preg Kevlar®, Pre-Preg Fiberglass, Airex® Core and Nomex® Core. Factor in the patient’s height, weight, activity level, ankle tendency and the knowledge and experience of their practitioner, and we can create a brace that goes from the box to the patient with relative ease.

We believe a custom made composite brace has a lot to offer, to both the patient and the practitioner alike. For the patient, a custom made brace offers greater comfort and an increase in the function of the brace, adding to the quality of their life. For the practitioner, it reduces the fitting time and all the wedging, padding and posting that an off-the-shelf brace may require. These benefits, combined with a price that is competitive to the cost of an off-the-shelf brace, make a custom made composite brace an appealing alternative.

Less is best. The theory of under-bracing has been around for a long time. Many times it is hard to determine how much of a brace the patient needs. Usually after a stroke or recent trauma the patient may need a lot of stability and depend heavily upon the brace (see contraindications to carbon bracing, page 2), but as the process of recovery continues less of a brace is required. Over-bracing decreases the patient’s need to use their own strength to control the extremity and creates a dependence on the brace. Under-bracing challenges the patient to strive for greater gains in strength and balance and replaces just the functions that are missing. Low-profile composite braces are generally more accepted by patients and are used more as a result. Identify the missing function and select a design that replaces it. Think less rather than more and challenge the patient to achieve greater function, balance and strength.
**afo selection guide**

This guide is to help you understand the differences between each of our AFO’s and to assist you in determining which design is most appropriate for your patients. Please call us toll free at 866-273-2230 if you have any questions.

<table>
<thead>
<tr>
<th>afo design</th>
<th>benefits</th>
<th>indications/activity level</th>
<th>flexibility rating*</th>
</tr>
</thead>
<tbody>
<tr>
<td>energy return afo’s</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FlexorBand</td>
<td>Unrestricted dorsi-plantar flexion, mild lateral ankle control</td>
<td>Drop foot with wide ROM needed/all activity levels, various</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>sports (running, hiking, etc)</td>
<td>3-4-5-5-4-3</td>
</tr>
<tr>
<td>Lateral Strut</td>
<td>Dynamic toeplate response, mild lateral ankle control, lightweight</td>
<td>Drop foot or similar/low to moderate activity level</td>
<td>4-4-4-4-3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>and low-profile</td>
<td></td>
</tr>
<tr>
<td>Posterior Lateral Strut</td>
<td>Dynamic toeplate response, mild recravatum control, lightweight and low-profile</td>
<td>Drop foot, MS pts needing recravatum control/low to moderate activity level</td>
<td></td>
</tr>
<tr>
<td>Spiral</td>
<td>Dynamic toeplate response, mild ML and AP control at the ankle, lightweight and low-profile</td>
<td>Drop foot, MS, flail foot, stroke pts without spasticity/low to moderate activity level</td>
<td></td>
</tr>
<tr>
<td>Hybrid Medial Strut</td>
<td>Dynamic heel and toe response, mild stance ankle control, lightweight and low-profile</td>
<td>Drop foot, stroke pts without spasticity, CMT, MS pts that need more midstance control/low to high activity level</td>
<td></td>
</tr>
</tbody>
</table>

| solid ankle afo’s |                                                                         |                                                                                             |                     |
| SA Posterior       | Ankle stability, hind foot control, heel protection                      | Calcanial fractures, hind foot instability/all activity levels                               |                     |
| SA Anterior Medial | Highest level of ankle stability, maximum floor reaction, most rigid design | Ankle instability, ankle fracture, CMT, failed fusion, knee instability requiring floor reaction AFO/all activity levels |                     |

* Flexibility Rating is based on a 0 to 6 scale. The higher the rating the greater the overall flexibility of the brace.

**contraindications to carbon bracing**

Carbon composite braces are not for everyone. Patients that require a lot of skin contact to hold the leg in proper alignment are not the best candidates for a composite brace. This material is not adjustable, and since the ability to adjust the brace is key to success with these patients, a thermoplastic is more appropriate.

Additionally, patients with spasticity or mild to severe clonus are often stimulated with an energy return brace. Therefore, they too are not good candidates for a composite brace.
Because each of our AFO’s are custom made, we rely on you, the practitioner, to send us an accurate casting of your patient. Please use these instructions as a guide when taking a casting. Doing so will help minimize any delay in your order. The casting instructions are the same regardless of which AFO design you choose. If you have any questions, please call us toll free at 866-273-2230.

