

User's Manual



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Introduction

The Breg VPULSE® provides a unique combination of preventative and rehabilitative therapies:

- Intermittent sequential compression therapy to help prevent hospital-acquired venous thromboembolism.
- Intermittent dynamic compression therapy to help reduce swelling.
- Controlled cold therapy to reduce discomfort and swelling.

Designed to provide a continuity of care from the hospital, surgery center, and clinic to self-treatment at home, the VPULSE helps patients comply with post-operative instructions.

Contents of Package

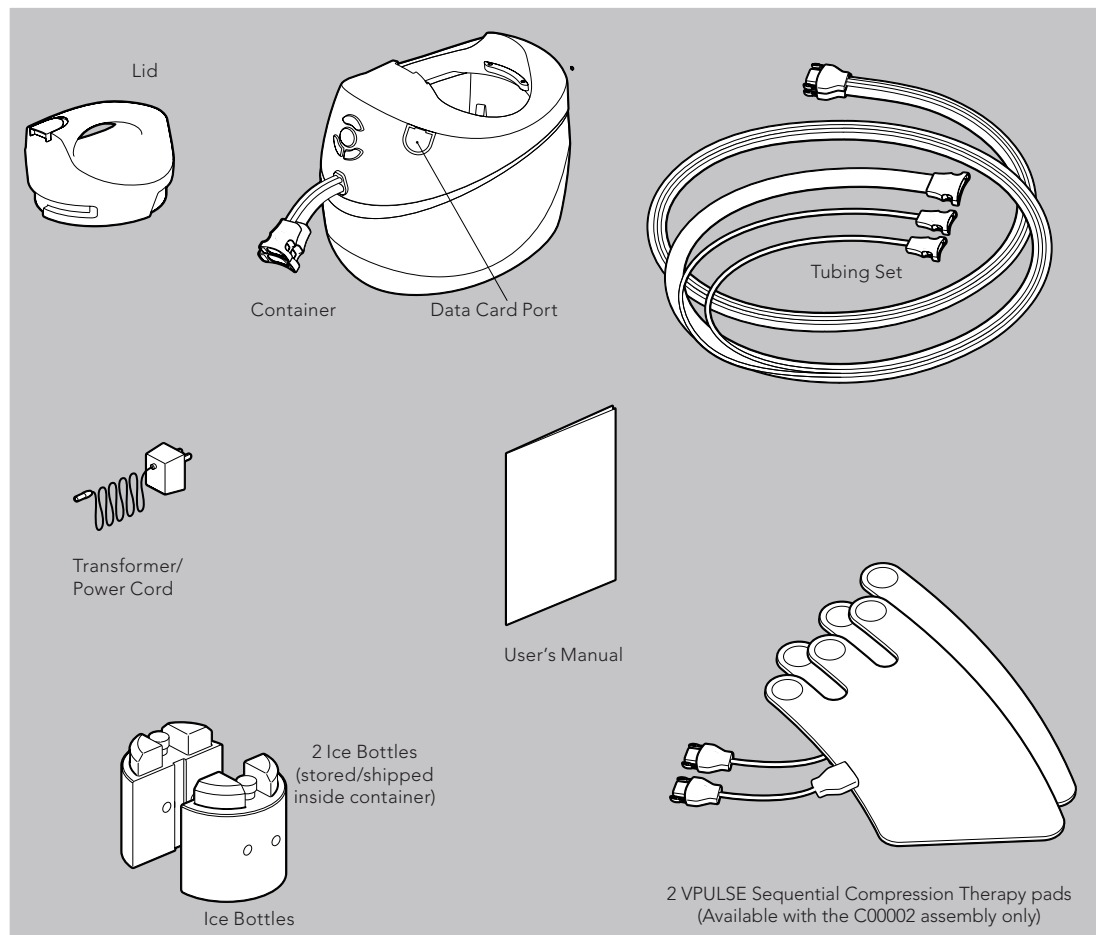




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CAUTION: Federal Law restricts this device to sale by, or on the order of, a licensed healthcare practitioner.


Symbols

 The Caution or Warning symbol precedes an operational step that could cause damage to the user or instrument if the patient 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.

 Symbol ISO 7010-M002: refer to the Users Manual for instructions for product usage.

 This device is offered for sale by or on the order of a licenced healthcare practitioner. Use only as prescribed.


 Medical Device Safety Symbol IEC 60417-5333: Type BF Applied part complying with IEC 60601-1 to provide protection against electric shock. The part of the device in contact with the patient is floating from earth ground.


 Protected against spraying water.


 Medical Device Symbol IEC 60417-5031: The product operates from direct current.


 Medical Device Symbol IEC 60417-5172: Class II Equipment.


 Medical Device Symbol IEC 60417-5570: Unlocking, Handle.


 Medical Device Symbol IEC 60417-5569: Locking, Handle.


 Minimum water reservoir fill line. Step 1 of filling the water reservoir.


 Maximum ice reservoir fill line. Step 2 of filling the water reservoir. Note that either ice or the VPULSE Ice Bottles can be used for cold therapy.

 Cold therapy enable function.

 Start /Stop the therapy session.

 Dynamic compression therapy enable function.


 Sequential compression therapy enable function.


 Follow local governing ordinances and recycling plans regarding disposal or recycling of device components. If unclear, please refer to Breg for proper disposition of this product.

 Manufactured by Breg, Inc.

 This product conforms to the directive 93/42 EEC for medical devices. The identification number of the Notified Body is 2797.

 Date of manufacture, year XXXX, week YY.

 Single patient multiple use.

