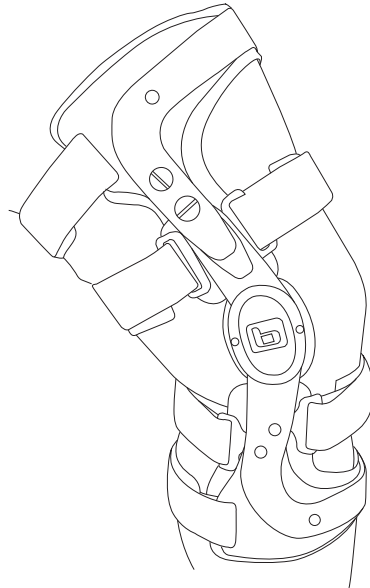




DUO by Bledsoe



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



For product information or questions pertaining to sales or service, please contact the sales representative in your area or Bledsoe Brace Systems directly.

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Unfasten Buckles

1. Release all four straps on the back side of the brace by squeezing the gray levers on either side of the buckle and withdrawing the over-center buckle. Loosen the front strap(s).

Positioning the Brace (Fig. A)

2. With the knee bent at 45°, lay the brace on the leg and align the hinge as shown above. Position the center of the hinge on an imaginary line that goes across the top of the knee cap. Push the hinges posteriorly until the hinges are in the center of the knee joint when viewed from the side.

Anchoring the Brace (Fig. B)

3. Wrap the upper rear calf strap around the calf as high as possible over the calf muscle.

Insert the over-center buckle into the base. Push the buckle until you hear the gray levers click on both sides.

Adjust the strap by releasing the hook and pile tab and pull the strap until a snug and comfortable fit is achieved. (Fig. C)

Fastening Lower Calf Strap

4. Insert the over-center buckle into the base on the lower calf shell of the brace. Push the buckle in until you hear the gray levers click on both sides.

Adjust strap until a comfortable fit is achieved. (If the strap tab reaches its limit without achieving the desired fit, see strap length adjustment in figure F.)

Fastening Rear Thigh Straps

5. Following the same instructions as in Steps 3 and 4, fasten the lower and then upper rear thigh strap.

Adjusting Front Tibia Strap (Fig. D)

6. Tighten the front tibia strap. If the strap overlaps too far, see strap length adjustment in figure F.

Center the strap pad.

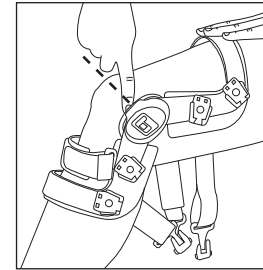
Adjusting Front Thigh Strap (Fig. E)

8. Tighten the front thigh strap. Note: Overtightening the front thigh strap can cause the brace not to function properly.

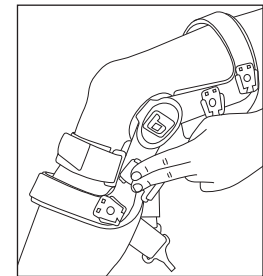
Stand up and walk or jog around to see how your new DUO brace feels. Straps should not be so tight that blood circulation is restricted. Re-adjust as needed.

If this is your first time to wear a functional knee brace, it might take a few hours of wear to get used to how it feels.

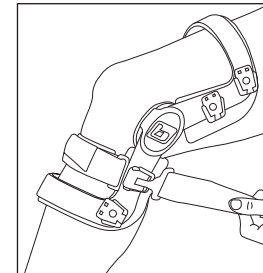
A.



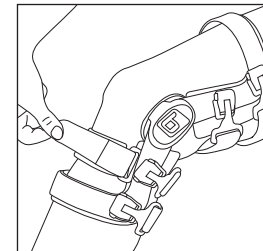
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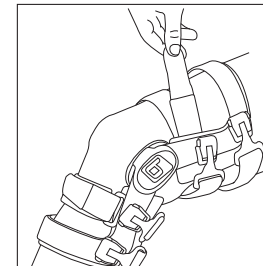
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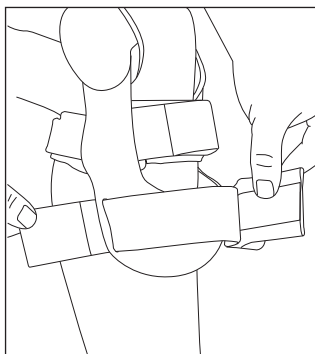
D.



E.



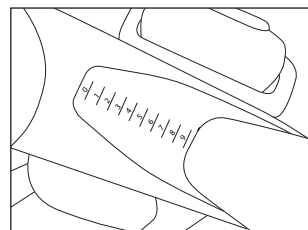
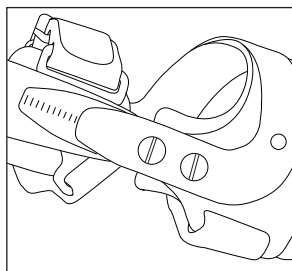
F.



Strap Length Adjustment (Fig. F)

All straps have additional length adjustment at the end opposite the tab. Release the strap and adjust the length of the strap using the hook and pile fastener. Center the strap pad.

G.



Adjust OA Load (Fig. G)

9. The DUO brace comes with the setting at 4. Put the brace on and walk around in it to see if the brace provides pain relief. If it does not, the brace can be adjusted. Remove brace, then remove the "b" shaped tool hanging on the brace. Insert the tool into the top screw and turn to the left to loosen. Repeat with the bottom screw.

To decrease the amount of load, slide the arm down to a lower setting.

To increase the amount of load, slide the arm up to a higher setting.

Use the tool to tighten the screws by turning it to the right until snug. Reapply the brace and walk around again in the brace to check for comfort and pain relief. Repeat process until desired pain relief is achieved.

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 to prevent injuries or reduce or eliminate the risk of reinjury.

Indications: The DUO brace can be configured to address medial or lateral osteoarthritis. The brace is designed to decrease joint pain by creating a space between the bones on the affected side of the knee.

Contraindications: The DUO is contraindicated to treat medial osteoarthritis with a lateral osteoarthritis brace or to treat lateral osteoarthritis with a medial osteoarthritis brace.

Warning: Federal Law Restricts this Device to Sale by or on the Order of a Licensed Health Care Practitioner.

Warning: For Single Patient Use Only.

Caution: Activity modification and proper rehabilitation are an essential part of a safe treatment program. If any additional pain or other symptoms occur while using this device, discontinue use and seek medical attention.

Caution: This device will not prevent or reduce all injuries.

Caution: Carefully read fitting instructions and warnings prior to use. To ensure proper performance of the brace, follow all instructions. Failure to properly position the brace and fasten each strap will compromise performance and comfort.

Caution: This device has been developed for the indications listed above, and may be damaged by unusual activities such as sports, falls, or other accidents, or exposure of the hinges to debris or liquids. Do not leave this device in 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. To avoid the risk of accident and possible injury to the patient, discontinue use if such an incident has occurred.

Warranty: This device is warranted to be free from defects in material and workmanship for a period of 90 days for wraps, pads and straps and normal wear components; 12 months on all other parts; and 3 years against hinge 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 1.800.527.3666.

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