1. Have the patient sit in a chair.

2. Prepare casting materials: Water, plaster or synthetic casting material, cotton stockinet, and cut-off strip, etc. Mark the neck of the fibula for a height reference.

3. Wrap the leg with casting material in the usual manner. Place patient’s foot on the floor (use a footplate or a piece of plastic to simulate the proper heel height). Try to duplicate the patient’s natural standing angle (valgus or varus) in this seated position. Be sure to cast the entire foot. We use a full length footplate.

4. Apply slight downward pressure to the top of the knee to simulate a semi-weight bearing condition. If large deviations in the ankle occur during stance, a full weight bearing cast is recommended.

5. Remove cast in the usual manner once the casting material has set.

6. Wrap several layers of newspaper around cast and additional cushioning material if needed for shipping. Please do not just put the plaster cast in a plastic bag (this tends to keep the cast wet and it may loose shape).

7. Include a tracing of the sound side to determine the length of the footplate (only necessary for partial foot patients).

8. Include a completed AFO Order Form (page 15) along with the casting.

9. Mail to: Custom Composite Mfg, Inc
   170 Macklin Street
   Cranston, RI 02920

Each AFO is custom made and comes with the following accessories at no extra charge.*

- **Custom Foam Footbed.** The footbed is glued to the footplate of the AFO and can be removed if either the footbed or footplate needs to be modified.

- **Foam Liner.** The liner is glued to the brace and can be removed if any modifications are necessary.

- **Velcro® Strap.** Includes one strap around the calf band unless otherwise noted.

- **Cosmetic Finish.** (Available at an additional charge.) For the more cosmetically minded patients, we now offer an alternative to the natural look of composite materials. The flesh tone finish is a paint that is applied to the composite parts of the brace after fabrication and adds one additional day to the in-house turnaround time. Cosmetic finish is available on all AFO’s and comes with a Plastazote foam liner instead of the standard black foam.

> Shown: Hybrid Medial Strut AFO (with anterior shell, page 8)
The FlexorBand AFO is our first AFO with a joint. This lightweight, dorsiflexion assist AFO is designed for foot drop patients who need a wide range of motion at the ankle (-30 degrees dorsiflexion, unlimited plantarflexion).

The joint, located over the lateral malleolus, consists of integrated hemispherical stainless steel washers separated by a nylon washer. Tension is provided by a Gaffney-Flexor band anterior to the joint.

The FlexorBand AFO is custom made from a cast of the patient and comes with a foam liner, Velcro® strap and custom foam footbed.

Please see page 3 for Casting Instructions.

indications/activity level

Drop foot with wide ROM needed/all activity levels, various sports (running, hiking, etc)

contraindications

Please see page 2 for Contraindications.

suggested l-codes

L-1980
Ankle foot orthosis, single, upright free plantar-dorsiflexion, solid stirrup, calf band/cuff, custom fabricated

L-2210
Addition to lower extremity, dorsiflexion assist (plantarflexion resist)

L-2755
Addition to lower-extremity orthosis, high strength, lightweight material, all hybrid lamination/prepreg composite, per segment, for custom-fabricated orthosis only

L-2820
Addition to lower extremity orthosis, soft interface for molded plastic, below knee section
The Lateral Strut AFO offers patients a flexible, extremely lightweight brace that maximizes energy storage and release with each step. It fits easily into shoes and can be used for patients of all ages. The Lateral Strut is custom made from a cast and comes with a foam liner, Velcro® strap and custom foam footbed.

Please see page 3 for Casting Instructions.

indications/activity level

Drop foot, Flail foot, Hemiplegia, selective stroke patients or similar/low to moderate activity level

contraindications

Please see page 2 for Contraindications.

suggested l-codes

**L-1940**
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

**L-2755**
Addition to lower-extremity orthosis, high strength, lightweight material, all hybrid lamination/prepreg composite, per segment, for custom-fabricated orthosis only

**L-2820**
Addition to lower extremity orthosis, soft interface for molded plastic, below knee section
The Posterior Lateral Strut AFO is designed similarly to the Lateral Strut AFO, but wraps posteriorly, using the calf section of the leg to pickup the toe. It also provides an anteriorly directed force at heel strike to help correct recravatum. The Posterior Lateral Strut is custom made from a cast and comes with a foam liner, Velcro® strap and custom foam footbed.

Please see page 3 for Casting Instructions.

