

Bledsoe Conformer Diabetic Boot

Application Instructions CP020178 Rev. H 4/04



Council Directive 93/42/EEC
of 14 June 1993 concerning
Medical devices

REPLACES TOTAL CONTACT CASTING

From the family whose name means braces



This device is offered for sale by or on the order of a physician or other qualified medical professional. This device is not intended for reuse on a second patient or for extended use beyond 180 days. This device is generally not intended for patients in excess of 250 lbs. (114 kilos). This device is not intended to prevent injuries or reduce or eliminate the risk of reinjury.

Indications: The Bledsoe Conformer Diabetic Boot is indicated to replace total contact casting for the treatment of ulcerative or pre-ulcerative conditions of the bottom of the foot. It is also indicated for the treatment of moderate to severe plantar fasciitis or other foot conditions that would benefit from a more even distribution of body weight on the sole of the foot.

Contraindications: The Bledsoe Conformer Diabetic Boot is contraindicated when the foot width will not fit within one size range larger than a normal size shell.

WARNING: The white foam layer on this boot may exhibit brittle characteristics at temperatures below 50° F (10° C). Please do not handle the foam while it is cold. Make sure the entire boot is allowed to warm to room temperature before use. Do not leave this device in the trunk of a car on a hot day or in any other place where the temperature may exceed 150° F (65° C) for any extended period of time. If any additional pain or symptoms occur while using this device, seek medical attention.

Warranty: This device is warranted to be free from defects in material and workmanship for a period of 90 days. These warranties apply to devices that have not been modified or subjected to misuse, abuse or neglect. This device is expressly subject to Bledsoe's Product Line Limited Warranty. Copies of this limited warranty can be obtained from your medical professional, via the internet at www.bledsoebrace.com or by calling (800) 527-3666.

Manufactured by:

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For product information or questions pertaining to sales or service, please contact the sales representative in your area or the manufacturer.

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Maximum foot width: The dual density, super compliant midsole will accommodate many Charcot foot patients or patients with abnormally shaped feet. The only limiting factor is the width of the foot at the metatarsal heads. See the chart below for maximum foot width for each size available.

Size	Max foot width
4-5	3 9/16
6-7	3 3/4
8-9	4 1/16
10-11	4 5/16
12-13	4 5/8
14-15	4 13/16

Note: Additional ankle width can be gained by reforming the uprights and the shell wider where the uprights attach.



Step 1

Step 1. If an open wound is present on the foot, cover and dress the wound appropriately according to your physician's instructions. Apply a clean cotton sock, or the Diabetic sock included with the boot, over the foot and dressing. **Warning: Never allow the bare foot to directly contact the white innersole. The foot must be allowed to breathe. Always wear a sock.**

Step 2. Remove the foam wrap "bootie" from the boot and open the hook-to-pile closures on the leg and forefoot sections. Slip the foot into the bootie with the toes beneath the tongue. Push the foot all the way to the back of the bootie. Make certain the foot is centered from left to right on the white innersole section. Close the three layers of foam on the forefoot. Wrap the foam section around the leg by tucking in the long end of the foam cuff, tension the wrap, and close the hook-to-pile closure at the front of the leg. If the cuff is excessively long, the excess material may be trimmed with scissors.



Step 2

Step 3.

Make sure that the plastic covers are still in place on the uprights of the boot. Slip the bootie into the boot and position it evenly from front to rear. Be certain the bootie is positioned centered from left to right as well. When properly positioned, the white innersole should fit completely inside the black midsole and the ends of the bootie should not overhang either end of the boot. The stitched periphery of the bootie must remain outside of the molded foot-shaped indentation in the black midsole. Stand and place full body weight on the boot for at least 30 seconds to properly compress the Automold innersole. While still bearing weight, align the uprights with the sides of the leg in line with the bones and make certain that the foot is pointed directly forward. With the boot uprights properly aligned with the lower leg, and while still bearing weight, slip the plastic covers off of the uprights one at a time and press the uprights against the side of the leg to engage the hook material to the pile surface on the cuff. You should save the plastic covers to permit easy reapplication if the foam cuff is removed for washing.

