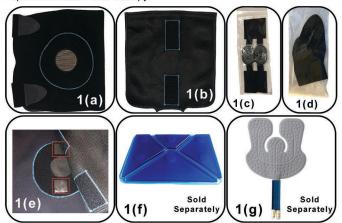
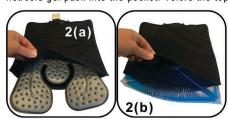
1. Packaging & Components. The CryoKnee contains three (3) main components that make up the brace. The prescribing provider will provide details as to which components are needed for each patient.

1(a) The CryoKnee softgood will fit both the left and right knees and is universal in size. 1(b) The Hot/Cold Gel Pack or Circulating Cold Pad sleeve, hereinafter referred to as "Hot/Cold Sleeve". Please note that the CryoKnee softgood and Hot/Cold Sleeve come packaged attached to each other. 1(c) The Range-of-Motion (ROM) Hinge utilized to restrict range-of-motion (flexion and extension) and stabilize the knee joint. 1(d) Velcro thigh/calf wrap pieces. 1(e) There are two (2) Velcro squares that adhere the Hot/Cold Sleeve to the CryoKnee softgood.

Components Available Separately: There is an optional 1(f) Hot/Cold Gel Pack or 1(g) Circulating Cold Pad available for patients that require hot and/or cold therapy.



2. Circulating Cold Pad or Hot/Cold Gel Pack Insertion. OPTIONAL (not provided, sold separately). The CryoKnee can accommodate most circulating cold pads or a hot/cold gel pack. Neither products are provided. They are sold separately and may require a prescription form a medical provider. Circulating Cold Pad Insertion: 2(a) To insert a circulating cold pad, position the hot/cold sleeve with the all black material facing up and the rectangle Velcro loop pieces edged with blue stitching facing down. Open the large pocket by opening the Velcro that holds it closed. Insert the circulating cold pad with the side that is to be applied closest to the skin facing up. Ensure tubing is inserted through the small opening at the bottom of the hot/cold sleeve. Velcro the top pocket back together. Hot/Cold Gel Pack Insertion: 2(b) To insert a hot/cold gel pack, position the hot/cold sleeve with the all black material facing up and the rectangle Velcro loop pieces edged with blue stitching facing down. Open the large pocket by opening the Velcro that holds it closed. Insert the hot/cold gel pack into the pocket. Velcro the top pocket back together.

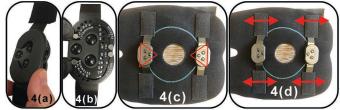


3. Hot/Cold Sleeve. 3(a) The hot/cold sleeve comes attached to the CryoKnee softgood with two Velcro squares. If hot or cold therapy is not needed, the hot/cold sleeve and two Velcro squares can be

removed. 3(c) To reapply the hot/cold sleeve, place the two Velcro squares at the top and bottom of the brace. Then apply the hot/cold sleeve rectangle loop area to the Velcro squares. See Section 2 for applying a hot/cold gel pack or circulating cold pad.



4. Range of Motion (ROM) Hinge Fitting, OPTIONAL. A pair of Range-of-Motion (ROM) Hinges are included with every CryoKnee. The hinges will fit both the left and right knees and Velcros onto the main softgood. To set the ROM settings on the hinges, 4(a) flip open the plastic cover on the side without rivets. 4(b) Remove and replace metal pins to set appropriate flexion and extension settings. Repeat steps 4(a) and 4(b) with other hinge so that settings match. 4(c) Place the ROM hinges in a rough position that will fit the patient's leg. Note that the rivets that form a triangle should be pointing towards the patella. 4(d) Test fit and adjust placement of ROM hinges as necessary.



