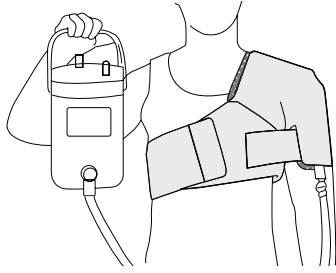


CRYO/SW/10 - Promedics Cryo Universal Wrap - Shoulder

Thermal Therapy Pack

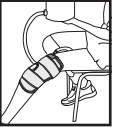


Unit and Accessories
(Available Separately)

CRYO/COOLER Promedics Cryo Cold Therapy Cooler



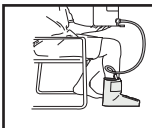
CRYO/KW/10 Promedics Cryo Universal Wrap – Knee



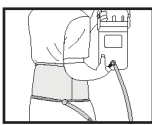
CRYO/EW/10 Promedics Cryo Universal Wrap – Elbow



CRYO/AW/10 Promedics Cryo Universal Wrap – Ankle



CRYO/BW/10 Promedics Cryo Universal Wrap – Back



CRYO/TUBE Promedics Cryo Replacement Tube



MD MEDICAL DEVICE

1P SINGLE PATIENT - MULTIPLE USE

! CAUTION

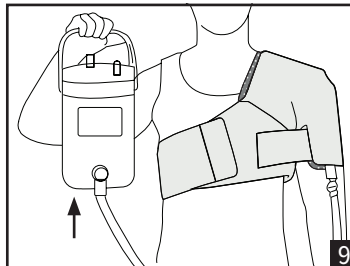
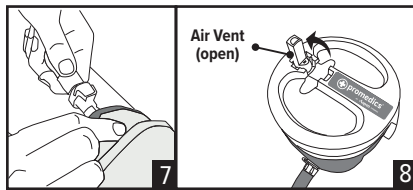
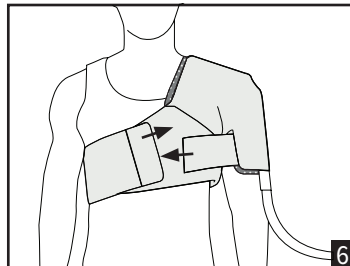
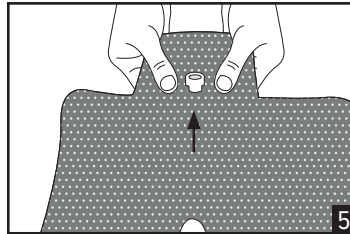
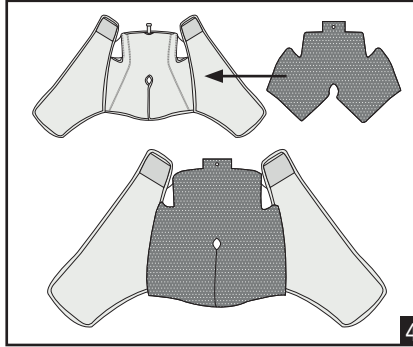
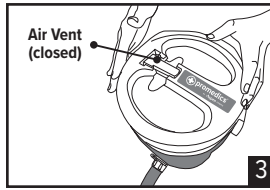
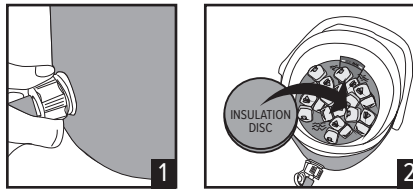


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CRYOSWIFUD revised 8/24



ENGLISH

BEFORE USE ENSURE THE COMPLETE INSTRUCTIONS ARE READ CAREFULLY. IT IS VITAL THAT THE DEVICE IS USED APPROPRIATELY TO ENSURE SAFE FUNCTIONING.

Product Description

Cold therapy system to exchange chilled water between cooler and cold wrap by gravity to provide localised cold therapy.

Usage Information (See diagram)

Prepare cooler: Connect the tube to the cooler (Fig 1). Add water up to line marked 'WATER MIN' inside the cooler, then fill with ice up to 'ICE MAX' for 6 to 8 hours of treatment. Lay the insulation disc on top of ice (Fig 2). Attach cooler lid snugly, with air vent closed (Fig 3). Allow a few minutes with occasional shaking to chill water.

