

CAUTIONS AND WARNINGS

CAUTION: To reduce the risk of adverse reactions and malfunction, the Cool Flow® System must be used in accordance with the all instructions. Read and follow ALL included instructions.

Use only under the direction and supervision of a licensed healthcare practitioner:

Patients first need to be assessed by and discuss treatment with their physicians for contraindications, risk factors, and medical history before using this product. If used improperly, use of the Cool Flow[®] System could result in serious injury. Supervision may be necessary to ensure precautions are followed, especially with young children and the elderly. Adhere strictly to your doctor's instructions regarding use, treatment times, treatment frequency, settings, self-assessment and best practices regarding your specific condition.

Contraindications – Including but not limited to:

- History of cold injury, frostbite, or adverse reactions to cold application
- History of injury or adverse reactions to treatment •
- Special care monitoring must be provided for children, patients on prolonged therapy, unconscious or incapacitated ٠ patients, patients with diabetes, and those with poor circulation
- Application areas with compromised local circulation •
- Potential wound healing problems, including those from multiple surgical procedures
- Circulatory syndromes such as 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 ٠

Risk Factors for Cold-Induced Injury – Including but not limited to:

- Pathological sensitivity to cold •
- Young children and the elderly
- Behaviors that negatively affect circulation, such as poor nutritional habits, using tobacco, caffeine abuse, and alcohol abuse
- Medications that negatively impact mental capacity •
- Patients with diabetes
- Application area desensitization due to local anesthesia or regional nerve blocks
- Medications that have a negative effect on peripheral vascular circulation: beta adrenergic blockers and localized epinephrine
- Excessive moisture at the application site •
- Hand/wrist or feet/ankle surgery
- Communication barriers that would cause improper use of the system ٠

WARNING:

- The Cool Flow[®] System can seriously injure skin if used improperly •
- Follow ALL instructions to ensure product safety for patients and medical professionals ٠
- If you are pregnant, please consult your healthcare practitioner prior to use
- If you have sensitive skin, or skin sensitivity, please consult your healthcare practitioner •
- Cool Flow[®] system should be kept out of reach of infants and children •
- Do not use while asleep •
- The Cool Flow[®] System should not be used by an invalid, unconscious person or a person with low blood circulation without supervision
- Do not leave system unattended when operating •
- Discontinue use if you experience persistent discomfort or a rash
- Monitor patients skin condition during therapy (every 20 minutes)
- The system should not be applied to cancerous lesions, wounds, infected areas or some open sores
- Never unplug by pulling on the connecting cords
- Turn off when not in use
- Patients should use extreme caution when using unit and should monitor skin conditions underneath pad every 20 • minutes. It is recommended to take rest time from treatments. Always follow your healthcare practitioner's directions. CAUTION: The Cool Flow[®] System can seriously injure skin if improperly used.

Follow all instructions to ensure patient safety.



Read and follow all Instructions, Cautions and Warnings before operating this therapy system.

OPERATING INSTRUCTIONS

WARNING: The Cool Flow[®] System can seriously injure skin if improperly used. Follow all instructions to ensure patient safety. Use only under the direction and supervision of a licensed healthcare practitioner. Polar Products, Inc. will not be liable for injuries that result from misuse or misapplication of this system.

Use Only as Prescribed

Patients first need to be assessed by their physicians for contraindications, risk factors, and medical history before using this product. Supervision may be necessary to ensure precautions are followed, especially with young children and the elderly. Adhere strictly to your practitioner's instructions regarding use, treatment times, treatment frequency, settings, selfassessment and best practices regarding your specific condition. See page 4 of this instruction manual for more information on warnings, and risk factors for cold induced injury and / or contraindications.

Wear Proper Insulating Fabric

Always wear a protective layer of fabric between the skin and the Cool Flow[®] head cap. If post-surgery dressing or bandages on target therapy area do not completely cover the skin, place a piece of fabric over the bandage to ensure complete skin coverage. CAUTION: Never use this non-sterile head cap on broken skin.

