

DONJOY FULLFORCE Four Points of Leverage Brace User Guide

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Important Information

BEFORE USING THE DEVICE, PLEASE READ THE FOLLOWING INSTRUCTIONS COMPLETELY AND CAREFULLY. CORRECT APPLICATION IS VITAL TO THE PROPER FUNCTIONING OF THE DEVICE.

INTENDED USER PROFILE

The intended user should be a licensed medical professional, the patient or the patient's caregiver. The user should be able to read, understand and be physically capable to perform all the directions, warnings and cautions provided in the information for use.

INTENDED USE/INDICATIONS

The DonJoy FullForce Knee Brace with Fource Point Hinge is designed to support and protect the knee following

ACL injuries, ACL reconstructions and collateral ligament deficiencies. Soft-good/ semi-rigid designed to restrict motion through elastic or semi-rigid construction. Providing mild protection of a limb or body segment for acute and prophylactic care.

WARNINGS AND CAUTIONS

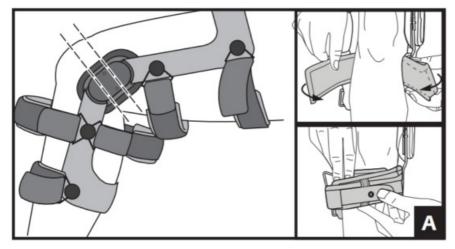
- Loss of circulation, patient discomfort and patient re-injury are potential effects caused by device failure.
- ROM settings should not be changed without supervision of a medical professional.
- This product must be prescribed and fitted by a healthcare professional.
- The frequency, duration of use and directions for use should be determined by your healthcare professional.
- If pain, swelling, changes in sensation or other unusual reactions occur while using this product, you should contact your doctor immediately.
- The support should be snug but not impair circulation.
- Do not use over open wounds.
- Do not use the device if it is damaged and/or the packaging has been opened.

NOTE: Contact manufacturer and competent authority in case of a serious incident arising due to usage of this device.

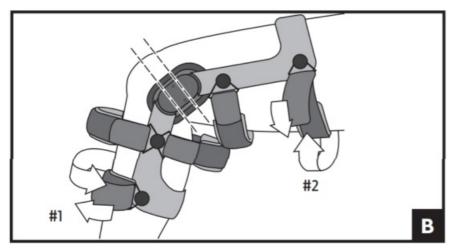
APPLICATION INFORMATION

This product was designed to complement the variety of medical treatments common to the above afflictions. For use on a patient who has achieved full extension.

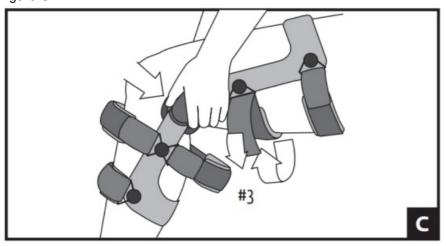
A) 1: While sitting on the edge of a chair, step through the brace. Flexing the knee to 45°, position the brace as shown in figure A, centering the hinge at the top of the kneecap and slightly past midline of the leg. Make sure the brace is not twisted on the leg.



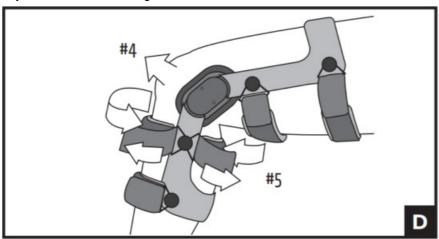
- 2: Secure the full circumference strap (anti-migration band) around the upper calf located within the #4 strap. Wait to strap #4 until step D.
- **B**) Secure the bottom calf strap first (#1), then the top thigh strap (#2).



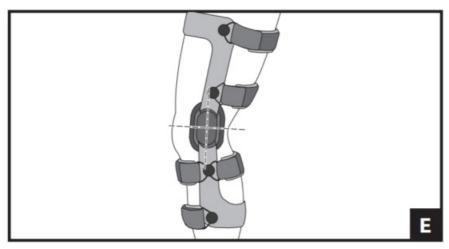
C) 1: Keeping the knee bent at 45 degrees, push both condyles (hinges) toward the back of the leg, as shown in figure C.