**indications/activity level**

Drop foot, MS patients needing recravatum control/low to moderate activity level

**contraindications**

Please see page 2 for Contraindications.

**suggested l-codes**

**L-1940**
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

**L-2755**
Addition to lower extremity orthosis, high strength, lightweight material, all hybrid lamination/prepreg composite, per segment, for custom-fabricated orthosis only

**L-2820**
Addition to lower extremity orthosis, soft interface for molded plastic, below knee section
The Spiral AFO gives patients mild ML and AP control, as well as providing needed energy return. It is custom made from a cast and comes with a foam liner, Velcro® strap and custom foam footbed.

Please see page 3 for Casting Instructions.

**indications/activity level**

Drop foot, MS, flail foot, stroke patients without spasticity/low to moderate activity level

**contraindications**

Please see page 2 for Contraindications.

**suggested l-codes**

**L-1950**
Spiral, (IRM type), plastic, custom fabricated

**L-2755**
Addition to lower-extremity orthosis, high strength, lightweight material; all hybrid lamination/prepreg composite, per segment, for custom-fabricated orthosis only

**L-2820**
Addition to lower extremity orthosis, soft interface for molded plastic, below knee section

Velcro® Strap
Foam Liner
Custom Foam Footbed
Lightweight Composite Construction
The Hybrid Medial Strut AFO offers patients an energy return brace with midstance stability and balanced heel/toe action. It features Airex® Core Technology which creates a rigid, durable strut that blends into the arch of the foot, centralizing it on the footplate. The Hybrid Medial Strut is available with an anterior shell with rear entry (as shown) or a more flexible calf band with side entry (as found on the Lateral Strut, page 5). It is custom made from a cast and comes with a foam liner, Velcro® strap and custom foam footbed.

Please see page 3 for Casting Instructions.

indications/activity level

Drop foot, stroke patients without spasticity, CMT, MS patients that need more midstance control/all activity levels

contraindications

Please see page 2 for Contraindications.

suggested l-codes

L-1940 (with calf band, not shown)
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

L-1945 (with anterior shell, shown right)
Molded to patient model, plastic, rigid anterior tibia section (floor reaction), custom fabricated

L-2755
Addition to lower-extremity orthosis, high strength, lightweight material, all hybrid lamination/prepreg composite, per segment, for custom-fabricated orthosis only

L-2820
Addition to lower extremity orthosis, soft interface for molded plastic, below knee section
The Solid Ankle Posterior AFO is significantly different from a more traditional PLS AFO that it resembles. Airex® Core Technology is used to produce an I-beam effect which gives the brace its strength and rigidity. It features an open heel design and trimlines cut behind the malleoli to avoid potential problem areas. The Solid Ankle Posterior AFO is custom made from a cast and comes with a foam liner and a Velcro® strap around the top of the calf.

Please see page 3 for Casting Instructions.

**indications/activity level**

Calcanial fractures, hind foot instability/all activity levels

**contraindications**

Please see page 2 for Contraindications.

**suggested I-codes**

**L-1960**
A rigid orthosis to control the foot and ankle, custom molded from a model of the patient, custom fabricated, includes casting and cast preparation

**L-2755**
Addition to lower-extremity orthosis, high strength, lightweight material, all hybrid lamination/prepreg composite, per segment, for custom-fabricated orthosis only

**L-2820**
Addition to lower extremity orthosis, soft interface for molded plastic, below knee section

---

Flexible Calf Tabs and Velcro® Strap

Airex® Core and Lightweight Composite Construction

Trimlines Posterior to Malleoli

Foam Liner

Solid Ankle Rigidity

Open Heel Design
The Solid Ankle Anterior Medial AFO gives patients extreme rigidity in a lightweight, floor reaction AFO. This brace, using the same Airex® Core Technology found in the Solid Ankle Posterior AFO, flows out of the arch an anteriorly up the patient's leg. The Solid Ankle Anterior Medial AFO is custom made from a cast and comes with a foam liner and Velcro® strap at the top of the calf and around the ankle.

