**ANKLE USE GUIDE**

**ASSEMBLY**

The Heat Exchanger (PN 520330-03, 520340-03) fits inside the Sleeve (PN 510330, 510340) and comes as part of a pre-assembled Wrap (PN 590330-03, 590340-03). If the Heat Exchanger is removed to launder the Sleeve, or for any other reason, please use the following instructions to re-insert the Heat Exchanger into the Sleeve.

1. Place the Sleeve on a flat surface with logo side up, and determine the opening location.
2. Insert the Heat Exchanger into the Sleeve with the blue side down (The blue side of the Heat Exchanger should touch the blue side of the Sleeve).
3. Be sure the Heat Exchanger is flat inside the Sleeve with no folds or creases. Zip up the Sleeve, if applicable. After assembly, lay the blue side up and ensure the Heat Exchanger is uniformly laid out and smooth inside the Sleeve.

**REMOVAL OF HEAT EXCHANGER**

1. Disconnect the Connector Hose from the Wrap
2. Unzip the zipper
3. Gently pull out the Heat Exchanger

**STORAGE OF YOUR WRAP**

Hang your Wrap on a wide hanger or lay flat. Do not fold or stack it, as this could kink the fluid chamber and the Wrap will not work properly.

**SIZING SPECIFICATIONS**

- Size: Large, Extra Large
- Large fits U.S. men's shoe size 11 and under
- Extra Large fits U.S. men's shoe size 12–18

**WARNING**

It is mandatory to fully read and understand your System’s User Manual before using the device. Failure to follow operating instructions could result in serious injury.

**IMPORTANT**

Read complete indications, contraindications, cautions, and warning before using this product. Keep this document for future reference.
BEFORE INITIAL USE

Prime the Wrap using the following steps:

- With the GRPro 2.1 Control Unit off, attach the Connector Hose to the Control Unit and the Wrap
- Lay the Wrap open and flat next to the Control Unit (not on the body)
- Turn the System on and run for 2 minutes with No Pressure

- With the Med4 Elite Control Unit off, attach the Connector Hose to Patient 1 on Control Unit and the Wrap
- Lay the Wrap open and flat next to the Control Unit (not on the body)
- Press the On/Off button above the touchscreen
- Choose Patient 1 and run Cold Therapy with No Pressure for 2 minutes

ANKLE WRAP APPLICATION

Put the Ankle Wrap on by first placing it flat on the floor, placing the foot of the affected ankle as shown above. Wrap the the sides around the leg toward the front as shown above.

 Ensure that the Ankle Wrap has been applied uniformly against the foot and leg with a close and snug fit around the ankle.

Attach the Wrap to the Control Unit with the Connector Hose. There should be an audible “click”. To disconnect, simply press the blue or gray button and remove the connector from the Wrap.

NOTE: The same procedure applies to both the Large and Extra Large Wrap on either the Left or Right ankle.

GENERAL

IMPORTANT

READ THIS COMPLETE USE GUIDE AND GAME READY GRPRO 2.1 SYSTEM USER MANUAL AND/OR MED4 ELITE SYSTEM USER MANUAL INCLUDING INDICATIONS, CONTRAINDICATIONS, CAUTIONS AND WARNINGS BEFORE USING THIS PRODUCT!

WARNINGS

- Follow the recommendations of your health care practitioner regarding the frequency and duration of use.
- Improper placement or prolonged use of the Game Ready System or Med4 Elite 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. A layer between Wrap and skin is recommended for all patients.
- 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.
- To avoid potential damage to the Control Unit, do not use other manufacturers’ Wraps with the Control Unit.
- Use extra caution during the immediate postoperative period, especially when sedated or on any medication that could alter normal pain sensation. Check the skin of the treated region frequently and use mid-to-higher (warmer) temperature range settings or leave more time between treatments, if necessary.
- Monitor the level of heat throughout treatment session. Caution should be used with the Med4 Elite System or any thermotherapy (Heat Therapy) device generating high intensity heat at 113°F or above. Check the skin of the treated region frequently and use mid-to-lower (cooler) temperature range settings or leave more time between treatments, if necessary.
- The Med4 Elite System is not intended for use with numbing agents.
- When using heat and rapid contrast therapy, skin should be protected in heat-sensitive or high-risk patients, especially over regions with sensory deficits.
- Heating of the gonads should be avoided.

NOTES

Apply Wrap with a uniformly close fit, ensuring there are no kinks which may impede water flow. Ensure connector hose is placed to prevent the Wrap from folding or kinking at the hose inlet location of the Wrap.

CARE AND CLEANING

For daily care and to minimize formation of mildew, remove Heat Exchanger from Sleeve and wipe with dry towel to remove any condensation that may form. Turn Sleeve inside out and hang both the Sleeve and Heat Exchanger to release excess moisture. For multi-patient use, if needed, use Sterifab® according to manufacturer’s instructions to minimize microbe transfer.

