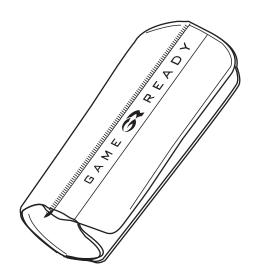


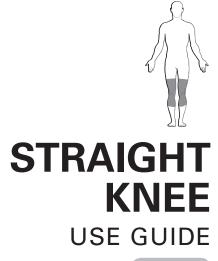
(XTA

FOR USE WITH

GAME READY GRPRO® 2.1 SYSTEM

MED4 ELITE™ SYSTEM





**ENGLISH** 

### SIZING SPECIFICATIONS

- Size: One Size
- Length: 17"
- Circumference (top): 32"
- Circumference (bottom): 24"

#### **ASSEMBLY**

The Heat Exchanger (PN 520100-03) fits inside the Sleeve (PN 510100) and comes as part of a pre-assembled Wrap (PN 590100-03). 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.



## **WARNING**

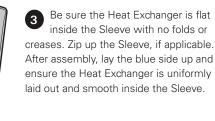
It is mandatory to fully read and understand your System's User Manual before using the device. Failure to follow operating instructions could result in serious injury.



## **IMPORTANT**

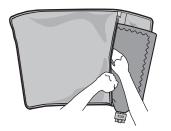
Read complete indications, contraindications, cautions, and warning before using this product. Keep this document for future reference.

Place the Sleeve on a flat surface with logo side up, and determine the opening location.





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).



## **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.

## **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

## STRAIGHT KNEEWRAP APPLICATION

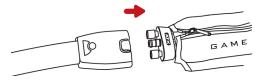


Put the Straight Knee Wrap on by first placing it behind the affected knee, wrapping the the sides around the leg toward the front as shown above.

2 Ensure that the Straight Knee Wrap has been applied uniformly against the leg and knee with a close and snug fit.



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.



## **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 heatsensitive 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**

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

## **GRPRO 2.1 CONTRAINDICATIONS**

2200	X = Absolute Contraindication — Therapy in these situations should <b>not</b> 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	e stages of inflammatory phlebitis in the affected region.		х	
Who have any currer the affected region.	nt clinical signs suggestive of deep vein thrombosis in		х	
Who have significant the affected region.	t arteriosclerosis or other vascular ischemic disease in		х	
(e.g. pulmonary emb	icant risk factors or current clinical signs of embolism polus, cerebral infarction, atrial fibrillation, endocarditis, , or atheromatous embolic plaque).		x	
	n in which increased venous or lymphatic return is not ed extremity (e.g., carcinoma).		x	
Who have decomper	nsated hypertonia in the affected region.		x	
Who have an open w	vound in the affected region (the wound must be of Game Ready).		R	
Who have an acute,	unstable (untreated) fracture in the affected region.		R	
	der 18 years old or patients who have cognitive unication barriers, whether temporary (due to anent.	R	R	
Who have a cardiac i	insufficiency or congestive heart failure (with associated nities or lungs).		R	
Who have a localized gangrene, or recent	d unstable skin condition (e.g., dermatitis, vein ligation, skin graft).	R	R	
Who have erysipelas	or other active infection in the affected region.		R	
_	t vascular impairment in the affected region (e.g., from tes, arteriosclerosis or ischemia).	х		
1	matological dyscrasias which affect thrombosis (e.g., noglobinuria, cryoglobulinemia, sickle-cell disease, ns).	x		
Who have Raynaud's	s disease or cold hypersensitivity (cold urticaria).	R		
Who have hypertens	ion or extreme low blood pressure.	R		
Who have diabetes.		R		
	ised local circulation or neurologic impairment (including compromise due to multiple surgical procedures) in the	R		
Who have rheumato	id arthritis in the affected region.	R		

# CONTACT US In the U.S. call Ga

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 590100-03) includes Sleeve (PN 510100) & Heat Exchanger (PN 520100-03)





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