 Do not dispose this product in the unsorted municipal waste

Indications

The VPULSE is intended to function as an intermittent, external compression device for extremities to prevent and reduce complications of poor circulation. This includes:


- Deep vein thrombosis
- Chronic venous insufficiency
- Venous stasis ulcers
- Post-mastectomy edema and chronic lymphedema
- Reduction of edema associated with soft tissue injuries such as burns, postoperative edema, and ligament sprains
- Localized cold therapy for post-traumatic and post-surgical medical and/or surgical conditions
- Aid in blood flow back to the heart
- Treatment and assistance in healing of cutaneous ulceration (wounds), reduction of wound healing time, enhancement of arterial circulation (blood flow), reduction of compartmental pressures, reduction of edema (swelling), reduction of the need for anticoagulant (blood thinning) medications

Contraindications: Cold Therapy


Medical professionals and patients should be aware of situations where cold therapy may not be appropriate, detrimental to a specific condition or otherwise contraindicated for use, including patients with:

- Diabetes
- Cold urticaria
- Cryoglobulinemia
- Raynaud's syndrome
- Proximal cold hemoglobinuria
- Vasospastic disease
- Cold hypersensitivity
- Compromised local circulation
- History of cold injury, frostbite, or adverse reactions to local cold application
- Patients who are incoherent due to general anesthesia, sedation, or coma
- Local tissue infection
- Hand/wrist or feet/ankle surgery with polyneuropathy


Warnings: Cold Therapy


 If the patient has any of the following clinical risk factors, use of cold therapy may result in serious cold-induced injury, including full thickness skin necrosis:


- Pathologic sensitivity to cold
- Behaviors that negatively affect circulation, including poor nutritional status, smoking and tobacco use, excessive caffeine use, and excessive alcohol use
- Cold application area desensitization due to local anesthesia or regional nerve block
- Taking medications that have a negative effect on peripheral vascular circulation, including beta adrenergic blockers and local epinephrine use (such as in local anesthetics)

 If the risk of cold-induced injury outweighs the benefits of cold therapy, do not prescribe the VPULSE cold therapy. If you prescribe this product to patients with risk factors, consider taking special measures to control the risk, such as:

- Recommend more frequent skin checks.
- Require more frequent follow-up examinations.
- Use an insulation barrier between the pad and skin.
- Prescribe shorter durations of application, less frequent application, or eliminate nighttime application.

 The VPULSE can be cold enough to cause serious injury including full skin necrosis.

 Excessive moisture at the application site due to excessive bleeding, sweating, or condensation may increase the risk of serious cold-induced injury, including full thickness necrosis.

 Inspect the skin under the cold therapy pad (by lifting the edge) as prescribed, typically every 1 to 2 hours. Do not use VPULSE cold therapy if dressing, wrapping, bracing or casting over the cold therapy pad prevents skin checks. Stop using and contact your practitioner immediately if you experience any adverse reactions, such as: increased pain, burning, increased swelling, itching, blisters, increased redness, discoloration, welts, other changes in skin appearance, or any other reaction identified by your practitioner

⚠ Be aware of any nerve irritation and/or muscular reaction that are associated with skin sensitivity and irritation. If observed, discontinue therapy until the cause is determined.

⚠ DO NOT operate without water in the system. Doing so may damage your system and void the product warranty.

Contraindications: Compression Therapy

Patients with the following conditions should NOT USE Intermittent Pneumatic Compression Therapy:

- Presumptive evidence of congestive heart failure
- Suspected/observed pre-existing deep vein thrombosis or pulmonary embolism
- Suspected/observed deep acute venal thrombosis (phlebothrombosis)
- Suspected/observed inflammatory phlebitis process
- Suspected/observed pulmonary edema
- Suspected /observed pulmonary embolism
- Suspected/observed acute inflammations of the veins (thrombophlebitis)
- Suspected/observed decompensated cardiac insufficiency
- Suspected/observed arterial dysregulation
- Suspected/observed erysipelas
- Suspected/observed carcinoma and carcinoma metastasis in the affected extremity
- Suspected/observed decompensated hypertonia
- Suspected/observed acute inflammatory skin diseases or infection
- Suspected/observed venous or arterial occlusive disease
- Determined venous and lymphatic return is undesirable
- Suspected/observed Raynaud's Disease
- Suspected/observed poor peripheral circulation
- Suspected/observed hypersensitivity to cold
- Medical situations where increased venous and lymphatic return is undesirable
- Leg gangrene
- Recent skin graft
- Extremity containing a fracture
- Extremities that are not sensitive to pain

Warnings: Compression Therapy

⚠ If patient experiences pain, swelling, sensation changes or any unusual reactions while using the compression therapy, they are to stop using the therapy and consult their medical professional immediately.

⚠ Special attention should be given to those patients with neuropathies or tissue viability problems (i.e. diabetes, arterial or venous insufficiencies).

⚠ If pulsations or throbbing occur, the cuff may be wrapped too tightly. Loosen Immediately.

⚠ To prevent extremity compartment syndrome, special attention should be given to patients who are positioned in the supine lithotomy position for extended lengths of time. This includes patients with or without cuffs.

⚠ Patients should not walk with tubing connected to cuffs.

⚠ Cuffs used in combination with warming devices may cause skin irritation. Regularly check for patent discomfort, compliance, and skin irritation.

⚠ Close supervision is necessary when this appliance is used by unconscious or incapacitated patients and those with poor circulation.

⚠ When using this system, regularly check the skin where the pads are applied as prescribed.

Warnings: Cold and Compression Therapies

⚠ Patients with any of the following cognitive risk factors should only use VPULSE under direct supervision of a medical professional or the direct supervision of a caretaker, if prescribed by a medical professional:

- Young children and elderly
- Cognitive disabilities
- Communication barriers
- Use of medications that have a negative effect upon mental capacity

If patient has any of the cognitive risk factors, above, medical professional or caretaker should provide skin checks.

⚠ Patients should take caution in applying therapy pads over open sores and abrasions. At a minimum, these areas should be cleaned and bandaged.

⚠ As with all prescription medical devices, failure to follow product instructions or adjusting setting and performing therapy applications without the express direction and/or supervision of your trained health care provider may lead to improper product performance and the potential for serious injury. For medical questions, please consult your health care provider.

⚠ Use only according to your practitioner's instructions regarding the frequency and duration of application and length of breaks between uses, how and when to inspect the skin, and total length of treatment. Do not use this device if you did not receive or do not understand the instructions.

