

Description and Use

This device is a segmented inflatable sleeve ("garment") which is intended to be connected to Bio Compression Systems' Sequential Circulator pneumatic compression pump. The pump cyclically inflates the garment's segments ("chambers") in sequence from the distal end toward the trunk of the body, increasing circulation on the limb worn. Refer to your Sequential Circulator instruction manual for specific indications, additional precautions and warnings, and other important information.

Warnings and Precautions

Do Not Use •If you have, or suspect you have, a blood clot, pulmonary embolism, or deep vein thrombosis (DVT) •If you have thrombophlebitis •If you have lymphangiosarcoma •If you have severe peripheral neuropathy or difficulty sensing hot or cold. •If the pump, accessories, or power cord are damaged or have been immersed in water •With any accessories or power cord not specified or provided by Bio Compression Systems •In the presence of flammable anesthetics or in an oxygen rich environment •In an MRI environment •Near water, in a wet environment, or where aerosols are being sprayed •While sleeping •For any use not described in the pump manual

Ask A Doctor Before Use If You Have •Heart, vascular, or circulatory problems (e.g., congestive heart failure (CHF), ischemic vascular disease) •Insensitive, irritated, injured skin, or skin conditions in/around treatment sites •An infection in the limb or inflammation of the skin (e.g., cellulitis, erysipelas) •Edema or swelling

Ask A Doctor Before Use If You Are •Pregnant

When Using This Product •Examine the before using or cleaning •Handle with care - do not fold or crease, use near a heat source, handle with sharp objects, clean with abrasive materials, or place in a washing machine or dryer •Do not stand or walk while wearing as this can cause a fall •Always wear clothing, bandages, or stockings underneath garments for hygienic reasons and to avoid irritation •Never share or use someone else's garments - single-patient use only •With a hot or cold compress, do not use for more than twenty minutes every two hours •Avoid folding, pinching, or kinking tubing as this can obstruct air flow •Do not wrap tubing around limb as this can restrict blood flow •Do not carry or suspend the device using tubing or valves •Do not submerge or allow liquids to enter the device •Never attempt to open, repair, or modify the device

Stop Use And Ask A Doctor If •Changes in skin appearance occur such as color changes, blisters, welts, or increased swelling •You feel burning, itching, increased pain, numbness, or tingling

In the event the pump stops working, release pressure by disconnecting

Any serious incident that has occurred in relation to the device must be reported to Bio Compression Systems. In the European Union (EU), incidents should also be reported to the competent authority of the Member State in which the user and / or patient is established.

Intended for use by adults. Keep out of reach of children and pets.

Operating and Care Instructions

Preparing the Device for Use •After removing from plastic bag, unroll, and spread flat

Connecting the Garment(s) •Locate the connector bar at the end of garment tubing •Line up numbers on connector bar with numbers on pump •Squeeze the sides and insert into pump – you will hear a "click" when connected •If an 8-chamber garment, locate the second connector bar and repeat previous steps •When using two garments, remove blocker bar(s) from pump and repeat previous steps

Putting the Garment(s) On •Leg sleeve: unzip, place leg in and make sure heel is back and down and toes are inside the sleeve, use straps to guide garment on, pull up zipper to secure •Bio Pants: unzip, place legs in garment and make sure heels are back and down and toes are inside the sleeve, use straps to guide on, pull up zipper on each leg to secure •Bio Abdominal: unzip, place leg in garment and make sure heel is back and down and toes are inside sleeve, use straps to guide on, secure flaps, pull up zipper on leg to secure •Arm sleeve: slide arm through larger opening, hand should be flat with fingers inside the sleeve •Arm & Shoulder: slide arm through larger opening, use opposite arm to secure flaps. Hand should be flat and fingers inside the sleeve •4-Chamber Vest: place head through hole like a t-shirt and then secure flaps in front •Elite-8 Bio Vest (left or right): Unzip, slide arm through larger hole, secure flaps, and then zipper in front. Hand should be flat with fingers inside the sleeve •Elite-8 Bio Vest (bilateral): Unzip, slide arm through first hole, slide arm through second hole, zipper in front. Hand should be flat with fingers inside the sleeve •When using gel inserts, align Velcro and press to attach before putting on.

Removing Garment(s) •At the end of treatment, squeeze sides of connector bar and pull to disconnect garment from pump •Press garment to remove remaining air until loose enough to remove •Unzip (if applicable) and remove garment

Cleaning •The garment and tubing can be wiped down using a damp (not wet) soft cloth while disconnected from the pump – if more thorough pump cleaning or garment disinfection is desired, use the following directions.

Tubing disinfection •Unplug and wipe down using a damp (not wet) soft cloth with mild antibacterial soap as needed •Do not use bleach

Garment disinfection •Disconnect from pump and open to expose all sides •Prepare 1/3 cup of laundry detergent per 1 gallon of warm water (20 mL laundry detergent per 1 L water) in a sink or container large enough to hold the garment •Place garment in solution but do not submerge or place connectors in water as this will damage the device •Soak for 30 minutes with mild agitation every 5-10 minutes - hard to remove soil may require hand washing using a soft clean cloth while garment is in solution •Rinse with warm water and allow to air dry •Repeat previous steps using a solution of 1 cup of bleach per 1 gallon of warm water (60 mL bleach per 1 L warm water)

Troubleshooting (does not deflate or pressure seems low) •Check connection to pump •Check tubing for damage, kinks, or twists •Check for damage •Contact Bio Compression Systems – tampering, modifying, or dismantling this device in any way voids the warranty

Environmental Specifications

Consumables and Resources Used •70 mL laundry detergent and 250 mL bleach per 7.6 liters water for garment cleaning - only as needed

Instructions for Minimizing Environmental Impact •Do not clean garment unless soiled - this minimizes the consumables used •Reuse packaging for storing and transporting device

Operation Environment •Intended for use in a healthcare or home environment •Not intended of use in the presence of flammable anesthetics, an oxygen rich environment, or an MRI environment •Altitude up to 6561 feet (2000 m) •Temperature 50°F – 100°F (10°C – 38°C) •Humidity 30-75% RH •Atmospheric pressure 700-1060 hPa

Transportation and Storage Environment •Temperature -20°F – 110°F (-29°C – 43°C) •Humidity 30-75% RH •Atmospheric pressure 700-1060 hPa

End of Life Management •Does not contain hazardous substances requiring special handling and treatment •Dispose of in a responsible manner in accordance with regional requirements •Contact Bio Compression Systems if you have questions or concerns regarding disassembly and disposal

Symbols

	Batch code (lot number)
	Catalog number
	Caution
	Date of manufacture

Contact Information

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