

VitalWraps



Users Manual

Thank you for purchasing a new VitalWrap® to go with your VitalWear® System. Your new VitalWrap® will work with your VitalWear® System to address specific therapy needs for specific locations on your body.

Please read this instruction manual completely prior to using the unit to ensure reliable and safe operation.

VitalWrap Introduction	2
Available VitalWraps for Your System	3
Warranty	4
System Operation	5
Notes, Cautions And Warnings	6
Safety Symbols And Warnings	7
Indications & Contraindications	9
Operating Instructions	11
Wrapping Body Parts	12
Tubing Set Instructions for Use	18
Cleaning The Wraps	19
Storage	19
Notes	20

A significant number of Americans suffer from some type of persistent or recurrent acute pain sufficient to significantly impact their lives. The VitalWear Systems have a patent pending technology that applies a unique combination of cooling, heating and compression to the human body, providing a range of key benefits:

- Combination of compression and thermal therapy to the affected body part at any desired temperature between 40°F and 105°F,
- Compression via a proprietary VitalWrap[™] providing for greater fluid management in the injured area,
- Continuous thermal therapy to minimize tissue damage and scarring, to reduce pain and discomfort, and to reduce dependency on pain medication,
- Variable and rapidly changeable temperature control allows for extended application minimizing the risk of skin/nerve damage and for uniquely beneficial treatments such as cryotherapy,
- Safe and effective for both the professional practitioner and individual user,
- A portable injury therapy system that is affordable, easy to use at a clinic, home
 or at work,
- Universal personal wraps convenient, familiar, and easy to apply to the body, conforming comfortably to the major joints and muscles,
- Applications cover treatment of chronic pain or injury of back, knee, hip, foot and ankle, hand and wrist, shoulder, elbow, chest, breast, face and jaw, head, neck, and other specific applications.

Designed to help reduce pain and swelling, the VitalWear cooling, heating and compression therapy system can be used from the earliest stages of post-operative recovery, through rehabilitation, to postrecovery home use for treatment of pain and residual swelling.

Available VitalWraps for Your VitalWear® System

10	VIT-00001 Assembly, VitalWrap, 6x60" width	The state of the s	VIT-00397 Assembly, VitalWrap, Medium Knee
A	VIT-00255 Assembly, VitalWrap, 4x48" width		VIT-00393 Assembly, VitalWrap, Ankle
	VIT-00118 Assembly, VitalWrap, 8x72" width		Alike
	VIT-00119 Assembly, VitalWrap, Shoulder	7	VIT-00394 Assembly, VitalWrap, Wrist
6	VIT-00122 Assembly, VitalWrap, Cervical	1	VIT-00395 Assembly, VitalWrap, Large Shoulder
	VIT-00392 Assembly, VitalWrap, Large Knee		VIT-00396 Assembly, VitalWrap, Dual Hand

Please contact us to find out about the latest VitalWraps that may be right for you.

3

Warranty

VitalWear, Inc. guarantees this product free from defects in material and workmanship for a period of 1 year from the date of purchase except as noted below. This warranty extends only to the original retail purchaser.

This VitalWear product warranty does not cover damage caused by misuse or abuse; accident; the attachment of any unauthorized accessory; alteration to the product; or any other conditions whatsoever that are beyond the control of VitalWear. VitalWear shall not be responsible for any type of incidental, consequential or special damages. All implied warranties, including but not limited to those implied warranties of fitness and merchantability, are limited in total duration of 1 year from the original purchase date.

To obtain warranty service on your VitalWear System, either hand deliver or mail the unit and your dated sales receipt (as proof of purchase), postpaid, along with a certified check or money order in the amount of \$5.00 payable to VitalWear, Inc. (384 Oyster Point Blvd., Suite 16, South San Francisco, CA 94080-6523) to cover handling. Be sure to include the serial number of your unit and your phone number on any correspondence.

Upon receipt, VitalWear will repair or replace, as appropriate, your VitalWear System and return it to you, postpaid. Warranty is solely through VitalWear Service Center. Service of this product by anyone other than VitalWear Service Center voids warranty.

This warranty provides you with specific legal rights. You may have additional rights, which may vary from state to state. Because of individual state regulations, some of the above limitations and exclusions may not apply to you.

