

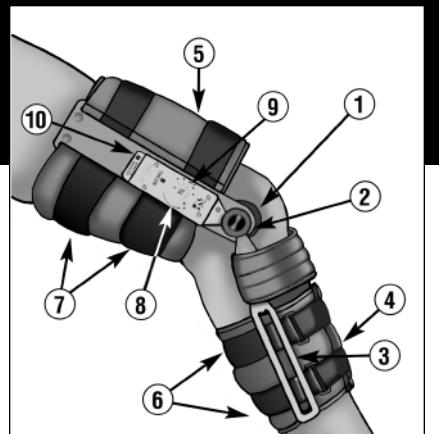


DeRoyal®

DeRom® Knee

Single Patient Use Only

Rx Only



IMPORTANT

Read instructions before applying unit.

INTENDED USE

The DeRoyal® Range Of Motion (DeROM®) dynamic knee orthosis was designed for the treatment of joint stiffness, and established soft tissue contractures, which may have resulted from trauma, immobilization, or neurological disorders. The orthosis should only be used under the supervision of a qualified health care professional. Protocols for use vary depending on the diagnosis and should be determined after consulting with the patient's physician. This dynamic orthosis combines flexion and extension in one unit.

CONTRAINDICATIONS

The DeROM® orthosis should not be used if any of the following conditions exist: Severe spasticity, severe osteoporosis, phlebitis or thrombophlebitis. Diabetes requires frequent skin checks. If pain, numbness, swelling, or skin irritation occurs while wearing the orthosis, it should be removed. The patient should be re-evaluated and appropriate adjustments made.

DIRECTIONS FOR USE

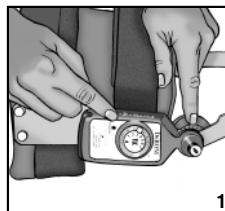
IMPORTANT: Set Tension Indicator Dial to 0. The Tension Indicator Dial (8) must be set to "0". Push the Tension Release Lever (10) in the direction of the arrow. At the same time turn the Tension Indicator Dial to "0". All slack must be

taken out of the cable before applying tension. After applying orthosis, push in on the black hinge knob (2) and rotate the pulley until the cable is taut.

1. To set up for extension assist:

The Tension Indicator Dial (8) must be set to "0". See "Important" above. Position the red cable (1) around the top of the pulley on both hinges. Push in and hold the black hinge knob (2). At the same time pull the calf cuff strut (3) to its upper most position. Release the black knob, and push the calf cuff to its lower most position. Repeat until the red cable is wrapped around the top of the pulley, and tension is felt on the cable.

2. To set up for flexion assist: The Tension Indicator Dial (8) must be set to "0". See "Important" above. Position the red cable (1) around the bottom of the pulley. Push in and hold the black hinge knob (2). At the same time push the calf cuff strut (3) to its lower most position. Release the black knob, and pull the calf cuff to its upper most position. Repeat until the red cable is wrapped around the bottom of the pulley, and tension is felt on the cable.



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INTENDED USE

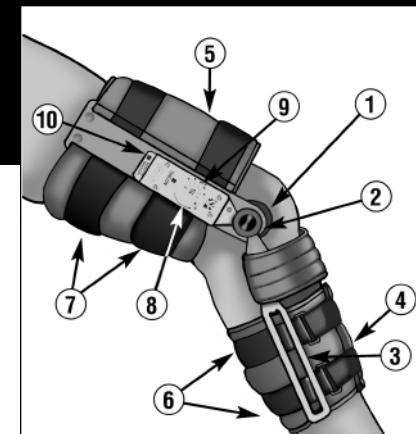
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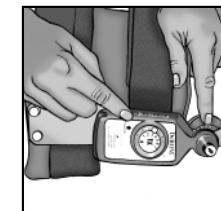
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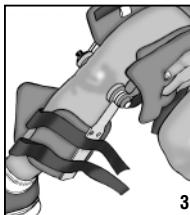
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Repeat until the red cable is wrapped around the top of the pulley, and tension is felt on the cable.