For extended care, carefully remove the Heat Exchanger from the Sleeve and turn the Sleeve inside out. Hand or machine wash the Sleeve in cold water and mild detergent, or antibacterial soap. Hang to dry. Hand wash the Heat Exchanger with warm water and mild detergent, do not machine wash or place in a dryer. Hang to dry.

AVERAGE LIFE EXPECTANCY

The life expectancy of Sleeves and Heat Exchangers will vary widely depending on frequency of use. Please reference chart below to determine when to replace product.

**Sleeve**

- Light Use (Personal) .................................................. 12 months
- Medium Use ............................................................ 6 months
- Heavy Use (Clinic or training facility) .......................... 3 months

**Heat Exchanger**

- Light Use (Personal) .................................................. 24 months
- Medium Use ............................................................ 18 months
- Heavy Use (Clinic or training facility) .......................... 12 months

WARRANTY INFORMATION

**Sleeve:** In case of manufacturer defect, Sleeve may be returned within 7 days of purchase.

**Heat Exchanger:** 1 year from date of purchase. See warranty card included with Heat Exchanger.
### MED4 ELITE CONTRAINDICATIONS

<table>
<thead>
<tr>
<th>X = Absolute Contraindication –</th>
<th>R = Relative Contraindication –</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapy in these situations should <strong>not</strong> be used in patients who have:</td>
<td>Therapy for these conditions should be used only under the supervision of a licensed healthcare practitioner in patients who have:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>THERAPY MODE</th>
<th>Thermotherapy</th>
<th>Cryotherapy</th>
<th>Compression</th>
<th>Rapid Contrast</th>
</tr>
</thead>
</table>

- **Current clinical signs in the affected region of significant peripheral edema (e.g., deep vein thrombosis, chronic venous insufficiency, acute compartment syndrome, systemic venous hypertension, congestive heart failure, cirrhosis/liver failure, renal failure).**
  - Absolute Contraindication
  - X

- **Significant vascular impairment in the affected region (e.g., from prior frostbite, arteriosclerosis, arterial insufficiency, diabetes, vascular dysregulation, or other vascular ischemic disease).**
  - Absolute Contraindication
  - X

- **Known hematological dyscrasias that predispose to thrombosis (e.g., paroxysmal cold hemoglobinuria, cryoglobulinemia, sickle-cell disease, serum cold agglutinins).**
  - Relative Contraindication
  - R

- **Tissues inflamed as result of recent injury or exacerbation of chronic inflammatory condition.**
  - Relative Contraindication
  - R

- **Extremities with diffuse or focal impaired sensitivity to pain or temperature that prevent the patient from giving accurate and timely feedback.**
  - Relative Contraindication
  - R

- **Compromised local circulation or neurologic impairment (including paralysis or localized compromise due to multiple surgical procedures) in the affected region.**
  - Relative Contraindication
  - R

- **Cognition or communication impairments that prevent them from giving accurate and timely feedback.**
  - Relative Contraindication
  - R

- **An acute, unstable (untreated) fracture in the affected region.**
  - Absolute Contraindication
  - X

- **Local malignancy.**
  - Absolute Contraindication
  - X

- **Areas of skin breakdown or damage (damaged or at-risk skin) producing uneven heat conduction across the skin (e.g., open wound, scar tissue, burn or skin graft). Any open wound must be dressed prior to use of the Med4 Elite.**
  - Relative Contraindication
  - R

- **Actively bleeding tissue or hemorrhagic conditions.**
  - Relative Contraindication
  - R

- **Recently radiated tissues or areas affected by heat-sensitive skin diseases (e.g., eczema, psoriasis, vasculitis, dermatitis).**
  - Relative Contraindication
  - R

- **Localized unstable skin condition (e.g., dermatitis, vein ligation, gangrene, or recent skin graft) in the affected region.**
  - Relative Contraindication
  - R

- **Any active local or systemic infection.**
  - Relative Contraindication
  - R

- **Current clinical signs of inflammatory phlebitis, venous ulcers, or cellulitis.**
  - Absolute Contraindication
  - X

- **A pregnancy.**
  - Absolute Contraindication
  - X

- **Any significant risk factors or current clinical signs of embolism (e.g. pulmonary embolus, pulmonary edema, cerebral infraction, atrial fibrillation, endocarditis, myocardial infarction, or artheromatous embol plaque).**
  - Absolute Contraindication
  - X

- **A condition in which increased venous or lymphatic return is not desired in the affected extremity (e.g., lymppedema after breast cancer or other local carcinoma and/or carcinoma metastasis in the affected extremity).**
  - Relative Contraindication
  - R

