Defender™ Mobile Blood Clot Prevention Device

Name of Product: Defender™ Mobile Blood Clot Prevention

Product Number: 08-0028 Defender™ Mobile Blood Clot Prevention device

Product Configuration: 08-0028 Defender™ Mobile Blood Clot Prevention device, Each

Manufacturer: Ortho8 Inc.

Customer Service Phone: 800-604-2807

Customer Service E-mail: patientsupport@pmpmed.com

Vendor: Lovell Government Services

Vendor FSS #: V797D – 50450

Vendor Classification: American Manufacturer

Vendor DUNS #: V797D – 50450

Vendor CAGE #: 71G35

Vendor EIN: 46 – 3795418

Vendor Address: 223 W Gregory St Pensacola, FL 32503

Vendor Phone: 850-684-1867

Vendor Fax: 850-254-9853

Vendor E-mail: customerservice@lovellgov.com

FSS Pricing: 08-0028 Defender™ Mobile Blood Clot Prevention device, $791.71

FDA Approval #: K212731

Indications for Use:
The Defender Vascular Therapy System, model 08-0028, 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
• Reducing wound healing time
• Aid in the treatment of: stasis dermatitis, venous stasis ulcers, arterial and diabetic leg ulcers, chronic venous insufficiency, and reduction of edema in the lower limbs.
• As prophylaxis for Deep Vein Thrombosis (DVT) by persons expecting to be stationary for long periods of time.

Contraindications:
The Defender Vascular Therapy System MUST NOT be used to treat the following conditions:
• Persons with suspected, active, or untreated: deep vein thrombosis, ischemic vascular disease, severe arteriosclerosis, pulmonary edema, severe congestive heart failure, thrombophlebitis, or an active infection.
• On the legs 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.
• On any neuropathy
• On extremities that are insensitive to pain
• Where increased venous or lymphatic return is undesirable
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**Mechanism of Action**
Defender™ Mobile Blood Clot Prevention device is a self-contained, compact DVT therapy device delivering asymmetric compression that duplicates the blood flow of an ambulating patient.

**Safety Statement**
Defender™ Mobile Blood Clot Prevention has been subjected to testing to demonstrate that this device is safe for the indicated use.

Defender™ Mobile Blood Clot Prevention is a safe and effective means of preventing potentially fatal blood clots. Defender™ can help reduce the usage of expensive and adverse pharmaceuticals. Defender™ protects patients from the hospital setting to their at-home recovery when they are most vulnerable of developing a blood clot. The easy to use design, and long-lasting battery can lead to greater patient compliance.

**Economic Justification/ Advantage**

1. PLACE ON CALVES
2. EASY ONE-TOUCH OPERATION
3. 24 HOURS OF ALL DAY PROTECTION

**Technical Specifications**

- **Device dimensions:** 5.17” x 2.6” x 1.48” (125mm x 62.5mm x 33.3mm)
- **Weight:** approximately 0.74 lbs. (335g)
- **Modes of operation:** cyclic
- **Source of power:** 5Vd.c. @ 2A
- **Battery:** 3.7 Li-ion battery (runtime 24 hours)
- **Cycle time:** 60 seconds
- **Leg compression pressure (non-adjustable):** 55 mmHg

**TRM Approved**
Yes

**FIPS Compliant**
Yes

**Package Barcode**
Yes

**Sterile Product**
No