

Intermittent Pneumatic Compression

Device RP100

Product Code: MI329

Alleva Medical's RP100 is a single-patient portable intermittent pneumatic compression (IPC) device designed to prevent the onset of deep vein thrombosis by stimulating blood flow and increasing venous flow velocity. Its portable and lightweight characteristics are especially ideal for home and community settings. Each RP100 unit is capable of delivering to the calf area 50mmHg of IPC pressure, a level that is clinically proven to improve hemodynamics in deep vein*. It is intended for individuals 21 years or older with high risks of venous thromboembolism (VTE) – individuals who are temporarily or permanent immobilized, undergoing long-distance travel, are post-surgery, older, cancer or obese.




Indications for Use:

- Aids the prevention of DVT onset
- Enhances blood circulation in lower extremities
- Diminishes post-operative pain and swelling
- Reducing wound healing time
- Aiding in the treatment of: stasis dermatitis, venous stasis ulcers, arterial and diabetic leg ulcers, chronic venous insufficiency and reduction of edema in lower limbs


Features and Benefits:

✓ Meaningful Compression:
Providing IPC up to 50mmHg

✓ Alert System:
Status Indicator light visible to user during use



✓ Ease of Use:
Position line and Left/Right text indicating area of pressure and ensures device is used properly




✓ No Tubing:
No tubing to pump unit means patient can be ambulatory if s/he desires

✓ Extended Battery Life:
16 hours without charging

✓ Patient Compliance Tracker:**
Device can track usage up to 300 sessions

✓ Conversion to a Multi-User Unit:
Removable pump body also allows limited reuse of the unit, lowering cost



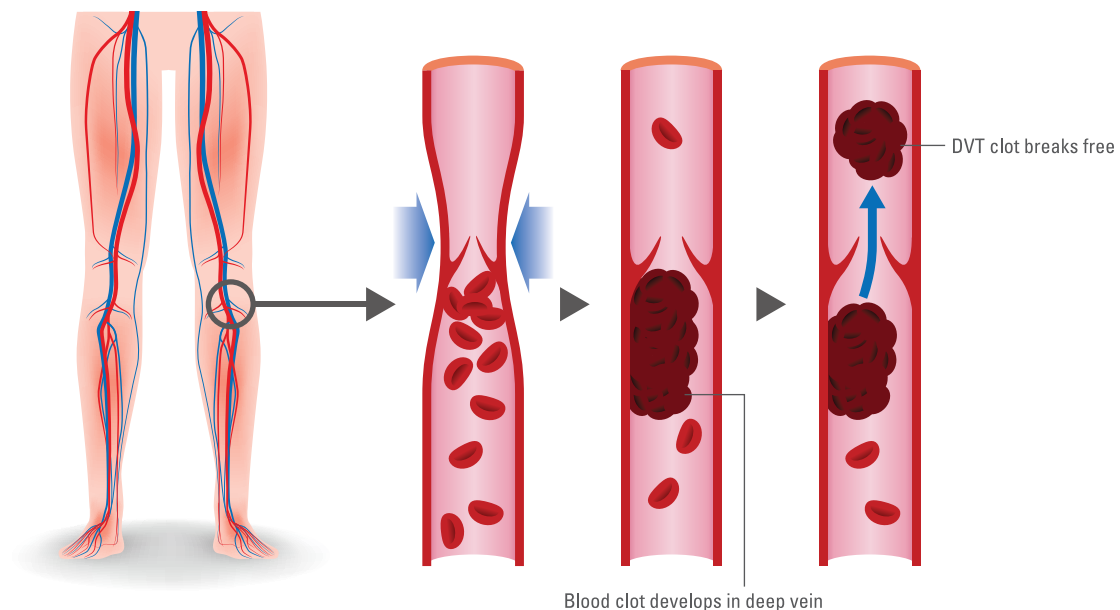
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|-------------------------------|------------------------------|
| Pump dimension | 13,5 x 7,2 x 3,4cm |
| Sleeve length | 61 x 27cm |
| Battery type | Bespoke 3,7V Lithium battery |
| Operating time | 16 hours |
| Charging time | ~5 hours to full charge |
| Pre-set pressure level | 50±5 mmHg |
| Inflation time | ≤20 seconds |
| Rest period | 50 seconds |
| IP class | IP22 |
| US FDA | 510k cleared (K191107) |
| Europe | CE certified |



| Product code | Product description | Packaging | SHIPMENT dimensions |
|--------------|---------------------------|----------------------|---------------------|
| MI329 | RP100 DVT Prevention Unit | 10 pairs per shipper | 41 x 32 x 42 cm |

Background on Deep Vein Thrombosis (DVT)

Venous thromboembolism (VTE) refers to a blood clot that starts in a vein, and is associated with increased morbidity and mortality. According to American Heart Association, VTE is the third leading vascular diagnosis after heart attack and stroke, affecting between 300,000 to 600,000 Americans each year. When blood clot develops in the deep vein in the lower leg, DVT occurs. Low blood velocity and lack of blood flow due to immobility are the major causes of clot formation. When DVT clot breaks free from a vein wall, it could travel to the lungs and then blocks some or all of the blood supply, causing a condition called Pulmonary Embolism (PE) and potentially endangering the life of the patient.



* Selected Clinical References

Nose Y, Murata K, Wada Y, Tanaka T, Fukagawa Y, Yoshino H, Susa T, Kihara C, Matsuzaki, M. Journal of Cardiology (2010) 55, 384-390. The impact of intermittent pneumatic compression devices on deep venous flow velocity in patients with congestive heart failure

Malone MD, Cisek PL, Comerota AJ Jr, Holland B, Eid IG, Comerota Aj. Journal of Vascular Surgery (1999) 29(4), 593-9. High-pressure, rapid inflation pneumatic compression improves venous hemodynamics in healthy volunteers and patients who are post-thrombotic

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