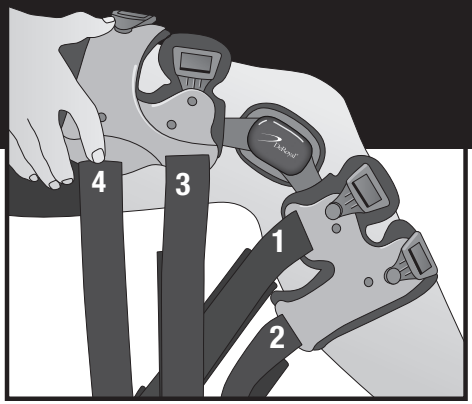
OA SINGLE UPRIGHT KNEE BRACE



	SINGLE PATIENT USE
NON STERILE	NON-STERILE
MD	MEDICAL DEVICE
	NOT MADE WITH NATURAL RUBBER LATEX
RX ONLY	FEDERAL U.S.A. LAW RESTRICTS THIS DEVICE TO SALE OR USE BY OR ON THE ORDER OF A PHYSICIAN OR PROPERLY LICENSED PRACTITIONER.

IMPORTANT INFORMATION

Please read all instructions, warnings and cautions before use. Correct application is essential for proper product function and to reduce the risk of injury or re-injury inherent with the use of any brace. Use only on the person it was provided to by a healthcare professional and only for the use it was intended.

INTENDED USE

The DeRoyal® OA Single Upright Knee Brace is designed to help:

- Mild to severe unicompartmental knee osteoarthritis
- Increased rehabilitative and functional support for diagnoses that require reduced medial or lateral joint loads

⚠WARNING

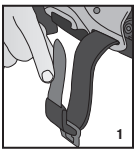
- Inspect brace for damaged or missing components before use.
- Discontinue use and consult your prescriber if the brace or its components break or become damaged.
- Prolonged usage can result in muscle atrophy in the user. The user may require (1) a weaning period from the brace to build muscle strength (2) regular physical therapy exercises to maintain the strength of the leg (3) a limitation on duration of use, or (4) some combination of these. The prescriber should communicate these risks to the user and determine the treatment plan.

CAUTIONS

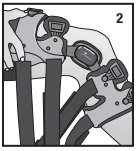
- A physician or properly licensed practitioner (a "prescriber") who is familiar with the use and purpose of this brace must fit it to the user. The prescriber has a duty to provide wearing instructions and risks related to the use of this brace to other healthcare practitioners treating the users and the users themselves, including duration of use. The instructions provided in this sheet do not supersede hospital protocol or direct orders of the prescriber. Use only as directed.
- Inspect the fit of the brace on the patient to ensure fit is proper. **DO NOT OVERTIGHTEN**. Check regularly to ensure circulation is not compromised.
- Consult your prescriber immediately if you experience sensation changes, unusual reactions, swelling or increased pain while using this brace. Discontinue use if pressure injuries develop.
- While not an absolute contraindication to the use of this brace, take special care if the user is diabetic or has poor circulation. These users may have decreased skin sensitivity and are at greater risk for poor peripheral circulation and pressure injuries.
- Once the sizing and range of motion limitations are set, use caution while wearing to ensure these setting are not inadvertently adjusted.
- Metal components could cause injury to the user or others. Exercise care in situations where contact is likely, such as contact sports.

INSTRUCTIONS FOR USE

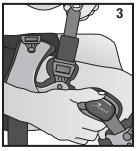
1. To simplify application, attach each strap back onto itself to minimize tangling (See Image 1).



2. While sitting at edge of chair, bend knee slightly and apply brace to lateral side (outside) of leg. Align center of hinge with top of kneecap and position slightly behind midline of leg. **NOTE**: When positioning the off-the-shelf brace for initial fitting, it should first be adjusted to neutral. This is achieved by setting the correction angle (see Step 5) so the cuffs and hinge rest on leg without gapping or pressure. Medial or lateral compartment correction will be adjusted in Step 5 (See Image 2).

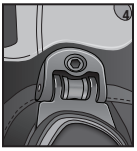


3. Attach straps in sequence indicated on strap ends. Connect buckles then tighten straps. Hold brace at hinge to prevent rotation while tightening straps. Fasten Strap 1 snugly just above calf muscle. Strap 1 is important in maintaining brace position. Fasten Strap 2 around middle of calf. Fasten Strap 3 around lower thigh. Fasten Strap 4 around upper thigh. All straps should be comfortably tightened to properly secure brace and provide relief. **NOTE**: Elastic strap extension may be used on Strap 3 for medial compartment and Strap 4 for lateral compartment. Remove Strap 3 or 4. Place elastic extension through frame slot and attach to strap as shown (See Images Main & 3).