Lay the insulation barrier flat. Open the wrap and lay flat, with the inside of the wrap facing upwards. Place the insulation barrier onto the wrap (Fig 4). Secure by placing the wrap's tube connector through the hole of the insulation barrier (Fig 5). Apply the empty wrap, securing the hook/loop straps (Fig 6).

Connect tube to wrap (Fig 7). Open air vent on cooler lid (Fig 8) and raise cooler NO MORE THAN 40 cm above the wrap for about 30 seconds (Fig 9). You will begin to feel the wrap fill with chilled water. When filled, close air vent on cooler lid. If preferred, the cooler can now be disconnected from wrap through valved connector for quick disconnection.

Note: Do not raise the cooler higher than 40 cm, to avoid excessive water and pressure.

It is recommended that treatment is ceased for at least 30 minutes between cold therapy sessions. In a 2 hour period, it is recommended each session should last no longer than 30 minutes.

Re-chill water, re-connect the tube to wrap and open air vent on cooler lid. Lower the cooler below wrap, and the warmed water inside wrap flows back to cooler. Allow a minute or two for the water to mix with the ice and re-chill, then raise the cooler and repeat the filling process. At first, re-chill the water in the wrap after 15 or 30 minutes, then once an hour or as needed. Ensure the skin is checked every hour on a routine basis.

Indications for Use

Suitable for providing relief for a number of indications. This includes the following: General haemarthrosis, Inflammation, Post-injury swelling and pain, Post-surgical swelling and pain, Rehabilitation, Sporting injuries and Trauma.

Contraindications

Raynaud's or other vasospastic diseases; diabetics; poor local circulation; local tissue infection; cold allergy, cold hypersensitivity.

Warnings and Precautions

We recommend the initial fitting of this device be conducted by a suitably qualified healthcare professional who will advise the period of use.

- Carefully read all instructions and warnings prior to use.
- Follow all instructions to ensure proper performance.
- This system can be cold enough to cause serious injury, including tissue necrosis. Skin condition must be checked beneath the insulation barrier regularly. DO NOT use if skin condition cannot be checked frequently.
- Do not use if liniments, ointments, gels, creams or any other substances have been applied to the affected area.
- Do not re-use for another patient, doing so risks cross infection and can compromise product integrity.
- Perform regular skin and circulation checks. Do not use the product if you cannot frequently check your skin condition.
- Should any adverse reactions occur (pain, numbness, discolouration, blisters, irritation or other changes in skin condition) please cease use and contact your healthcare professional or provider of this product.
- The durability of the product may be compromised by certain factors, e.g., objects with sharp edges or damage to the hook and loop fasteners. To prevent this the hook and loop fasteners should always be fastened when the brace is not being worn or when being washed.
- Care must be taken to ensure that patients or their carer understand that skin monitoring must be carried out.

Washing and Care Instructions

1. After use, completely drain water out from cuff, tube, and cooler. (To drain tube, elevate tube while pressing the tip of valved connector)
2. Clean the tube and cooler with running water; For disinfection, wipe the cooler and wrap surface with a cloth dipped in 75% alcohol or ethanol disinfectant. After disinfection or cleaning and air drying, lay wrap flat for later use.
3. Stored in temperature range -10 °C to 30 °C, relative humidity is not more than 80%, in well ventilated room.

Washing and Care Instructions for CRYO/SW/BARRIER

1. Hand wash insulation barrier in cool water using mild detergent.
2. Rinse and dry flat.
3. Do not spin or tumble dry.
4. Do not use fabric conditioner at any time.
5. Check for any degradation that may affect use.

Storage and Transport Conditions

Store in a cool, dry place out of direct sunlight, in the original packaging.

Recycling and Disposal

Packaging and constituent parts should be recycled or safely disposed in accordance with local or national laws.

Serious Incident

Report any serious incident to the manufacturer and the competent authority of the EU Member state, or country in which you reside.



SCAN QR CODE to watch the Promedics Cryo fitting video.