

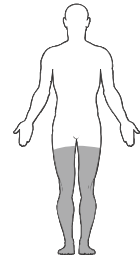
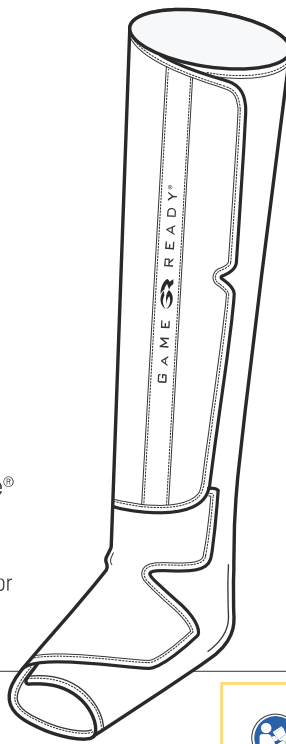


FOR USE WITH

GRPRO® 2.1 SYSTEM

MED4 ELITE® SYSTEM*

*The Full Leg Boot is not cleared for use with the Med4 Elite® in the United States. For countries that accept CE Marking, the use of the Full Leg Boot with the Med4 Elite may be permissible. Check with your local Game Ready distributor for usage details in your country or region.



FULL LEG BOOT USE GUIDE

ENGLISH

Rx ONLY

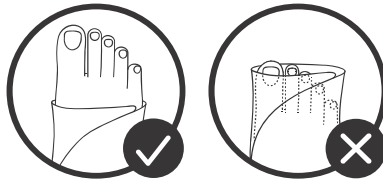
United States Federal Law restricts this device to sale by, or on the order of, a licensed health care practitioner.

SIZING SPECIFICATIONS

Size	Actual Wrap Length (Adjustment ranges)	Approximate In-Seam	Anatomical Orientation
M (Medium)	30–32"	27–33"	All sizes fit left or right leg
L (Large)	34.5–36.5"	33–37"	

BEST PRACTICES

- Keep the Control Unit (GRPro 2.1) on a table to prevent drainage from the Wrap.
- If you are using two Full Leg Boot wraps (one on each leg), we recommend using the Med4 Elite or two GRPro 2.1 Control Units to administer therapy. We do not suggest using the dual connector hose with the GRPro 2.1.
- Never cover the toes when applying the Full Leg Boot.



PRIMING THE WRAP

To prevent 04 errors at the beginning of therapy with the Full Leg Boot when used with the GRPro 2.1 Control Unit, it is important to prime (pre-fill) the Wrap before a therapy.

To prime the Wrap for use with the **GRPro 2.1 Control Unit**:

1. With the **GRPro 2.1 Control Unit** off, attach the Connector Hose to the Control Unit and the Wrap.
2. Lay the Wrap open and flat next to the Control Unit (not on the body).
3. Turn the System on and run a therapy with no compression. Pause after 45 seconds.
4. Disconnect the Full Leg Boot from the Control Unit so water remains in the Wrap. It is now ready for use.

NOTE: If you are priming the Full Leg Boot for the first time using the GRPro 2.1, you may encounter a **04 Error** 60 seconds after pressing play. If this occurs, power off the Control Unit by pressing the power button. Power it back on, and repeat the steps listed above.



WARNING

It is mandatory to fully read and understand the Game Ready GRPro 2.1 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.

GRPRO 2.1 INDICATIONS FOR USE

The Game Ready GRPro 2.1 System combines cold and compression therapies. It is intended to treat post-surgical and acute injuries to reduce edema, swelling, and pain for which cold and compression are indicated. It is intended to be used by or on the order of licensed healthcare professionals in hospitals, outpatient clinics, athletic training settings, or home settings.

MED4 ELITE INDICATIONS FOR USE

The Med4 Elite combines cold, heat, contrast, and compression therapies. It is intended to treat postsurgical and acute injuries to reduce edema, swelling and pain for which cold and compression are indicated. It is intended to treat post traumatic and post surgical medical and/or surgical conditions for which localized thermal therapy (hot or cold or contrast) are indicated.