Please see page 3 for Casting Instructions.

indications/activity level

Ankle instability, ankle fracture, CMT, failed fusion, knee instability requiring floor reaction AFO/all activity levels

contraindications

Please see page 2 for Contraindications.

suggested l-codes

L-1945
Molded to patient model, plastic, rigid anterior tibia section (floor reaction), custom fabricated

L-2755
Addition to lower-extremity orthosis, high strength, lightweight material, all hybrid lamination/prepreg composite, per segment, for custom-fabricated orthosis only

L-2820
Addition to lower extremity orthosis, soft interface for molded plastic, below knee section
partial foot prosthesis

Designed specifically for Chopart and TMA patients, the Partial Foot Prosthesis restores normal foot bio-mechanics and properly transfers energy from a rigid lever arm to a two-stage progressive resistance carbon footplate. The Partial Foot Prosthesis is lightweight, durable, custom made from a cast and comes with a foam liner, Velcro® strap and toe filler.

Please see page 3 for Casting Instructions.

indications/activity level

Chopart, TMA, Lisfranc/all activity levels

suggested l-codes

L-5020
Partial foot, molded socket, tibial tubercle height, with toe filler

L-5634
Addition to lower extremity, Symes type, posterior opening (Canadian) socket

L-5654
Addition to lower extremity, socket insert, Symes, (Kemblo, Pelite, Aliplast, Plastazote or equal)

L-5785
Addition, exoskeletal system, below knee, ultra-light material (Titanium, carbon fiber or equal)

L-5976
All lower extremity prostheses, energy storing foot

Anterior Shell with Airex® Core Creates a Rigid Lever Arm (Includes Foam Liner)

Two-Stage Progressive Resistance Carbon Footplate with Toe Filler

Velcro® Strap
**carbon footplates**

Made of 100% carbon for maximum strength and durability, Carbon Footplates are available in a right and left or neutral configuration. Standard heel heights are $\frac{3}{8}$", but custom heel heights and lengths are also available. They can also be made with a rigid mid-foot section and a spring toe section.

Fax a tracing of the patient’s foot or send us a cast.

**indications**

Conditions of the foot when a stiff innersole is required. They can be used to reduce motion at the metatarsals and mid-foot after surgery, or when excessive motion produces a painful gait.
**price list**

The following prices are subject to change without notice. Please call us at 866-273-2230 to verify prices.

Please note, the Suggested L-Codes are only recommendations. The final and sole responsibility for correct coding, within established laws, rules, and standards of practice, rests upon the party submitting the claim.

<table>
<thead>
<tr>
<th>price* (as of 2/1/06)</th>
<th>suggested l-codes</th>
</tr>
</thead>
</table>

**energy return afo's**

<table>
<thead>
<tr>
<th></th>
<th>Call for pricing</th>
<th>L-1940, L-2755, L-2820</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lateral Strut AFO</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FlexorBand AFO</td>
<td></td>
<td></td>
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<tr>
<td>Posterior Lateral Strut AFO</td>
<td></td>
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<tr>
<td>Spiral AFO</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hybrid Medial Strut AFO</td>
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<td></td>
</tr>
</tbody>
</table>

**solid ankle afo's**

<table>
<thead>
<tr>
<th></th>
<th>Call for pricing</th>
<th>L-1960, L-2755, L-2820</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solid Ankle Posterior AFO</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Solid Ankle Anterior Medial AFO</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* The cost of each AFO includes the composite brace, foam liner, Velcro® strap and custom foam footbed.

**cosmetic finish**

<table>
<thead>
<tr>
<th></th>
<th>Call for pricing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flesh Tone Finish</td>
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</table>

**prosthetics**

<table>
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<tr>
<th></th>
<th>Call for pricing</th>
<th>L-5020, L-5634, L-5654, L-5785, L-5976</th>
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</thead>
<tbody>
<tr>
<td>Partial Foot Prosthesis</td>
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</table>

**carbon footplates (sold individually)**

<table>
<thead>
<tr>
<th></th>
<th>Call for pricing</th>
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<tbody>
<tr>
<td>Standard (Flat or 3/8” heel height)</td>
<td></td>
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<tr>
<td>Neutral (Allows you to shape as desired)</td>
<td></td>
</tr>
<tr>
<td>Custom (Non-standard mold used)</td>
<td></td>
</tr>
<tr>
<td>From Cast (Made from a cast)</td>
<td></td>
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</tbody>
</table>
warranty & policies

**product warranty**

**FlexorBand AFO, Lateral Strut AFO, Posterior Lateral Strut AFO, Spiral AFO, Hybrid Medial Strut AFO**

Custom Composite Mfg, Inc warranties the FlexorBand AFO, Lateral Strut AFO, Posterior Lateral Strut AFO, Spiral AFO and Hybrid Medial Strut AFO from defects in materials and workmanship for a period of 6 months from the date of manufacture. During the first 6 months a free replacement will be issued for the defective AFO upon its return and inspection of defect. One free replacement will be issued in a calendar year per patient using the original mold. From 7 to 12 months a prorated warranty will be used and reimbursement will be adjusted accordingly. Skin contact parts (foam and straps) are warranted from defect in materials and workmanship for 30 days from the date of manufacture.

