

Description and Use

This device is an inflatable sleeve ("garment") which is intended to be connected to Bio Compression Systems' Multi-Flo DVT Combo pneumatic compression pump. The pump cyclically inflates the garment, increasing circulation on the limb worn. Refer to your Multi-Flo DVT Combo 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 pulmonary edema •Cryo garments if you have lymphedema • 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 this manual

Ask A Doctor Before Use If You Have •Heart, vascular, or circulatory problems (e.g., arteriosclerosis, 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 (e.g., Cryo garment), 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 • Place gel insert flat in freezer for 4 hours - do not place directly on metal rack as this could damage inset.

Connecting the Garment(s) • Connect tubing to garment valve by turning clockwise until secure •Attach Quick-Connect connector at end of tubing to the pump by firmly pushing inwards until it snaps in

Putting the Garment(s) On • Apply garments and secure using Velcro fasteners •When using gel inserts, align Velcro and press to attach before putting on.

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

Foot and cryo 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 foot or cryo 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



Manufacturer

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