

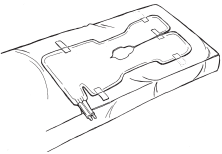


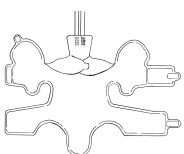
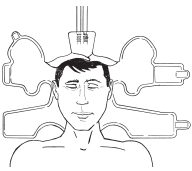
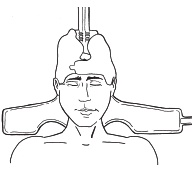
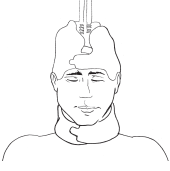
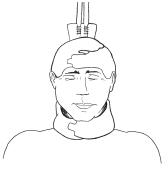


KIT CONTAINS:

1. TRANSLATED INSTRUCTIONS

1. PATIENT VEST

1. HEAD WRAP

1. LOWER BODY PAD

| | | | |
|--|---|---|--|
|  |  |  |  |
| <p>Unfold Patient Vest & place on bed, stretcher or table.</p> | <p>Position patient on Vest.</p> | <p>Fold flaps over shoulders & chest of patient. Connect to hyper/hypothermia device. Fill pad with water. Adjust to fit patient.</p> | <p>Open Head Wrap and connect to the hyper/hypothermia device. Be sure pad is filled with water.</p> |
|  |  |  |  |
| <p>Position patient on Head Wrap.</p> | <p>Fit pad to forehead.</p> | <p>Fit pad to neck.</p> | <p>Fit pad to top of head.</p> |
| <div data-bbox="57 1065 380 1234">  </div> <div data-bbox="606 1153 1213 1513">  </div> | | | |



WARNINGS:

1. Physicians order is required for temperature setting and for use of therapy. Patients should be checked at least every 20 minutes or as directed by a physician. Higher risk patients including pediatric, temperature sensitive and operating room patients should be checked more frequently.
2. Monitor patient skin temperature and condition paying particular attention to bony prominences. Notify physician for changes in patient condition.
3. Do not position patient on insulated tubing. Patient injury may occur.
4. Follow physician order/hospital policy for discontinuation of therapy. Notify physician for changes in patient condition.
5. Leaky components or hoses should never be used. Water leaks present a risk of infection and should be handled accordingly.
6. Do not wrap head wrap tightly enough to restrict blood flow. Filling the wrap after it has been fastened around the patient could cause constriction. Use care when fitting the components, specifically the head wrap to the forehead and neck.
7. When positioning the head wrap, do not cover ears with the product. Thermal injury may occur.
8. Do not place sharp objects in contact with the components or hoses as punctures may occur. Do not use pins to secure the components.
9. Do not place several layers of sheets or other materials that will reduce the heat transfer between the component and the patient. Conductive therapy effectiveness will be reduced if the components are not placed in direct contact with the patient.
10. The Kool-Kit® is intended for single patient use only. Reuse may result in biocontamination or cross-infection.
11. Do not use the device distal to arterial cross clamping. Non-observance can lead to thermal injury.
12. Do not use with a patient with an ischemic limb. Thermal injury may occur.

CAUTIONS:

1. Caution: Federal Law restricts the device to sale by or on the order of a licensed healthcare professional.
2. Presence of water or gel on the pad while the unit is not operating may cool the patient.
3. Use of unapproved equipment or hoses is not recommended. The Kool-Kit® has been designed and tested for use with CSZ Blanketrol® thermal regulating system.

INDICATIONS FOR USE

The Kool-Kit® is intended to be used by trained healthcare professionals as part of CSZ's thermal regulating systems, specifically the Blanketrol®. The Blanketrol® Hyper-Hypothermia Temperature Management System is used to lower or to raise a patient's temperature and/or maintain a desired patient temperature through conductive heat transfer.

CONTRAINDICATIONS

1. None Known.

SET UP

1. Check the reservoir in the hyper-hypothermia unit to ensure it is full of distilled water. Check Kit integrity prior to each use.
2. Attach male and female coupling from the Cat#286 hose to the unit. Make sure they "click" as they lock together.
3. Attach the Kit component to the Cat#286 hose by inserting the component connectors into the hose connectors. Connectors should "click" as they lock together.
4. Turn the unit on and select the desired temperature setting.
5. Position the patient on the Kit components.
6. After filling and positioning, make sure the Kit components and hoses are free of any kinks that may restrict water flow.

OPERATING INSTRUCTIONS

1. Follow the CSZ Blanketrol® operation manual for operating instructions.
2. To discontinue therapy: Turn off unit and allow the water to drain back into the reservoir. Hold the connector above the level of the pad and disconnect the pads from the connecting hoses. The connecting hoses have self-sealing fittings to prevent water leakage. Retain connecting hose for next use.

CLEANING

1. The Kool-Kit® is single patient use only. Discard the Kit according to hospital/institution protocol after each use. Do not reprocess or sterilize.

STORAGE

1. Store unused Kit in a cool, dry environment, free from items that may puncture the Kit components.