

Lower Limb Orthosis

- University of California Berkeley Orthosis (UCB)
- Supramalleolar Orthosis (SMO)
- Ankle Foot Orthosis (AFO)
- Knee Orthosis (KO)
- Knee Ankle Foot Orthosis (KAFO)
- Hip Knee Ankle Foot Orthosis (HKAFO)
- Reciprocating Gait Orthosis (RGO)



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PRODUCT DESCRIPTION

The Lower Limb Orthosis, including University of California Berkeley Orthosis (UCB), Supramalleolar Orthosis (SMO), Ankle Foot Orthosis (AFO), Knee Orthosis (KO), Knee Ankle Foot Orthosis (KAFO), Hip Knee Ankle Foot Orthosis (HKAFO), Reciprocating Gait Orthosis (RGO), is a device intended to address lower limb conditions by providing support, improving alignment, controlling motion, minimizing pain, immobilizing or protecting the limb, and correcting or preventing the progression of deformities. It is used to treat neuromusculoskeletal disorders or acquired conditions.

MATERIALS

The Lower Limb Orthosis is made from various types of metal and plastic materials. The materials include low density polyethylene, co-polymer, polypropylene, carbon fiber, acrylic resin, aluminum, nickel plated brass, nylon, pressure sensitive adhesive, polyethylene foam, crosslinked polyolefin foam, and hook-and-loop fasteners.

INTENDED USE AND INDICATIONS FOR USE

The lower limb orthosis is intended to address lower limb conditions by providing support, improving alignment, controlling motion, minimizing pain, immobilizing or protecting the limb, and correcting or preventing the progression of deformities.

CONTRAINDICATIONS

Do not use the Lower Limb Orthosis in the presence of any contraindication. Contraindications include but are not limited to:

- Material sensitivity documented or suspected.
- Inability to follow treatment protocol and care instructions.

WARNINGS AND PRECAUTIONS

- Federal Law restricts the Lower Limb Orthosis to sale by, or on the order of, a qualified physician or healthcare provider and is only to be used as prescribed.
- Any orthosis that encompasses the foot is intended to be worn with shoes. Wearing this type of orthosis without a shoe may result in:
 - Reduced functional benefits of the orthosis.
 - Increased risk of slips and falls.
 - Potential damage to the orthosis, which is not covered under warranty.
- It is important to prevent skin irritation, such as soreness, redness, or rashes while wearing your orthosis.
 - Always wear a barrier (e.g. leg/foot sock) under the orthosis to protect the skin.
 - Make sure there are no wrinkles in the sock before putting on the orthosis.
 - If you notice areas of redness that do not fade after 30 minutes after the orthosis is removed or are causing pain, blistering, or bruising, please consult your healthcare provider.
 - Improperly fitted, wrinkled, damp, and/or dirty barrier (e.g. leg/foot sock), or a lack of barrier protection between the product and intact skin may create a risk of irritation, soreness, redness, blisters, or pressure ulcers.
 - Be sure to wear your orthosis tightly. A loose-fitting orthosis may create a risk of chaffing and/ or impact device performance and outcomes.
 - Lack of routine cleaning, leaving soil on device, may allow for microorganism growth.
- Contact your orthotist if any of the following issues arises:
 - Any redness or irritation that does not go away within 30 minutes after removing the orthosis.
 - Complaints of discomfort after the break-in period.
 - Worn-out straps or padding.
 - Cracks or breaks in the plastic.
 - It appears the orthosis is too small due to growth.
- Never use an orthosis that is damaged, broken or not functioning properly. Device damage, wear, and tear would compromise the outcome as well as the use of the orthosis outside the intended use.
- Components may be affected by extreme temperatures, and device breakage could occur in the environment. Monitor and discontinue to use if broken or damaged.

- Lack of adherence to the treatment plan by users based on the plan of care from the clinical care provider or improper use may impact device performance and outcomes.
 - Contributing factors may include:
 - Off label use
 - User errors
 - Product sizing incorrect
 - Poor Fit

Boston Brace International, Inc. does not provide medical treatment, advice or recommendations about the risks and benefits of medical treatment, including treatment that involves the use of the Lower Limb Orthosis. This information should be provided solely by the clinical care provider treating your child. If you have questions about your child's treatment, it is important for you to discuss those questions with the appropriate healthcare provider.

MRI SAFETY INFORMATION

The Lower Limb Orthosis is MR unsafe and should remain outside the MRI scanner room.

