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Distributed By:

Gentherm Medical, LLC

12011 Mosteller Road,

Cincinnati, Ohio, U.S.A 45241

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www.Gentherm.com

REF 812-NS

Shoulder cold therapy pad

Size: 8 in X 12 in (20.32cm X 30.48cm)

TEMP-PAD Cold Therapy Pad

FOR LOCALIZED COLD THERAPY



Package Contains: 10pcs

Applications: Shoulder

INSTRUCTIONS FOR USE:

1. Read Operation Manual before connecting pad to unit.
2. Check reservoir in unit to ensure it uses sterile water or water that has been passed through a filter less than or equal to 0.22 microns only
3. Connect pad to unit by inserting connectors on hose to connectors on unit. Connectors should "click" as they lock together.
4. Position pad on patient with seal pattern toward patient skin. Attach pad to hose by inserting connectors on pad into hose connectors. Connectors should "click" as they lock together.
5. Turn unit ON, set temperature and select operating mode (if required) as prescribed by a physician.
6. After pad has filled, check water level in unit. Add sterile water or water that has been passed through a filter less than or equal to 0.22 microns if necessary.
7. When therapy needs to be paused, disconnect the pad from the Electric-Cool II and allow the unit to continue to run.
NOTE: Reconnect the pad when ready to resume therapy.
8. When therapy is no longer needed disconnect pad from hose by pressing metal clips. Dispose of pad.
9. Turn unit "OFF" at the power switch and unplug the power cord from the outlet.

INSTRUCTIONS FOR DISPOSAL:

1. Hold the connectors above the level of the pad and disconnect the pad from the connecting hose by pressing metal clips. The connecting hose has self-sealing fittings to prevent water leakage.
2. Discard the pad after use. RETAIN CONNECTING HOSE FOR NEXT USE.

INDICATIONS:

For localized temperature therapy.

CONTRAINDICATIONS

None Known.

WARNINGS:

1. Check the patient's temperature and skin condition, especially those areas in contact with the pad, at least every 20 minutes, or as directed by a physician. Patients vary in degree of sensitivity to cold, heat and pressure. Particular attention should focus on all bony prominences.
2. Do not wrap so tightly as to constrict blood flow. Do not use pins to secure pads or hoses. Do not allow pad or hoses to come into contact with sharp objects.
3. This disposable device is intended for single patient use only. Reuse may result in biocontamination or cross-infection.
4. Do not use the device distal to arterial cross clamping. Non-observance can lead to thermal injury.
5. Hazard of patient injury. Thermal injury may occur if heating/cooling therapy is applied to Ischemic limbs.

CAUTIONS:

1. Federal (USA) Law restricts this device to sale by or on the order of a physician.
2. Conductive pad therapy effectiveness will be reduced if the pad is not placed in direct contact with the patient. Do not place pad under OR pads, sheets or other objects that will reduce heat transfer.



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