

COLD THERAPY PROTOCOL

Treatment Period	Awake/Asleep	Frequency / Duration	Inspect Skin Every:
Day:	Awake		
Through			
Day:	Asleep		
Through			
Day:	Awake		
Through			
Day:	Asleep		
Through			
Day:	Awake		
Through			
Day:	Asleep		
Through			

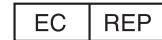
PRODUCT INSERT FOR POLAR CARE® KODIAK®



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PRODUCT SPECIFICATIONS

Symbols used on the Polar Care Unit

Symbol	Description
	This is the safety alert symbol. It is used to alert you to potential personal injury hazards. Obey all safety messages that follow this symbol to avoid possible injury or death.
	Type BF, applied part.
	Class II Equipment
	Operating Instructions
	Refer to instruction manual / booklet
	Single patient multiple use.
IP22	Protected against solid foreign objects of 50 mm and greater. Protected against vertically falling water drops when tilted up to 15°.

Product #:	Weight	Average Operating Range	Expected Service Life
100291-000	4.0 lbs (1.8kg) Empty 14.5 lbs (6.6kg) Filled	Average operating range of Intelli-Flo Pad with Polar Dressing ≥ 45°F (≥7.2°C).	1 year from date of first use.

Physical and Electrical Specifications

Unit Rated: 6Vdc, 600-1000mA Power supply is specified as part of ME Equipment Manufacturer: Group West Rated Input: 100-240V~, 50-60Hz	Model: 18UR-06-1000 Output: 6Vdc, max. 1.0A
Environmental Requirements: Transport & Storage:	-25°C (-13°F) no humidity control to 70°C (158°F) up to 93%RH
Operating:	5°C to 40°C (41°F to 100°F) 15-93%RH 700 hPa to 1060 hPa
Standards Compliance:	Designed to conform to applicable requirements of: EN 60601-1, 3rd Edition
Electrical Classifications:	Class II, Continuous Operation. Not suitable with flammable anesthetics.

INFORMATION FOR PATIENTS & MEDICAL PROFESSIONALS



⚠ WARNING

Breg's Polar Care Cold Therapy can be cold enough to seriously injure skin. Follow this information, the Operating Instructions in this product insert, and the Cold Therapy Pad Fitting Instructions (provided with each Cold Therapy Pad).

⚠ Discuss Treatment with your Licensed Health Care Practitioner

Provide a complete medical history including any reactions to cold. Certain medical conditions make cold-induced injury more likely. Ask your practitioner about potential adverse reactions and cold-induced injuries.

⚠ Use Only as Prescribed

Use only as instructed by your practitioner regarding the frequency and duration of cold application and breaks, how and when to inspect the skin, and total length of treatment.

⚠ Apply Insulation Barrier & Intelli-Flo® Pad

Always use an insulation barrier (such as Webriil, Kerlix, cast padding or elastic bandage) between the Intelli-Flo Pad and skin. Do not let any part of the pad touch skin. If a sterile dressing has been applied to the treatment site that does not completely cover the skin under the pad, use an additional insulation barrier. Use only Breg Intelli-Flo Pads designed for the specific body part. Other pads may be colder, increasing the risk of skin injury.

1. With the insulation barrier in place, apply the pad with the blue side up.

2. Use elastic straps to hold the pad in place.

Setup and Operation

- Unlock handle and remove lid.
 - Fill with cold water to line, then ice to line.
 - Replace lid and lock with handle in upright position.