After completing the previous steps, check the water level in the Control Unit. If necessary, add more water. Be careful not to overfill the Control Unit, and allow room for water to return from the Wrap after therapy. Check the User Manual of your Control Unit for more information on adding water.

If you do not plan to use the Full Leg Boot within the next 24 - 48 hours, allow the water to drain from the Wrap back into the Control Unit by leaving it connected to the Control Unit for 2 to 3 minutes. This will help prevent mildew from forming inside the Wrap and keep your Wrap performing as expected.

NOTE: It is not necessary to prime the wrap for use with the **Med4 Elite Control Unit**.

If water has been in the Wrap for more than one hour, we recommend pre-cooling/pre-heating the Wrap prior to running a therapy on a patient.

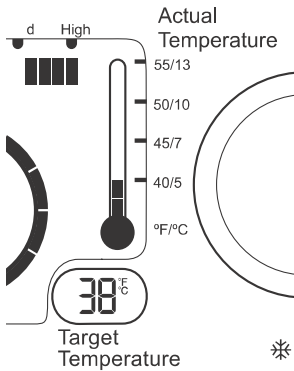
See *Pre-Cooling/Pre-Heating Your Wrap* for instructions on how to pre-cool/pre-heat the Full Leg Boot.

PRE-COOLING/PRE-HEATING YOUR WRAP

The Full Leg Boot is designed to deliver therapy over the entire leg and foot (except the toes). During a therapy, a large amount of water is being circulated through the Wrap. Pre-cooling/Pre-heating your Wrap will help to deliver the best therapy possible. From time to time, you may see the *actual* temperature deviate from the *target* temperature. This is normal.

PRE-COOLING YOUR WRAP WITH GRPRO 2.1

1. First, prime your Full Leg Boot. See *Priming the Wrap*.



2. With water in the Wrap, and the water level of your Control Unit at full, run a Cold Therapy with no compression for 5 minutes.

This will allow the temperature of the water in the Wrap to equalize with that of the water in the GRPro 2.1 reservoir.

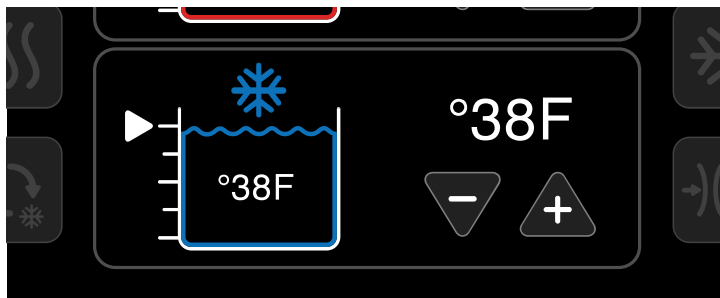
Run a therapy as desired. Refer to the User Manual of your Control Unit.

PRE-COOLING YOUR WRAP WITH MED4 ELITE

1. Run a Cold Therapy with no compression for 2 to 3 minutes.

2. Once the actual reservoir temperature is within 2 - 3 °F (1 - 2 °C) of the target temperature, the Wrap can be applied.

3. Stop the current therapy. Apply the Wrap.



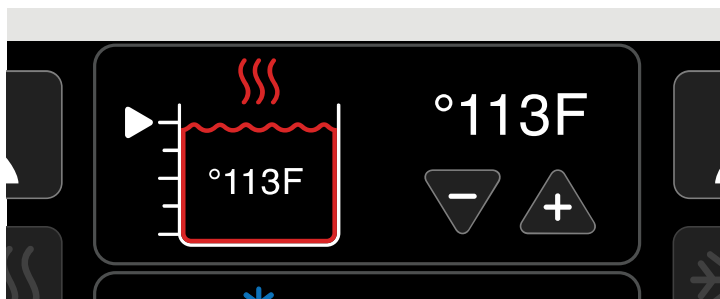
4. Run a therapy as desired. Refer to the User Manual of your Control Unit.