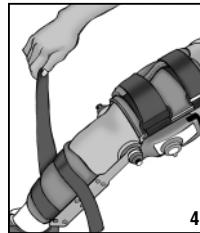
2. To set up for flexion assist: The Tension Indicator Dial (8) must be set to "0". See "Important" above. Position the red cable (1) around the bottom of the pulley. Push in and hold the black hinge knob (2). At the same time push the calf cuff strut (3) to its lower most position. Release the black knob, and pull the calf cuff to its upper most position. Repeat until the red cable is wrapped around the bottom of the pulley, and tension is felt on the cable.



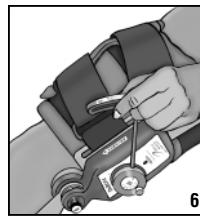
3. Donning the unit: Position the leg in its end range. Unfasten and open the calf cuff (4) and thigh cuff (5).



4. Secure the thigh cuff: Wrap the thigh cuff (5) around the thigh, and fasten with the hook and loop closure. Thread the two thigh straps (7) through the "D" rings and fasten.



5. Secure the calf cuff: Wrap the calf cuff (4) around the calf, and fasten with the hook and loop closure. Thread the two calf straps (6) through the "D" rings and fasten. **Note:** Set Tension Indicator Dial to "0" prior to taking slack out of the red cable. See "Important". All slack must be taken out of the cables before applying tension. Push in on the black hinge knob (2) and rotate the pulley until the cable is taut.



6. Applying tension: Remove the adjustment tool (10) from the back of the plastic housing and insert it into one of the holes on the edge of the tension indicator dial (8). Rotate the dial in the direction of the "Tension" arrow. Each "click" increases the tension. Adjust tension to patient tolerance. Repeat on the second hinge. **Note:** both hinges must be adjusted to the same tension level. Replace the adjustment tool by snapping it into the rear of the plastic housing.

7. Releasing tension: Push the Tension Release Lever (10) at the back end of the plastic housing, in the direction the arrow indicates, on both hinges.

8. Tension Locking Control (TLC): Once the appropriate tension level is determined, unscrew the TLC knob (9), and position it in the threaded hole nearest the tension indicator arrow, to prevent applying excessive tension. Screw the TLC knob completely in.

9. Removing orthosis: Release tension per step #7. Open the two calf straps (6), and open the calf cuff (4). Open the two thigh straps (7), and open the thigh cuff (5).

CARE INSTRUCTIONS

Clean exterior of hinge with non-abrasive cleaner. Straps may be machine-washed. Air-dry cuffs and straps prior to wearing.

PRECAUTION

Caution should be used if any of these conditions exist: peripheral vascular disease, healing skin wounds, mild spasticity, heterotrophic ossification, and mild osteoporoses and diabetes.



Manufacturer

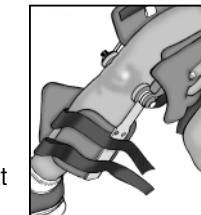
DeRoyal
200 DeBusk Lane, Powell, TN 37849 U.S.A.
888.938.7828
865.938.7828

Authorized Representative

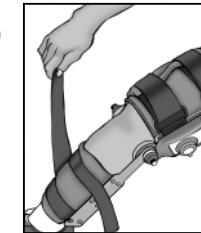
DeRoyal Europe, Ltd.
Virginia Road, Kells, County Meath Ireland
353.46.9280100

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Part #1-4109 Revision 06
Revised 2/06

3. Donning the unit: Position the leg in its end range. Unfasten and open the calf cuff (4) and thigh cuff (5).



4. Secure the thigh cuff: Wrap the thigh cuff (5) around the thigh, and fasten with the hook and loop closure. Thread the two thigh straps (7) through the "D" rings and fasten.



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DeRoyal Europe, Ltd.
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