2. To connect unit to pad:

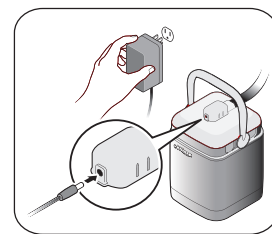
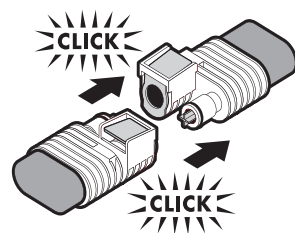
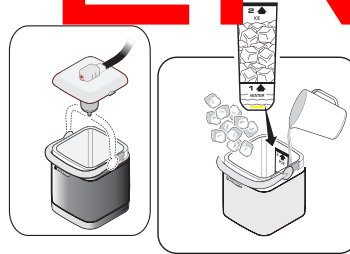
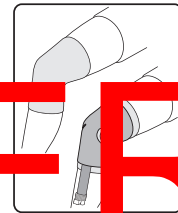
- Push down on the two metal tabs.
- Push connectors together until metal tabs pop up.

3. To turn on/off:

- Plug power supply into wall and receptacle on lid.
- Operation begins automatically with power.
- Unplug power supply to turn off.

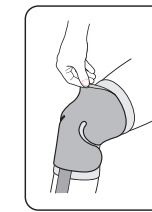
4. To refill:

- Turn off.
- Press down on two metal tabs to disconnect unit and pad.
- Remove lid and place upside down on a flat surface.
- Drain and follow fill instructions.



⚠ Skin Checks

Inspect the skin under the pad (by lifting the edge) as prescribed, typically every 1 to 2 hours. Do not use if dressing, wrapping, bracing, or casting over the pad prevents skin checks. Stop using and contact your practitioner immediately if you experience any adverse reactions, such as increased pain, burning, increased swelling, itching, blisters, increased redness, discoloration, welts, other changes in skin appearance, or any other reaction identified by your practitioner.



⚠ ELECTRICAL SAFETY

Like all electrical products, you must follow precautions to avoid electrocution, fire, burns, or other injuries. Operator do not touch exposed transformer pins and patient at the same time. Use only the transformer provided with the Breg Polar Care Cold Therapy unit to meet the requirements of EN 60601-1.

⚠ Keep electrical connections dry and free of debris

Even though the Polar Care unit is designed to hold and pump water, the electrical connections at the power outlet and from the power cord to the Polar Care unit must be kept dry. Do not handle the transformer or electrical cord with wet hands. Always keep the unit in a place where the connections will not fall into water (e.g., a tub, sink, etc.). If the electrical connections fall into water, do not touch any wet part of the product. Unplug only at dry electrical connections.

⚠ Avoid flammables and oxidizers

Do not use in places with flammable vapors or gasses (e.g. flammable anesthetics), high oxygen concentrations, or other oxidizers (e.g. nitrous oxide).

⚠ Protect the power cord and transformer

Keep the cord and transformer away from heated surfaces. Set up and use this equipment in a low traffic location away from children and pets. Never operate this product if it has a damaged cord, transformer, or plug which could result in a shock or fire. If the cord, transformer, or plug is damaged, unplug and contact Breg Customer Care, (800) 321-0607 or (760) 795-5440.

⚠ Unplug to stop the product when not in use

Unplugging the Polar Care unit turns it off. Always unplug immediately after use. Never leave it plugged in while unattended. Never run pump without water. Running the unit without water will cause permanent damage.

⚠ Electromagnetic Interference and Emissions

This Polar Care unit may cause electromagnetic or other interference with other electrical devices. To check whether the Polar Care unit is interfering with another device, unplug the Polar Care unit. If this corrects the problem, move the Polar Care unit or other device, or use an outlet on a different circuit.

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation.

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Kodiak including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

SUPERSEDED

⚠ GENERAL SAFETY

Keep cords and hoses away from the neck to avoid risk of strangulation.

No modification of this equipment is allowed.

The device is intended for single patient multiple use.

