

Arjo ReNu DVT Garment

INSTRUCTIONS FOR USE (IFU)

Garments

- To be used only under the direction of a physician
- Only for use with Flowtron® DVT prevention pumps manufactured by Arjo
- Not made with natural rubber latex
- Non-sterile

Indications

- To help prevent Deep Vein Thrombosis (DVT)

Contraindications

- IPC should not be used in the following conditions
- Severe arteriosclerosis or other ischemic vascular diseases.
- Known or suspected acute Deep vein Thrombosis (DVT) or phlebitis.
- Severe congestive cardiac failure or any conditions where an increase in fluid to the heart may be detrimental.
- Pulmonary Embolism.
- Any local condition in which the garments would interfere, including gangrene, recent skin graft, dermatitis or untreated leg wounds.
- If you are unsure of any contraindications refer to the patient's physician before using the device.

Serious Incident

If a serious incident occurs in relation to this medical device, affecting the user, or the patient then the user or patient should report the serious incident to the medical device manufacturer or the distributor.

Recommendations

- Continuous intermittent pneumatic compression is recommended until the patient is fully ambulatory. Uninterrupted use of this system is recommended.
- In the non-surgical patient, the system should be initiated immediately once the risk of DVT formation is identified,
- Garments should be removed regularly to inspect the skin for signs of redness or pressure points.

Cautions

- Garments should be removed immediately if patient experiences tingling, numbness or pain.
- When used for DVT prophylaxis, continuous use is recommended and any interruption of therapy for a substantial length of time should be at the discretion of physician.
- Lower limb positioning in relation to the garment and tubing should also be considered particularly when a patient is unconscious, or has reduced sensation/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 oedema.
- This product cannot be adequately cleaned and/or sterilized by the user in order to facilitate safe reuse and is therefore intended for single patient use. Attempts to self-clean or sterilize these devices may result in a biocompatibility, infection or product failure risk.

End of Life Disposal

Garment material or any other textiles, polymers or plastic materials etc. should be sorted as combustible waste. An alternative is to engage with Arjo ReNu for reprocessing.