Note: To reduce forefoot pressure during rock-through, on forefoot ulcers, you may tilt the upper end of the uprights about 1/2" forward (which is plantar flexing the ankle) before engaging the hook material of the uprights to the pile surface on the foam cuff. For heel ulcers, you may tilt the uprights 1/2" backward (which is dorsi flexing the ankle) to reduce pressure on the heel during heel strike.

WARNING: Failure to stand and compress the Automold innersole prior to removing the plastic covers and engaging the foam cuff, may allow the leg to piston up and down excessively causing friction between the leg and the foam cuff.



Step 3

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Step 4

Step 4.

While still standing, wrap the forefoot straps over the top of the foot, through the D-rings, and pull back to tension. Place the double-sided hook pieces in position on the straps to allow as much strap adjustment as possible. Trim the excess strap length on the forefoot straps with scissors.



Step 5a

Step 5a.

Remove the small hook pieces that hold the calf straps neatly rolled. Beginning at the ankle, and while still standing, wrap both strap ends firmly forward to engage the straps with the hook material on the outside of the uprights. Loop the end of the strap through the D-ring and pull back to tension. Press the hook end back to the strap to engage. Repeat this procedure for the remaining straps working up the leg.

The boot is now ready for use.

You should read the card enclosed with the boot that explains how to properly walk in your new Bledsoe Conformer Diabetic Boot, and how to properly care for your feet.



Step 5b

Step 5b.

Note: The two black cable ties may be used to prevent boot removal for the first two physician visits.

Slip the end through the slot at the back edge on the side of the shell. Wrap it around the ankle inside the opposite upright, then wrap it around the front of the ankle, around the outside of the first upright. Slip the end through the engaging slot at the end of the cable tie. Pull it carefully closed without too much tension. Trim the excess length with scissors. In order to remove the boot, this cable tie must be cut.

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Step 6

Step 6.

Following your physician's instructions, the boot may be removed to change the sock and dressing. To remove the boot, unfasten the straps and stick the strap ends back to themselves to prevent entanglement. Do not detach the straps from the uprights unless removing the foam cuff for washing. Peel open the foam cuff and forefoot closures and remove the foot.



Step 7

Step 7.

Using isopropyl alcohol, clean the white inside surface of the bootie.

Note: Chlorinated cleaners or sanitizers may also be used if specified by your physician.

If the foam cuff requires cleaning, peel the straps away from the hook material on the uprights. Pull the plastic covers (that were previously saved) down over the uprights while separating the foam cuff from the uprights. With the plastic covers in place, slide the foam bootie out of the boot. Remove the rear plastic plate with the straps attached from the back of the foam wrap. Wash the foam cuff by hand, using a detergent for delicate fabrics, such as Woolite™. Rinse the cuff three times, squeeze out the excess water between rinses, and allow to air dry.

WARNING: Make certain that the foam cuff is absolutely dry before reapplying it to the leg.



Step 8

Step 8.

When reapplying the plastic plate that contains the straps, reposition the top edge of the plate about one inch below the top edge of the foam cuff centered on the bootie at the back of the calf. The straps should remain attached to the plate which should position the straps in line with the hook patches on the outer sides of the uprights. If necessary, the plate may be positioned a little higher or lower to allow the straps to properly contact the hook patches on the uprights. The three straps are different lengths. The shorter strap is just above the ankle. The longest strap is at the top of the foam cuff. The D-rings should be between the uprights on the front of the leg. The strap ends alternate left and right. To reapply the boot, slip the foot back into the boot and carefully center the foot properly in the molded foot shape that was created during walking. Close the forefoot section as previously shown, then close the foam wrap around the leg. Stand up and apply full weight on the innersole for 10 to 15 seconds before fastening and tensioning the forefoot straps and the leg straps.