

CVI by the Numbers

6 MILLION

People in USA with CVI.¹

37-69%

Recurrence Rate of VLU's after Treatment.^{3/4}

\$3 BILLION

Cost to USA for Treatment of CVI, annually, est.²

2 MILLION

Work days lost to dressing changes, each year in USA.²

Overview:

Aero-Wrap™ is a revolutionary, FDA-cleared gradient compression product designed to effectively treat chronic venous insufficiency and leg edema by delivering precise gradient compression to the lower leg.

Aero-Wrap™ is an air-filled compression therapy device made of light, flexible materials with hook and loop straps for easy application. Aero-Wrap™'s proprietary AeroGauge™ inflation system allows clinicians, patients, and caregivers the ability to accurately apply and manage compression therapy. Unlike compression bandages and stockings, Aero-Wrap™ and AeroGauge™ provides adjustable, sustainable, and measurable gradient compression.

Aero-Wrap™ Products Have Been Designed To:

- Be easily applied by a healthcare professional, self-applied, or even applied by an unskilled caregiver.
- Allow for quick wound dressing changes.
- Be worn without slippage and/or wrinkling.
- Provide accurate compression that can be consistently maintained during the treatment cycle even with reductions in swelling.
- Deliver comfortable therapeutic compression levels while walking (working compression) or standing (resting compression).

	Aero-Wrap™	Aero-Wrap Acute™
Chronic Venous Insufficiency (CVI)	●	●
Open Venous Leg Ulcers and Stasis Dermatitis		●
Healed Venous Leg Ulcers	●	
Lymphatic Obstruction & Lymphedema	●	
Swollen, Achy Legs	●	●



Aero-Wrap Acute™

Select the desired compression range

Patented bladder technology provides gradient profile



Aero-Wrap™

Case Study Background

The images below document the ongoing treatment of a venous leg ulcer patient. The patient is a 79 year old female with chronic venous insufficiency and a large circumferential venous ulcer with a 2-year history of non-healing.

She is being treated with a short stretch Unna's bandage and Aero-Wrap Acute™ inflated to provide 40-50 mmHg compression. Dressing changes occurred every 4-5 days for the first 2 weeks under treatment and then once a week until healing. Previous treatments that have failed include 2-layer and 4-layer compression bandages applied once weekly by visiting nurse services.



Day 0 (pre-treatment)

Day 0 (pre-treatment)
close-up

Treatment Layer 1:
Unna Boot

Treatment Layer 2:
Aero-Wrap Acute™

Day 5

Day 14



Day 29

Day 49 (follow up)

Case Study Results and Analysis

The photographs depict the progress of the wound throughout a 29 day period as well as follow-up on day 49. The patient in this case study responded well to the treatment regimen of Unna's bandage as primary dressing and Aero-Wrap Acute™ for compression.

Note the epithelium migrating from the hair follicles and dermal adnexa by day 5 as well as a significant reduction in edema and wound depth. Notice healthy new epithelium and 100% granulating wound bed by day 14. By day 29, the patient's wound had completely closed.

This patient has suffered from CVI and a history of a non-healing leg ulcer of greater than two years and has shown meaningful progress using the Aero-Wrap Acute™ with full wound closure in 29 days. The patient's ulcer remains closed at day 49 exhibiting a significant improvement of the CVI symptoms and underlying venous disease with continued use of the Aero-Wrap™ for compression therapy after wound closure.

To learn more about Aero-Wrap Acute™ and this ongoing case study, please visit: www.Aero-Wrap.com

Clinical Study

Sun Scientific participated in a non-inferiority study of 15 consecutive study patients over 12 weeks in order to evaluate and compare the use of Aero-Wrap™ Gradient Compression System vs. the standards of care, 4-Layer Bandaging (4LB), on the healing rate of VLU and management of CVI symptoms.

Effectiveness of a Novel Static Pneumatic Gradient Compression Therapy Device for the Treatment of Venous Leg Ulcers and Chronic Venous Insufficiency

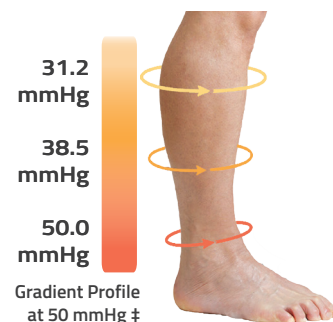
Participants

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Clinical Outcome	Aero-Wrap™	4LB
Mean Wound Score ##	2.3 ✓	2.0
Patients with 50% Wound Closure at 4 weeks	60% ✓	52%
Leg Edema Reduction ☒	21.8% ✓	20.5%



Gradient Profile (mmHg) ‡: Average compression gradient from Alvarez, et. al study. Variation from patient to patient may exist

Mean Wound Score ## : +3 = complete closure; +2 = >50% closure at 4 weeks; +1 = 25-49% closure at 4 weeks; -1 = 1-24% closure at 4 weeks; -2 = no improvement; -3 = wound deterioration

Leg Edema Reduction (cm) ☒ : Reduction of mid-calf circumference between the baseline and week 4

Study Conclusions:

- Compression therapy with Aero-Wrap™ was at least as effective as traditional compression bandage therapy.
- Aero-Wrap™ is easily self-applied, can be worn with normal shoes, and can be easily removed for showering and sleeping.
- Aero-Wrap™ may provide a cost-effective alternative for those who do not wish to visit the doctor weekly or those who desire a more active lifestyle.

REFERENCES:

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3. McDaniel HB, Marston WA, Farber MA, Mendes RR, Owens LV, Young ML, et al. Recurrence of chronic venous ulcers on the basis of clinical, etiologic, anatomic, and pathophysiologic criteria and air plethysmography. J Vasc Surg. 2002; 35:723-8
4. Langer V. Preventing leg ulcer recurrence. Indian Dermatology Online Journal. 2014 Oct-Dec; 5(4): 534-535.