

INSTRUCTIONS FOR USE
POLAR CARE GLACIER™, POLAR CARE KODIAK®, POLAR CARE CUBE™

Caution: Federal law restricts this device to sale by or on the order of a medical professional.

Contact Information

For questions or product inquiries, contact Breg at 1-800-321-0607 or 760-795-5440.

INDICATIONS FOR USE

Breg's Polar Care is intended for application of external cold therapy for temporary reduction of pain, swelling, and/or inflammation resulting from injury or surgery.

CONTRAINDICATIONS

Patients with any of the following conditions should not use Polar Care:

- History of cold injury, frostbite, or adverse reactions to local cold application.
- Patients who 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.
- 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.

WARNINGS

⚠ Patients with any of the following cognitive risk factors should only use Polar Care under direct supervision of a medical professional or the direct supervision of a caretaker, if prescribed by a medical professional:

- Cognitive disabilities.
- Communication barriers.
- Use of medications that have a negative effect upon mental capacity.
- Young children and the elderly.

⚠ If the patient has any of the following clinical risk factors, use of Polar Care may result in serious cold-induced injury, including full thickness skin necrosis:

- Pathologic sensitivity to cold.
- Behaviors that negatively affect circulation, including poor nutritional status, smoking and tobacco use, excessive caffeine use, and excessive alcohol use.

- Cold application area desensitization due to local anesthesia or regional nerve blocks.
- Diabetes.
- Hand/wrist or feet/ankle surgery.
- Taking medications that have a negative effect on peripheral vascular circulation, including beta adrenergic blockers and local epinephrine use (such as in local anesthetics).

⚠ 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:

- Recommend more frequent skin checks (see PATIENT DISCHARGE PROTOCOL). If patient has any of the cognitive risk factors above, medical professional or caretaker should provide skin checks.
- Require more frequent follow-up examinations.
- Use a thicker insulation barrier between the pad and skin (see PATIENT DISCHARGE PROTOCOL).
- Prescribe shorter durations of application, less frequent application, or eliminate nighttime application.

⚠ Excessive moisture at the application site due to excessive bleeding, sweating or condensation may increase the risk of serious cold-induced injury, including full thickness necrosis.

MEDICAL PROFESSIONAL PATIENT DISCHARGE PROTOCOL

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

Fill in the Cold Therapy Protocol on the reverse of this document and provide to the patient (or caregiver) upon discharge or transfer from the recovery room.

1. Patient Screen. Screen the patient for any contraindications and/or applicable warnings. If the patient has any contraindications (see **CONTRAINDICATIONS**), do not dispense Breg's Polar Care Cold Therapy to the patient. If any of the warnings apply to the patient (see **WARNINGS**), determine the appropriateness of application of Breg's Polar Care 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 on the reverse side of this document and affixed to the unit with each patient.

3. Prescription. Instruct the patient regarding the licensed healthcare practitioner's prescribed protocol: frequency and duration of cold application and length of breaks between uses, how and when to inspect the skin, and total length of treatment. 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. Instruct the patient to take a break by disconnecting the power from the unit, or removing the pad from the application site for a specified period of time. As the application duration is increased, the frequency of the skin inspections should increase (see **WARNINGS**).

4. Potential For Injury. Inform the patient that improper use can result in serious skin injury, including full thickness skin necrosis. Emphasize the importance of following the prescribed protocol, proper pad application, and skin inspection.

5. Proper Pad Application. Instruct the patient that an insulation barrier must be between the Polar Care Cold Therapy Pad and skin during use. No part of the Polar Care Pad should touch the skin for any period of time. If a sterile dressing has been applied to the treatment site that does not completely cover the skin under the pad, instruct the patient to use an additional insulation barrier. The pad alone can be too cold to be applied directly to the skin. Instruct the patient to use only Breg Polar Care Cold Therapy Pads designed for the body part being treated; other pads may be colder, increasing the risk of serious cold-induced injury, including full thickness skin necrosis.

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

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 Polar Care Cold Therapy Pad prevents the ability of the patient to perform skin checks under the pad regularly, 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 his/her licensed health care practitioner immediately if he/she experiences any adverse reactions, such as: increased pain, burning, increased swelling, itching, blisters, increased redness, discoloration, welts, or other changes in skin appearance.

8. Documentation. Provide the patient a prescription for the duration of the total treatment period, the frequency and duration of individual treatment sessions, and the frequency of skin inspections.