- 2: While maintaining the position of the hinges, secure the lower thigh strap (#3).
- **D**) 1: Draw the hinges forward slightly before fastening the front tibial (shin) strap (#4). Do not pull the hinges beyond midline of the leg.



- 2: Next, secure the upper calf strap (#5). Do not over-tighten straps.
- **E**) 1: When all strapping is complete, the hinge should center just above the top of the kneecap and slightly behind midline.



2: To ensure that no migration occurs during activity, it is recommended to do a few knee bends or walk for a few minutes. Then re-tighten the straps following steps A-D for a secure and comfortable fit.

INSTRUCTIONS FOR HINGE ADJUSTMENT

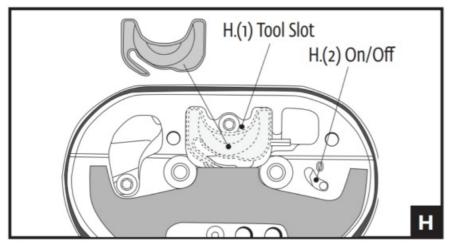
Resistance Adjustment Screws (Fig. F) Remove brace, remove condyle pads, remove key from inside of hinge, remove adjustment screw. Re-insert adjustment screw into desired location according to patient's comfort and physician's rehabilitation protocol (1-low, 2-medium, 3-high). Push adjustment screw down until threads contact surface of hinge (F1) turn Allen key to tighten adjustment until top of screw is flush with hinge surface (F1). Do not over tighten. Repeat procedure for other hinge. Both hinges must be on the same setting.



Changing Standard External Flexion Stops (Fig. G) Completely remove screw. Remove the stop and insert the new stop.



Align with the hole in the hinge plate, reinsert the screw, and tighten. Repeat procedure for other hinge. Both hinges must have the same stop. Turn Resistance On And Off. (Fig. H) Remove tool from inside of hinge cover(H1). Place brace in flexion, insert tool into on/off slot (H2) and slide over.



The "O" represents the brace is "off" or has no resistance. When moved away from "O" the brace is "on" or has resistance. Once adjustment is made to both hinges, replace tool in slot.

Note: Extension stop kits at 0°, 20°, 30°, 40° are sold separately.

10° extension stops are installed.

USE AND CARE

- This product is intended for single patient use only.
- If during activity, re-tightening is necessary, re-tighten all straps following steps in the application instructions.
- All straps and pads may be trimmed to fit individual variations in limb circumference.
- The brace may be used in fresh or salt water. Following use in water activities, drain thoroughly and rinse with clean, fresh water and then air dry.
- Hand wash your liners and condyle pads in cold water with mild detergent. AIR DRY ONLY, DO NOT HEAT DRY LINERS OR PADS.
- Periodically inspect hinge screws for tightness and retighten as needed.
- Lubricate hinges periodically with dry lubricant or Teflon™ spray. To lubricate internal hinge mechanism, place brace in flexion and spray into the back side of the hinge cover.
- This device is not intended to be used with other devices except those specifically listed as accessories to this device.

RX ONLY

INTENDED FOR SINGLE PATIENT USE.



NOT MADE WITH NATURAL RUBBER LATEX.

WARRANTY: DJO, LLC will repair or replace all or part of the product and its accessories for material or workmanship defects for a period of six months for softwoods and one year on brace frame/hinges from the date of sale.

NOTICE: WHILE EVERY EFFORT HAS BEEN MADE IN STATE-OF-THE-ART TECHNIQUES TO OBTAIN THE MAXIMUM COMPATIBILITY OF FUNCTION, STRENGTH, DURABILITY AND COMFORT, THERE IS NO GUARANTEE THAT INJURY WILL BE PREVENTED THROUGH THE USE OF THIS PRODUCT.

CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED HEALTHCARE PROFESSIONAL.

CUSTOMER SUPPORT

MDSS GmbH Schiffgraben 41 30175 Hannover, Germany

DJO, LLC

1430 Decision Street Vista CA 92081-8553 USA ©2021 DJO, LLC 13-3917-0-00000 REV H – 2021-05-14



Documents / Resources



<u>DONJOY FULLFORCE Four Points of Leverage Brace</u> [pdf] User Guide 13-3917-0-00000 REV H, FULLFORCE Four Points of Leverage Brace, FULLFORCE, Four Points of Leverage Brace, Leverage Brace, Brace

References

• User Manual

Manuals+, Privacy Policy

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