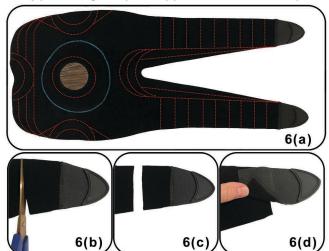
5. CryoKnee Fitting. Position the leg in full extension or with a slight bend. If a hot/cold sleeve is being utilized with a circulating cold pad or hot/cold gel packs attached to the CryoKnee, 5(a) ensure that the large Velcro pouch opening is located at the top and the small opening at the bottom. 5(b) Position the CryoKnee with circle over the patella. Note that straps can either be wrapped around the inside or the outside of the knee. 5(c) Wrap the lower strap around the calf and 5(d) adhere it to the brace. 5(e) Wrap the upper strap around the thigh and 5(f) adhere it to the brace. ***DO NOT OVERTIGHTEN THE STRAPS*** They should be snug but allow for ample circulation. CryoKnee can be used with or without ROM hinges.



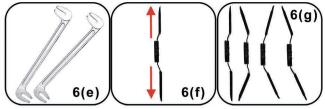
6. Custom Fitting Modifications.

The following modifications should only be made by a certified orthotist or an individual who has specialized training in the provision of orthosis to fit them item to the individual beneficiary. All modifications should be properly documented in the patient medical records.

The neoprene softgood of the CryoKnee can be substantially modified in order to be custom fitted to a knee. This includes but not limited to: thigh/calf strap customization, open popliteal, open patella, anterior thigh/calf contouring, etc. 6(a) Below is an outline of several common cut lines. 6(b) If the thigh and/or calf straps are trimmed, cut and 6(c) remove the sewn in Velcro tabs and then apply the 1(d) Velcro thigh/calf pieces 6(d) to the end of the cut strap.

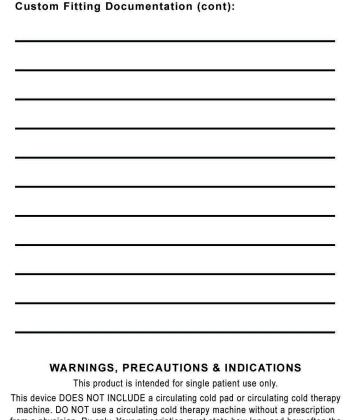


The ROM Hinges of the CryoKnee can be substantially modified in order to be custom fitted to a knee. This includes but not limited to: varus/valgus angles of the knee, disproportionate thigh to calf ratios, excessive soft tissue, fibular head prominence, anterolateral/posteromedial tibial bowing, etc. The use of 6(e) bending irons is highly recommended although a hard corner surface can be used. 6(f) Bend/contour the hinges starting at the joint and work your way outward. Be careful not to bind the joint. 6(g) The hinge can be bent/contoured in several different ways to accommodate the leg.



Please visit our website at www.cryo-knee.com for a detailed documentation worksheet.

Custom Fitti	ing Docum	entation:			
	(highlight)	/circle cutli	nes mac	de)	
(document	how hinge	es were mo	dified)	Right	□Left



from a physician. Rx only. Your prescription must state how long and how often the device should be used and the length of breaks between uses. DO NOT use this device if a prescription has not been provided to you or if you do not understand the prescription. Use of this device without a prescription or failure to follow the prescription may result in serious injury, including tissue necrosis.

The responsibility for accurate coding lies solely with the provider treating the patient. Outcome-Based Technologies, LLC (OBT) assumes no responsibility or liability for the provider's coding decisions. OBT's coding suggestions rely on its best judgement and are subject to revision based on additional information or changes in the alpha-numeric system.

INDICATIONS: . Post-op arthroscopic knee procedures . Mild to moderate ACL, PCL, MCL and/or LCL tears • Mild to moderate knee sprains and strains • Instability or laxity of the knee . Post-op total knee replacement to provide stabilization

CARE: Hand wash in lukewarm water with a mild detergent. Air dry (do not place on radiators/heaters or other heat sources. Do not use bleach or chlorine. Do not iron.

WARRANTY: Outcome-Based Technologies, LLC will repair or replace all or part of the unit and its accessories for material or workmanship defects for a period of three (3) months from the date of sale.

Class I FDA Registered Device. Made in Mexico.

Outcome-Based Technologies, LLC 15207 N 75th St, Suite 111 Scottsdale, AZ 85260

CRYOKNEE

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202020CRYOKNEE-IFU Rev A







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