

# POLAR CARE 500 Product Insert

Product description: The purpose of the Polar Care 500® is to provide continuous cold therapy following surgery or injury in order to decrease pain, swelling and edema as well as minimize secondary injury.

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**CAUTION:** FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED HEALTH CARE PRACTITIONER.

**WARNING:** A LICENSED HEALTH CARE PRACTITIONER MUST CONSIDER PATIENT HEALTH HISTORY AND COLD SENSITIVITY PRIOR TO ALLOWING PATIENT USE. CONTRAINDICATIONS INCLUDE, BUT ARE NOT LIMITED TO, USERS WITH SENSITIVITY TO COLD; PRIOR ADVERSE REACTIONS TO COLD APPLICATION; COMPROMISED CIRCULATION, INCLUDING LOCALIZED COMPROMISE DUE TO MULTIPLE SURGICAL PROCEDURES; COLD APPLICATION AREA DESENSITIZATION; DIABETES; CIRCULATORY SYNDROMES; COGNITIVE DISABILITIES OR COMMUNICATION BARRIERS.

**WARNING:** CONSULT YOUR LICENSED HEALTH CARE PRACTITIONER PRIOR TO USING THIS PRODUCT TO DETERMINE THE PROPER TEMPERATURE RANGE AND DURATION OF USE. DO NOT USE BELOW PRACTITIONER RECOMMENDED TEMPERATURE.

**WARNING:** CAREFULLY READ WARNINGS AND INSTRUCTIONS PROVIDED WITH THE POLAR CARE AND POLAR PAD BEFORE USE. THIS PRODUCT SHOULD BE USED WITH BREG POLAR PADS ONLY.

**WARNING:** ALWAYS APPLY A DRESSING OR MOISTURE BARRIER BETWEEN THE POLAR PAD AND SKIN. PROVIDE COMPLETE COVERAGE BETWEEN SKIN AND PAD. DO NOT ALLOW DIRECT CONTACT OF THE PAD WITH SKIN FOR ANY PERIOD OF TIME.

**WARNING:** CONSULT YOUR LICENSED HEALTH CARE PRACTITIONER PRIOR TO USING THIS PRODUCT REGARDING POTENTIAL ADVERSE REACTIONS. PROVIDE A COMPLETE MEDICAL HISTORY AND ANY HISTORY OF PREVIOUS REACTIONS TO COLD APPLICATION. WHILE IN USE, INSPECT SKIN RECEIVING COLD TREATMENT REGULARLY. SHOULD CHANGES IN SKIN APPEARANCE OCCUR, SUCH AS: BLISTERS, INCREASED REDNESS, DISCOLORATION, WELTS, OR ANY OTHER REACTION IDENTIFIED BY YOUR PRACTITIONER, DISCONTINUE USE AND CONSULT YOUR PRACTITIONER IMMEDIATELY. DISCONTINUE USE AND CONSULT YOUR PRACTITIONER IMMEDIATELY IF BURNING, ITCHING, INCREASED PAIN OR SWELLING OCCUR.

**WARNING:** TO AVOID ELECTRICAL SHOCK DO NOT HANDLE ELECTRICAL CORD WITH WET HANDS. DO NOT ALLOW WATER TO CONTACT ELECTRICAL COMPONENTS.

## IMPORTANT SAFEGUARDS

WHEN USING ELECTRICAL PRODUCTS, ESPECIALLY WHEN CHILDREN ARE PRESENT, BASIC SAFETY PRECAUTIONS SHOULD ALWAYS BE FOLLOWED, INCLUDING THE FOLLOWING:

READ ALL INSTRUCTIONS AND WARNINGS PRIOR TO OPERATION.

### SAVE THESE INSTRUCTIONS

**DANGER:** To reduce the risk of electrocution:  
Always unplug this product immediately after using.  
Do not use while bathing.  
Do not place or store product where it can fall or be pulled into a tub or sink.  
Do not place or drop into water or other liquid.  
Do not reach for a product that has fallen into water. Unplug immediately.

### WARNING: TO REDUCE THE RISK OF BURNS, ELECTROCUTION, FIRE, OR INJURY TO PERSONS:

Keep the cord away from heated surfaces. Never operate this product if it has a damaged cord or plug. If it is not working properly, If it has been dropped or damaged, or dropped into water, call BREG's Customer Service. A product should never be left unattended when plugged in. Close supervision is necessary when this product is used by, on, or near children or invalids. Do not use outdoors or operate where aerosol (spray) products are being used or where oxygen is being administered. Connect this product to a properly grounded outlet only.

**CAUTION:** UL/C-UL Classification with respect to electric shock, fire, mechanical hazards only in accordance with UL 60601-1/CAN/CSA C22.2 No. 601.1.

**CAUTION:** This equipment may cause electromagnetic or other interference between other devices. If this occurs, move the device away from the affected equipment.

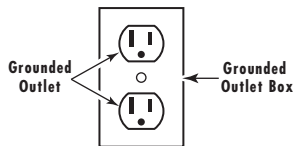
**WARNING:** Set up and use of this equipment should be in a low traffic location and way from children and pets.

