

Bledsoe Axiom Sport / Ultimate CI Brace

Application Instructions & Patient Use Manual CP020141 Rev G 03/07



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

ULTRA LIGHT SPORT BRACE FOR ACL, PCL, MCL, LCL, & MENISCUS DEFICIENCIES



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. This device is generally not intended for patients in excess of 350 lbs (159 kg).

Indications: Indicated for increased support of knees following injury to or reconstruction of the anterior cruciate ligament, posterior cruciate ligament, medial or lateral collateral ligament, or menisci either alone or in combinations. Also indicated for increased support for patients who have continued symptoms of giving way, poor quadriceps or hamstring strength, or a desire for an early return to sports activities.

Contraindications: Contraindicated in patients with triple varus knees that have damage to the postero-lateral structures combined with stretched lateral structures and varus thrust.

WARNING: 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, discontinue use and seek medical attention.**

Warranty: This device is warranted to be free from defects in material and workmanship for a period of 90 days for pads, straps and normal wear components, 12 months on all other parts and 5 years against shell breakage. 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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1. LOCATE THE CENTER POINT

Bend the leg 80° to 85° of flexion. The brace must be applied in an flexed position, except for PCL injuries. Locate the adductor tubercle (large bony knot on the inside of the knee).



2. POSITION THE BRACE AND ADJUST SHAPE

Loosen the two front brace straps to the maximum length. Position the brace with the upper hinge pivot point overlying the adductor tubercle on the medial side of the knee. Push the brace 1/2" (1.5 cm) more superior on the thigh to allow for settling. If the shape is not correct, slightly bend the shells to achieve a better fit on the thigh and calf. The hinges must remain parallel and operate smoothly. **NOTE:** The minimum bend radius is 3/4" (4.5 cm) for any tool bending and should be



3. APPLY THE UPPER REAR CALF STRAP

Pass the rear calf strap behind the knee and position it as high up as possible over the calf muscles. Pass strap end through the D-ring, pull tension and fasten strap. If necessary, the strap pad may be cut shorter in increments.

NOTE: Failure to position this strap or the brace as stated in these instructions may result in some brace slippage.



4. TIGHTEN THE FRONT SHIN STRAP

Tighten the shin strap comfortably without pulling the brace too far forward. The front shin strap and the upper calf strap form a ring around the leg at the small part of the upper calf muscles. This ring suspends the brace and prevents slippage. Patients with poor calf musculature or swollen knees may experience brace slippage. It is important to tighten these straps as stated without causing circulatory problems to keep the brace in the proper position.



5. FASTEN LOWER REAR CALF STRAP

Pass the lower calf strap around the leg and through the D-ring on the opposite side. Pull back and tension lightly before fastening. The opposite strap end may be adjusted to shorten the length. This strap should not be very tight. It's purpose is to hold the shell against the leg. Over-tightening of this strap will increase the chance of brace slippage and decrease comfort.



6. APPLY LOWER REAR THIGH STRAP

Pass the lower rear thigh strap around the leg and fasten it through the D-ring in the same manner as the other straps.

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7. APPLY THE UPPER REAR THIGH STRAP

Pass the upper rear thigh strap around the back of the thigh as high as possible. Place it through the D-ring on the opposite side and tension it lightly. The purpose of this strap is also to hold the thigh shell in contact with the thigh. Over-tensioning of this strap will decrease comfort and promote slippage.



8. ADJUST FRONT THIGH STRAP

Adjust the tension on the front thigh strap comfortably but not too tight. Excessive tension on this strap will increase brace slippage and discomfort. The opposite strap end may be adjusted to shorten the length. The brace is now fitted and ready for any special strap adjustments according to the injury type.

This instruction manual should be used by the patient or medical professional as a reference guide.

SPECIAL ADJUSTMENT FOR COLLATERAL LIGAMENT INJURIES

The brace should be adjusted as stated in the application instructions with no “shear force” or specific strap pretension applied. The shear force should be neutral since the greatest concern is medial-lateral stability. For increased medial or lateral force, it may be desirable to have an Orthotist pre-bend the brace with 5°- 8° of excess varus or valgus angulation to provide increased pressure against certain pathological movements. Consult your Physician or local Orthotist for help with this procedure.

SPECIAL ADJUSTMENT FOR ANTERIOR CRUCIATE LIGAMENT INJURIES

In order to provide increased resistance against tibial subluxation or to reduce force on a reconstructed ACL, it may be desirable to pretension the straps to provide a “shear force” across the knee by increasing the tension on the front calf strap on the tibia and the lower rear thigh strap on the back of the thigh. All straps for ACL patients should be adjusted with the leg bent at 80°-85°. Loosen the front thigh strap and increase the tension on the lower rear thigh strap and, if necessary, the front shin strap to provide a pre-loaded strap force that helps prevent anterior tibial subluxation (forward movement of the lower leg relative to the upper leg) when the leg is extended.

