Reprocessed by
ReNu Medical, Inc.

Instructions for Use
Reprocessed DVT Garments

Reprocessed Device for Single Use

Symbol Legend:

	Date of Reprocessing		Reprocessor/Manufacturer
	Do Not Reuse		Not made with natural rubber Latex
	Consult instructions for use		Fragile, handle with care
	Do not use if package is damaged		Keep dry
	Non-Sterile – High Level Disinfection	Rx Only	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Caution See Instructions for use	OEM	Original Equipment Manufacturer Catalog#
REF	ReNu Medical Catalog#	LOT	ReNu Medical Sales Order
CID	Customer ID#, if none specified; ReNu Medical Catalog#	QTY	Qty of Devices included in Pkg/Cs

ReNu Medical, Inc.
830 80th Street SW Suite 100
Everett, WA 98203
www.renumedical.com
877-252-1110

Reprocessed DVT Garments

Deep Vein Thrombosis Garments Description

Deep Vein Thrombosis (DVT) Garments are part of an external compression system, in which intermittent or sequential compression is provided using a pump/controller and limb garment. The system consists of the following three main components: a control unit, inflatable limb garments and conduit tubing with detachable connections.

Indications for Use

When coupled with an appropriate inflation system, garments are intended for use in preventing deep vein thrombosis (DVT) as well as the treatment of edema secondary to venous insufficiency. The devices are sued in both the home and institutional settings.

Contraindications

Reprocessed compression garments are contraindicated in the presence of the following conditions:

- Severe arteriosclerosis or other ischemic vascular disease.
- Congestive heart failure.
- Pulmonary edema.
- Known or suspected deep vein thrombosis or phlebitis
- Extreme limb deformities
- Any local condition in which the garments would interfere.
  - Gangrene
  - Untreated infected wounds
  - Recent skin graft
  - Dermatitis

Note: If you are unsure of any contraindications refer to the patient's physician before using the device.

Warnings

- Prior to use, read and follow the Original Equipment Manufacturer's Operator's Manual for the compression pump pressure recommendations and pump compatibility.
- Do not repair or replace the tubing connectors as this may result in unwanted inflation of the garments.
- Do not operate in the presence of flammable gases (e.g. flammable anesthetics).
- Do not expose to excessive heat or freezing.
- Patients with diabetes, poor circulation, insensitive extremities, fragile skin, those on anticoagulation therapy and those predisposed to tissue viability problems should receive special attention. Use the lowest effective pressure and timing and additional padding.
- Check the patient every 8 to 12 hours for skin reddening and any early signs of tissue viability problems.
- Clinical judgement is required to determine if the patient's skin condition requires additional protective measures, or if the therapy should be discontinued.
- Compression therapy may contribute to circulatory failure if excess inflation pressure is applied or if patient has peripheral vascular ischemic disease.
- Compression therapy may increase the risk for compartment syndrome or peripheral neuropathy.

Precautions

ReNu Medical, Inc.
830 80th Street SW Suite 100
Everett, WA 98203
www.renumedical.com
877-252-1110

- Proper garment sizing and application is essential.
- Ensure proper garment positioning to lower the risk of pressure points on the limb.
- Use of anti-embolism stockings under compression devices may provide greater comfort to the patient.
- Ensure proper connections to the external pump controller.
- Ensure that tubing is not kinked or twisted as this could restrict airflow.
- Maximum inflation pressure should not exceed patient's diastolic pressure. Check for dorsalis pedis and posterior tibial pulses during maximal inflation.
- Do not elevate patient's feet above the level of the heart.
- Immediately remove garments if patient experiences numbness, tingling or leg pain.
- To minimize local air movement, turn garment cooling off when using garments in the operating room.
- If compression is interrupted for more than 30 minutes in patients at risk for deep venous complication, resume continuation of the compression therapy only after noninvasive reevaluation of the new situation.
- Lower limb position in relation to the garment and tubing should also be considered particularly when a patient is unconscious or has reduced sensation or the ability to move their legs.
- Additional care should be taken when placing the garments on any deformed leg or foot, or on legs with significant edema.

Additional Precautions

Garments Designed for Foot Application:
Refrain from walking and weight bearing while wearing foot garments.
Periodically check the skin condition under patients wearing stockings or stockinette's.

Directions for Use

1. Remove the device from the package.
2. Inspect the device for overall condition and physical integrity. Do not use the device if any damage is noted.
3. Prepare garment for correct positioning following the directions and symbols/icons on the inside of the garment or otherwise provided by the original equipment manufacturer.
4. Center patient's limb on the inside of the garment.
5. Before starting to wrap the garment around the leg, make sure the pump controller is in the OFF position.
6. Start by wrapping the side without a hook tape or fastener. Follow by wrapping the side with fasteners.
7. Wrap the garment snugly around the patient's limb with the inflatable bladder on the rear side of patient's extremities. Attach the hook/fastener securely to the garment, starting with the ankle of the patient's limb. Achieve a snug and secure, but not too tight, fit around all sections of the patient's limb.
8. If more than one limb is to receive treatment, repeat the above steps on the other side.
9. In the case of single leg application, refer to the original equipment manufacturer Operation Manual for Compression Therapy Settings.

ReNu Medical, Inc.
830 80th Street SW Suite 100
Everett, WA 98203
www.renumedical.com
877-252-1110

10. Do not position the garment such that the tubing can form pressure points on the patient's limb. If a patient will be placed in certain surgical positions like kneeling or similar positions, rotation of the garment with the tubing facing away from the patient will prevent pressure points.
11. Before attaching the garment to the air tubing, make sure the tubing is not kinked or twisted.
12. Attach the air tubing to the pump. Push the connectors together firmly to properly engage. To uncouple the connectors, firmly pull them apart.
13. Adjust the pump pressure to the recommended pressure setting for the garment in use, unless otherwise directed by the physician.
14. Turn the control unit ON after the tubing is correctly attached to the garment and the control unit.
15. Depress the garment-cooling button, if cooling is desired.
16. Device is intended for use during a single patient procedure.
17. Refer to original equipment manufacturer literature for pump compatibility, accessory information and further guidance

Additional Directions for Use

Garments Designed for Foot Application

1. Place the inflatable bladder under the arch of foot.
2. Apply stocking or stockinette over foot and ankle and smooth any wrinkles.
3. Close the fastener over the top of the foot. Next bring the rear strap around the heel and close the fastener.
4. Position the foot below heart level during pump operation for best results.
5. Inflate only after proper placement.

The names of the actual Original Equipment Manufacturer and products mentioned within this document and any information listed on the label is provided as identification prior to High-Level Disinfection reprocessing and may contain trademarks of unrelated third parties who may not represent the device after reprocessing.

ReNu Medical, Inc.
830 80th Street SW Suite 100
Everett, WA 98203
www.renumedical.com
877-252-1110