Setting Up the System

- a) CAUTION: <u>Always</u> begin with power supply unplugged. Do not turn on the system until all connections are complete and the hose from the cooler to the therapy head cap is free from bends or restrictions, as this will restrict water flow through the system.
- b) Open the reservoir and *fill with ice* to the tube located near the top of the cooler. *TIP! Fill* the reservoir with large blocks of ice for an extended cooling time. For example: freeze water in milk cartons, then tear away the carton.
- C) Add cold tap water to the fill line, approximately 1.5 to 2 quarts. Always ensure the water covers the pump. DO NOT OVERFILL. NEVER OPERATE THE UNIT WITHOUT WATER! This will cause pump failure.
- together.
- Plug power supply into the unit and into a wall outlet. If using a battery pack, follow instructions with the pack. e)
- **f**) the top return tube to the cooling reservoir.
- g) Put the cap on the head; tie strap beneath chin (if your cap style includes ties.) See page 2, "Instructions for Use of bandage) between the therapy head cap and the skin.
- the reservoir with ice and water. (See steps 'b' and 'c'.)
- i) Confirm that water is flowing through the return flow tube at the top of the cooler when the system is on.

Skin Inspection

Inspect the skin under the head cap as prescribed by your health care practitioner. Do not use this system if dressing, wrapping, bracing, or casting prevents skin checks. CAUTION: Stop use and contact your practitioner immediately if you experience any adverse reactions, such as increased pain, burning, itching, increased swelling, blisters, increased redness, discoloration, welts, other changes in skin appearance, or any other reaction identified by your practitioner.

Ending Session

Turn the unit off and disconnect the power supply. Breakaway couplings are simply pulled apart. If your couplings have a metal tab, depress the metal tabs on the hose coupling and gently pull apart. Empty the reservoir and wipe out after each use.

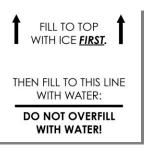
Care and Maintenance

Empty and wipe out cooling reservoir after each use. When necessary, wipe cooling reservoir and hoses with warm, antibacterial soapy water. Once a month, and before extended storage, pour 16 ounces of Isopropyl (Rubbing) Alcohol in the reservoir with the ice and water while system is in use.

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Cool Flow[®] Head Cap System (#AIS-H) Instructions – page 1



d) Connect the therapy head cap hose to the cooler hose. Breakaway couplings are simply pushed in place. If your female couplings have a metal tab, be sure to push in this tab before connecting. Couplings "click" when they are properly locked

Adjust the temperature control to "Coldest" and turn the timer knob clockwise to turn the unit on. Allow the unit to run a few minutes for the temperature to stabilize before using the system. Always ensure that there is water flowing through

Therapy Head Cap". CAUTION: Always use an insulation barrier (such as Webril, Kerlix, cast padding, or elastic

h) Adjust the temperature control to the desired level. When the temperature has risen above the desired temperature, refill

1.800.763.8423



Instructions for Use of the Head Cap

NOTE: For use only with the Cool Flow[®] System manufactured by Polar Products, Inc.

WARNING: Read and follow ALL Instructions, Cautions and Warnings provided with the Cool Flow[®] System before using this head cap or operating the therapy system. This product must be used in accordance with all instructions provided with the system. Polar Products, Inc. will not be liable for injuries that result from misuse or misapplication of this system.

<u>CAUTION</u>: Always wear a protective layer of fabric between the Head Cap and the skin. Use an additional insulation barrier over a sterile dressing that does not completely protect the skin. Never use this non-sterile Cap directly on the skin.

- 1. Do not turn the system on until all connections are complete and the hose from the cooler to the wrap is free from bends or restrictions.
- 2. CAUTION: Always use this head cap with a protective insulating layer between the cap and the skin.
- 3. Place the cap comfortably on the head and adjust for a snug fit.
- 4. Connect the cap tubes to the Cool Flow[®] System tubes with the guick connect couplings. The system is equipped with breakaway high-flow breakaway couplings. Push the couplings together until you hear a "click" sound. This click is the sound of the couplings connecting and locking into place.
- 5. Be sure the hoses are not restricted or bent, as this will restrict water flow through the entire system.