**CAUTION:** It is important to install and use this equipment in accordance with the instructions, to prevent harmful interference to other devices in the vicinity. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the other device(s).
- Increase the separation between the equipment and any other device(s).
- Connect this equipment into an outlet on a circuit different from that to which any other device(s) may be connected.
- Consult the manufacturer for help.
- There are no serviceable parts, contact the manufacturer with any questions
- This is a single patient use only product.
- Dispose of product properly.

### SAFETY PRECAUTIONS:

- Read and adhere to all warnings and instructions listed on the Polar Care 500® and Instruction sheet.
- If you suspect the Polar Care 500® is not working properly, unplug the unit and contact BREG Customer Service.
- Use only the transformer provided with the Polar Care 500® in order to meet the requirement of UL 60601-1.



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**STANDARDS COMPLIANCE:** Designed to conform to applicable requirements of: UL 60601-1, CSA C22.2/ No. 601.1

**CONTENTS:** 1 Polar Care 500® product, including cooler, water pump, and transformer.

**USE INSTRUCTIONS**

1. **APPLY POLAR PAD ACCORDING TO INSTRUCTIONS INCLUDED WITH PAD.** Always apply a dressing or moisture barrier between the Polar Pad and skin. Provide complete coverage between skin and pad. Do not allow any part of the pad direct contact with skin for any period of time.
2. **PLACE PUMP IN ICE AND WATER.** Fill cooler with ice to line. Add water to the top of the ice. Place the cooler at or below the height of the pad, but no more than 2 feet (0.6 meters) below. Using the "bowtie" bracket included, submerge PUMP and make sure it is covered with water.
3. **CONNECT PUMP TO PAD.** Push couplings together until you hear a "click."
4. **START PUMP.** With dry hands, plug transformer into an electrical outlet and insert molded plug into Polar Pump electrical housing receptacle. Use only the BREG transformer provided. (BREG P/N 6.00230)

ATTENTION: Utilizer seulement avec le chargeur BREG.



5. **TEMPERATURE ADJUSTMENT.**

- A. Set green flow knob on the flow controller to the line with a green dot.
- B. Wait 10 minutes for temperature to stabilize; read temperature gauge and adjust as needed to licensed health care practitioner's recommended temperature.
- C. Adjust green flow knob one line at a time to change temperature, clockwise for warmer and counterclockwise for colder. Wait 10 minutes after each flow knob adjustment for the temperature to stabilize. Common operating temperature is 45° to 55°F (7.2° to 12.8°C) for continuous use; however, patient comfort and health history must be considered when using for any period of time. Do not adjust temperature below practitioner recommendation.
- D. Inspect your skin receiving cold treatment regularly during use. Discontinue use and contact your licensed health care practitioner immediately should you experience any adverse reactions.
- E. Periodically move flow knob to maintain practitioner recommended operating temperature.

**TIPS AND PROBLEM SOLVING**

- Wait at least 10 minutes to get an accurate thermometer reading when adjusting temperature.
- If pad leaking is suspected, condensation is the probable cause. Some condensation on the lines, controller and pad are normal, particularly in humid environments. To help reduce this effect, provide insulating layers of web roll or other similar material over the pad before the securing wrap is applied.
- The height of the cooler affects the pressure in the pad. It is important to keep the height of the cooler at or below the pad height, but no more than 2 feet (0.6 meters) below.
- The couplings are self-sealing, however it is normal for a small amount of water to escape when disconnecting the couplings.
- If the pad is not cooling properly, check the following:
  - Be sure that the pad is not folded or kinked.
  - Make sure the pump is covered completely by ice water.
  - Check for proper connection at the electrical housing and the wall outlet.
  - Check couplings for proper connection. Listen for "click" when connecting.
- Although the pump is screened, if a piece of ice or other object gets into the system, a blockage may occur. To eliminate the blockage, turn the control until pointed toward the small raised dot on the controller. Wait 30 seconds with the pump running, then return the knob to the previous setting.

**Table 1. Symbols used on the Polar Care 500®**

Symbol	Description
	Attention: Consult User's manual before use.
	Type B, applied part.

**SPECIFICATIONS**

Product:	#02020 #02000 (pump only)
WEIGHT	5 lb. (2.3 kg) Empty, 21 lb. (9.5 kg) Filled
OPERATING RANGE	36° to 70°F (2.2° to 21.1°C)
MAXIMUM PRESSURE	5.0 PSI (34.5 kPa)
PLUG	2.5 mm CTR. PIN POSITIVE
THERMOTETER ACCURACY	+/- 2°F (1.1°C)
POWER	0.8A, 120VAC, 60Hz

**WARRANTY**

BREG, Inc. warrants that this product is free from defects in workmanship, materials, and fitness for use for 90 days from initial purchase under normal use for which it was intended if it has been properly used 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.

**Table 2. Physical and Electrical Specifications**

<b>Electrical Specifications:</b>	
Input	110/120 VAC 60Hz 4 W
<b>Environmental Requirements:</b>	
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 – 75% R.H.
Transport & Storage	10 – 100% R.H., non-condensing
Atmospheric Pressure:	700 hPa to 1060 hPa
<b>Standards Compliance</b>	Designed to conform to applicable requirements of: UL 60601-1, CSA C22.2/ No. 601.1
<b>Classifications</b>	Class II, Continuous Operation. Not suitable with flammable anesthetics.



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