

INSTRUCTIONS FOR USE

PlasmaWave® Sleeves

BEFORE USING THIS DEVICE, PLEASE READ THE FOLLOWING INSTRUCTIONS COMPLETELY AND CAREFULLY. CORRECT APPLICATION IS VITAL TO THE PROPER FUNCTIONING OF THE DEVICE.

INTENDED USE/INDICATIONS:

The PlasmaWave is intended to be an easy to use portable system, prescribed by a physician, for use in the home or clinical setting to help prevent the onset of DVT in patients by stimulating blood flow in the extremities (simulating muscle contractions). This device can be used to:

- Aid in the prevention of DVT;
- Enhance blood circulation;
- Diminish post-operative pain and swelling;
- Reduce wound healing time;
- Aid in the treatment and healing of: stasis dermatitis, venous stasis ulcers, arterial and diabetic leg ulcers, chronic venous insufficiency and reduction of edema in the lower limbs.

The unit can also be used as an aid in the prophylaxis for DVT by persons expecting to be stationary for long periods of time.

Rx only   See PlasmaWave's Operator's manual for pump set-up and use.

CAUTION: FEDERAL LAW (U.S.A) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED HEALTH CARE PROFESSIONAL.

SIZING:

Model	Name	Size (Instep Circumference)
M-21	Deep Vein Thrombosis - Standard Foot Garment	Up to 20"
M-40	Standard Calf	Up to 20"
M-42	Deep Vein Thrombosis Garment - XL Calf Sleeves	Up to 25"
M-50	Deep Vein Thrombosis - Standard Thigh Garment	Up to 32"



WARNINGS AND PRECAUTIONS:

- Cuffs used in combination with warming devices may cause skin irritation. Regularly check for patient comfort, compliance and skin irritation.
- Special attention should be given to those patients with neuropathy, Tissue viability, diabetes, vascular insufficiencies and patients prone to compartment syndrome.
- If you experience any pain, swelling, sensation changes or any unusual reactions while using this device, consult your medical professional immediately.

CONTRAINDICATIONS:

- The PlasmaFlow must not be used to treat the following conditions:
- Persons with suspected, active or unrelated: deep vein thrombosis, ischemic vascular disease, severe arteriosclerosis, pulmonary edema, severe congestive heart failure, thrombophlebitis or an active infection;
- On a leg where cuffs would interfere with the following conditions: vein ligation, gangrene, dermatitis, open wounds, a recent skin graft, massive edema or extreme deformity of the leg; where increased venous or lymphatic return is undesirable.

APPLICATION INFORMATION:

Cuffs are latex free and may be placed directly against the skin or over a light compression dressing.

1. Apply each cuff with the aircell centered on back of the leg with tubes toward foot.
2. Secure cuff straps until the fit is snug, but not tight.
3. Attach the tube assemblies to cuffs and pump. Be sure to check that all tube assemblies are securely connected to the cuffs to achieve appropriate pressure. Connect the male connectors until a click is heard.
4. Turn "ON" the pump to activate system. There is a 10 second period to select treatment mode. Always turn "OFF" pump before adjusting or removing cuffs.

SINGLE LEG APPLICATION:

1. Apply single cuff as specified in Steps 1-4 as listed in Application Information above.
2. During the initial 10-second waiting period, press the button continuously to select from unilateral foot, bilateral foot, unilateral calf/calf-thigh, or bilateral calf/calf-thigh modes. The LCD screen will reflect the selections accordingly. If the single leg operation mode is selected within three minutes of powering on and two cuffs are connected instead of one, a leg alarm will be activated as well.
3. Always turn "OFF" pump before adjusting or removing cuff.

CLEANING INSTRUCTIONS:

- The PlasmaWave non-sterile Calf Cuffs are intended for single patient use only. The tube assembly is reusable. Both the cuffs and tube assembly can be cleaned with mild soap solution, antiseptic or disinfectant wipes. Air dry thoroughly.

WARRANTY:

- ManaMed will repair or replace all of part of the cuff and tube assemblies for material or workmanship defects for a period of six months from the date of sale.

SYMBOL GLOSSARY:

- For an explanation of symbols, please refer to <https://www.manamed.com/glossary/symbol-glossary.pdf>



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