ELECTRICAL SAFETY

Like all electrical products, you must follow precautions to avoid electrocution, fire, burns, or other injuries.

⚠ 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.

⚠ 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.

⚠ 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 electric shock. If the cord, transformer, or plug is damaged, unplug and contact Breg Customer Care at (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.

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.

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

No modification of this equipment is allowed.




Keep hoses out of pathways to avoid a risk of tripping. There are no user serviceable parts.

Disposal

Dispose of product according to local regulations.

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 B, applied part.
	Class II Equipment

Physical and Electrical Specifications

Unit Rated:	6Vdc, 600-1000mA	
Electrical Specifications:	Manufacturer: Hon-Kwang Model: D0660 Rated Input: 120V~, 60Hz Output: 6Vdc, max. 600mA	
	Manufacturer: Group West Model: 18UR-06-1000 Rated Input: 100-240V~, 50-60Hz Output: 6Vdc, max. 1.0A	
Environmental Requirements:	Temperature: Operating 50°F to 100°F (10°C to 40°C) Transport & Storage -40°F to 158°F (-40°C to 70°C) Humidity: Operating 30 to 75% R.H. Transport & Storage 10 to 100% R.H., non-condensing Atmospheric Pressure: 700 hPa to 1060 hPa	
Standards Compliance:	Designed to conform to applicable Requirements of: UL 60601-1, CSA C22.2 / No. 601.1	
Electrical Classifications:	Class II, Continuous Operation. Not suitable with flammable anesthetics.	

Product #:	Weight	Average Operating Range
10601, 10701	4.0 lbs (1.8kg) Empty 14.5 lbs (6.6kg) Filled	At coldest setting (if applicable), average operating range of Polar Pad with Polar Dressing ≥ 45°F (≥7.2°C)
10901	5.0 lbs (2.3kg) Empty 19.7 lbs (8.9kg) Filled	

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⚠ WARNING
 Breg's Polar Care Cold Therapy can be cold enough to cause serious injury including full skin necrosis. Read and understand all warnings and follow this information, the Operating Instructions in this product insert, and the Cold Therapy Pad Fitting Instructions (provided with each cold therapy pad) prior to using this device.

Cold Therapy Protocol*

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

* To be completed by a licensed Health Care Professional

⚠ 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 according to your practitioner's instructions regarding the frequency and duration of cold application and length of breaks between uses, how and when to inspect the skin, and total length of treatment. Do not use this device if you did not receive or do not understand the instructions. Unless your practitioner provides different instructions, to take a break between uses simply disconnect the power from the unit or remove the pad from your body for a minimum of 30 minutes. Federal law restricts this device to sale by or on the order of a licensed health care practitioner.

⚠ Apply Insulation Barrier & Cold Therapy Pad
 Do not let any part of the pad touch skin. Always use an insulation barrier (such as Breg Polar Dressing, Webril™, Kerlix™, cast padding or elastic bandage) between the Cold Therapy Pad and 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 with the Breg Cold Therapy Pads. Other pads may be colder, increasing the risk of serious cold-induced injury, including full thickness necrosis.

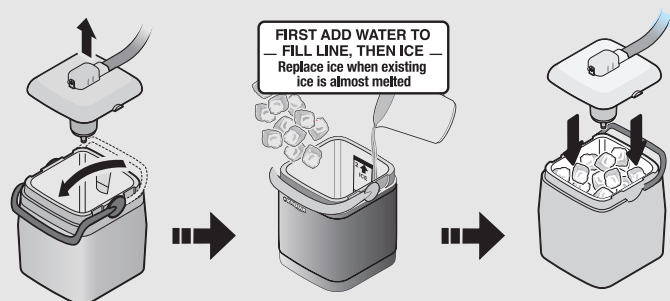
⚠ Check for Moisture
 Check for moisture on the barrier between your skin and the cold pad. Discontinue use if the barrier is moist. Change to a dry skin barrier before resuming use.

⚠ Inspect Skin Regularly
 Inspect the skin under the Cold Therapy Pad (by lifting the edge) as prescribed, typically every 1 to 2 hours. Ask your practitioner to instruct you on how to inspect the skin area which is being treated by the device. Do not use the Polar Care unit if dressing, wrapping, bracing, or casting over the Cold Therapy 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.