TROUBLESHOOTING GUIDE

Problem: Pump not running, water not flowing to pad, or pad not cold

Possible solutions:

- Use larger ice for optimal performance.
- Allow 10 minutes for flow and pressure to stabilize.
- Ensure power outlet is working and plugs are fully engaged.
- Ensure unit has both ice and water.
- Ensure hose is not kinked.
- Disconnect and reconnect the pad and unit.
- Release air by depressing the black plus-shaped part inside the unit connector. Note: water may be released.
- Place unit on a table or other raised surface.
- Decrease tension of bandages or straps around the pad.
- Remove pad and lay it flat. Allow pad to fill; reapply.
- Clean filter: Disconnect pad. Remove unit lid. Pull filter cap from bottom of lid. Remove foam filter. Rinse filter cap and filter to remove clogs. Reassemble.

Problem: Condensation

Possible solutions:

- Wrap material over pad and hose to minimize air exposure.
- Protect the wound site by using a sterile dressing with waterproof barrier.

Problem: Unit is leaking

Possible solutions:

- Disconnect unit connector. Ensure the metal tabs are pressed down; reconnect.
- Apply lubricant to o-rings of connectors.
- If leaking continues, or if a leak is detected in the pad or unit lid, stop using the unit and contact Breg Customer Care at 800-321-0607 or 760-795-5440.

DISPOSAL

Dispose of product according to local regulations.

CLEANING, MAINTENANCE & SERVICE

After use, drain and dry pump with a soft cloth. Warm water and mild detergent may be used occasionally to clean the pump and tubes. There are no serviceable parts. Contact Breg Customer Care for replacement parts.

WARRANTY

Breg, Inc. warrants that this product is free from defects in workmanship, materials, and fitness for use for 180 days from initial purchase under normal use for which it was intended and under direct supervision of a licensed health care practitioner. Breg, Inc.'s obligation under this warranty is limited to the replacement or repair of any defective part or parts of this product. All express or implied warranties, including the warranty of merchantability and fitness for a particular purpose, are limited to the actual warranty period set forth above. No other warranty, express or implied, is given and no affirmation of or by seller, by words or action, will constitute a warranty.

Polar Care® PRODUCT INSERT

INFORMATION FOR MEDICAL PROFESSIONALS

GUIDELINES FOR USE

1. Screen Patients for Contraindications and Risk Factors

Before prescribing cold therapy, always consider the patient's medical history, particularly any contraindications or risk factors. If not appropriately prescribed, motorized cold therapy can result in serious cold-induced injury, including full thickness skin necrosis.

CONTRAINDICATIONS	
Patients with any contraindications should not use Polar Care	
<ul style="list-style-type: none"> History of cold injury, frostbite, or adverse reactions to local cold application. Patients that are incoherent due to general anesthesia, sedation, or coma. Application areas with compromised local circulation or potential wound healing problems, including localized compromise due to multiple surgical procedures. 	<ul style="list-style-type: none"> Circulatory syndromes, including Raynaud's disease, Buerger's disease, peripheral vascular disease, vasospastic disorders, sickle cell anemia, and hypercoagulable clotting disorders. Local tissue infection. Hand/wrist or feet/ankle surgery with polyneuropathy. Diabetic Polyneuropathy.

RISK FACTORS for Cold-Induced Injury	
<ul style="list-style-type: none"> Pathologic sensitivity to cold. Behaviors that negatively effect circulation, including poor nutritional status, smoking and tobacco use, excessive caffeine use, and excessive alcohol use. Patients with cold application area desensitization due to local anesthesia or regional nerve blocks. Medications that have a negative effect on peripheral vascular circulation, including beta adrenergic blockers and 	<ul style="list-style-type: none"> local epinephrine use (such as in local anesthetics). Medications that have a negative effect upon mental capacity. Excessive moisture at the application site due to excessive bleeding, sweating, or condensation. Diabetes. Hand/wrist or feet/ankle surgery. Cognitive disabilities. Communication barriers. Young children and the elderly.

If the risk of cold-induced injury outweighs the benefits of cold therapy, do not prescribe Breg's Polar Care Cold Therapy. If you prescribe this product to patients with risk factors, consider taking special measures to control the risk, such as:

- Recommending more frequent skin checks.
- Requiring more frequent follow-up examinations.
- Using a thicker insulation barrier between the pad and skin.
- Prescribing shorter durations of application, less frequent application, or eliminating nighttime application.