SPECIAL ADJUSTMENT FOR POSTERIOR CRUCIATE LIGAMENT INJURIES

In order to provide increased resistance against posterior tibial subluxation or to reduce force on a PCL reconstruction, it may be desirable to provide a “shear force” across the knee by increasing tension on the upper rear calf strap and the front thigh strap. All straps for PCL patients should be adjusted with the leg in full extension. Loosen the lower rear thigh strap and the front calf strap and increase tension on the front thigh strap and upper rear calf strap to provide a pre-loaded shear force that prevents posterior tibial subluxation (backward movement of the lower leg relative to the upper leg) as the leg bends.

CAUTIONS and WARNINGS

- Never leave dirt, sand or other abrasive particles in the hinge. Always clean it completely.
- Do not use lacquer thinner or other paint solvents to clean the brace. Damage may result to the plastic and the outer shell finish.
- Do not over-tighten the hinge screws or the nut plates as damage may occur.
- Do not use harsh chemical cleaners on the finish. Clean the outer surface with ordinary glass or surface cleaner.
- Do not continue to use the brace if parts are excessively worn, missing or broken. To do so may result in brace failure or injury.
- If a severe impact occurs, such as an accident or fall when playing sports or riding a motorcycle, inspect all brace parts for possible damage or signs of excessive strain and repair as necessary.
- Inspect the straps and strap tabs frequently for signs of wear and replace them before they wear through. Straps and pads are normal wear items. If straps should fail, the chance for injury may increase.
- Wash the straps and pads with a detergent intended for delicate fabrics. Hand wash, rinse thoroughly and line dry. DO NOT place the pads in a heated dryer as damage may result. Use of regular laundry detergents may make it difficult to thoroughly rinse the pads and straps leaving a residue on the parts which could cause skin irritation.
- Always use a padded covering on the brace when playing contact sports to help prevent injury to other players.
- This brace is intended to increase support and proprioception on a previously injured or healing knee. It is not intended to prevent injuries or to prevent reinjury after surgery.
- If any pain or other symptoms occur with brace use, discontinue use and seek medical attention.

Hinge Stop Application Instructions

The Bledsoe Ultimate Series Braces now come with externally replaceable flexion and extension stops. The stops are very simple to use when you follow these steps:

Step 1. Decide on the range of motion desired. The extension stops are available in 10° increments from 0° - 50°. Flexion stops are included from 50° - 100°. Each stop has two numbers etched on the surface and can be used as extension stops or flexion stops depending on which side of the hinge it is inserted. For example, a stop may be labeled E0 - F100. When this is used as the extension stop, the hinge will extend completely. The very same stop placed as a flexion stop will stop the hinge at 100° flexion. Extension stops are inserted from the front side of the hinge while flexion stops are inserted from the backside of the hinge.

Step 2. If stops are present in the hinge, use the 1/16" hex wrench included with the brace to remove the screws from the face of the hinge cover. Place the brace within the range of motion desired and lift out the existing stops.

Step 3. Make certain you have selected the appropriate stop for the extension side. If you desire a range of 20° to 70° for example, you would select the stop labeled E20 - F80 to use as the extension stop, and E30 - F70 to use as the flexion stop.

Step 4. Place the appropriate stop into the hinge from the front side (extension stop side) in between the two molded hinge plates with the V-shaped area of the stop pointing into the hinge. When the stop drops into place the V-shaped area will rest on a plastic V-shaped tray. Using the 1/16" hex wrench, insert one of the screws into the hole located on the face of the outer hinge plate to the front side of the hinge (extension stop side). Tighten the screw without over torquing. Be careful not to strip out the plastic hinge plates by turning on the screw too tightly. This can be accomplished by tightening the screw until the underneath side of the screw head makes contact with the outer hinge cover.

Step 5. Repeat Step 4 for the opposite hinge to complete the extension stops. **Warning: Always use stops in both hinges and they must be the same limits! Use of different stops on the left and right sides of the brace may result in brace failure!**

Step 6. Now repeat the same actions on the backside (flexion stop side) of the hinge for both the left and right hinges. Make certain you read the "F" number for the flexion stop. Make certain that both flexion stops are the same and both extension stops are the same. Also check to make sure that the stops will remain in position (that the screw actually went through the hole of the stop to capture it).

Step 7. Extend and flex the brace against the stops to be certain if stops at the correct angle. It is more important where the leg stops due to soft tissue deflection than the hinge stop position. Compensate as necessary for excess fatty or soft tissue.

Step 8. If the optional European version stops are included, you may choose the E0 - F100 as an extension stop along with a special F0 stop to lock the hinge in full extension. Choosing the E10 - F90 stop along with the special F10 stop will lock the hinge at 10° of flexion.

