

Instructions for Use

DonJoy® Cold Therapy Unit Cold Therapy Unit

LEGEND/SYMBOL DESCRIPTION

Attention Read Manual	Class II Equipment	Cold Temperature	CE Mark
(*	CE
Action Required by User	Rx Only	Type B Equipment	
	R	Ŕ	

Blue
Yellow
Orange

Action Required by User Proceed With Caution Warning

For product support within the U.S.A. call +1-888-405-3251 or +1-760-727-1280.



DJO, LLC 1430 Decision Street • Vista, CA 92081-8553 • USA t 800.336.6569 • f 800.936.6569 DJOglobal.com ©2011 DJO, LLC



WARNING! Read and understand all warnings and Instructions for Use before using this device.

WARNING! DO NOT use this device without a prescription from a physician. Rx only. Your prescription must state a temperature, how long and how often the device should be used and the length of breaks between uses. **DO NOT** use this device if a prescription has not been provided to you or if you do not understand the prescription. Use of this device without a prescription or failure to follow the prescription may result in serious injury, including tissue necrosis.

WARNING! This device can be cold enough to cause serious injury, including tissue necrosis. You must be able to check your skin condition under the cold pad frequently (at least every hour). **DO NOT** use this device if you cannot check your skin condition frequently (at least every hour). Check for increased pain, burning, numbness, tingling, increased redness, discoloration, itching, increased swelling, blisters, irritation or other changes in skin condition under the cold pad or around the treatment area. If you experience any of these conditions, immediately discontinue use of this device and contact your physician.

WARNING! This device is intended only for single patient use. Secondary use can cause serious injury, including infection.

WARNING! Application of the cold pads directly on the skin may result in serious injury, including tissue necrosis. **DO NOT** let any part of the cold pad touch your skin. **ALWAYS** use with a barrier between your skin and the cold pad.

WARNING! The barrier between your skin and the cold pad may develop moisture during use, which may create colder temperatures on the skin. Temperatures that are too cold may result in serious injury, including tissue necrosis. **ALWAYS** check for moisture on the barrier between your skin and the cold pad. If moisture is present on the barrier, immediately discontinue use of this device.

WARNING! Poor connections between hoses may cause leaking, which may result in serious injury, including infection and tissue necrosis. **ALWAYS** listen for a "snap" or "click" when connecting the IceMan[®] CLASSIC cold therapy unit hose to the cold pad hose.

WARNING! Use of the IceMan[®] CLASSIC with wet hands or in a wet location may result in electrical shock and serious injury. **DO NOT** handle transformer or power cord with wet hands or in a wet location.

WARNING! DO NOT use the IceMan[®] CLASSIC near flammable anesthetics, which may result in explosion and serious injury.

PRECAUTIONS

When to exercise special care when prescribing the IceMan® CLASSIC Exercise special care prescribing this device for the following patients: those with arthritic conditions; peripheral vascular disease; children under the age of 12; those with decreased skin sensitivity; poor circulation, or compromised local circulation; hypercoagulation disorders; diabetes or neuropathies.

THIS DEVICE CAN BE COLD ENOUGH TO CAUSE SERIOUS INJURY. READ AND UNDERSTAND ALL WARNINGS AND INSTRUCTIONS FOR USE BEFORE USING THIS DEVICE.

INTENDED USE / INDICATIONS FOR USE

When to use the IceMan® CLASSIC

The intended use of the IceMan[®] CLASSIC is for the temporary reduction of swelling and pain after surgery or injury. This is a non-sterile prescription device for single patient use to provide localized external application of cold therapy. This device may not be used for any other purpose.

CONTRAINDICATIONS

When not to use the IceMan® CLASSIC

DO NOT use this device on patients with Raynaud's phenomenon or other vasospastic conditions; Buerger's disease; cold allergy or hypersensitivity; cryoglobulinemia; paroxysmal cold hemoglobinuria or other cold agglutinin disorders; pheochromocytoma; sickle cell anemia or history of cold injury.

LIMITATIONS ON SPECIAL PATIENT POPULATIONS

Limit the use of the IceMan® CLASSIC with these patients Limit the use of this device with patients who are unresponsive, incapacitated, have altered mental status or altered pain perception. Post-surgical patients under sedation or on analgesics or anesthetics, as well as patients taking hypnotics, anxiolytics, or antidepressants, must be monitored frequently during use of this device. These patients may not be able to perceive pain, burning, numbness, tingling or decreased sensation and may be susceptible to injury. Discontinue cold therapy immediately at the first sign of cold injury.