- **Raynaud’s disease or cold hypersensitivity (cold urticaria).**
  - Relative Contraindication
  - R

- **Hypertension, Cardiac failure, extreme low blood pressure, or decompensated cardiac insufficiency.**
  - Relative Contraindication
  - R

- **Children under 18 years old**
  - Absolute Contraindication
  - X

- **Had recent toe surgery in the affected region.**
  - Relative Contraindication
  - R

- **Obtunded or with diabetes mellitus, multiple sclerosis, poor circulation, spinal cord injuries, and rheumatoid arthritis.**
  - Relative Contraindication
  - R

- **Decompensated hypertonia in the affected region.**
  - Relative Contraindication
  - R
## GRPRO 2.1 CONTRAINDICATIONS

<table>
<thead>
<tr>
<th><strong>X = Absolute Contraindication</strong> – Therapy in these situations should <strong>not</strong> be used in patients:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>R = Relative Contraindication</strong> – Therapy for these conditions should be used only under the supervision of a licensed healthcare practitioner in patients:</td>
</tr>
</tbody>
</table>

### Therapy Mode

<table>
<thead>
<tr>
<th>THERAPY</th>
<th>MODE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cryotherapy</td>
<td>Compression</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Situation</th>
<th>Therapy Mode</th>
</tr>
</thead>
<tbody>
<tr>
<td>Who are in the acute stages of inflammatory phlebitis in the affected region.</td>
<td>X</td>
</tr>
<tr>
<td>Who have any current clinical signs suggestive of deep vein thrombosis in the affected region.</td>
<td>X</td>
</tr>
<tr>
<td>Who have significant arteriosclerosis or other vascular ischemic disease in the affected region.</td>
<td>X</td>
</tr>
<tr>
<td>Who have any significant risk factors or current clinical signs of embolism (e.g. pulmonary embolus, cerebral infarction, atrial fibrillation, endocarditis, myocardial infarction, or atheromatous embolic plaque).</td>
<td>X</td>
</tr>
<tr>
<td>Who have a condition in which increased venous or lymphatic return is not desired in the affected extremity (e.g., carcinoma).</td>
<td>X</td>
</tr>
<tr>
<td>Who have decompensated hypertonia in the affected region.</td>
<td>X</td>
</tr>
<tr>
<td>Who have an open wound in the affected region (the wound must be dressed prior to use of Game Ready).</td>
<td>R</td>
</tr>
<tr>
<td>Who have an acute, unstable (untreated) fracture in the affected region.</td>
<td>R</td>
</tr>
<tr>
<td>Who are children under 18 years old or patients who have cognitive disabilities or communication barriers, whether temporary (due to medication) or permanent.</td>
<td>R</td>
</tr>
<tr>
<td>Who have a cardiac insufficiency or congestive heart failure (with associated edema in the extremities or lungs).</td>
<td>R</td>
</tr>
<tr>
<td>Who have a localized unstable skin condition (e.g., dermatitis, vein ligation, gangrene, or recent skin graft).</td>
<td>R</td>
</tr>
<tr>
<td>Who have erysipelas or other active infection in the affected region.</td>
<td>R</td>
</tr>
<tr>
<td>Who have significant vascular impairment in the affected region (e.g., from prior frostbite, diabetes, arteriosclerosis or ischemia).</td>
<td>X</td>
</tr>
<tr>
<td>Who have known hematological dyscrasias which affect thrombosis (e.g., paroxysmal cold hemoglobinuria, cryoglobulinemia, sickle-cell disease, serum cold agglutinins).</td>
<td>X</td>
</tr>
<tr>
<td>Who have Raynaud’s disease or cold hypersensitivity (cold urticaria).</td>
<td>R</td>
</tr>
<tr>
<td>Who have hypertension or extreme low blood pressure.</td>
<td>R</td>
</tr>
<tr>
<td>Who have diabetes.</td>
<td>R</td>
</tr>
<tr>
<td>Who have compromised local circulation or neurologic impairment (including paralysis or localized compromise due to multiple surgical procedures) in the affected region.</td>
<td>R</td>
</tr>
<tr>
<td>Who have rheumatoid arthritis in the affected region.</td>
<td>R</td>
</tr>
</tbody>
</table>

### CONTACT US

In the U.S. call Game Ready Customer Service at 1.888.426.3732 (+1.510.868.2100). From outside of the U.S. please refer to www.gameready.com to find your local distributor’s contact information.

A list of current patent(s) covering Game Ready technology can be found at: www.gameready.com/patents.

**Warning:** To comply with California Proposition 65, the following warning has been included: This product contains chemicals known to the State of California to cause cancer, birth defects or other reproductive harm.

Wrap (PN 590330-03, 590340-03) includes

Sleeve (PN 510330, 510340) & Heat Exchanger (PN 520330-03, 520340-03)