⚠ DO NOT wrap the therapy pads as to restrict blood or fluid flow. Regularly check the therapy area.

⚠ DO NOT place a cast over a pad. Casting over the pad and tubing set may restrict necessary air circulation and proper operation.

Medical Professional Patient Discharge Protocol

Follow this protocol prior to discharging the patient from facility care to home use

1. Patient Screen. Screen the patient for any contraindications and/or applicable warnings. If the patient has any contraindications, do not dispense the Breg VPULSE to the patient. If any of the warnings apply to the patient, determine the appropriateness of application of the VPULSE to that patient.

2. Instructions for Use. Instruct the patient on how to properly use the Breg VPULSE. Review the Operating Instructions in this document and affixed to the unit with each patient.

3. Prescription. Instruct the patient regarding the licensed healthcare practitioner's prescribed protocol: frequency and duration of use and length of breaks between uses, how and when to inspect the skin, and total length of treatment. The duration of acyclic application may vary depending upon the patient. If the patient does not experience pain relief, the physician may increase the duration of cold therapy application. As the application duration is increased, the frequency of the skin inspections should increase.

4. Potential for Injury. Inform the patient that improper use can result in serious skin injury, including full thickness skin necrosis. Emphasize the importance of following the prescribed protocol, proper pad application, and skin inspection.

5. Proper Pad Application. Instruct the patient to use only the Breg VPULSE Cold Therapy Pads designed for the body part being treated; other pads may be colder, increasing the risk of serious cold-induced injury, including full thickness skin necrosis. Do not cover the VPULSE Cold Therapy Pad with dressing, wrapping, bracing or casting that prevents the patient from checking the skin under the pad.

6. Skin Inspection. Instruct the patient to inspect the skin receiving cold treatment per the practitioner's instructions, typically every 1 to 2 hours. If dressing, wrapping, bracing, or casting over the VPULSE Cold Therapy Pad prevents the ability of the patient to perform skin checks under the pad regularly, do not dispense Breg VPULSE Cold Therapy to the patient.

7. Discontinue. Instruct the patient to stop using Breg VPULSE and contact his/her licensed health care practitioner immediately if they experience any adverse reactions, such as: increased pain, burning, increased swelling, itching, blisters, increased redness, discoloration, welts, or other changes in skin appearance.

8. Documentation. Provide the patient a prescription for the duration of the total treatment period, the frequency and duration of individual treatment sessions, and the frequency of skin inspections

System Operation

The VPULSE consists of a container, tubing set and a family of single-patient application pads. The pads are applied to the body to deliver three different and important therapeutic treatments. There are two types of pads to deliver three different therapies:

- The patient can apply (1) or (2) sequential compression therapy pad(s) to the calves for preventative treatment of venous thrombo-embolism.

And/Or

- The patient can apply (1) thermal-compression pad to a specific body part such as the knee or shoulder for cold therapy and/or dynamic compression therapy to manage pain and swelling for post-operative recovery

The container contains:

- An air pump and reservoir for inflating portions of each pad;
- A water pump and patient-filled ice water container for circulating water into the thermal-compression pad; and supporting controls to deliver and monitor the treatment therapies.

Once power is connected to the VPULSE, it is powered ON. The patient can then select which therapies to use and start the treatment session.

Pressurized air and/or cooled water is circulated through the tubing set from the container to the pads. The air pressure is cycled until the therapy session is stopped by the patient.

The temperature of the therapy is not adjustable and designed not to drop below 42°F (5.5°C). The compression of the therapy is not adjustable.

NOTICE TO USERS

If any serious incident has occurred in relation to the device, report to Breg and the competent authority of the Member State in which the user and/or patient is established.

Operating Instructions

Using the System with Ice and Water

Every VPULSE is quality tested before being sold. When un-packing your new system, it is normal to find moisture in the VPULSE water reservoir due to the testing.

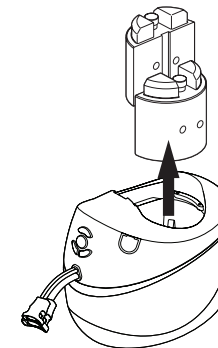
⚠ DO NOT overfill.

⚠ DO NOT operate without water.

⚠ DO NOT operate with hot water.

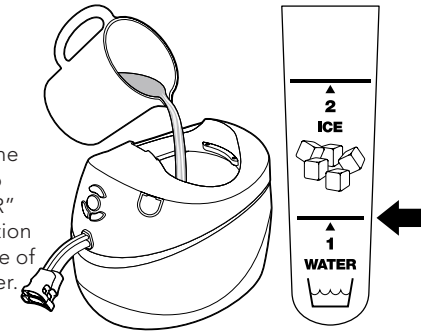
1

Remove the two Ice Bottles from the container.



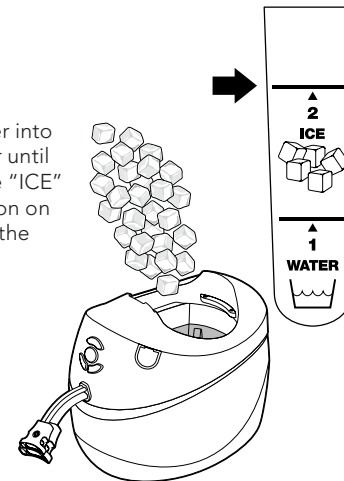
2

Pour cold water into the container to the "WATER" level indication on the inside of the container.



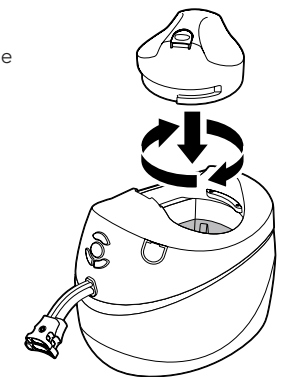
3

Pour ice water into the container until even with the "ICE" level indication on the inside of the container.



4

Place the lid onto the container and turn clockwise until the handle clicks into position.