15-quart



AIS-H



AIS-HL

WARRANTY AND SERVICE

Polar Products, Inc. warrants that the Cool Flow[®] System is fit for use under the normal use for which it is intended and free of any defects in materials and/or workmanship for 6 months from the date of initial purchase. Polar's obligation under this warranty is limited to the replacement or repair of any defective part(s) of this product. If you encounter a problem with your Cool Flow[®] System, please call our Customer Service at 1-800-763-8423 to obtain a Returned Goods Authorization number (RGA.) To obtain warranty service on your system, please return the system, dated sales receipt (or packing list, as proof of purchase) and RGA number to: Polar Products, Inc. 3380 Cavalier Trail, Stow, OH 44224. Please include your phone number, any correspondence, and an explanation of the problem. Upon receipt, Polar's Service Department will determine the cause of failure and, if determined to be an issue covered by the warranty, will repair (or replace, as necessary) your system and return it to you, postage paid.

PLEASE NOTE: HEALTH REGULATIONS PROHIBIT US FROM ACCEPTING RETURNS ON COLD THERAPY SYSTEMS UNLESS THERE IS A PROBLEM WITH ITS OPERATION (AS COVERED BY THE WARRANTY.) If the unit is within its 6 month warranty period, it will be repaired or replaced with a new unit. Couplings are a wear item and may need to be replaced. They are available for individual purchase.

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If the solutions suggested below do not address your question or issue, please call our Customer Service department at 1.800.763.8423 and we will do everything possible to help.

IF THE PUMP IS NOT RUNNING:

Confirm that the transformer is properly plugged into the unit and the wall outlet. A small green light (located on the transformer box) should be on if the transformer has power.

IF THE HEAD CAP IS NOT GETTING COLD:

FIRST: Is water flowing out of the top water return tube in the cooler? If water is <u>NOT</u> flowing out of the top water return tube:

- Check the temperature control knob. Ensure that the temperature control knob located on the top of the blue box is turned to maximum cold ("COLDEST"). Always adjust this control to ensure there is a flow of water from this top water return tube.
- Check the water level in the cooler. Confirm that the pump is completely submerged in the water.
- Check for kinks. Ensure there are no kinks or pinches in the hoses, tubing or therapy pad.
- Adjust the fit. Ensure that the ties securing the cap to the head are not too tight and impeding flow.
- **Check for obstructions.** Turn the system off. Disconnect couplings to ensure there is not an obstruction. Remove anything lodged in the coupling or tubing. Also ensure there are no obstructions at the bottom pump intake.
- Check the couplings. Confirm that the head cap hose couplings are properly seated. Reseat connectors between the hose and the cap. Turn off the unit, disconnect couplings and reconnect.
- **Check the pump.** Occasionally an air bubble can get lodged in the pump intake. Turn the pump motor, located in the reservoir, vertically to horizontally to dislodge any air bubble.

TROUBLESHOOTING TIP! A good way to isolate the problem is to remove the couplings from the insulated tubing attached to the reservoir. To do this, simply turn off the unit, pull off (or cut off) the couplings, place the end of the hoses over a sink and turn the system on. If water flows freely, the obstruction is in the couplings, tubing or head cap. Couplings can become blocked with minerals, hair etc. Use a paper clip to clear the blockage. A new coupling or head cap may be necessary. To reattach the couplings simply cut the tubing back to unused tubing and push the coupling back into the tube.

If water IS flowing out of the top water return tube:

- Ensure that the reservoir is <u>filled</u> with ice. Note the line inside the cooler.
- Adjust temperature control to "COLDEST" (see picture above).

IF THE UNIT IS LEAKING AT THE CONNECTIONS:

If a leak exists, turn off the unit. Disconnect and reconnect the head cap couplings and ensure both sides are clicked in properly. If your couplings have a metal tab, when connecting the coupling ensure that the silver release clip platform on the female coupling is pressed down prior to insertion. NOTE: Couplings have rubber "O" rings that can become worn and dysfunctional. Replacement couplings may need to be purchased from Polar Products.

TROUBLESHOOTING TIP! To replace the couplings simply cut off the coupling just above where the coupling barbs extend into the tube. Trim the blue insulation if necessary and push in the new coupling. Always push the new coupling into trimmed tubing.

Note: Never overfill the unit with water. This reduces how long the ice will last and may cause leakage.

Cool Flow[®] Head Cap System (#AIS-H) Instructions – page 3 **TROUBLESHOOTING GUIDE**

Water Return Tube







Male (top) & Female Breakaway Couplings