System Operation

The VitalWear System is comprised of a control unit, a tubing set and a thermal wrap. This VitalWrap is the part of the system that you actually apply to the body to provide thermal and compression therapy. Different wraps can be applied to specific areas of the body.

Setting up the system is a simple three-step process. (1) The user first fills the portable, leak-proof container of the control unit with ice and water, (2) then applies the VitalWrap around the injured area and secures it with its Velcro™ closure, and (3) finally, attaches the control unit to the wrap via the tubing set.

Once the control unit is turned on, cooled or warmed fluid is passed through the tubing set from the control unit to the wrap. The fluid is then circulated through the wrap, drawing heat from or applying to the body and deeply cooling or heating the body part. The fluid is then passed back through the tubing set to the control unit where it is re-cooled or re-warmed and then re-circulated back to the wrap.

When using this system, please check the skin where the wrap is applied periodically. Discontinue use if continued numbness and skin discoloration are present. Please refer to your health care professional prior to applying this system and/or using the system for extended periods of time.

The benefit of compression can continue even if the user chooses to disconnect the tubing set from either the control unit or the wrap.

5

A

Notes, Cautions And Warnings

Notes, cautions and warnings are used to highlight certain operating procedures and recommendations. A Note indicates a special procedure, an exception to normal operation or something else of specific interest to the reader. Notes are preceded by the word "Note" in italics.



Caution or Warning symbol precedes an operational step that could damage the instrument if the user does not take certain precautions. Cautions or Warnings are located in the main text, are preceded by a Caution or Warning statement and are accompanied by this symbol in the left margin.



Caution: risk of electric shock.

Important Safety Instructions

Read all instructions before using.

This equipment has been tested and found to comply with the limits for medical devices to the IEC 60601-1.

Follow local governing ordinances and recycling plans regarding disposal or recycling of device components.

Grounding reliability can only be achieved when the equipment is connected to an equivalent receptacle marked 'hospital only' or 'hospital grade'.

When using an electrical appliance, especially when children are present, basic safety precautions should always be followed.

Safety Symbols And Warnings



DANGER -To reduce the risk of electric shock:

- 1. Always unplug this appliance from the electrical outlet immediately after using and before cleaning.
- 2. DO NOT use while bathing or in a shower
- DO NOT place or store appliance where it can fall or be pulled into a tub or sink. DO NOT place in or drop into water or other liquid.
- 4. DO NOT reach for a product that has fallen into water. Unplug immediately.



An appliance should never be left unattended when plugged in. Unplug from outlet when not in use, and before putting on or taking off parts.



Close supervision is necessary when this appliance is used by, on, or near children, invalids, or disabled persons. This appliance should not be used by or on children without parental supervision.



Use this appliance only for its intended use as described in this manual. DO NOT use attachments not recommended by the manufacturer.



Never operate this appliance if it has a damaged cord or plug, if it is not working properly, if it has been dropped or damaged, or dropped into water.

7

- 1. Ensure the top of the appliance is properly installed and the handle is fully engaged prior to carrying the appliance.
- 2. DO NOT carry this appliance by supply cord or use cord as a handle.
- 3. Keep the cord away from heated surfaces.
- 4. Never operate the appliance without the Fluid Canister, the Top Assembly, the Tube set, and the Wrap completely connected.
- 5. Never operate the appliance with any foreign objects in the Fluid Canister.
- 6. Never drop or insert any object into any opening.
- 7. To disconnect, turn off power ("O" position), then remove plug from outlet.
- 8. Use cooling surfaces carefully. Do not use over insensitive skin areas or in the presence of poor circulation. The unattended use of cooling by children or incapacitated persons may be dangerous. Consult your physician.
- 9. DO NOT stand on or in the appliance.
- 10. Do not use while sleeping or drowsy.
- 11. Do not place the appliance or operate the appliance while it is on a surface more than 3 feet above the floor.
- 12. Unplug this product before filling. Fill with water and ice only. Do not overfill.
- 13. Do not operate without water.
- 14. Do not operate with hot water.
- 15. Do not place the Tubing set, Power cord or use any wrap other than the Cervical (neck) wrap around the neck.

