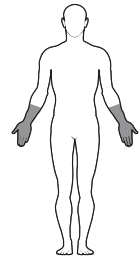




FOR USE WITH
**GAME READY
GRPRO® 2.1 SYSTEM**
MED4 ELITE™ SYSTEM



HAND/WRIST USE GUIDE

ENGLISH

SIZING SPECIFICATIONS

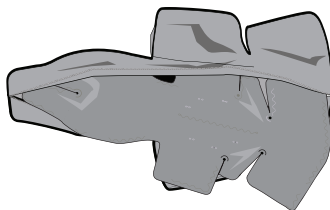
- Size: One Size
- Anatomic Orientation: Left, Right

ASSEMBLY

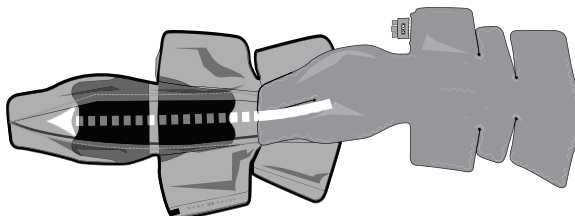
The Heat Exchanger (PN 520811-03) fits inside the Sleeve (PN 510811) and comes as part of a pre-assembled Wrap (PN 590811-03). If the Heat Exchanger is removed to launder the Sleeve, or for any other reason, please use the following instructions to re-insert the Heat Exchanger into the Sleeve.

- 1 Place sleeve on flat surface with logo side up and determine opening location.

- 2a To assemble the wrap so that the insulation is not being used, insert the heat exchanger into the sleeve with blue side down and thread the heat exchanger under just one or both of the foam insulating layers (blue side of heat exchanger should touch blue side of sleeve). The two upper tabs on each side of the heat exchangers fit together into the larger side sections of the sleeve.



- 2b To assemble the wrap so that the insulation is not being used, insert the heat exchanger into the sleeve with blue side down and thread the heat exchanger under just one or both of the foam insulating layers (blue side of heat exchanger should touch blue side of sleeve). The two upper tabs on each side of the heat exchangers fit together into the larger side sections of the sleeve.



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.

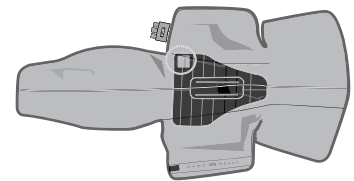


IMPORTANT

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

- 3 Be sure the heat exchanger is flat inside the sleeve with no folds or creases.

- 4 Once the heat exchanger is in place, position the base plate. There is a rectangle loop inside the sleeve between the zipper and 3-port connector which lines up with the hook on the base plate. Take the base plate with the hand support facing down, and align the top of the plate with the top of the center attachment wings. Press the hook fastener onto the loop inside the sleeve.



- 5 To lay the hand flat during therapy, the hand support can be removed by unfastening the hook and loop which secures it to the base plate. Do not remove the base plate; this should be used at all times for effective therapy.

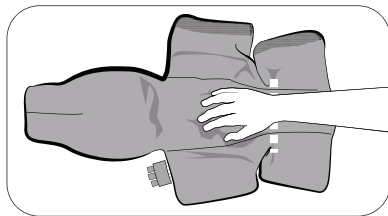
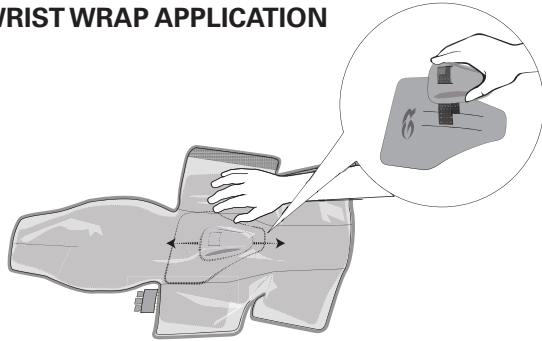
- 6 Close the zipper to complete assembly. Lay the blue side up and ensure the heat exchanger is uniformly laid out and smooth inside the sleeve.

BEFORE INITIAL USE

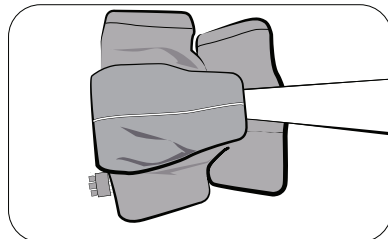
Prime the Wrap using the following steps:

- 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

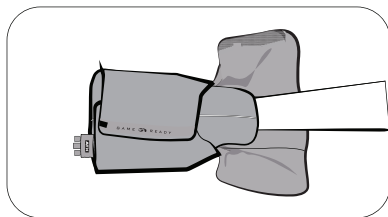
HAND/WRIST WRAP APPLICATION



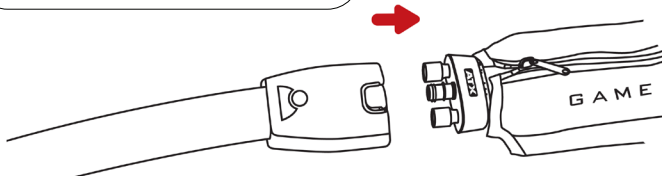
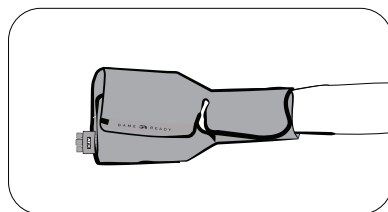
- 1 Place the affected hand/wrist palm down on the hand support as shown.