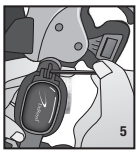


4. Once straps are secure, center of hinge should be aligned with middle of kneecap and positioned

slightly behind midline of leg. To ensure proper fit for activity, walk a short distance. It is normal for brace to drop or settle into position. Make strap and position adjustments as necessary.



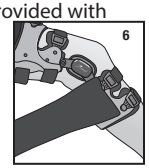
5. For initial fitting of OA Single Upright Knee Brace: With the brace in neutral (from Step 2 above), bend the knee to 90°. With the provided allen key, turn the Q-hinge screw ¼ turn clockwise (important) to increase lateral compartment relief or ¼ turn counterclockwise to increase medial compartment relief. This is a good starting point for initial use (See Images 4 & 5).



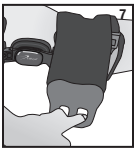
6. Stand and walk a short distance to ensure comfort and proper correction after each adjustment. If there is any discomfort in the knee joint or leg, turn the angle adjustment back slightly. If more relief is required, turn Q-hinge screw no more than 1/8 turn. Walk after the adjustment and check as above. Over-adjusting the Q-hinge may cause discomfort and skin pressure issues. Adjust conservatively.

CALF SUSPENSION WRAP APPLICATION

A suspension wrap may have been provided with your brace if necessary. This wrap is designed to aid suspension and brace position by applying even compression to soft tissue.



1. Attach hook and loop strip to the inside two straps of the lower half of the brace.
2. Pull the wrap around the outside of the leg and brace (See Image 6).
3. Continue the wrap all around the brace and leg and attach it to itself with the finger pull end (See Image 7). **NOTE**: Wrap should be positioned so that top edge of wrap is ½" above the strap right below the knee.



TROUBLESHOOTING

It is normal for the brace to drop slightly after initial application so the hinge centers align with the center of the kneecap. If the brace drops below knee center, reapply the brace using the following troubleshooting tips:

- **STRAP 1**: Should rest on top of the calf muscle.
- **STRAP 4**: Should not be too tight.
- **STRAP 2**: Should be secure and snug, without restricting blood flow or causing discomfort. Tightening this strap also helps balance the pressure from the lower cuff across the tibia (shin).
- **STRAPS 2 AND 3**: Provide the most suspension control and may require adjustment to maintain proper suspension.
- Excess soft tissue, undefined calf muscles or unusual leg contour may require use of an undersleeve to help suspend your brace. Contact your orthotic professional for more information about undersleeves.

RANGE OF MOTION ADJUSTMENTS

The brace comes with standard 0º extension stops. Additional flexion and extension stops may be installed if they are prescribed by your physician or needed for optimal performance or fit of the brace. These should be inserted by the technician who fits your brace.

Optional 5°, 10°, 15°, 20°, and 25° extension stops and optional 45°, 60°, 75° and 90° flexion stops are included with each brace.

WEAR TIME

Gradually increase brace wear time to allow your body to adjust to the brace. Start with 30 minutes on day one and gradually increase. Pain caused by osteoarthritis may take time to subside. It is important that you routinely wear the brace during weight bearing activities (e.g. when on your feet) as it will reduce joint loading and allow you to begin feeling relief. It may take a number of weeks for relief to become significant.

CLEANING AND/OR MAINTENANCE

- Salt water, sand, dirt and other elements can cause damage. Thoroughly rinse brace with fresh water after exposure to these conditions. Towel or air dry.
- Liners should be removed and hand washed as needed using cold water and mild detergent. Rinse thoroughly and air dry (Do not machine wash. Do not machine dry).
- Lubricate hinge with dry silicone spray as needed.
- Wrap should be removed and handwashed as needed using cold water and mild detergent. Rinse thoroughly and air-dry (do not machine-dry).

STORAGE AND TRANSPORT CONDITIONS

	KEEP DRY
	KEEP AWAY FROM SUNLIGHT

In addition to the competent authority in the country where the patient resides, serious incidents must be reported to DeRoyal Industries, Inc.

WARRANTY

DEROYAL® PRODUCTS ARE WARRANTED FOR NINETY (90) DAYS FROM THE DATE OF SHIPMENT FROM DEROYAL AS TO PRODUCT QUALITY AND WORKMANSHIP. **DEROYAL'S WRITTEN WARRANTIES ARE GIVEN IN LIEU OF ANY IMPLIED WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.**

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