OPERATING INSTRUCTIONS

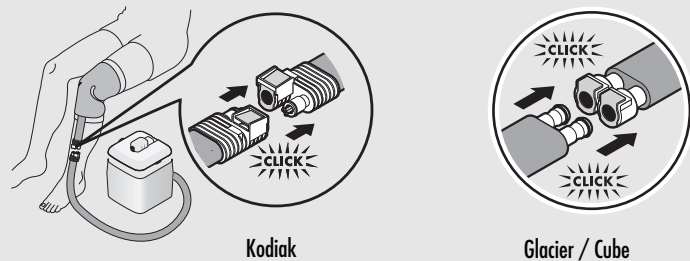
Setup

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



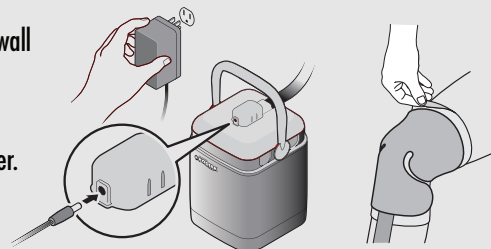
Coupler Connections

- To connect unit to pad:
 - Push down on the two metal tabs.
 - Push connectors together until metal tabs pop up.



Operation

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



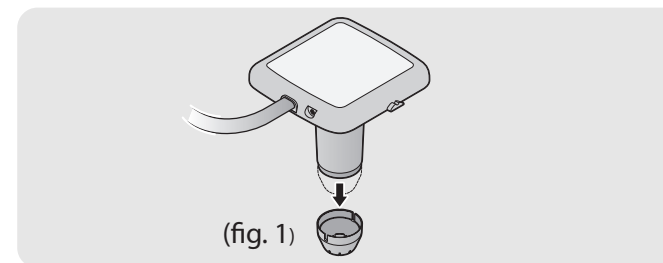
USAGE TIPS

- Use cubed or chunked ice for optimal performance.
- When using a Breg Polar Care Cold Therapy unit with a detachable Cold Therapy Pad, it is recommended to drain the pad between uses. To drain the pad, hold the Cold Therapy Pad upright with the hose pointed toward the ground. Depress the black plunger and allow the water to drain out of the pad.
- You may disconnect the Cold Therapy Pad from the unit without removing the pad from the affected area by depressing the silver tabs on the hose coupling and gently pulling the hoses apart. The Breg Polar Care Cold Therapy Pad and unit will seal itself and will not leak. Note: Some dripping during release is normal.
- DO NOT RUN PUMP WITHOUT WATER!** The pump in this unit is designed to run with water. Running the unit without water will cause permanent damage to the pump.
- Unplug unit before removing lid.

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. (Fig. 1).

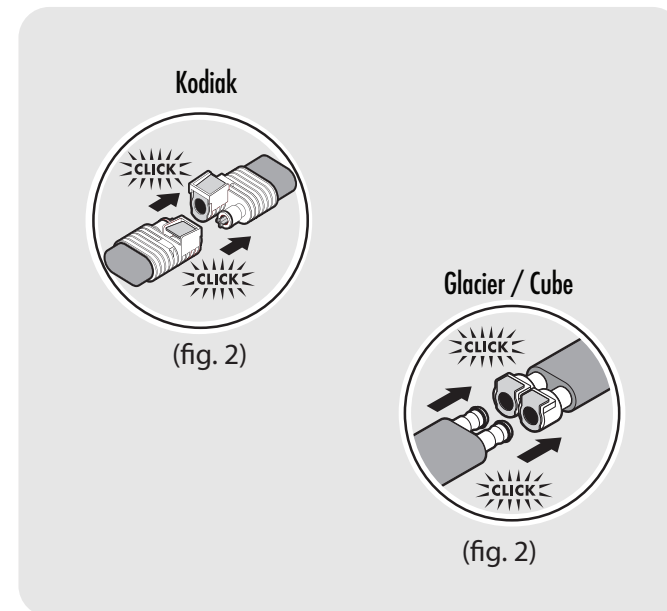


Problem: Condensation

- 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 (fig. 2).
 - 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.



CLEANING, MAINTENANCE AND SERVICE

After use, empty and dry the unit with a soft cloth. Warm water and mild detergent may be used occasionally to clean the pump and tubes.

⚠ Avoid flammables and oxidizers. Do not use in places with flammable vapors or gases (e.g., flammable anesthetics), high oxygen concentrations, or other oxidizers (e.g., nitrous oxide).

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 expressed 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.