

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 | | |

PRODUCT INSERT FOR POLAR CARE KODIAK®



AW-1.90288 REV B 0312

INFORMATION FOR PATIENTS & MEDICAL PROFESSIONALS

USAGE TIPS

1. Use cubed or chunked ice for optimal performance.
2. If using a Polar Care Cold Therapy unit with a detachable Cold Therapy Pad, it is possible to drain the pad between uses. To drain the pad between uses, 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.
3. 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 Polar Care Cold Therapy Pad and unit will seal itself and will not leak. Note: Some dripping during release is normal.
4. 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 from water.

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 Customer Service if replacement parts are needed.

ELECTRICAL SAFETY

Like all electrical products, you must follow precautions to avoid electrocution, fire, burns, or other injuries. Supervise children and invalids near this product to ensure that these precautions are followed.

Keep electrical connections dry

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 are not waterproof and 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.).
- Do not use outdoors.

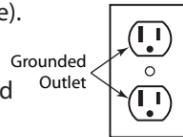
If the electrical connections fall into water, do not touch any wet part of the product. Unplug only at dry electrical connections.

Avoid flammables and oxidizers

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

Use a grounded outlet

Connect this product to a properly grounded outlet only.



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. If the cord, transformer, or plug is damaged, unplug and contact Customer Service, (866) 592-0488.

Start the product

Use only the transformer provided with the Polar Care Cold Therapy unit, to meet the requirements of UL 60601-1. With dry hands, connect the transformer to the electrical connection located on the top of the cooler. Next, plug the transformer into an appropriate electrical outlet. The unit will automatically start running at this point.

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.

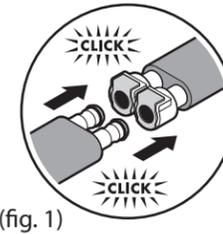
Electromagnetic Interference

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, 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.

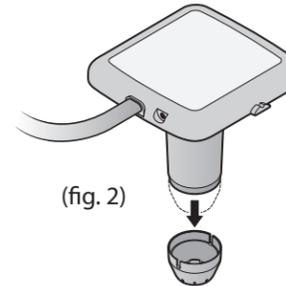
TROUBLESHOOTING GUIDE

Pump not running Water not flowing to the pad Pad is not getting cold

1. Make sure the transformer is plugged into the wall outlet.
2. Confirm that the ice and water are filled to the indicated levels.
3. Make sure there are no kinks in the pad.
4. Gently pull on the blue tube to make sure the tube/pad junction is straight.
5. Remove the pad from the treatment site and fill it while the pad is lying flat; then reapply.
6. Confirm that the pad couplings are securely attached to the unit. Listen for the double clicks (Figure 1) to confirm the pad couplings are securely attached.
7. Remove cap, which contains the foam filter, from the bottom of the pump (Figure 2) and clean out any debris. Replace cap ensuring the foam filter is in place.



(fig. 1)



(fig. 2)

Leaks

Note: Some condensation on the lines, controller, and pads is unavoidable, especially in warmer climates.

1. If using a Polar Care Cold Therapy unit with a detachable Cold Therapy Pad, and a leak exists (other than condensation on the lines) disconnect the pad couplings. Make sure the silver tabs on the couplings are depressed before reconnecting the pad to the pump hose; then confirm both sides of the coupling are properly clicked in.
2. If the coupling continues to leak or a leak is detected in the pad itself, stop using it and call Customer Service at (866) 592-0488.

DISPOSAL

Dispose of product according to local regulations.

WARRANTY

TopShelf warrants that this product is free from defects in workmanship and materials for 6 months from initial purchase under normal use for which it was intended. TopShelf's obligation under this warranty is limited to the replacement or repair of any defective part or parts of this product. TopShelf expressly disclaims any and all other warranties and representations, including, without limitation, the warranty of merchantability and fitness for a particular purpose.

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 |
|------------|--|---|
| 20.10601 | 4.0 lbs (1.8 kg) Empty 14.5 lbs (6.6 kg) Filled | Average operating range of Polar Pad with Polar Dressing ≥ 45°F (≥ 7.2°C) |

POLAR CARE® PRODUCT INSERT

INFORMATION FOR MEDICAL PROFESSIONALS

⚠ WARNING

Polar Care Cold Therapy can be cold enough to seriously injure skin. Follow this information, the Operating Instructions (on the back and side of the unit), and the Cold Therapy Pad Fitting Instructions (provided with each Cold Therapy Pad).

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

- 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.
- 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

- 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 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 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 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, visit www.topshelfortho.com.

2. Apply Insulation Barrier and Cold Therapy Pad

Always use an insulation barrier (such as Polar Dressing, 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 is too cold to be applied directly to the skin.

Use only Intelliflo pads. Other pads may be colder, increasing the risk of skin injury.

Use only Intelliflo Pads designed for the body part. 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

Polar Care Cold Therapy units are classified by the FDA as a Class II medical device 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 from the recovery room. Common operating temperatures for patients without risk factors for extended use (longer than 20 minutes) is 45° to 55° F (50° to 60° F for extremities). When used with a body part appropriate Cold Therapy Pad and an insulation barrier, the average operating temperature of the 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 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 unit, and the Cold Therapy Pad Fitting Instructions.

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 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° - 55° F* | Inspect skin under pad every 1-2 hours |
| | While asleep: Continuous | 45° - 55° F | Upon waking |
| Day 4-10 | While awake: Cyclic: 1 hour on and 1 hour off | 45° - 55° F | Periodically inspect the skin under pad |
| | While asleep: Continuous | 45° - 55° F | 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° - 55° F | Periodically inspect the skin under pad |

*50° - 60° F for the ankle and wrist pads.

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 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 Polar Care Cold Therapy to that patient.
- 2. Instructions For Use.** Instruct the patient on how to properly use 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.

All 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° - 55° F | 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° - 55° F | 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° - 55° F | Periodically inspect the skin under pad |
| | While asleep: Continuous | 45° - 55° F | Upon waking |
| Day 30 and beyond | As needed for pain control: Continuous for 1 hour intervals; not to exceed 12 hours/day | 45° - 55° F | 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 Polar Care Cold Therapy to the patient.
- 7. Discontinue.** Instruct the patient to stop using 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) form filled out.