PATIENT INFORMATION AND OPERATING INSTRUCTIONS

Directions for use of the IceMan® CLASSIC

- A physician must prescribe treatment to be rendered by this device, which must state a temperature, how long and how often the device should be used and the length of breaks between uses. You must follow the individual prescription provided to you by your physician.
- This device can be cold enough to cause serious injury, including tissue necrosis. You must be able to check your skin condition under the cold pad. **DO NOT** use if you cannot check your skin condition frequently (at least every hour). People are sensitive to cold in diverse ways and may react differently to cold treatment.
- Check for increased pain, burning, numbness, tingling, increased redness, discoloration, itching, increased swelling, blisters, irritation or other changes in skin condition under the cold pad or around the treatment area. If you experience any of these conditions, immediately discontinue use of this device and contact your physician.
- Inform your physician if any of the following apply to you: arthritic conditions; peripheral vascular disease; under the age of 12; decreased skin sensitivity; poor circulation or compromised local circulation; hypercoagulation disorders; diabetes or neuropathies.
- Check for moisture on the barrier between your skin and cold pad. If moisture is present on the barrier, immediately discontinue use of this device.
- Do not cast or bandage over IceMan[®] cold pads.
- Use only approved IceMan[®] cold pads with the IceMan[®] CLASSIC cold therapy unit.
- To ensure a reliable connection between the IceMan[®] CLASSIC and IceMan[®] cold pad, "snap" or "click" hoses together into place so that the fit is tight and snug. Monitor hose connections during use.
- This device is intended for single patient use.
- Follow all precautions necessary to avoid electrical shock, fire, burns, or other personal injury from electrical power by using the device indoors, with dry hands, and in a dry location. Keep all electrical connections away from water.

- Never use this device if the power cord or plug is damaged. Always use a grounded outlet.
- To avoid the risk of electrical shock, do not disassemble the IceMan[®] CLASSIC. If device is not functioning properly, please contact DonJoy[®] product support.
- The IceMan[®] CLASSIC is non-sterile and is not intended to be sterilized. Do not attempt to sterilize the unit by any means.
- Rx only.

APPLICATION INSTRUCTIONS

1) Add ice to fill line inside the device.

2) Add cold water to fill line.

3) Place lid on the device.

4) Connect the IceMan[®] CLASSIC hose to the cold pad hose. To ensure a reliable connection, "snap" or "click" hoses together into place so that the fit is tight and snug.

WARNING! When applying the cold pad, **DO NOT** let any part of the cold pad touch your skin. Always use with a barrier between your skin and the cold pad.

Check for moisture on the barrier between the patient's skin and cold pad. If moisture is present on the barrier, immediately discontinue use of this device.

5) To turn the device on, insert cord into connection on the back of the device and plug power supply into the wall outlet.

6) Set temperature control on the hand console starting at the blue dot. Allow 10 minutes after the cold pad is placed on the patient for the temperature to stabilize. Then adjust the temperature to range prescribed by the physician. **DO NOT** use if you do not have a prescription.

STORAGE INSTRUCTIONS

Unplug the power supply from the electrical outlet. **TO AVOID DANGER OF ELECTRICAL SHOCK, DO NOT UNPLUG THE POWER SUPPLY WITH WET HANDS.** Disconnect pad from hose. Drain cooler and wipe dry. Drain pad by holding so that the hose is hanging downward. Press in the buttons at the end of the hose and allow all water to drain out of the pad.

WARRANTY:

DJO, LLC will repair or replace all or part of the unit and its accessories for material or workmanship defects for a period of six months from the date of sale.

NOMINAL OPERATING ENVIRONMENT

Ambient Temperature: 10°C - 40°C Relative Humidity: 30% - 75% Atmosphere Pressure: 700 h Pa - 1060 h Pa

POWER SUPPLY

DonJoy[®] IceMan[®] CLASSIC Domestic Power Supply: DJO P/N 13-4882-0-00000

SAFETY CLASSIFICATIONS

Mode of Operation - Continuous Operation	
External Electrical Power Source - Class II Equipment	
Degree of Protection Against Electric Shock - Type B Equipment	Ŕ
Ordinary Equipment - IPX0 - Not protected against water ingress.	
With respect to electric shock, fire, and mechanical haz- ards the IceMan® CLASSIC complies with UL 60601-1.	