Leada Boot Ankle / Foot Orthosis

INDICATIONS FOR USE:

- Plantar Flexion Contracture
- Internal/External Hip Rotation
- Heel Pressure Relief

FITTING INSTRUCTIONS:

NOTE: Semi Rigid Insert can be removed from liner and heat molded for plantar flexion contractures greater than 15° from neutral.

1. Open all hook and loop closures.
2. With the patient in a supine position, passively stretch the ankle/foot. Flex the knee to 45° or as close to 45 as comfort will allow.
3. Place the patient's foot in the AFO ensuring that the heel of the foot is at the apex of the AFO heel
4. While maintaining proper alignment of the foot in the AFO, bring the loop side of the foot portion of the liner over the top of the foot. Bring the opposite side of the liner over the top of the foot and secure the hook and loop closure, snug but not too tight.
5. Bring the loop side of the calf portion of the liner over the calf. Bring the opposite side of the liner over the calf and secure the hook and loop closure, snug but not too tight.
6. Place the anterior ankle pad over the top of the ankle and bring the unsecured end of the ankle strap through the open slot at the bottom of the heel, and secure the strap back onto itself. Adjust to a comfortable fit, secure enough to hold the ankle in place. The strap should be snug, but not tight. If needed, adjust both ends of the anterior strap if the strap needs to be centered to maintain a good closure.
7. Check to ensure the heel is floating free and not touching the plastic insert.
8. Move the hip control bar if needed for internal or external hip rotation.
9. Attach the removable pull strap by placing the center of the strap under the top of the foot plate and securing the hook and loop. Take each end of the strap up through the D ring on the top back of the AFO and secure the strap onto itself at the desired therapeutic tension. Tighten both straps to treat plantar flexion.
10. Determine wearing schedule per therapy and/or physician's order
11. Use the device in a recumbent position only. ***This device is not an ambulating AFO***

IMPORTANT:

- Do not apply the device if there is significant skin redness that would come in contact with the device.
- Upon removal of the device, closely inspect skin integrity. If any redness is present, discontinue device use until skin integrity issues are resolved and the device is adjusted and/or wearing schedules adjusted accordingly

CONTRA-INDICATIONS:

- An ankle/foot with grade three plus edema
- An ankylosed ankle or and ankle/foot that is broken or dislocated

LAUNDRY INSTRUCTIONS:

1. Always remove soft cover from the frame before washing. Wipe frame with damp cloth or antibacterial wipe.
2. Close all hook and loop attachments on soft cover.
3. Hand or machine wash, gentle
4. Air or tumble dry low heat
5. No bleach or fabric softener
6. **DO NOT USE COMERCIAL WASHER OR DRYER**

WARNING: The product should be fit by trained personnel. The product is designed for single patient use only in order to avoid cross contamination. Any substitution or removal of the product's parts voids the manufacturer's warranty. OCSI Inc. will assume no liability if the above instructions are not followed.

REPORT A SERIOUS INCIDENT: The user and/or patient must report any serious incident that has occurred in relation to the device to the manufacture/distributor and the competent authority of the Member State in which the user and /or patient is established.

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EC REP

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