PRE-HEATING YOUR WRAP WITH MED4 ELITE

1. Run a Heat therapy with No Compression for 2 to 3 minutes.

2. Once the actual reservoir temperature is within 2 - 3 °F (1 - 2 °C) of the target temperature, the Wrap can be applied.

3. Stop the current therapy. Apply the Wrap.



4. Run a therapy as desired. Refer to the User Manual of your Control Unit.

NOTE: Never exceed the upper and lower markers when adjusting the boot. The top edge should always be between the shortest and longest in-seam markers.

ADJUSTING THE IN-SEAM LENGTH

The Full Leg Boot is designed to accommodate various in-seam lengths.

The Wrap comes ready to use with the standard length. If needed, you may adjust the length to be either longer or shorter by following the steps below.



Align top edge of boot to this line to lengthen the in-seam length.



Align top edge of boot to this line to shorten the in-seam length.

TO LENGTHEN THE WRAP (LONGER IN-SEAM)

1. Detach the hook & loop of the boot section of the Wrap so that the entire Wrap lays flat on the floor or table

2. Fold the boot section over so that the top edge aligns with the lower marker (see icon at left). This will add approximately 1" to the standard in-seam length.

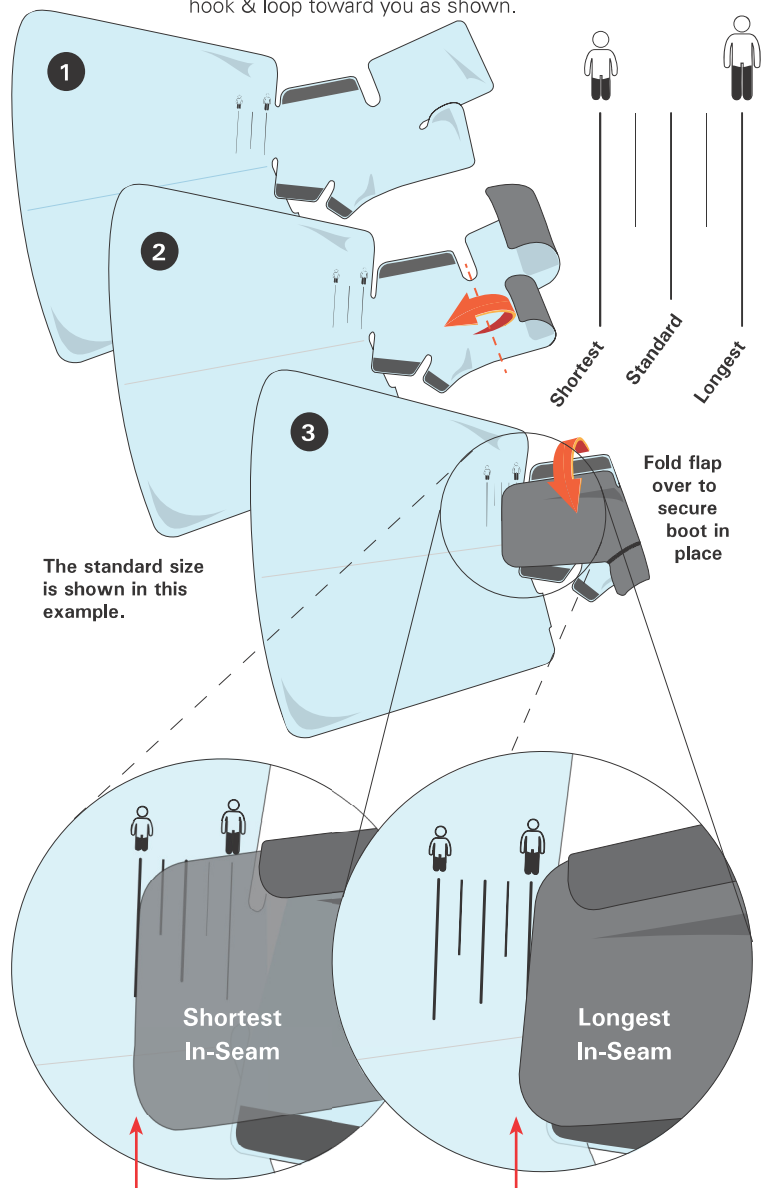
3. Secure the boot in place by folding the top piece of hook & loop toward you as shown.