Operating Instructions

Using the System with Ice Bottles

If your VPULSE includes the Ice Bottle pair or you purchased them as an accessory, please follow the instructions below to prepare the Ice Bottles for use.

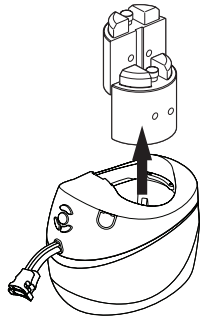
1. Fill the Ice Bottle with tap water. Freeze the filled Ice Bottle for a minimum of 6 hours in any household freezer to ensure maximum cold therapy.
2. Place the frozen Ice Bottle into the container. Make sure water is already in the VPULSE unit up to the water line. For longer duration of sustained cold water temperature, add ice in addition to the Ice Bottle to the water reservoir (as desired). Only fill the Ice Bottles with water.

The time the Ice Bottle will stay frozen is approximately 2 to 6 hours. Use additional Ice Bottles for longer treatment.

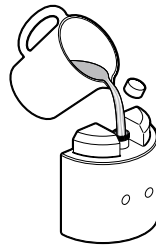
To order additional Ice Bottles please call 1.800.321.0607 or 1.760.795.5440.

⚠ Fill Ice Bottles with water only

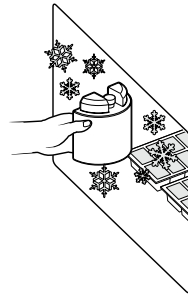
- 1**
Remove the two Ice Bottles from the container.



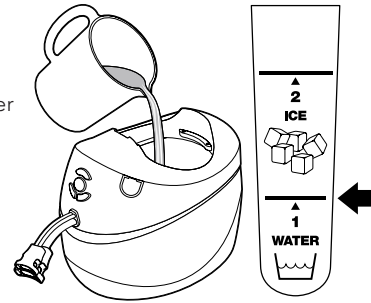
- 2**
Fill Ice Bottles with water.



- 3**
Freeze Ice Bottles.

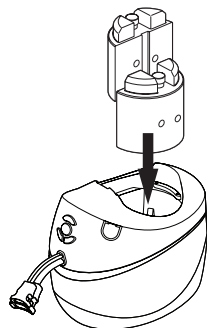


- 4**
Pour cold water into the container to the "WATER" level indication on the inside of the container.

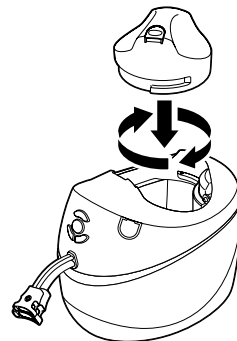


⚠ To avoid skin irritation or cold burn, DO NOT hold frozen Ice Bottles for an extended period. DO NOT use the Ice Bottles directly on skin for therapeutic purposes.

- 5**
Place the two Ice Bottles into the container.



- 6**
Place the lid onto the container and turn clockwise until the handle clicks into position.



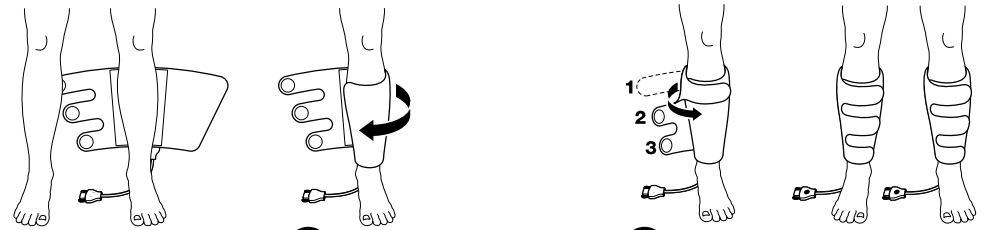
Operating Instructions

Applying Therapy Wraps and Pads

⚠ Apply therapy pads only to body part indicated for the associated pad. Failure to follow the product instructions may lead to improper product performance and the potential for serious injury.

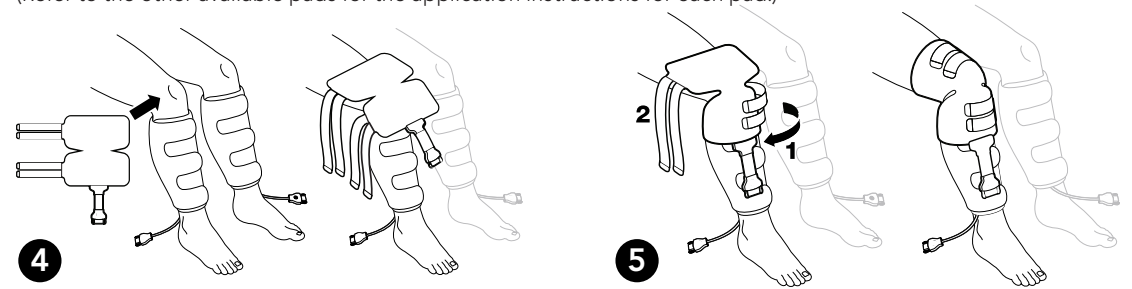
Apply the Sequential Compression Therapy pads to the patient's calves.

- 1**
Center the pad behind the patient's calf.
- 2**
Wrap one side of the pad, as shown, around the front of the patient's leg.
- 3**
Secure by wrapping the 3 "fingers" in the order shown around to the front. Apply pads to both calves. Adjust so snug. Do not over tighten.