VitalWear does not have an authorized service center. However, if this appliance is still under warranty, return it to the VitalWear Consumer Service Department at 1.800.553.4081.



Please refer to VitalWear for proper disposable of this product.

Indications & Contraindications

General Indications for Cold Therapy

There are general indications for using cold therapy across the body and in various situations:

- First aid after trauma,
- Relief of pain,
- Fever reduction,
- · Control of bleeding,
- Prevention or reduction of swelling of traumatic origin,
- Prevention or reduction of inflammation,
- · Decrease of muscle guarding and spasm,
- Temporary reduction of spasticity.

Cold is preferred during treatment of acute injury, sub-acute injury where swelling persists, and acute stages of inflammation.

General Indications for Heat Therapy

There are general indications for using heat therapy across the body and in various situations:

- Pain relief.
- · Reduction of muscle spasm,
- Increase of local blood flow,
- Facilitate tissue healing,
- Prepare stiff joints and muscle for exercise.

Contraindications for Cold Therapy

Users should be aware of situations where cold therapy may not be appropriate, detrimental to a specific condition or otherwise contraindicated for use:

- Users with specific cold sensitivity symptoms such as:
- Cold uticaria,
- Cryoglobulinemia,
- Raynaud's syndrome,
- Proximal cold hemoglobinuria,
- Vasospastic disease,
- Cold hypersensitivity,
- Peripheral neuropathy (as in some cases in diabetes),
- Compromised local circulation.

Users should take caution in applying cold therapy over open sores and abrasions. At a minimum these areas should be cleaned and bandaged.

When using this system, please check the skin where the wrap is applied periodically. Discontinue use if continued numbness and skin discoloration are present. Please refer to your health care professional prior to applying this system and/or using the system for extended periods of time.

Contraindications for Heat Therapy

Users should be aware of situations where heat therapy may not be appropriate, detrimental to a specific condition or otherwise contraindicated for use:

- Application over area that lack thermal sensation,
- Application over areas affected by vascular insufficiency or disease,
- Application over areas of recent hemorrhage or potential hemorrhage,
- Application over areas of known malignancy,
- Application over areas of acute inflammation,
- Application over areas of infection,
- Application over areas where liniments or heat rubs have been recently applied,
- Application over areas of significant swelling.

Users should take caution in applying heat therapy over open sores and abrasions. At a minimum these areas should be cleaned and bandaged. Areas subject to infection should not be exposed to heat therapy.

Note: Thermal therapy should not be used for persons with Raynaud's or other vasospastic disease, cold hypersensitivity, heat hypersensitivity, peripheral neuropathy (as in some cases of diabetes) or compromised local circulation.

General Indications for Compression

There are general indications for using compression across the body and in various situations:

- Edema/lymphedema,
- Venous insufficiency,
- Post sclerotherapy,
- Venous ulcers,
- Thrombophlebitis.

Contraindications for Compression

Users should be aware of situations where compression may not be appropriate, detrimental to a specific condition or otherwise contraindicated for use:

- Arterial occlusive disease,
- Any circumstance where increased venous return is desired.

Note: When operating, the VitalWrap will apply additional compression as the fluid bladder inflates. Adjust the compression of your VitalWrap so that it is comfortable. Users should be aware of situations where compression may not be appropriate, detrimental or otherwise contraindicated for use.

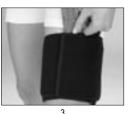
Consult your physician. Not all treatments are appropriate in every patient, and you should have a discussion with your doctor to determine which treatments are appropriate for your condition.

Operating Instructions

Please refer to your VitalWear System Manual for Setting Up and Operating your VitalWear System.





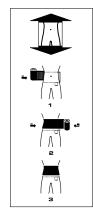


- Roll it: Begin with the wrap in a tight roll, with the tubeset connector on the outside of the roll.
- 2. Start Wrapping: Place the bladder portion of the wrap around the treatment
- Secure it: Finish wrapping using the Velcro closure. Connect the wrap to the tubeset by aligning the Orientation Dots as shown. Press both buttons on the tubeset connector to connect and disconnect (_____).

Once wrapped, please refer to your VitalWear System Manual for Operating your VitalWear System.