INDICATIONS FOR USE

The extended use of motorized cold therapy modalities, such as Breg's Polar Care Cold Therapy, have been shown to have many beneficial effects following surgery. Motorized cold therapy has repeatedly been shown to decrease postoperative pain, swelling, inflammation, and narcotic use following a variety of surgical procedures, such as surgery to the shoulder, knee, and back. For a bibliography of extended use motorized cold therapy studies, contact Breg, Inc. at 800-321-0607 or 760-795-5440.

2. Apply Insulation Barrier and Cold Therapy Pad

Always use an insulation barrier (such as Webril, Kerlix, cast padding, elastic bandage) between the Cold Therapy Pad and skin. **Do not let any part of the Pad touch skin.** If a sterile dressing has been applied to the treatment site that does not completely cover the skin under the pad, use an additional insulation barrier. The Pad alone can be too cold to be applied directly to the skin.

Use only Breg Cold Therapy Pads. Other pads may be colder, increasing the risk of skin injury.

Use only Breg Cold Therapy Pads designed for the body part being treated. Multi-Use and Rectangle Pads may be used on shoulders, knees, back, and hips. If the Cold Therapy Pad is placed on a body part that it is not designed for, or if another brand of pad is used, the skin can get too cold and be injured.

Do not cover the Cold Therapy Pad with dressing, wrapping, bracing or casting that prevents the patient from checking the skin under the Pad.

3. Provide Prescription and Instructions

Breg Polar Care Cold Therapy units are classified by the FDA as Class II medical devices that must be prescribed by a physician or licensed healthcare practitioner. A proper prescription for use must include:

- Frequency and duration of use (and breaks if applicable);
- Frequency and instruction on skin inspections;
- Treatment Period.

Use the Physician Prescription Form on the other side of this document. This document should be given to the patient (or caregiver) upon discharge or transfer to the recovery room. Common operating temperatures for patients without risk factors for extended use (longer than 20 minutes) are 45° to 60° F (7° to 16° C) for core regions and 50° to 60° F (10° to 16° C) for extremities. When used with a body part appropriate Cold Therapy Pad and an insulation barrier, the average operating temperature of the Breg Polar Care Cold Therapy System will automatically fall within these ranges.

A variety of extended use motorized cold therapy protocols are reported in the literature. Treatment protocols vary based upon specific patient conditions and health history, physician experience with motorized cold therapy application, and medical judgment. See the Sample Cold Therapy Protocols to the right.

Tell patients how to inspect skin under the Cold Therapy Pad without compromising the sterile site and how often to do so.

Instruct patients to stop using Breg's Polar Care Cold Therapy and contact you immediately if they experience any adverse reactions such as: increased pain, burning, increased swelling, itching, blisters, increased redness, discoloration, welts, or other changes in skin appearance.

Review all product information with your patient.

Review the Information for Patients and Medical Professionals in this document, the Operating Instructions on the reverse side of this product insert, and the Cold Therapy Pad Fitting Instructions.

NOTICE TO USERS

If any serious incident has occurred in relation to the device, report to Breg and the competent authority of the Member State in which the user and/or patient is established.

SAMPLE COLD THERAPY PROTOCOLS

The following protocols are examples of appropriate post-operative extended (>20 minute application) motorized cold therapy for patients with no risk factors. Therefore, these sample protocols would not apply to use on extremities, which may require extra precaution as described in Section 1. This is not a comprehensive list of treatment possibilities. Treatment protocols for extended motorized cold therapy may vary based upon specific patient conditions and health history, physician experience with cold therapy, and medical judgment.

When used with a body part appropriate Cold Therapy Pad and an insulation barrier, the average operating temperature of the Breg Polar Care Cold Therapy System will automatically fall within these ranges.

