

EN - Caution: This product has been designed and tested based on single patient usage and is not recommended for multiple patient use. If any problems occur with the use of this product, immediately contact your medical professional.

FR- Attention: Ce produit a été conçu et testé pour être utilisé par un patient unique et n'est pas préconisé pour être utilisé par plusieurs patients. En cas de problème lors de l'utilisation de ce produit, contactez immédiatement un professionnel de santé.

ES- Atención: Este producto se ha diseñado y probado para su uso en un paciente único y no se recomienda para el uso de varios pacientes. En caso de que surja algún problema con el uso este producto, póngase inmediatamente en contacto con su profesional médico.



- Attention - See operating instructions



- Meets IEC type B leakage current requirements



- Class II Device



- Attention – Voir les instructions d'utilisation



- Conforme aux exigences de courant de fuite IEC de type B



- Appareil de classe II



- Atención - Consulte las instrucciones de funcionamiento



- Cumple los requisitos IEC de tipo B para las fugas de corriente



- Dispositivo de clase II

ENGLISH

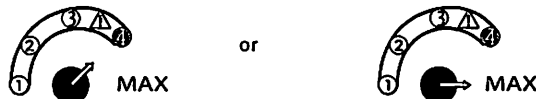
SAFETY PRECAUTIONS

- READ THE FOLLOWING INSTRUCTIONS CAREFULLY BEFORE OPERATING THE COLD RUSH COLD THERAPY SYSTEM.
- Correct temperature range for each patient's skin should be determined on an individual basis by a licensed healthcare practitioner. Patients vary in sensitivity to cold. Periodically monitor the temperature and appearance of the skin being treated once steady flow of water through the pad is achieved.
- The temperature at the surface of the skin may vary depending upon the amount of dressing used and other factors beyond the control of the manufacturer. Temperature and color of the skin, at the treatment site, must be monitored by a licensed healthcare practitioner.
- Fill with water and ice only, do not overfill.
- The Cold Rush Pad should never be applied directly to the patient's skin. *Do not use* the Cold Rush Cold Therapy System without first applying an insulation barrier between the Cold Rush Pad and the patient's skin.
- Unit is not suitable for use in the presence of flammable anesthetic mixture with air, oxygen or nitrous oxide.
- Follow local ordinances or regulations for proper disposal of device, accessories and packaging.
- **Caution:** Federal law requires this device to be sold by a physician or by the order of a physician.

WARNING

READ THE FOLLOWING TREATMENT WARNING PROTOCOL INSTRUCTIONS CAREFULLY BEFORE OPERATING THE COLD RUSH COLD THERAPY SYSTEM.

- The flow control knob should **never** be set at the maximum settings (number "4" or "MAX") for more than 30 minutes.



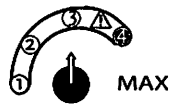
- The Cold Rush pad should **never** be applied directly to the patient's skin. Do not use the Cold Rush Cold Therapy System without first applying an insulation barrier between the Cold Rush pad and the patient's skin.
- Patients should **never** utilize cold therapy while they are asleep or unable to check their skin every 1-2 hours unless specifically instructed to do so by the prescribing health care provider. If the patient is instructed to utilize cold therapy while asleep or unable to check their skin every 1-2 hours, turn the flow control knob counterclockwise to the number "1" setting.



IMPORTANT WARNING!

Patients who fail to turn the flow control knob counterclockwise to the number "1" setting when using cold therapy while asleep or unable to check their skin every 1-2 hours can suffer cold-related injuries, including full thickness skin necrosis.

- When using while awake, patients must check their skin every 1-2 hours once steady flow of water through the pad is achieved. Turn the flow control knob counterclockwise to increase the temperature (warmer), and clockwise to decrease the temperature (colder).
- When turning the unit on, turn the flow control knob clockwise to the number "3" setting wait 10 minutes to allow the temperature to stabilize before making any additional temperature adjustments.



- The following patients should ALWAYS turn the flow control knob counterclockwise to the number "1" setting when using cold therapy
 - * Patients whose treatment area has been desensitized due to local anesthesia or regional nerve blockers
 - * Patients taking prescribed medications that may negatively affect peripheral vascular circulation, including beta adrenergic blockers and local epinephrine use (such as in local anesthetics)
 - * Patients taking prescribed medications that negatively affect their mental capacity or judgment
 - * Patients suffering from diabetes
 - * Patients who have recently undergone hand/wrist or foot/ankle surgery
 - * Patients suffering from cognitive disabilities
 - * Young children and the elderly
- *Caution:* Contact your healthcare provider immediately and discontinue the use of your Cold Rush Cold Therapy Unit if you experience any adverse reaction to the treatment area such as: increase in pain, burning, blistering, itching, increased swelling, discoloration of the skin, increased redness, welts or any other changes in the appearance of the skin.
- Care should be taken during prolonged use for children, diabetics, incapacitated patients and those with decreased skin sensitivity or poor circulation.
- A licensed healthcare practitioner must determine the correct frequency and duration of treatment for each patient.
- If prescribed by a licensed healthcare practitioner for home use, the healthcare practitioner must provide each patient with training for appropriate use and proper application of the Cold Rush Cold Therapy System.
- The health care practitioner must monitor the patient's use of the device to assure appropriate use and proper application of cold therapy, including but not limited to application of an insulation barrier between the patient's skin and the Cold Rush Pad.
- The product should never be left unattended when plugged in.
- Never drop or insert any object into any opening or hose.