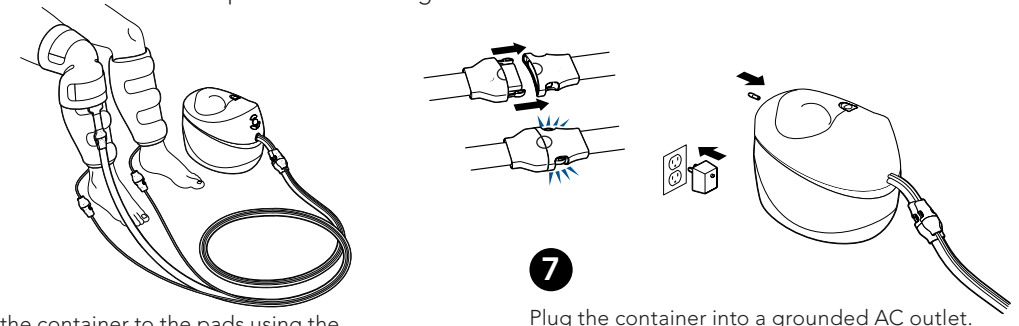
Apply 1 Cold-Dynamic Compression pad to the appropriate body part (Example: knee)
(Refer to the other available pads for the application instructions for each pad.)

- 4**
Center the pad over the patient's knee with the connector pointing down.
- 5**
Wrap straps around the knee to secure the pad.



Attach the Container to the pads via the tubing set.

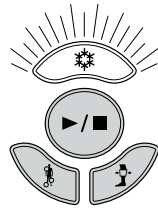
- 6**
Attach the container to the pads using the corresponding colored connectors as shown. The connectors make a "click" sound when fastened properly.
- 7**
Plug the container into a grounded AC outlet.



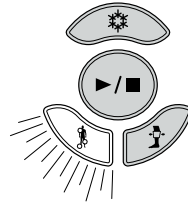
Operating Instructions

Using the Start/Stop button to start, change, pause or stop therapies.

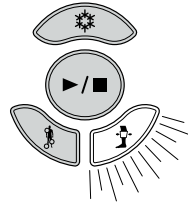
Press the button of the desired therapy or combination of therapies. The buttons selected will be illuminated.



Cold Only

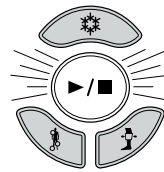


Dynamic Compression Only



Sequential Compression (Calf) Pad Only

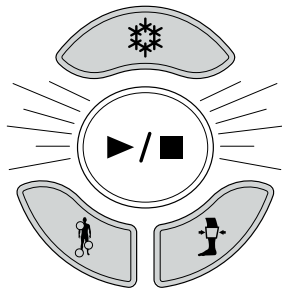
Push the Start/Stop button to begin.



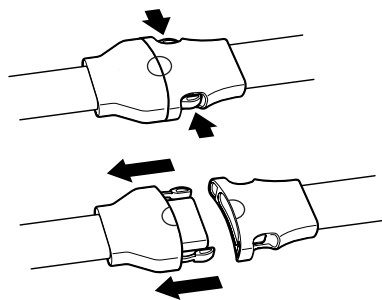
Start/Stop

To add therapy, first press Start/Stop button, select the therapy button and press the Start/Stop button again to continue.

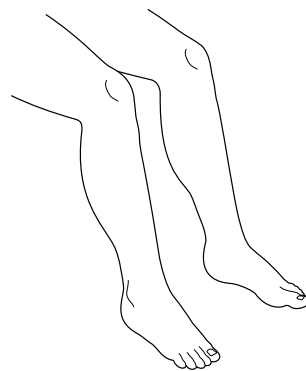
To Pause or Discontinue Use.



Press the Start/Stop button to stop.



Disconnect by depressing the side buttons of the connectors.



Remove the Sequential Compression Therapy pads and Thermal-Compression pad.

Alarms

When an alarm occurs, the system will stop the therapy session, sound an audible alert and illuminate in RED the function key of the alarm area.

To stop an alarm, press the function key that is flashing.

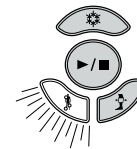


Cold Therapy may alarm if:

- Too low or too high a therapy temperature may be detected by the system.

To resolve:

- Check the tube connection at the container and at the cold-compression pad.
- Ensure appropriate ice or water level.
- Activate the cold therapy and press start. If the issue is not resolved, press the cold therapy button to deactivate.
- If prescribed, ensure the sequential therapy is activated and press Start/Stop button to resume sequential therapy. Contact Customer Care for further instructions.

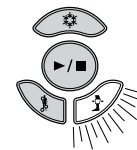


Dynamic Compression may alarm if:

- The time to inflate the pad is too short or too long.

To resolve:

- Check the tube connection at the container and at the cold-compression pad.
- Make sure the cold-compression therapy pads are properly applied to the body and connected properly.
- Press dynamic compression and then press the Start/Stop button. If the issue is not resolved, contact Customer Care for further instructions.



Sequential Compression may alarm if:

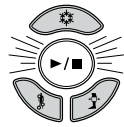
- The time to inflate the pad is too short or too long.

To resolve:

- Make sure the sequential compression therapy pads are properly applied to the calf and connected properly.
- Press sequential compression and then press the Start/Stop button. If the issue is not resolved, contact Customer Care for further instructions.

Should the system fail to restart after an alarm has sounded and the stated resolutions have not reset the System, contact Customer Care at Breg, 1.800.321.0607 or 1.760.795.5440 for further assistance.

Alerts

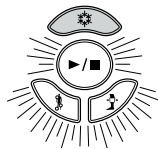


Flashing GREEN

- The Stop/Start button will flash when the system is initializing.

To resolve:

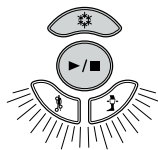
- This may occur after power disruption or after the system was improperly shut down.



Dynamic Compression and Sequential Compression keys Solid RED

To resolve:

- The SD card is not properly installed, the card is full or faulty. Remove or reinstall the card. If this condition persists contact Customer Care.
- Cold Therapy is still active during this condition.



Dynamic Compression VIOLET and Sequential Compression RED

To resolve:

- The air pump is not achieving pressure, contact Customer Care

Troubleshooting

Frequently asked questions in troubleshooting the VPULSE:

1. What should I do if the VPULSE does not seem to get cold?

- Check the inside and outside of the water reservoir for cracks, punctures or other signs of damage. If damage is noted, please contact Customer Care at Breg, 1.800.321.0607 or 1.760.795.5440.
- Make sure that the water container is properly filled with water.