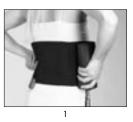
Wrapping Body Parts

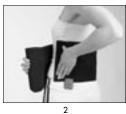
The 6" VitalWrap included with your system can be applied to the calf, knee, hamstring/thigh, hip, upper and lower back, abdomen, and chest. Please contact VitalWear for additional VitalWraps for the shoulder, elbow, hand/wrist, foot/ankle, sports bra, face, head, jaw and neck and athletic support.



BACK, VIT00001 - 6in VitalWrap or VIT00118 - 8in VitalWrap

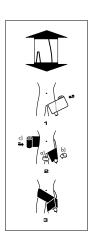
Roll it: Begin with the wrap in a tight roll, with the tubeset connector on the outside of the roll (see page 11, image 1-"Operating Instructions").







- 1. Start Wrapping: Place the bladder portion of the wrap around the treatment area.
- 2. Wrap it: Continue to wrap snugly around the waist.
- 3. Secure it: Finish wrapping using the Velcro closure. Connect the wrap to the tubeset by aligning the Orientation Dots as shown. Press both buttons on the tubeset connector to connect and disconnect ().



HIP, VIT00001 - 6in VitalWrap

Roll it: Begin with the wrap in a tight roll, with the tubeset connector on the outside of the roll (see page 11, image 1-"Operating Instructions").



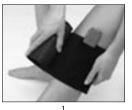




- 1. Start Wrapping: Place the bladder portion of the wrap around the treatment area.
- 2. Wrap it: Continue to wrap snugly around the hip.
- 3. Secure it: Finish wrapping using the Velcro closure. Connect the wrap to the tubeset by aligning the Orientation Dots as shown. Press both buttons on the tubeset connector to connect and disconnect ().

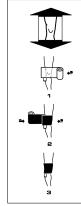
KNEE, VIT00001 - 6in VitalWrap

Roll it: Begin with the wrap in a tight roll, with the tubeset connector on the outside of the roll (see page 11, image 1-"Operating Instructions").









- 1. Start Wrapping: Place the bladder portion of the wrap around the knee.
- 2. Wrap it: Continue to wrap snugly around the knee.
- 3. Secure it: Finish wrapping using the Velcro closure. Connect the wrap to the tubeset by aligning the Orientation Dots as shown. Press both buttons on the tubeset connector to connect and disconnect ().

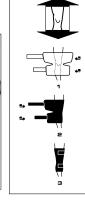
KNEE, VIT00392 (Large) & VIT00397 (Medium) Knee VitalWrap

Unfold it: Begin by unfolding the wrap and detaching all the Velcro straps.

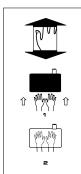








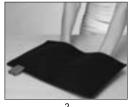
- Start Wrapping: Place the center of the wrap onto the knee with the tubeset connector pointing down the leg. Make sure the bladder portion of the wrap is facing down and is on top of the knee.
- 2. Wrap it: Continue to wrap the top and bottom portion snugly around the knee.
- Secure it: Finish wrapping using the Velcro closure. Connect the wrap to the tubeset by aligning the Orientation Dots as shown. Press both buttons on the tubeset connector to connect and disconnect ().



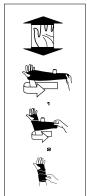
HAND, VIT00396 - Dual Hand VitalWrap

Place it: Begin by placing the wrap on a flat surface. Make sure the tubeset is on the right side of the wrap pointing away from user.





- Wrap it: Place hands inside the wrap after connecting the wrap to the tubeset by aligning the Orientation Dots as shown. Press both buttons on the tubeset connector to connect and disconnect ().
- 2. Secure it: Adjust temperature of wrap or adjust positions to optimize comfort and pain relief.



WRIST, VIT00394 - Wrist VitalWrap

Loop it: Begin by unfolding your wrist wrap.







- 1. Start Wrapping: Put thumb through loop and hang the wrap off the palm of the hand. Make sure the tubeset connector points towards user.
- 2. Wrap it: Continue to wrap snugly around the wrist.
- 3. Secure it: Finish wrapping using the Velcro closure. Connect the wrap to the tubeset by aligning the Orientation Dots as shown. Press both buttons on the tubeset connector to connect and disconnect ().