TO SHORTEN THE WRAP (SHORTER IN-SEAM)

1. Detach the hook & loop of the boot section of the Wrap so that the entire Wrap lays flat on the floor or table.

2. Fold the boot section over so that the top edge aligns with the upper marker (see icon at left). This will subtract approximately 1" from the standard in-seam length.

3. Secure the boot in place by folding the top piece of hook & loop toward you as shown.



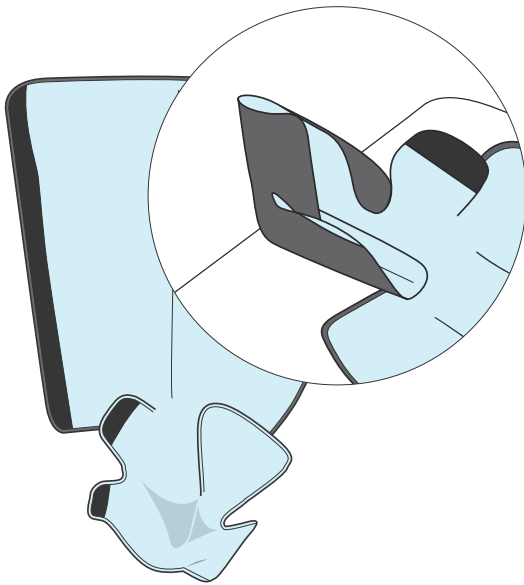
FULL LEG BOOT WRAP APPLICATION

Application of the Full Leg Boot should always be performed with the assistance of a second person. To prevent injury, never attempt to apply the Wrap to yourself.

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

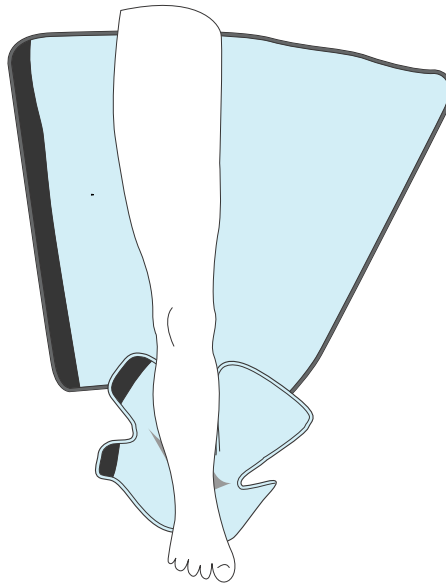
NOTE: Always have the Wrap applied while either sitting or lying down with your legs straight.

The Full Leg Boot may be applied to either the left or right leg.

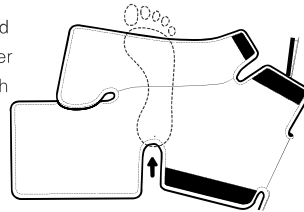


- 1** Place the Full Leg Boot flat on the floor or on a therapy table.

The Full Leg Boot ships with the boot section already formed.

