Instructions for Use
Reprocessed Arjo Flowtron Tri Pulse 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

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Deep Vein Thrombosis Garments Description

Deep Vein Thrombosis (DVT) Garments are part of an external compression system, in which sequential compression is provided using an OEM ACS800 and ACS900 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

Reprocessed Tri Pulse Compression Garment are to be used as a non-invasive therapeutic method to help prevent Deep Vein Thrombosis (DVT) and resulting pulmonary embolism.

Contraindications

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

1. Severe arteriosclerosis or other ischemic vascular diseases.
2. Severe congestive cardiac failure or any condition where an increase of fluid to the heart may be detrimental.
3. Known or suspected acute deep vein thrombosis, thrombophlebitis or pulmonary embolism.
4. Any local condition in which the garments would interfere, including:
    - Gangrene
    - Recent skin graft
    - Dermatitis
    - On untreated, infected leg wounds.

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, 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.

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Precautions

1. Proper garment application and connection to the OEM recommended pump is essential.
2. Garments should be positioned to prevent sustained pressure points on the skin, paying particular attention to patients who are unconscious, cannot feel or have reduced sensation and/or ability to move their leg(s)s.
3. While using the system, the patient's skin should be inspected frequently and regularly, paying particular attention to bony prominences such as the malleolus and heel. It is recommended that these checks should be performed not less than every hour if the patient cannot feel or has reduced sensation and/or ability to move their leg(s); in all other patients, perform these checks not less than every 6 hours.
4. The patient's skin should be inspected frequently during every shift
5. Clinical judgment is required to determine if the patient's skin condition requires additional protective measures, or if the therapy should be discontinued.
6. Garments should be removed immediately if the patient experiences tingling, numbness, or pain, and the physician notified.
7. Continuous intermittent pneumatic compression is recommended until the patient is fully ambulatory. Uninterrupted use of the system is recommended.
8. The system should be USED WITH CAUTION on patients with insensitive extremities, diabetes, and impaired circulation. The system should only be used on intact skin.

Note: These are guidelines only and should not replace clinical judgement or experience.

Guidelines and Recommendations:

- While using the system, the patient's limbs should be checked not less than every six hours, and more often if the patient has known circulatory or skin problems, or is diabetic.
- Note: Many patients are at risk for pressure ulcers on the heel. Use of the foot garments does not negate the necessity for heel protection and proper skin care.
- Clinical judgment should be used to determine if the patient's skin condition requires additional measures, or if the treatment should be discontinued and alternative modalities used.
- Refer to OEM recommendation to not use compression stockings with its system. If these are ordered by the physician, the clinician should ensure that the compression stockings are properly measured, applied and worn by the patient. Any compression stocking used should be routinely checked to ensure continued proper fit and application, in addition to assessing the condition of the skin.
- Where appropriate, patients should be instructed in the proper use of the system, the purpose of therapy and that any problems should be reported to the nursing staff.
- In the event the user would like to clean the compression garment, the garment may be cleaned with a washcloth and mild, soapy water and allowed to air dry.

General Recommendations

- Check that three are no kinks in the pump tubeset and garment tubing.
- Regularly check that the garments remain correctly fitted to the patient.

DVT Prophylaxis

- The system should be applied to the patient preoperatively, prior to the induction of anesthesia.

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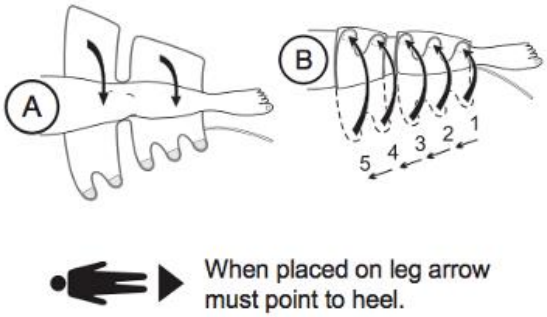
- The system should be used continuously for no less than 72 hours post-operatively or until the patient becomes fully ambulatory.
- If the garment cannot be applied to the operative limb during surgery, it may be applied to the limb once the patient reaches the recovery unit.
- In the non-surgical patient, the system should be initiated immediately the risk of DVT formation is identified.

Directions for Use

Note: Refer to the relevant OEM Instructions For Use, for complete information on the use of the system.

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. Before starting to wrap the garment around the leg, make sure the pump is in the OFF position.
4. The garments may be used on either leg. Unfold a garment and position the inflatable bladder directly behind the patient's calf as indicated below.

Note: the arrow on the underside of the garment must point to the heel.



5. Wrap the garment around the patient's leg. Then starting at the ankle working upwards, secure each fastener tab in turn, ensuring that the entire garment fits snugly. Repeat with the other leg.

Note: Garments are for single patient use only. Do not use the garments on a different patient after treatment.

6. Attach the garments to the OEM specified pump tubeset.
7. Power On the pump.
8. Follow the OEM Pump Instructions for use to determine the display is correct.
9. Follow the OEM Pump Instructions to start and end the therapy.
10. In the case of single leg application, refer to the original equipment manufacturer Operation Manual for Compression Therapy Settings.
11. Refer to original equipment manufacturer literature for pump compatibility, accessory information and further guidance

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List of Reprocessed Tri Pulse Garments

DVT Garment Item No.	Item Description
RM-TRP10	Flowtron Regular Sequential Calf Garment
RM-TRP20	Flowtron Large Sequential Calf Garment
RM-TRP30	Flowtron Regular Sequential Thigh Garment
RM-TRP40	Flowtron Large Sequential Thigh Garment
RM-TRP60L	Flowtron Bariatric Sequential Calf Garment

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.

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