SHOULDER, VIT00119 (Medium) & VIT00395 (Large) Shoulder VitalWrap

Slip it on: Begin by sliding arm through the wrap with the connector facing down towards the elbow.









- 1. Adjust the underarm strap so that the wrap fits snugly.
- 2. Adjust chest strap. It may be necessary to adjust back strap before using wrap.
- Finish wrapping by attaching Velcro closure under opposite shoulder. Connect
 the wrap to the tubeset by aligning the Orientation Dots as shown. Press both
 buttons on the tubeset connector to connect and disconnect ().

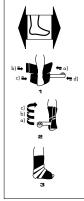
FOOT/ANKLE, VIT00393 - Foot & Ankle VitalWrap

Unfold it: Begin by unfolding the wrap and detaching all the Velcro straps.









- Start Wrapping: Place foot inside the wrap with the connector pointing up towards the knee.
- 2. Wrap it: Continue to wrap the top and bottom portion snugly around the ankle and foot.
- 3. Secure it: Finish wrapping using the Velcro closure. Connect the wrap to the tubeset by aligning the Orientation Dots as shown. Press both buttons on the tubeset connector to connect and disconnect ().

CHEST, VIT00118 - 8in VitalWrap

Roll it: Begin with the wrap in a tight roll, with the tubeset connector on the outside of the roll.







- 1. Wrap it: Place the bladder portion of the wrap around the treatment area, continue to wrap snugly around the chest.
- Secure it: Finish wrapping using the Velcro closure. Connect the wrap to the tubeset by aligning the Orientation Dots as shown. Press both buttons on the tubeset connector to connect and disconnect ().

ARM, VIT00255 - 4in VitalWrap

Loop it: Begin by creating a comfortable loop with the Velcro closure on the end of the wrap closest to the connector.







- 1. Start Wrapping: Put arm through loop of the wrap and slide onto lower part of arm.
- 2. Wrap it: Continue to wrap snugly around the arm.
- Secure it: Finish wrapping using the Velcro closure. Connect the wrap to the tubeset by aligning the Orientation Dots as shown. Press both buttons on the tubeset connector to connect and disconnect (______).

NECK, VIT00122 - Cervical VitalWrap

Slip it On: Place bladder portion of the wrap around the back neck. Make sure the tubeset is on the user's right side.

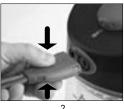


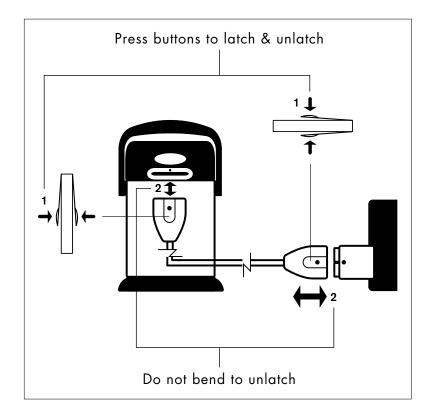


- 1. Wrap it: Continue to wrap snugly around the neck.
- Secure it: Finish wrapping using the Velcro closure. Connect the wrap to the tubeset by aligning the Orientation Dots as shown. Press both buttons on the tubeset connector to connect and disconnect ().

Tubing Set Instructions for Use







- 1. Press BOTH buttons on the Tubeset connector to connect & disconnect.
- $\begin{tabular}{ll} 2. Connect the Tubeset to the Fluid Connector located on the Top Assembly and VitalWrap. \end{tabular}$

Cleaning The Wrap

The VitalWrap can be washed in a conventional laundry machine. Notice the following cleaning instructions on the VitalWrap.

- Y	Machine Wash Cold	Ø	Do Not Iron
<u></u>	Delicate/Gentle Cycle	Ø	Do Not Dry Clean
*	Do Not Bleach	₩	Do Not Wring
	Line Dry In Shade		

Storage

Dry it Out: If wet, allow the wrap to line dry prior to storage.

Roll it Up: Roll or fold the wrap for storage.

Use the Carrying Bag: The VitalWear System and VitalWraps can be conviniently stored in the Carrying Bag.

Notes:	



VitalWear, Inc.
384 Oyster Point Blvd.
Suite 16
South San Francisco, CA 94080-1968
www.vitalwrap.com
1.800.553.4081