- 2 Fold the end of the wrap over the top of the hand ensuring a comfortable fit
- 3 Continue folding the side flaps over the hand, one at a time. Ensure that the wrap has been applied uniformly against the hand, wrist, and arm with a close and snug fit.



- 4 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.



GRPRO 2.1 CONTRAINDICATIONS



X = Absolute Contraindication – Therapy in these situations should **not** be used in patients:

R = Relative Contraindication – Therapy for these conditions should be used only under the supervision of a licensed healthcare practitioner in patients:

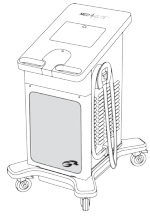
THERAPY MODE

Cryotherapy

Compression

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

MED4 ELITE CONTRAINDICATIONS



X = Absolute Contraindication –

Therapy in these situations should **not** be used in patients who have:

R = Relative Contraindication –

Therapy for these conditions should be used only under the supervision of a licensed healthcare practitioner in patients who have:

	THERAPY MODE			
	Thermotherapy	Cryotherapy	Compression	Rapid Contrast
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).	X	X	X	X
Significant vascular impairment in the affected region (e.g., from prior frostbite, arteriosclerosis, arterial insufficiency, diabetes, vascular dysregulation, or other vascular ischemic disease).	X	X	X	X
Known hematological dyscrasias that predispose to thrombosis (e.g., paroxysmal cold hemoglobinuria, cryoglobulinemia, sickle-cell disease, serum cold agglutinins).		X	R	X
Tissues inflamed as result of recent injury or exacerbation of chronic inflammatory condition.	X	R		X
Extremities with diffuse or focal impaired sensitivity to pain or temperature that prevent the patient from giving accurate and timely feedback.	X	R		X
Compromised local circulation or neurologic impairment (including paralysis or localized compromise due to multiple surgical procedures) in the affected region.	R	R	R	R
Cognition or communication impairments that prevent them from giving accurate and timely feedback.	X	R		X
An acute, unstable (untreated) fracture in the affected region.	X		R	X
Local malignancy.	X		R	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.	X	R	R	X
Actively bleeding tissue or hemorrhagic conditions.	X			X
Recently radiated tissues or areas affected by heat-sensitive skin diseases (e.g., eczema, psoriasis, vasculitis, dermatitis).	X			X
Localized unstable skin condition (e.g., dermatitis, vein ligation, gangrene, or recent skin graft) in the affected region.	R	R	R	R
Any active local or systemic infection.	X		X	X
Current clinical signs of inflammatory phlebitis, venous ulcers, or cellulitis.	R	X	X	X
A pregnancy.	X			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 arteromatous embolic plaque).		X	X	X
A condition in which increased venous or lymphatic return is not desired in the affected extremity (e.g., lymphedema after breast cancer or other local carcinoma and/or carcinoma metastasis in the affected extremity).		X	X	X
Raynaud's disease or cold hypersensitivity (cold urticaria).		X		X
Hypertension, Cardiac failure, extreme low blood pressure, or decompensated cardiac insufficiency.	R	R	X	R
Children under 18 years old	R	R	R	R
Had recent toe surgery in the affected region.		R	R	R
Obtunded or with diabetes mellitus, multiple sclerosis, poor circulation, spinal cord injuries, and rheumatoid arthritis.	R	R	X	R
Decompensated hypertonia in the affected region.		X		X

GENERAL



IMPORTANT

DO NOT SET THE GAME READY SYSTEM OR MED4 ELITE SYSTEM TO HIGH PRESSURE WHEN USING THE HAND/WRIST WRAP.

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

- **THIS WRAP PROVIDES AN OPTIONAL INSULATING LAYER. IF EXPERIENCING EXCESSIVE HEATING OR COOLING IN THE DIGITS, ENGAGE THE ADDITIONAL INSULATION AS NEEDED OR ADJUST THE CONTROL UNIT TEMPERATURE.**
- **FOLLOW RECOMMENDATION OF PHYSICIAN FOR APPROPRIATE USE OF INSULATING LAYER.**
- **NOT TO BE USED CONTINUOUSLY FOR GREATER THAN 15 MINUTES PER TREATMENT SESSION.**
- 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 of clothing 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.

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.



EMERGO EUROPE
Prinsessegracht 20
2514 AP The Hague
The Netherlands

 **COOLSYSTEMS®**, INC.
1800 Sutter Street, Suite 500
Concord, CA 94520 USA
1.888.GAMEREADEY +1.510.868.2100
www.gameready.com

©2017 CoolSystems, Inc. All Rights Reserved
Game Ready Dual Action Wrap Use Guide

Hand/Wrist Wrap PN 704581 Rev B

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.

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.



Symbol for "assembled in" a specific country (XXXX).



Symbol for "made in" a specific country (XXXX).

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 590811-03) includes Sleeve (PN 510811) & Heat Exchanger (PN 520811-03)

EMERGO AUSTRALIA
201 Sussex Street
Darling Park, Tower II, Level 20
Sydney NSW 2000
Australia