

INFORMED CONSENT FOR COLD THERAPY MACHINE

Contraindications

Compression Therapy (vasopneumatic compression) using the Game Ready System or any compression therapy device should not be used in patients:

- Who are in the acute stages of inflammatory phlebitis in the affected region.
- Who have any history or risk factors for deep vein thrombosis or pulmonary embolus (including prolonged bed rest) in the affected region (to be treated with this therapy).
- Who have significant arteriosclerosis or other vascular ischemic disease in the affected region.
- Who have a condition in which increased venous or lymphatic return is not desired in the affected extremity (e.g., carcinoma).
- Who have decompensated hypertension in the affected region.

Cryotherapy using the Game Ready System or any cryotherapy device should not be used in patients:

- Who have significant vascular impairment in the affected region (e.g., from prior frostbite, diabetes, arteriosclerosis or ischemia).
- Who have acute paroxysmal cold hemoglobinuria or cryoglobulinemia.

Warnings

- Improper placement or prolonged use of the Game Ready System could result in tissue damage.
- During the course of therapy, patients should monitor the skin surrounding the treated region or the digits of the extremities of the treated limb for any burning, itching, increased swelling, or pain. If any of these signs present, or any changes in skin appearance occur (such as blisters, increased redness, discoloration, or other noticeable skin changes), patients are advised to discontinue use and consult a physician.
- Game Ready Wraps are not sterile; do not place directly against open wounds, sores, rashes, infections, or stitches. The Wrap may be applied over clothing or dressing.
- Game Ready Wraps are available in multiple configurations but are not intended for all possible physiologic uses. For example, the Ankle Wrap is not designed for use on the toes and the Back Wrap is not designed for use in the abdominal region.

Compression Therapy (vasopneumatic compression) with the Game Ready System should be used only under the supervision of a licensed healthcare practitioner in patients:

- Who have an open wound in the affected region (the wound must be dressed prior to use of Game Ready).
- Who have an acute, unstable (untreated) fracture in the affected region.
- Who are children under 18 years old or patients who have cognitive disabilities or communication barriers, whether temporary (due to medication) or permanent.
- Who have a cardiac insufficiency or congestive heart failure (with associated edema in the extremities or lungs).
- Who have a localized skin condition (e.g., dermatitis, vein ligation, gangrene, skin graft) in the affected region.
- Who have erysipelas or other active infection in the affected region.

Cryotherapy with the Game Ready System should be used only under the supervision of a licensed healthcare practitioner in patients:

- Who have Raynaud's disease or cold hypersensitivity (cold urticaria).
- Who have hypertension or extreme low blood pressure.
- Who have diabetes.
- Who have compromised local circulation or neurologic impairment (including paralysis or localized compromise due to multiple surgical procedures) in the affected region.
- Who have rheumatoid arthritis in the affected region.

- Who have a known and uncontrolled peptic ulcer since wraps confining and/or cooling the abdomen can cause increased gastrointestinal motility and gastric acid secretion.