DO NOT operate the system with a water container not filled with water or not filled to the MINIMUM fill line, before ice or Ice Bottles are added.



DO NOT operate the system with a water container filled with water above the MAXIMUM fill line, or with a tubing set not properly connected.

- Check that enough ice is added to the water container and that the tubing is not kinked.
- Check the power connection.

2. What should I do if the tubing set does not connect to the VPULSE or pad?

- Check the tubing set and connectors for cracks, punctures or other signs of damage. If damage is noted, contact Customer Care at Breg, 1.800.321.0607 or 1.760.795.5440.
- Make sure the correct connectors are mating. Check the color and number of connections.
- Make sure no foreign objects are blocking the fluid connectors.

3. What should I do if the system does not turn on?

- Check wall adapter power connection at the wall.
- Check the outlet to ensure it is properly powered.
- Check wall adapter is connected at back of the Control Unit.

- Make sure no foreign objects are blocking the fluid connectors.
- Check that the front panel keys illuminate when pressed.
- Check that the Start/Stop key (▶/■) illuminates GREEN when pressed.

4. What should I do if the system is not pumping water through the pad?

- Check power connection.
- Check that the tubing set is properly connected.
- Check that the pads are properly connected.
- Check that the water reservoir is properly filled with cold water.
- Check that the Cold Therapy button has been selected and the function illuminates WHITE.
- Check that the Start/Stop key (▶/■) illuminates GREEN when pressed.
- Check that the tubing is not kinked.
- Start the system to ensure that the water is flowing into the water reservoir. A return stream is visible inside water reservoir.

5. What should I do if the system is not pumping any air through the pad?

- Check power connection.
- Check that the tubing set is properly connected.
- Check that the pads are properly connected.
- Check that the front panel keys illuminate when pressed and that a compression therapy is selected. If the compression keys are both continuously illuminated RED and VIOLET the air pump might not be providing sufficient pressure.
- If compression keys are both continuously illuminated RED, the DATA card may not be installed, the card may be full, or experiencing a problem. Open the DATA door and reinstall the DATA card.
- Check that the Start/Stop key (▶/■) illuminates GREEN when pressed.
- Check that pad is inflating.
- Check the dynamic or sequential therapy mode is enabled.

Refer to Breg Customer Care, 1.800.321.0607 or 1.760.795.5440 if these actions are ineffective.

Cleaning your VPULSE

To clean your VPULSE, please follow these simple steps:

1. Remove electrical cord.
2. Fill the empty water container to the MAX fill line with fresh, room temperature water. DO NOT USE ANY CLEANING SOLUTIONS IN THE WATER RESERVOIR AS THESE SOLUTIONS COULD DAMAGE THE WATER PUMP AND THERAPY PADS.
3. Replace the handle and connect power. Connect all pads and enable all functions.
4. Operate the system for 10 minutes.
5. Empty the water reservoir.
6. Repeat these actions periodically.

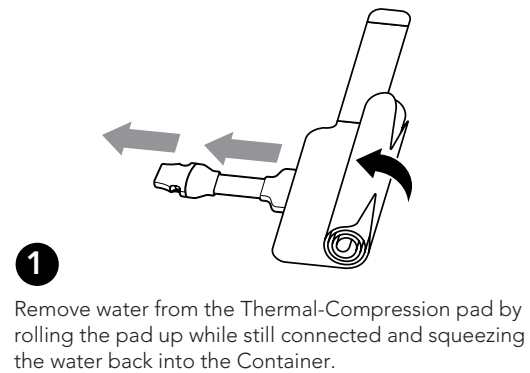
Please use only the following cleaning agents when cleaning the outside of your VPULSE system: warm water with mild detergent, Lysol®, 70% isopropyl alcohol, Cidex®, or 10% bleach solution.

Patients should not use cleaning or decontamination methods different from those recommended by the manufacturer without first checking with the manufacturer that the proposed methods will not damage the equipment.

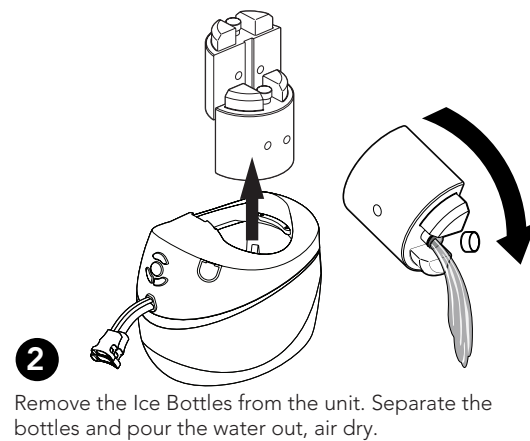
Care and Maintenance

- DO NOT store the pad in its shipping bag. The shipping bag may trap the moisture remaining in the pad.
- Store the VPULSE unit in a safe, cool and dry place when not in use.
- Ensure the water container is empty of water and dry to avoid bacterial growth and contamination.
- Wipe down the device with a soft, damp cloth. DO NOT use abrasive cleaner. NEVER immerse the unit into any liquid.
- Keep away from all solvents and harsh detergents. Please refer to cleaning instructions prior to cleaning your VPULSE.
- DO NOT attempt to repair the VPULSE. There are no patient-serviceable parts. Repair of the system by an unauthorized person may void the product warranty.
- To store, disconnect the electrical cord, the tubing set and the pad.

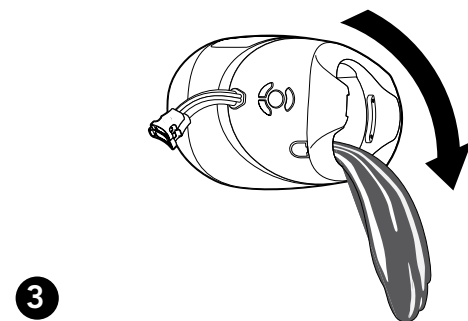
Storage



- 1 Remove water from the Thermal-Compression pad by rolling the pad up while still connected and squeezing the water back into the Container.