APPLYING ORTHOSIS INSTRUCTIONS

- **University of California Berkeley Orthoses (UCBs)**
 1. Wear a sock that covers the braced area of the limb, ensuring it is smooth and free of wrinkles.
 2. Place the UCB orthosis inside your shoe, then slide your foot in, ensuring the heel section is properly positioned at the back of the shoe.
 3. Securely fasten shoes over the orthosis.
 - a. Sneakers are the most suitable type of footwear to wear with an orthosis. They should be long enough to accommodate the device - typically ½ to 1 full size larger than the patient's usual shoe size.
 - b. If necessary, remove the insole from your shoe to create additional space.
- **Supramalleolar Orthoses (SMOs)**
 1. Wear a sock that covers the braced area of the limb, ensuring it is smooth and free of wrinkles.
 2. Open the front section that wraps around the foot and gently slide the foot into the orthosis. Ensure the foot is fully positioned at the back and bottom of the orthosis.
 - a. If the orthosis includes a removable inner boot, it may be helpful to first place the foot into the inner boot separately and then slide both the foot and inner boot together into the outer shell of the orthosis.
 3. Securely fasten all straps.
 - a. Properly tightened straps help keep the foot stable and prevent unwanted movement within the orthosis.
 - b. Straps that are too loose may lead to pressure points, skin irritation, or inadequate support.
 - c. Avoid overtightening, as this can cause excessive pressure and discomfort.
 4. Securely fasten shoes over the orthosis.
 - a. Sneakers are the most suitable type of footwear to wear with an orthosis. They should be long enough to accommodate the device - typically ½ to 1 full size larger than the patient's usual shoe size.
 - b. If necessary, remove the insole from your shoe to create additional space.
- **Ankle Foot Orthoses (AFOs)**
 1. Wear a full-length sock that covers the braced area of the limb, ensuring it is smooth and free of wrinkles.
 2. If necessary, remove the insole from your shoe to create additional space.
 3. Apply the orthosis while the patient is seated, with hips and knees flexed.
 4. If the orthosis includes a removable inner boot, open the front section and gently slide the lower leg and foot into the boot.
 - a. *Tip:* It may be easier to first place the foot and lower leg into the inner boot separately, then slide both into the outer shell together.
 - b. Ensure the heel is fully seated at the back and bottom of the orthosis.
 - c. If there is tightness, applying downward pressure on the knee, or further flexing the hip and knee, may help with proper positioning.
 5. Securely fasten all straps.
 - a. Begin by tightening the instep strap, followed by the leg strap(s).

- b. Properly tightened straps help stabilize the foot and limb stable and prevent unwanted movement within the orthosis.
 - c. Straps that are too loose may lead to pressure points, skin irritation, or inadequate support.
 6. Securely fasten shoes over the orthosis.
 - a. Sneakers are the most suitable type of footwear to wear with an orthosis. They should be long enough to accommodate the device - typically ½ to 1 full size larger than the patient's usual shoe size.
 - b. If necessary, remove the insole from your shoe to create additional space.
- **Knee Orthoses (KO)**
 1. Wearing a knee sleeve is optional. If the patient wears a knee sleeve, ensure it covers the braced area of the limb, and the sleeve is smooth and free of wrinkles.
 2. Apply the orthosis while the patient is seated, with knee flexed.
 3. Position the orthosis on the limb, aligning the knee joints with the center of the knee cap.
 4. Secure the calf straps first, followed by the thigh straps.
 5. Strap tension may need to be adjusted once the patient is standing or walking.
 6. If the brace slides down, loosen the straps, reposition the orthosis, and retighten the straps.
 - a. Pay special attention to the calf strap just below the knee, as it plays a key role in preventing the brace from slipping.
- **Knee Ankle Foot Orthoses (KAFOs)**
 1. Wear a full-length sock that covers the braced area of the limb, ensuring it is smooth and free of wrinkles.
 2. If necessary, remove the insole from your shoe to create additional space.
 3. Apply the orthosis while the patient is seated with hip and knee flexed.
 4. If the orthosis includes a removable inner boot, open the front section and gently slide the lower leg and foot into the boot.
 - a. *Tip:* It may be easier to first place the foot and lower leg into the inner boot separately, then slide both into the outer shell together.
 - b. Ensure the heel is fully seated at the back and bottom of the orthosis.
 - c. If there is tightness, applying downward pressure on the knee, or further flexing the hip and knee, may help with proper positioning.
 5. Pushing straight down on the knee may be helpful.
 6. Secure all straps starting at the ankle section and working toward the knee.
 - a. Properly tightened straps help keep the foot and limb stable and prevent unwanted movement within the orthosis.
 - b. Straps that are too loose may lead to pressure points, skin irritation, or inadequate support.
 7. Engage the knee joint locks securely. Verify that each joint is properly locked to ensure stability and prevent falls.
 8. Securely fasten shoes over the orthosis.
 - a. Sneakers are the most suitable type of footwear to wear with an orthosis. They should be long enough to accommodate the device - typically ½ to 1 full size larger than the patient's usual shoe size.
 - b. If necessary, remove the insole from your shoe to create additional space.
- **Hip Knee Ankle Foot Orthoses (HKAFO) or Reciprocating Gait Orthoses (RGOs)**
 1. Place the orthosis on its back on a flat and stable surface.
 2. Unlock all hips and knee joints.
 3. Wear full-length socks and a snug-fitting undershirt, avoiding any bulky clothing that could interfere with the orthosis. Smooth out any wrinkles.
 - a. All other clothing should be worn over the orthosis.
 4. Gently lay the patient into the orthosis.
 5. Positioning the orthosis:
 - a. Ensure the waist groove of the orthosis is correctly aligned with the anatomical waist, located between the patient's iliac crest and lower ribs.
 - b. If the orthosis includes a removable inner boot, open the front section and gently slide the lower leg and foot into the boot.

