### COLD THERAPY PROTOCOL

#### Physical and Electrical Specifications

**Product Specifications**

**Symbols used on the Polar Care Unit**

**WARNING**

Breg’s Polar Care Cold Therapy can be cold enough to seriously injure. 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 Webril, 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**

1. To fill:
   a. Unlock handle and remove lid.
   b. Fill with cold water to line, then ice to line.
   c. Replace lid and lock with handle in upright position.
2. To connect unit to pad:
   a. Push down on the two metal tabs.
   b. Push connectors together until metal tabs pop up.
3. To turn off:
   a. Plug power supply into wall and receptacle on lid.
   b. Operation begins automatically with power.
   c. Unplug power supply to turn off.
4. To refill:
   a. Turn off.
   b. Press down on two metal tabs to disconnect unit and pad.
   c. Remove lid and place upside down on an air surface.
   d. 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 transformer 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 outlets.

**Avoid flammables and oxidizers**

Do not use in places with flammable vapors or gases (e.g. flammable anesthetics, hydrogen sulfide, oxidizers). Do not store unit with flammable substances.

**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, unplugged, and replaced, 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**

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, plug in another Polar Care unit. If this corrects the problem, move the Polar Care unit or other device, or use an outlet on a different circuit.

**GENERAL SAFETY**

Keep cords and hoses away from the neck to avoid risk of strangulation. No modification of this equipment is allowed.

**WARNING**

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 1, applied part**

**Class II Equipment**

**Operating Instructions**

Refer to instruction manual / booklet

**IP22**

Protected against vertically falling water drops when tilted up to 15°. Protected against solid foreign objects of 50 mm and greater.

**Refer to instruction manual / booklet**

**Every: 14.5 lbs (6.6kg)**

**Intelli-Flo Pad with Polar Dressing ≥ 45°/ring.capF (≥7.2°/ring.capC).**

**Limitations:**

- Not suitable with flammable anesthetics.
- Pump not running, water not flowing to pad, or pad not cold.

**TROUBLESHOOTING GUIDE**

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

- 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 flat. Allow pad to fill; reapply.

**Problem: Condensation**

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, cold therapy can result in serious cold-induced injury, including full thickness skin necrosis.

2. **Apply Insulation Barrier and Cold Therapy Pad**
   Always use an insulation barrier (such as Webri, 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.

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 periods.

   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 from 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 for 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 cold therapy, and medical judgment. See the Sample Cold Therapy Protocols to the right.

   **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.

   **RISK FACTORS for Cold-Induced Injury**

   - Pathologic sensitivity to cold.
   - Behaviors that negatively affect local circulation, including poor nutritional status, smoking and tobacco use, excessive alcohol use, use, and excessive alcohol use.
   - Patients with cold application area desensitization due to local anesthetics or regional nerve blocks.
   - Medications that have a negative effect on peripheral vascular circulation, including beta adrenergic blockers and local epinephrine use (such as local anesthetic). Medicated 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 with polyneuropathy.
   - Cognitive disabilities.
   - Medications that have a decreased effect of local anesthetics.
   - Local epinephrine use (such as in local anesthetics). A prepared prescription for use must include:

   **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.

**SAMPLE COLD THERAPY PROTOCOLS**

<table>
<thead>
<tr>
<th>Sample Protocol 1</th>
<th>Treatment Period</th>
<th>Frequency / Duration</th>
<th>Temp.</th>
<th>Skin Inspection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 1-3</td>
<td>While awake:</td>
<td>As needed for pain</td>
<td>45° - 60° F (7° - 16° C)</td>
<td>Inspect skin under pad every 2-3 hours</td>
</tr>
<tr>
<td></td>
<td>When not awake:</td>
<td>Continuous</td>
<td></td>
<td>Upon waking</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Day 4-10</td>
<td>While awake:</td>
<td>As needed for pain</td>
<td>45° - 60° F (7° - 16° C)</td>
<td>Periodically inspect the skin under pad</td>
</tr>
<tr>
<td></td>
<td>When not awake:</td>
<td>Continuous</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sample Protocol 2</th>
<th>Treatment Period</th>
<th>Frequency / Duration</th>
<th>Temp.</th>
<th>Skin Inspection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 1-3</td>
<td>While awake:</td>
<td>Continuous</td>
<td>45° - 60° F (7° - 16° C)</td>
<td>Inspect skin under pad every 1-2 hours</td>
</tr>
<tr>
<td></td>
<td>When not awake:</td>
<td>Continuous</td>
<td></td>
<td>Upon waking</td>
</tr>
<tr>
<td>Day 4 to Surgeon removal (Day 7-14)</td>
<td>While awake:</td>
<td>As needed for pain control</td>
<td>45° - 60° F (7° - 16° C)</td>
<td>Periodically inspect the skin under pad</td>
</tr>
<tr>
<td></td>
<td>When not awake:</td>
<td>Continuous</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sample Protocol 3</th>
<th>Treatment Period</th>
<th>Frequency / Duration</th>
<th>Temp.</th>
<th>Skin Inspection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 1-3</td>
<td>While awake:</td>
<td>Continuous</td>
<td>45° - 60° F (7° - 16° C)</td>
<td>Inspect skin under pad every 1-2 hours</td>
</tr>
<tr>
<td></td>
<td>When not awake:</td>
<td>Continuous</td>
<td></td>
<td>Upon waking</td>
</tr>
<tr>
<td>Day 4 and beyond</td>
<td>While awake:</td>
<td>As needed for pain control</td>
<td>45° - 60° F (7° - 16° C)</td>
<td>Periodically inspect the skin under pad</td>
</tr>
<tr>
<td></td>
<td>When not awake:</td>
<td>Continuous</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*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 and home use.

1. **Patient Screening**
   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 the 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.

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, dressing, 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 healthcare 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.

**CONTRAINdications**

Patients with any contraindications should not use Polar Care Cold Therapy:

- History of cold injury, frostbite, or adverse reactions to local cold application.
- Patients that are incipient due to cardiac, cerebrovascular, or braces.
- Application area complicated by 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.
- History of deep vein thrombosis and related issues.
- Hand/wrist or feet/ankle surgery with polyneuropathy.
- Diabetic Polyneuropathy.

**Medications that have a negative effect on local anesthetics.**

**A variety of extended use motorized cold therapy protocols**

**Breg Polar Care Cold Therapy System**

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.

**Breg Polar Care Cold Therapy Products**

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.