Sample Protocol 1

Treatment Period	Frequency / Duration	Temp.	Skin Inspection
Day 1-3	While awake: Continuous	45° - 60° F* (7° - 16° C)	Inspect skin under pad every 1-2 hours
	While asleep: Continuous	45° - 60° F (7° - 16° C)	Upon waking
Day 4-10	While awake: Cyclic: 1 hour on and 1 hour off	45° - 60° F (7° - 16° C)	Periodically inspect the skin under pad
	While asleep: Continuous	45° - 60° F (7° - 16° C)	Upon waking
Day 11 and beyond	While awake: As needed for pain control: Continuous for 1 hour intervals; not to exceed 12 hours/day	45° - 60° F (7° - 16° C)	Periodically inspect the skin under pad

*50° - 60° F (10° - 16° C) for pads intended for use on hands, feet or face.

PATIENT DISCHARGE PROTOCOL

Follow this protocol prior to discharging the patient from facility care to home use.

- 1. Patient Screen.** Screen the patient for any contraindications and/or associated risk factors. If the patient has any contraindications, do not dispense Breg's Polar Care Cold Therapy to the patient. If the patient has any associated risk factors, consult with the licensed healthcare practitioner to determine the appropriateness of application of Breg's Polar Care Cold Therapy to that patient.
- 2. Instructions For Use.** Instruct the patient on how to properly use Breg's Polar Care Cold Therapy. Review the Operating Instructions affixed to the unit with each patient.
- 3. Prescription.** Instruct the patient regarding the licensed healthcare practitioner's prescribed protocol (frequency and duration of use and breaks if applicable), frequency and instruction on skin inspections, and treatment period.
- 4. Potential For Injury.** Inform the patient that improper use can result in serious skin injury, including necrosis. Emphasize the importance of following the prescribed protocol, proper pad application, and skin inspection.

Breg Polar Care Cold Therapy products have the ability to deliver cold after ice replacement for approximately 6 to 8 hours.

The duration of a cyclic application may vary depending upon the patient. If the patient does not experience pain relief, the physician may increase the duration of application. As the application duration is increased, the frequency of the skin inspections should increase.

Sample Protocol 2

Treatment Period	Frequency / Duration	Temp.	Skin Inspection
Day 1-3	While awake: Continuous	45° - 60° F (7° - 16° C)	Inspect skin under pad every 1-2 hours
Day 4 to suture removal (Day 7-14)	While awake: As needed for pain control: Continuous for 1 hour intervals; not to exceed 12 hours/day	45° - 60° F (7° - 16° C)	Periodically inspect the skin under pad

Sample Protocol 3

Treatment Period	Frequency / Duration	Temp.	Skin Inspection
Day 1-3	While awake: Cyclic: 1 hour on and 1 hour off	45° - 60° F (7° - 16° C)	Periodically inspect the skin under pad
	While asleep: Continuous	45° - 60° F (7° - 16° C)	Upon waking
Day 4 and beyond	While awake: As needed for pain control: Continuous for 1 hour intervals; not to exceed 12 hours/day	45° - 60° F (7° - 16° C)	Periodically inspect the skin under pad

5. Proper Pad Application. Instruct the patient that an insulation barrier must be between the Cold Therapy Pad and skin during use. No part of the Cold Therapy Pad should touch the skin for any period of time.

6. Skin Inspection. Instruct the patient to inspect the skin receiving cold treatment per the practitioner's instructions, typically every 1 to 2 hours. If dressing, wrapping, bracing, or casting over the Cold Therapy Pad prevents the ability of the patient to regularly perform skin checks under the pad, do not dispense Breg's Polar Care Cold Therapy to the patient.

7. Discontinue. Instruct the patient to stop using Breg's Polar Care Cold Therapy and contact their licensed health care practitioner immediately if they experience any adverse reactions such as: increased pain, burning, increased swelling, itching, blisters, increased redness, discoloration, welts, or other changes in skin appearance.

8. Documentation. Give the patient this document with the Cold Therapy Protocol (on reverse side, top left) filled out.