**Solid Ankle Posterior AFO, Solid Ankle Anterior Medial AFO, Partial Foot Prosthesis**

Custom Composite Mfg, Inc warranties the Solid Ankle Posterior AFO, Solid Ankle Anterior Medial AFO and Partial Foot Prosthesis from defects in materials and workmanship for a period of 1 year from the date of manufacture. During the period of 1 year a free replacement will be issued for the defective brace upon its return and inspection of defect. One free replacement will be issued in a calendar year per patient using the original mold. Skin contact parts (foam and straps) are warranted from defect in materials and workmanship for 30 days from the date of manufacture.

**Carbon Footplates**

Custom Composite Mfg, Inc warranties Carbon Footplates from defect in materials and workmanship for a period of 1 year from the date of shipping.

**guarantee of fit and satisfaction**

With all custom made devices, a large part of the quality of the fit is dependent upon the cast that is received. AFO Casting instructions are provided for each custom product and should be adhered to. In the event of a poor fitting brace or prosthetic component, the practitioner should call Custom Composite Mfg, Inc at 866-273-2230 to discuss the problem. If the fitting problem can not be resolved and requires a new product to be fabricated, this is only allowed with in the first 30 days and is also dependent upon the return of the original product. After the first 30 days, return of custom products is not permitted for reasons of poor fit.

**return policy**

Upon receipt of a product, the provider shall inspect it to ensure that it meets the requirements set forth in the order. If the product does not meet the order requirements, the provider must call Custom Composite Mfg, Inc at 866-273-2230. Prior to returning a product for any reason, the provider is required to obtain a Return Materials Authorization (RMA) number from Custom Composite Mfg, Inc. Return the product, along with the patient’s name and RMA. Final acceptance of all returned items remains the discretion of Custom Composite Mfg, Inc.

**single patient user policy**

As a condition of the sale of any Custom Composite Mfg, Inc product, the orthosis is restricted to a “Single User Only” by the originally fitted patient in order to protect the care provider and the patient against potentially adverse consequences of the infectious disease transmission, material instability in adapting to the configuration of the original user and/or decrease in orthotic therapy. Any express or implied warranties are voided if an attempt is made to reuse the orthosis. Additionally, a license of right to use under any relevant patents pertaining to the orthosis is terminated with the cessation of use by the original patient.
### Design Information

<table>
<thead>
<tr>
<th>Design Type</th>
<th>Side</th>
<th>Heel Height</th>
<th>Total Height</th>
<th>Cosmetic Finish</th>
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<tbody>
<tr>
<td>FlexorBand</td>
<td></td>
<td>Flat</td>
<td></td>
<td>Carbon (Standard)</td>
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<tr>
<td>Hybrid Medial Strut w/ Calf Band</td>
<td>Left</td>
<td>3(\frac{1}{8})&quot;</td>
<td>3(\frac{3}{4})&quot;</td>
<td>Flesh Tone</td>
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<tr>
<td>Hybrid Medial Strut w/ Anterior Shell</td>
<td>Right</td>
<td>1(\frac{1}{2})&quot;</td>
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<td>Solid Ankle Anterior Medial</td>
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<td>3(\frac{3}{4})&quot;</td>
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<tr>
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<td>Partial Foot Prosthesis</td>
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### Patient and Practitioner Information

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<tr>
<th>Patient</th>
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<tr>
<th>Ankle Position During Swing (During Stance for Solid Ankle AFO’s):</th>
<th>Varus</th>
<th>Valgus</th>
<th>Neutral</th>
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<tbody>
<tr>
<td>Activity Level</td>
<td>Low: Community ambulation, mainly on level surfaces</td>
<td>Moderate: Average walking, variable speeds</td>
<td>High: Variable speeds and terrain, light lifting, occasional recreation activity</td>
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<table>
<thead>
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### Shipping Information

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CUSTOM COMPOSITE MFG, INC
170 Macklin Street, Cranston, RI 02920

Toll Free 866-273-2230
www.cc-mfg.com