- 2 Remove the Ice Bottles from the unit. Separate the bottles and pour the water out, air dry.



- 3 Dump the water out of the side Control Unit so that the control buttons and other electrical components stay dry. When empty, let the unit "air dry" completely.

For long term storage, please use the shipping materials and container supplied with the VPULSE.

Lysol® is a registered trademark of Reckitt Benckiser Inc.
Cidex® is a registered trademark of Johnson & Johnson Corp.

Warranty

Breg, Inc. warrants that this product is free from defects in workmanship, materials, and fitness for use for 90 days from initial purchase under normal use for which it was intended and under direct supervision of a licensed health care practitioner.

Breg, Inc.'s obligation under this warranty is limited to the replacement or repair of any defective part or parts of this product. All expressed or implied warranties, including the warranty of merchantability and fitness for a particular purpose, are limited to the actual warranty period set forth above. No other warranty, express or implied, is given and no affirmation of or by seller, by words or action, will constitute a warranty.

General Safety

This section is used to highlight certain operating procedures and recommendations. Important Safety Instructions / Read all instructions before using.

- ⚠ The device should never be left unattended when plugged in. Unplug from outlet when not in use and before putting on or taking off parts.
- ⚠ No modification of this equipment is allowed.

DO NOT use around flammable materials.

Close supervision is necessary when this appliance is used near pets

- ⚠ The VPULSE pads are supplied non-sterile. DO NOT sterilize these pads. Doing so may compromise the functionality of the pad(s) and may result in possible patient injury.
- ⚠ All VPULSE pads are intended for single patient use and NOT intended for reuse or to be washed or cleaned. Doing so may compromise the functionality of the pad(s) and may result in possible patient injury.

⚠ DO NOT lay on top of the pad connectors. Doing so may result in patient injury.

⚠ DO NOT use pins or sharp objects to secure the therapy pads or hoses. Doing so may damage the system and compromise function.

The device is intended for single patient multiple use.

⚠ DO NOT kink or sharply bend the tubing set. Doing so may damage the system and compromise the function.

⚠ Use this appliance only for its intended use as described in this manual. DO NOT use attachments not recommended by the manufacturer. DO NOT use attachments from other manufacturers. Connecting parts not supplied by Breg will void the warranty and may cause damage to the system and potential injury to the patient.

⚠ Ensure the handle of the device is properly installed and fully engaged prior to carrying the system. For proper use, please reference the handle locking and unlocking icons.

⚠ Use proper precautions in carrying the device to avoid injury.

⚠ DO NOT carry this appliance by the supply cord or use the supply cord as a handle.

⚠ When setting up the system, route the supply cord and tubing set to avoid tripping and to encourage ease of walking around the device.

⚠ DO NOT carry this appliance by the tubing set or use the tubing set as a handle.

⚠ Keep the tubing set, the device and pads away from heated surfaces.

⚠ Never operate the appliance without the handle, the tubing set, and the pad(s) completely connected.

⚠ Never operate the appliance with any foreign objects (other than ice or Ice Bottles provided) in the water reservoir.

⚠ Never drop or insert any object into any opening

⚠ Excessive lint or dust may impede the flow of water through the system. To minimize this occurrence, keep the handle properly installed and fully engaged when not filling or emptying the device.

⚠ DO NOT stand on or in the appliance.

⚠ DO NOT place the appliance or operate the appliance while it is on a surface more than 1 foot above the floor.

⚠ Unplug this product before filling or cleaning. Fill with water and ice or water and Ice Bottles provided by Breg only. DO NOT use any Ice Bottles other than those provided by Breg.

⚠ DO NOT place the tubing set, power cord or use any pad around the neck to avoid the possibility of strangulation.

Electrical Safety

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

Electromagnetic Interference

This device has been tested and found to comply with the limits for Medical Devices according to IEC 60601-1-2:2014+AMD1:2020. These limits are designed to provide reasonable protection against harmful interference in typical medical installations. This equipment generates and radiates radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. There is no guarantee that interference does cause harmful occurrence in a particular installation.

If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user can try to correct the interference by one or more of the following measures:

- Reorient or relocate this device.
- Increase the physical separation between this device and the other devices(s).
- Connect the equipment into an outlet or circuit different from the one where the other device(s) are connected.

Essential Performance

This device contains Essential Performance per IEC 60601-1, Edition 3.2 and IEC 60601-1-2, Edition 4.1

The VPULSE system notifies the user through audible/visual alarms when the sequential therapy mode ceases to function or delivers a pressure out of the specified range.

Environmental Conditions

This device has been tested and found to comply with the environmental conditions for Medical Devices according to IEC 60601-1-2:2014+AMD1:2020 and IEC 60601-1-6:2010+AMD1:2013+AMD2:2020. These conditions are designed to provide reasonable environmental operating ranges for the equipment. Extreme changes in the environmental conditions or operating outside the specific operating ranges, such as temperatures, pressure and humidity, may impact the performance of this device. The user can try to correct these conditions by relocating this device to a more moderate environment.

Interference From Other Products

If this equipment is interfered with by other devices, which can be determined by turning that equipment off and on, the user can try to correct the interference by one or more of the following measures:

- Reorient or relocate this device.
- Increase the physical separation between this device and the other devices(s).

Electromagnetic Interference and Emissions

⚠ Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation.

⚠ Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

⚠ Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the VPULSE

including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

⚠ DANGER – TO REDUCE THE RISK OF ELECTRICAL SHOCK, DO NOT DISASSEMBLE THE UNIT. REFER SERVICING TO THE MANUFACTURER:

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.
3. 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.

⚠ Only use the power supply provided with the unit. Failure to do this could damage the unit, power supply, and/or create a potential injury to the patient. Please contact Breg Customer Care if a replacement wall adapter is required.

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

⚠ Keep the power cord away from heated surfaces.

