



DEROYAL® UNIVERSAL RECOVERY POST-OP KNEE BRACE

	SINGLE PATIENT USE
	NON-STERILE
	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 warnings and instructions 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® Universal Recovery Post-Op Knee Brace is used for external fixation or support of the knee.

INDICATIONS

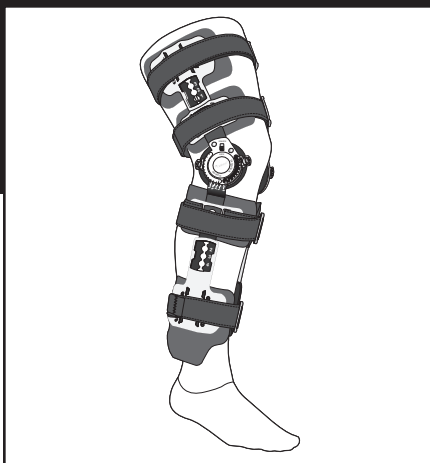
Post-operative stabilization and rehabilitation; post total knee replacement; Post ORIF; fractures of the femur, tibia, fibula or patella; ligament reconstructive procedures; meniscal repairs; post-fracture management.

WARNINGS

- 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 a contraindication, 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 settings are not inadvertently adjusted.



- Metal components could cause injury to the user or others. Exercise care in situations where contact is likely.

INSTRUCTIONS FOR USE

BASIC APPLICATION

- Open all four straps and press the quick-release button at the top of each lever buckle to open the brace (FIG 1).
- Loosen all straps.
- Disengage all straps from the blue strap lock hook (FIG 2) and pull the struts apart (FIG 3).
- Unlock each range of motion (ROM) hinge by sliding the blue drop lock button upward to the unlocked position. (FIG 4)
- Align the hinges of the brace with the knee joint.

POSITIONING CUFFS

- Adjust the length of the brace by pressing down on the round adjustment button (FIG 5) and slide the end cuff to the required length. Release the round adjustment button to lock the cuff in place. **IMPORTANT:** Adjust the length of the brace to provide optimal knee stability. Brace should fit 2” below groin and above the ankle. Ensure each strut is equal in length.
- The cuffs located below and above the ROM hinges can be moved to accommodate incision sites or for desired comfort or fit. To move these cuffs, press down on the round adjustment button and slide cuffs to the desired position (FIG 5). Once the desired position is achieved, release the round adjustment button to lock the cuffs in place.

SECURING TO PATIENT

- Hold the brace to prevent it from moving. Secure the straps by engaging the lever buckle (FIG 6).
- Straps lengths should be adjusted then tightened in the following order: upper calf, lower thigh, lower calf, then upper thigh.

STRAP LENGTH ADJUSTMENT

Strap length can be adjusted by removing the Y-tab closure on the strap ends, trimming straps to desired length, and reapplying the Y-tab closures to the strap ends. (FIG 7) **IMPORTANT:** Applying the straps too tight may lead to slow blood circulation or downward movement of the brace.

ADJUSTING FIT

From the side view, the hinge should be slightly behind the midline of the knee. It is normal for the brace to migrate during use. Adjust the position of the straps and brace if necessary.

ADDITIONAL STRAP PADDING

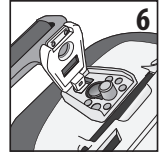
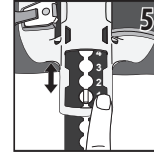
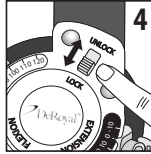
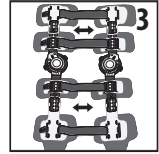
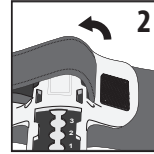
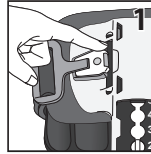
The DeRoyal Universal Recovery post-operative knee brace also features additional strap padding to help prevent



migration and enhance comfort of the device. To apply strap padding, determine the appropriate length of strap padding, trim to desired length and apply on the interior of the applicable strap. (FIG 8)

DROP LOCK ADJUSTMENT

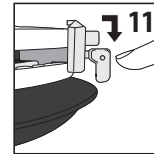
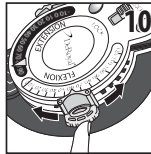
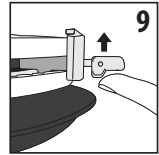
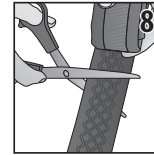
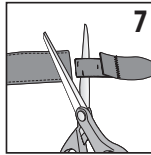
1. To quickly lock the ROM hinges to drop lock presets, first align the blue arrow on the face of the ROM hinge with the corresponding lock presets (-10, 0°, 10°, 20°, 30°) located on the brace lower strut, then push the blue drop lock slide button on the ROM hinge downward to the locked position. (FIG 4)
2. To unlock, slide the blue drop lock slide button on the ROM hinge upward to the unlocked position. (FIG 4)
3. Ensure both hinge drop lock settings match. **IMPORTANT:** If drop lock settings do not match, this could potentially cause discomfort or injury.



FLEXION/EXTENSION ADJUSTMENT

1. Unlock the ROM Adjustment Button by lifting the locking tab to be parallel with the button (FIG 9).
2. With the patient's leg and brace fully extended, press and hold down the ROM adjustment button and slide it to the desired degree of flexion and release the ROM adjustment button. (FIG 10)
3. Push the locking tab on the ROM adjustment button toward the leg (perpendicular with the button) to lock the ROM setting (FIG 11). Repeat these steps for the desired extension ROM. Perform this function on both ROM hinges. Ensure both ROM hinge settings match.

IMPORTANT: It is up to the healthcare professional to determine the flexion/extension angles and the amount of time to wear the brace.



REMOVING AND REAPPLYING BRACE

After the strap length adjustment is completed, the brace can be removed by pressing the quick-release button at the top of the lever buckle without modifying the strap length.

CARE AND MAINTENANCE

Remove liner from metal uprights. Hand wash liners with mild detergent in lukewarm water. Air dry completely prior to reapplication. Metal parts should not be washed with water.

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.**



Manufactured for:
DeRoyal Industries, Inc.
200 DeBusk Lane
Powell, TN 37849 USA
888.938.7828 or (001) 865.938.7828
www.deroyal.com

PART#0-2211 | REVISED 3/2024

©2024 DEROYAL INDUSTRIES, INC.
All Rights Reserved. DeRoyal and the DeRoyal logo are trademarks or registered trademarks of DeRoyal Industries, Inc.