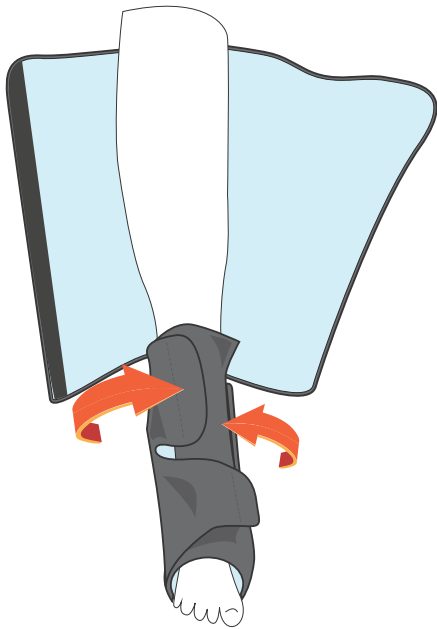


- 2** Place the affected foot into the lower section of the boot with the heel in the designated area.

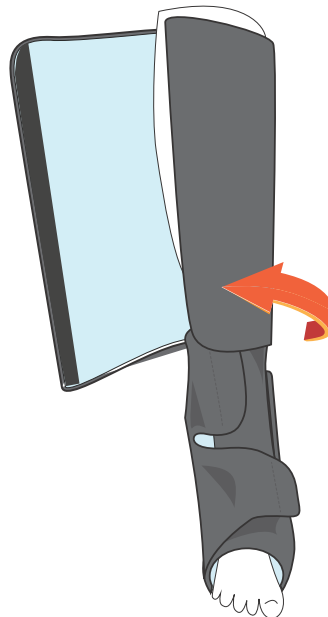


- 3** Fold the wrap across the top of the foot and secure on the opposite side of the foot.

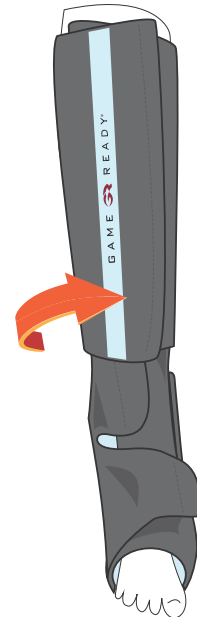
NOTE: Never cover the toes when applying the Full Leg Boot.



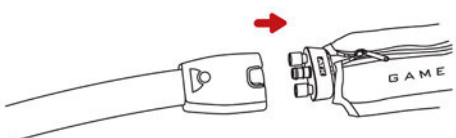
- 4** Fold the wrap around the ankle and secure on the opposite side of the leg.



- 5** Fold the loop side across the top of the leg, ensuring there are no wrinkles in the fabric and that it's tight against the leg.



- 6** Fold the hook side across the top of the leg in the other direction, ensuring there are no wrinkles in the fabric and that the wrap is tight against the leg.



- 7** 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.

- 8** To remove the Wrap, unhook the leg portion first, then unhook the foot portion. Set the Wrap away from the body.

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.
- Do not cover the toes with the Full Leg Boot.

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.

GRPRO 2.1 CONTRAINDICATIONS

	THERAPY MODE	
	Cryotherapy	Compression
 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:		
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) in the affected region.	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:

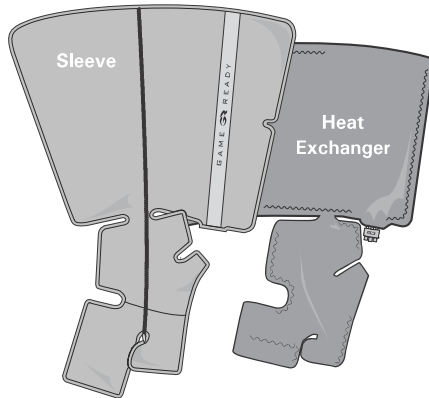
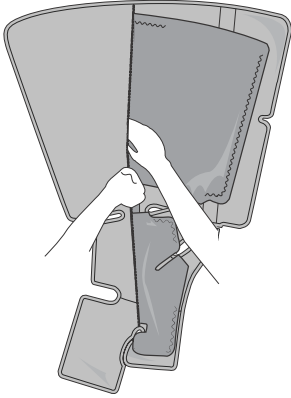
R = Relative Contraindication –
Therapy for these conditions should be used only under the supervision of a licensed healthcare practitioner in patients who have:

	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

ASSEMBLY

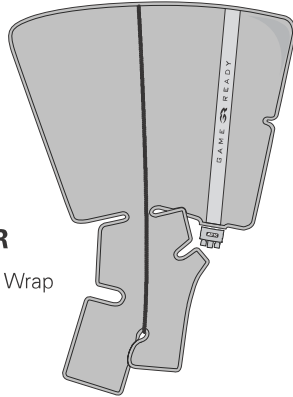
The Heat Exchanger (PNs 520922-03, 520923-03) fits inside the Sleeve (PNs 510922, 510923) and comes as part of a pre-assembled Wrap (PNs 590922-03, 590923-03). If the Heat Exchanger is removed to launder the Sleeve, or for any other reason, please use the following instructions to re-insert the Heat 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 remove the Heat Exchanger

CARE AND CLEANING

DAILY

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**, or as needed, use Sterifab® on the blue side of sleeve according to manufacturer's instructions to minimize microbe transfer.

EXTENDED CARE

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.

STORAGE

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.



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Game Ready Dual Action Wrap Use Guide

Full Leg Boot Wrap PN 705283 Rev D

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 can expose you to chemicals including cadmium, chromium, lead, polybrominated biphenyls, or mercury, which are known to the State of California to cause cancer or reproductive toxicity. For more information go to www.prop65warnings.ca.gov.

Wrap (PNs 590922-03, 590923-03) includes Sleeve (PNs 510922, 510923) & Heat Exchanger (PNs 520922-03, 520923-03)

The Full Leg Boot Use Guide may be updated from time to time. The most current version of the Use Guide can be found online in various languages at www.gameready.com.

If you require a paper copy of this manual, contact Game Ready Customer Service at 1.888.426.3732. International customers contact your local distributor.

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www.gameready.com

Dieses Betriebsbuch ist in verschiedenen Sprachen online unter www.gameready.com verfügbar

Este Manual del usuario está disponible en www.gameready.com en distintos idiomas

可前往在线获得本用户手册的多种语言版本
www.gameready.com

Denne brugervejledning kan findes online på forskellige sprog på www.gameready.com

Deze Gebruikershandleiding is online beschikbaar in verschillende talen op www.gameready.com

Tämä käyttöopas löytyy netistä eri kielillä: www.gameready.com

On peut trouver ce manuel de l'utilisateur dans plusieurs langues en ligne à www.gameready.com

Μπορείτε να βρείτε αυτό το Εγχειρίδιο Χρήσης σε ηλεκτρονική μορφή σε διάφορες γλώσσες στη διεύθυνση: www.gameready.com

אתאב תונוש תופשב שמתשמל הזה ירירדמה תא אוצמל ותינ www.gameready.com

Questo Manuale per l'utente è disponibile online in varie lingue su www.gameready.com

本ユーザー・マニュアルは、www.gameready.com
へ行けば様々な言語でオンライン閲覧できます。

www.gameready.com
에 가시면 이 사용자 설명서를 온라인에서 다양한 언어로 찾아보실 수 있습니다.

Niniejszą Instrukcję obsługi można znaleźć w internecie w różnych językach na stronie www.gameready.com

Este Manual do Usuário pode ser encontrado online em vários idiomas em www.gameready.com

Данную инструкцию по применению, а также ее переводы на различные языки, можно найти на веб-сайте www.gameready.com

Denna användarhandbok finns tillgänglig på olika språk på nätet via www.gameready.com

Bu Kullanıcı Kılavuzu, değişik dillerde çevrimiçi olarak www.gameready.com adresinde bulunmaktadır

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