Specifications


MODEL	VPULSE, C00001
PHYSICAL Size (approximately)	9.8" x 14.3" x 11.25" (249mm x 364mm x 286mm)
Weight (dry) Dual Tubing Set	5 lbs. (2.27 kg) 10 ft. (2.4m)
CONTROLS	Keypad interface
THERMAL SYSTEM Operating limit Operating period	42°F minimum (5.5°C) Ice or frozen Ice Bottles will last for 2-6 hours
Circulating System Reservoir Capacity Reservoir Fluid Water Flow Rate	Submersible pump 1.2 gallons (4.4 liters) water 3.2 gph (12 lph) typical
PNEUMATIC SYSTEM Dynamic Compression peak pressure Sequential Compression peak pressure	50mmHg (6.6kPa) ± 10% 60mmHg (8.0kPa) ± 10%
ELECTRICAL SYSTEM System Voltage Frequency Power Leakage Current	TPU Polyether bladder, Polyurethane foam with 100% Polyester fabric lamination PVC plastic bladder, Polyurethane foam with 100% Polyester fabric lamination 12VDC, 100-240Vac 50/60Hz 15W max 300µA max

Wall Adapter Input Frequency Output	UE24WCP1-120200SPA 100-240Vac, 800µA max 50/60Hz 12VDC, 2.08A
OPERATING ENVIRONMENT Atmospheric Pressure	525 to 795 mmHg (700hPa – 1060hPa) 15% to 93% relative non-condensing
Humidity	41°F – 104°F (5°C – 40°C)
Temperature	
TRANSPORT & STORAGE ENVIRONMENT Atmospheric Pressure	179 to 795 mmHg (240hPa – 1060hPa) up to 93%
Humidity	-13°F – 158°F (-25°C – 70°C)
Temperature	
REGULATORY Classification Type of Equipment	Class II Equipment Type BF IEC 60601-1, Edition 3.2 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
REGULATORY APPROVALS	CAN/CSA-C22,2 no 60601-1-08 (R2008): Medical Electrical Equipment Part1: General Requirements for Medical Electrical Equipment. IEC 60601-1-2:2014+AMD1:2020 edition 4.1 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests. VPULSE is a trademark of Breg, Inc.
Expected Service Life: 300 hours from date of first use.	

A brief summary of the tests carried out in accordance with IEC 60601-1-2:2014+AMD1:2020 is shown below.

The VPULSE is suitable for use in the specified electromagnetic environment. The consumer and/or user of the VPULSE should ensure that it is used in an electromagnetic environment as described below:

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF Emissions CISPR 11	Group 1	The VPULSE uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The VPULSE is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class B	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Immunity Test	IEC 60601-1-2 Test Level	Electromagnetic Environment Guidance
Conducted Disturbances induced by RF Fields IEC 61000-4-6	3V 0.15MHz – 80MHz 6V in ISM & amateur radio bands between 0.15Mz – 80MHz 80% AM at 1kHz	Portable and mobile RF communications equipment should be used no closer to any part of the VPULSE, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter. Recommended Separation Distance d=1,2√P d=1,2√P 80 MHz to 800 MHz d=2,3√P 800MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and is the recommended separation distance in metres (m).
Radiated RF EM fields IEC 61000-4-3	10 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey (a), should be less than the compliance level in each frequency range (b). Interference may occur in the vicinity of equipment marked with the following symbol: 

The VPULSE is suitable for use in the specified electromagnetic environment. The user of the VPULSE should ensure that it is used in an electromagnetic environment as described below:

Immunity Test	IEC 60601-1-2 Test Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV 100 kHz repetition frequency	Main power quality should be that of a typical commercial and/or hospital environment.
Surges (line to line) IEC 61000-4-5	± 0,5 kV, ± 1 kV	Main power quality should be that of a typical commercial and/or hospital environment.
Proximity Fields from RF Wireless Communications Equipment IEC 61000-4-3	Reference IEC 60601-1-2:2014+AMD1:2020 table 9	

Voltage Dips and Fluctuations IEC 61000-4-11	0% for ½-cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% for 1-cycle and 70% for 25 cycles at 0°	Main power quality should be that of a typical commercial and/or hospital environment. If the user of the VPULSE requires continued operation during power main interruptions, it is recommended that the VPULSE be powered from an uninterruptible power supply or a battery. If improper operation occurs, it may be necessary to position the VPULSE further from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to ensure that it is sufficiently low.
Voltage Interruptions IEC 61000-4-11	0% for 250 cycles	
Rated Power Frequency Magnetic Fields IEC 61000-4-8	30 A/m 50Hz	

Proximity Magnetic Fields IEC 61000-4-39	IMMUNITY TEST LEVELS TO DISTURBANCES FROM PROXIMITY MAGNETIC FIELDS		
	Test Frequency	Modulation	Immunity Test Level (A/m)
	30 kHz	CW	8
	134.2 kHz	Pulse modulation ¹	65
		2.1 kHz	
13.56 MHz	Pulse modulation ¹	7.5	
	50kHz		

¹Modulate carrier using 50% duty cycle square wave. Immunity test levels specified as RMS before modulation is applied.

Catalog Items

To order additional items from Breg, please refer to the following items:

Catalog Item Description

- C00001 Breg VPULSE w/o Pads
- C00002 Breg VPULSE with Sequential Compression Pad (2)
- C00003 Breg Cold/Compression Pad, Knee, L
- C00004 Breg Cold/Compression Pad, Shoulder
- C00005 Breg Cold/Compression Pad, Foot/Ankle
- C00013 Breg Cold/Compression Pad, Hip
- C00016 Breg Cold/Compression Pad, Universal
- C00017 Breg Cold/Compression Pad, Knee
- C00020 Breg Cold/Compression Pad, Back

Accessories

- C00006 Breg VPULSE Sequential Compression Pad set (2x)
- C00007 Breg VPULSE Spare Ice Bottle Set
- C00008 Breg VPULSE 12VDC-24W Wall Adapter
- C00009 Breg VPULSE Thermal/Compression Tubing Set
- C00010 Breg VPULSE Sequential Compression Tubing Set
- C00018 Breg VPULSE Complete Tubing set
- C00024 Breg VPULSE Power Extension Cable

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