Wright Fit: A Novel Ambulatory Compression Therapy Device for Chronic Venous Insufficiency

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Executive Summary

In the United States, approximately 7 million people are affected by chronic venous insufficiency (CVI). CVI results when the peripheral venous system is impaired, resulting in painful swelling, venous ulcers, and cutaneous abnormalities in the extremities. Traditional compression devices, which consist of heavy pumps and bulky sleeves, completely immobilize patients during treatment, decreasing quality of life and ability to work. To address this problem, our team has partnered with Wright Therapy to develop the Wright Fit, a novel ambulatory pneumatic compression therapy device that will apply gradient pressure to the legs to treat CVI without immobilizing the user. The estimated manufacturing cost of the Wright Fit is $365, allowing it to sell for a competitive price. The Wright Fit would be ideal for patients with mild to moderate cases of CVI who require treatment in a home clinical setting and want to maintain an active lifestyle.

Problem & Clinical Need

Chronic Venous Insufficiency

- Effects about 20% of men and 40% of women by age 50, or about 7 million people in the US3
- Occurs when the peripheral venous system is impaired by trauma, thrombosis, venous obstruction, or muscle and vein valve failure2
- Causes painful swelling, venous ulcers, varicose veins, and cutaneous abnormalities in the extremities (Figure 1)

Compression Therapy

- Effective treatment for CVI
- Devices provide active pressure that forces fluid from the extremities towards the direction of the heart, reducing swelling and promoting healing of ulcers and cutaneous abnormalities5
- Strict daily treatment regimens required to prevent worsening of symptoms12
- Existing venous ulcer failing to heal within 6 months prior to compression therapy12

Current products limit patients to a bed or chair for treatment, prescriptions may be filled without reimbursement13

- May be filled without reimbursement13
- 3 full time employees
- $245,000 total manufacturing employee salary11

Market Analysis

Market Size

- $1.16 Billion US Market5
- Only 40% is active compression5

Market Segmentation

- Market segmented by disease severity and clinical setting
- Wright Fit intended for mild to medium CVI treatment in a home setting
- Elderly patients are the target demographic

Competitor Analysis

- Only one ambulatory compression device on the market - the ACTouch by Tactile Medical
- Bulky device that hinders ease and discrete use, could lower patient compliance

Description of Design

Wright Fit: Compression Sleeve

- Features an adjustable, compact sleeve comprised of three compression chambers (Figure 4)
  - Angular pattern to better direct pressure up the leg
  - Three Vekro straps to adjust to patient calf size
  - Chambers heat-sealed to prevent pressure leaks
  - Flame resistant fabric
  - Small, compact 1/8" bonded tubing
- Provides gradient compression to the ankle and calf regions without hindering user movement
  - Distal chambers with higher pressures, proximal chambers with lower pressure

Wright Fit: Control System

- Arduino microcontroller (Figure 5)
- 3 miniature compressors connected to 3 transducers that can be turned on via a digital signal
- Serve can be signaled to turn on/off the valve
- Analog pressure sensors allow precise control of chamber pressure
- Diodes ensure no backward flow of current
- Replaceable batteries
- Encased in acrylic laser cut box
- On/off button (user controlled)

Wright Fit: User Experience

- Ambulatory
  - Flexible placement of control box
  - Dimensions: 8” x 4” x 2 1/8”
  - Black Vekro elastic strap allows adjustability and unhindered mobility
  - Can be placed around waist or upper leg (Figures 6 and 8)
- Uses conventional store-bought batteries
- Comfortable fit
- Available in small, medium, and large sleeve sizes

Wright Fit: Testing

- Inflation time: ~15 seconds
- Rest time: ~10 seconds
- Deflation time: ~1 seconds
- Pressure of chambers range between 40-60 mmHg, obtained from inline pressure sensors (Figure 7)

Wright Fit: Assembly Line Manufacturing

- Must fulfill requirement set forth in the Buy American Act14
- Compliance with FDA Regulatory Pathways
- Class II medical device
- Code CFR 807.300
- 501(k) submission required
- Minimal risk, similar to predicate devices
- Differences in products to its technical characteristics

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Medicare/Medicaid Reimbursement

- Reimbursed in full when requirements met
- Existing venous ulcer failing to heal within 6 months prior to compression therapy12
- Trial period of 4 weeks required
- Prescriptions may be filled without reimbursement14

Veterans Association Reimbursement

- Must fulfill requirement set forth in the Buy American Act14
- 50% of manufactured parts must be made in the US

References