- i. *Tip:* It may be easier to first place the foot and lower leg into the inner boot separately, then slide both into the outer shell together.
 - ii. Ensure the heel is fully seated at the back and bottom of the orthosis.
 - iii. If there is tightness, applying downward pressure on the knee, or further flexing the hip and knee, may help with proper positioning.
6. Secure all straps from the bottom up.
 - a. Properly tightened straps help keep the foot and the limb stable and prevent unwanted movement within the orthosis.
 - b. Straps that are too loose may lead to pressure points, skin irritation, or inadequate support.
7. Engage the hip and knee joint locks securely. Verify that each joint is properly locked to ensure stability and prevent falls.
8. Securely fasten shoes over the orthosis.
 - a. Sneakers are the most suitable type of footwear to wear with an orthosis. They should be long enough to accommodate the device - typically ½ to 1 full size larger than the patient's usual shoe size.
 - b. If necessary, remove the insole from your shoe to create additional space.
9. Carefully lift the patient and assist them into a walker or designated standing support area. Again, ensure that the hip and knee joints are securely locked before standing.
10. Regularly inspect the orthosis to ensure it is structurally sound, checking for any loose screws, rivets, or other signs of wear.

SAMPLE WEAR SCHEDULES

Unless otherwise directed, gradually increase the wear time as tolerated. A break-in period is necessary to allow the patient and the patient's skin to get used to the new orthosis. This is important even if you have used an orthosis before. The break-in schedule will vary depending on your level of involvement or any past bracing experiences. A commonly used break-in schedule is provided in the table below. At the end of the break-in period, you should be able to wear the device following your clinician's recommendations.

Day	Hours on	Hours off	Times per day
1-2	1	1	4
3-4	2	1	3
5-6	4	1	2
7-8	8	1	1

CARING FOR YOUR SKIN

Check your skin condition and/or redness each time you remove the orthosis. It is normal to see some pinkness on the skin due to the compression of the plastic and straps. However, any redness should fade within 30 minutes of removing the orthosis. Redness lasting longer than 30 minutes may indicate that an adjustment is needed.

FOLLOW UP

Visits should be scheduled with your orthotist every three months to check the fit of the orthosis and make adjustments as needed. Visits can also be scheduled sooner than every three months if necessary.

CLEANING INSTRUCTIONS

Cleaning the orthosis at least once a week or as needed. The orthosis can be cleaned using rubbing alcohol or a mild unscented soap and washcloths. The orthosis can be wiped dry with a towel or air dry. Do not use a hair dryer or other heat source to dry the orthosis as heat can ruin the plastic. The orthosis needs to be dry before putting it on. Lint can build up in the straps of the orthosis. This can be removed with a stiff bristled brush or comb.

SAFE DISPOSAL

The Lower Limb Orthosis can be disposed of in regular trash. None of the components of the device are recyclable.

STORAGE AND HANDLING

The Lower Limb Orthosis requires no special handling during transport or storage.










REUSING THE DEVICE

All parts were designed to be used by a single patient, multiuse under normal use conditions and as instructed by a clinical care provider.

IMPORTANT STATEMENT

- Instructions for Use (IFU) manuals are available in English. To obtain a copy of the paper IFU, please call the Customer Service Group at Boston Brace International, Inc. at 1-800-262-2235.
- The manufacturer and distributor are not liable for cases of material damage or personal injury caused by incorrect handling or non-compliance with instructions. Normal use is defined as a single user following intended use.
- If a user and/or patient experiences any serious incident that has occurred in relation to the device, it should be reported to Boston Brace International, Inc.

SYMBOL LEGEND

Symbol	Meaning	Symbol	Meaning
	Manufacturer		Catalogue Number
	Date of Manufacture		Batch Code
	Single Patient Multiple Use		Non-Sterile
	Consult Instructions for Use or Consult Electronic Instructions for Use		Prescription Device Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.
	MR Unsafe		