

Instructions For Use (IFU)

Cryothermic Cooling System® and Cryo Cooling Element®

Intended Use

“Bridge to Targeted Temperature Management Systems (TTM)” for Emergency Medical Services, Emergency Departments or Intensive Care Units (ICU)

Directions for Use

1. See Collar Placement section of this IFU if using Cryo Cooling Collar Accessory prior to activating Cryo Cooling Element™.
2. Remove Cryo Cooling Element from package.
3. Activate Cryo Cooling Element. Use thumbs to find inner liquid pouch. Squeeze firmly to break the liquid pouch inside (or lightly punch Cryo Cooling Element).
4. Shake VIGOROUSLY for at least 10 seconds to dissolve ingredients and initiate cooling reaction. The Cryo Cooling Element is ready to use immediately after shaking. Ingredients should be dissolved fully, and you should not be able to feel any granular ingredients inside.
5. Place the Cryo Cooling Element directly on the patient’s neck covering the both carotid triangle regions. The Element should make direct, gentle contact with the skin without undue pressure. You may use either the Cryo Cooling Collar or Cryothermic Wrap accessories to hold the element in place.
6. Replace the Cryo Cooling Element per your organization’s temperature management protocol. Upon replacement, check patient’s skin and discontinue use if skin damage is observed. Mild skin redness is expected.
7. Monitor patient temperature per temperature management protocol and replace Cryo Cooling Elements as needed.
8. Discard after use. If the Cryo Cooling Element has contacted biological fluids, it should be discarded along with other medical waste.

Cryo Cooling Collar Placement

1. Remove Cryo Cooling Collar from package.
2. If the patient is supine, slide the back portion of the Cryo Cooling Collar directly behind the patient’s neck. Rest the patient’s chin securely in the chin rest in the neutral alignment position.
3. If the patient is not supine, slide the front of the Cryo Cooling Collar along patient’s chest.
4. Hold the front of the collar in place, wrap the back of the collar around the back of the patient’s head and neck. Secure to the front of the collar with the hook and loop strap.
5. Open front door on collar and insert ONE Cryo Cooling Element in anterior opening by sliding it down the right side of the patient’s neck and then feeding the Element down the left. Once the Element is placed in the anterior opening, close the door. Adjust the tension of the door with the use of the hook and loop strap. Make certain the Cryo Cooling Element is in contact with the patient’s skin without undue pressure.

Storage and Handling

- The Cryo Cooling Elements should be used in specific operating conditions:
Operating Temperature range: 10°C to 30°C (50°F to 86°F)
- For best results, Cryo Cooling Elements should be stored in a cool, dry place between 2°C to 21°C (35°F to 70°F)
- Cryo Cooling Elements should not be exposed to direct sunlight for extended periods of time or be stored in a warm environment such as inside a car exposed to direct sun.

Warnings

- Discard the product after use to eliminate the risk of infection, or ineffective cooling.
- For external use only.
- Do not puncture. If bag breaks and fluid contacts skin or eyes, immediately flush area with large amounts of water.
- Do not swallow contents. If contents accidentally swallowed drink large amounts of water (not milk) and contact Poison Control Centre or physician.
- Device is not intended for use on open wounds.
- If used with the Cryo Cooling Collar, maintain neutral head and neck alignment during the entire procedure to prevent further extension or damage to the cervical spine or spinal cord.

Precautions

- Apply Cryo Cooling Elements according to local protocols & guidelines.
- Cryo Cooling Elements are intended for application by licensed health care practitioners.
- All directions are to be considered as guidelines and not an attempt to define medical practice.
- It is important that you only use accessories that are designed to work with the Cryo Cooling Element.

Explanation of Symbols



Batch code



Catalogue number



Manufacturer



Use by Date (Expressed as YYYY-MM)



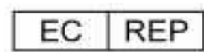
Do not re-use



Caution



Consult Instructions for Use



Authorized Representative in European Community



Temperature limitation



Keep away from sunlight



Keep product dry

Cryothermic® and Cryo® are registered trademarks of Cryothermic Systems Inc.

P/N: EXS-700-01 Rev A



Contact info@cryothermicsystems.com or for more information, visit: www.cryothermicsystems.com