- *Do not* operate where aerosol (spray) products are being used or where oxygen is being administered.
- *Do not* attempt to drag or reposition the Cold Rush Cold Therapy unit by pulling or tugging on the insulated hoses, as this may cause damage to the unit and/or cause the hoses to disconnect. Use handle when moving the Cold Rush Cold Therapy unit.
- If you experience disturbance in any other electrical equipment near the Cold Rush unit, please try to unplug it from the wall socket to verify that it is not the source of disturbance.

ELECTRIC SHOCK HAZARD

- Unplug unit before filling it with ice and water. To avoid danger of electric shock be certain that hands are dry before inserting or removing the power supply from wall socket.
- Avoid getting water or ice on the flow control panel or power adapter.
- Always unplug this product immediately after each use.
- *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 in or drop into water or other liquid.
- *Do not* reach for a product that has fallen into water. Unplug immediately.
- Never operate this product if it has a damaged electrical cord or plug, if it is not working properly, if it has been dropped or damaged, or dropped into water. Return the product to your healthcare provider for examination and repair.
- Keep cord away from heated surfaces.

NOTE:

To create the safest operating conditions possible, Össur has designed the Cold Rush Cold Therapy System to operate on a 12 volt power supply, significantly reducing the chance of dangerous electric shock. Great care should always be taken when using electricity near water.

PRODUCT DEFINITIONS

- The Cold Rush Cold Therapy System is designed for single patient use only.
- Use of Cold Rush Cold Therapy System is designed to reduce localized pain and swelling following surgical procedures or trauma.

LIST OF PARTS (Figure 1)

- Cold Rush Cold Therapy System
- Hose
- Couplings
- Flow Control Knob
- DC Connector
- 12V Power Supply
- Cold Rush Pad (Sold Separately)

TECHNICAL SPECIFICATION

Do not use any other power supply other than the one provided with the unit.

ELECTRICAL - POWER SUPPLY

- Model no: SA 1312-120100 US
- Input: 120V US, 240V EU

- Input frequency: 60Hz US, 50Hz EU
- Output power: 12W
- Output Voltage: 12V
- Output Current: 1A

SAFETY STANDARDS

Cold Rush™ Cold Therapy System is tested and certified to comply with the IEC60601-1 standard of electrical safety of medical devices and IEC/EN60601-1-2, electromagnetic compatibility for medical electrical devices. The company fulfills the requirements of ISO13485.

SETUP AND OPERATION

1. Ensure cold therapy unit is turned off, turn flow control knob counter clockwise to the off position. Do not plug in to wall socket (Figure 2)
2. Fill reservoir with water to the indicated fill line (Figure 3)
3. Add chopped or cubed ice to the reservoir up to the indicated fill line (Figure 4)
4. Attach the provided 12V power supply to DC power port, do not plug into wall circuit (Figure 5)
5. Apply insulation barrier over the patient's skin in the area to be treated (Figure 6a)
6. Apply Cold Rush Pad over insulation barrier. The Cold Rush Pad should never be applied directly over the patient's skin (Figure 6b)
7. Connect Cold Rush pad to hose extending from the unit. To ensure proper connection, push couplings together until they snap into place (Figure 7)
8. Plug the provided 12v power supply to wall socket (120V US, 240V Europe) (Figure 8)
9. Turn flow control knob clockwise to the number "3" setting, this will turn unit on (Figure 9)
10. Wait 10 minutes to allow temperature to stabilize before adjusting the temperature for comfort (Figure 10)
 - Turn flow control knob counterclockwise to increase temperature.
 - Turn flow control knob clockwise to decrease temperature.
11. To turn the cold therapy unit off, turn flow control knob counterclockwise until it stops.
12. Always turn the cold therapy unit off before disconnecting the Cold Rush pad or any hoses. To disconnect the hoses, press the release tabs on the coupling and pull the connectors apart.
13. Drain all of the water out of the cold therapy unit after each use.
14. Follow directions 2-10 before each use.

MAINTENANCE

Do not try to repair your Cold Rush unit as this may create a user hazard and will automatically void warranty. After talking with your healthcare provider, to ensure you are following the operating instructions properly, the unit shall be sent to Össur for repairs or maintenance. No other company or individual is allowed to service or repair the unit in any way.

CLEANING AND PROLONGED STORAGE

- When you have finished all of your cold therapy treatments, prior to prolonged storage, fill the unit with one gallon of water (or enough so the water level is at the ice fill line.
- Add 2 tablespoons of liquid bleach or 3 ounces of 3% hydrogenated peroxide to the water and mix.
- Connect hoses to the Cold Rush Pad, turn unit on to MAX setting.