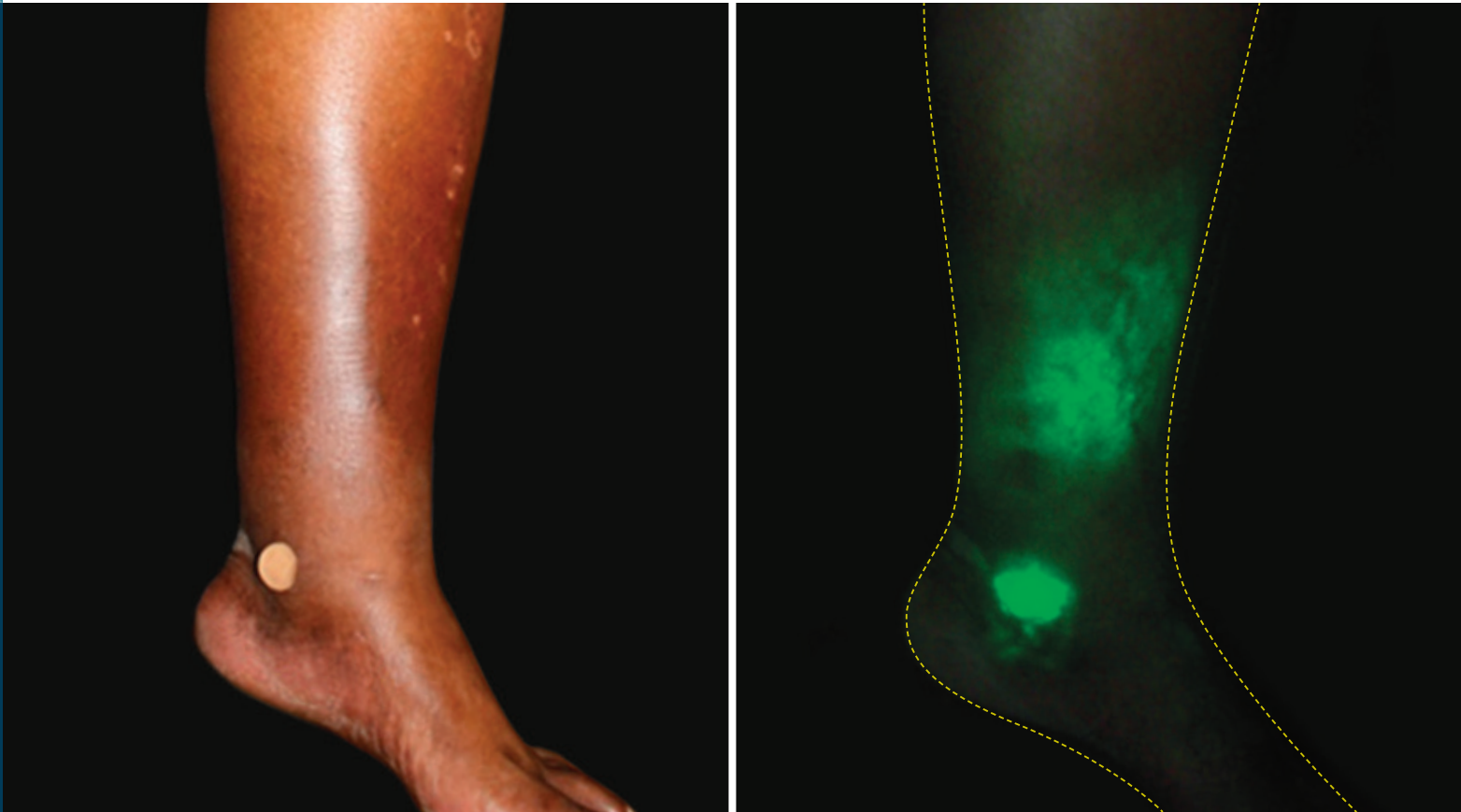


# Understanding lymphedema secondary to chronic venous insufficiency (CVI).

Augment patient care with effective at-home therapy to improve clinical outcomes.



*Fluorescence imaging illustrates lymphatic dysfunction associated with chronic venous insufficiency<sup>1</sup>*

# Chronic edema.

The veins and lymphatics form one interdependent fluid-balance system. For CVI patients with chronic edema (phlebolymphe~~de~~ma), this venolymphatic connection means that a singular focus on repairing veins may not resolve swelling — the lymphatics may also need to be addressed.<sup>2</sup>

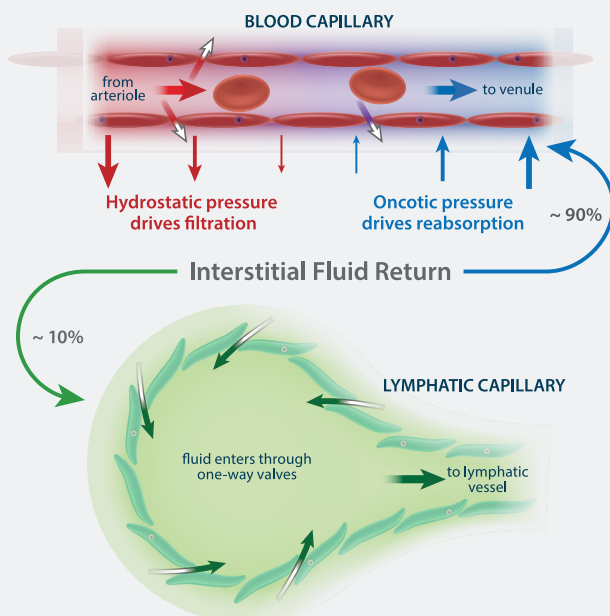
## Chronic edema indicates an inadequacy or failure of lymphatic drainage.

The classic model of the Starling Principle (*below, left*) held that capillary oncotic pressure drove reabsorption of interstitial fluid into the venules, leaving approximately 10 percent to be removed by the lymphatic system. However, subsequent research has revealed the role of the endothelial glycocalyx layer in the capillary bed: there is no net venous reabsorption and interstitial fluid returns to the circulation only via the lymphatics, as shown in the modern view below.<sup>3,4</sup>

### THE REVISED STARLING PRINCIPLE

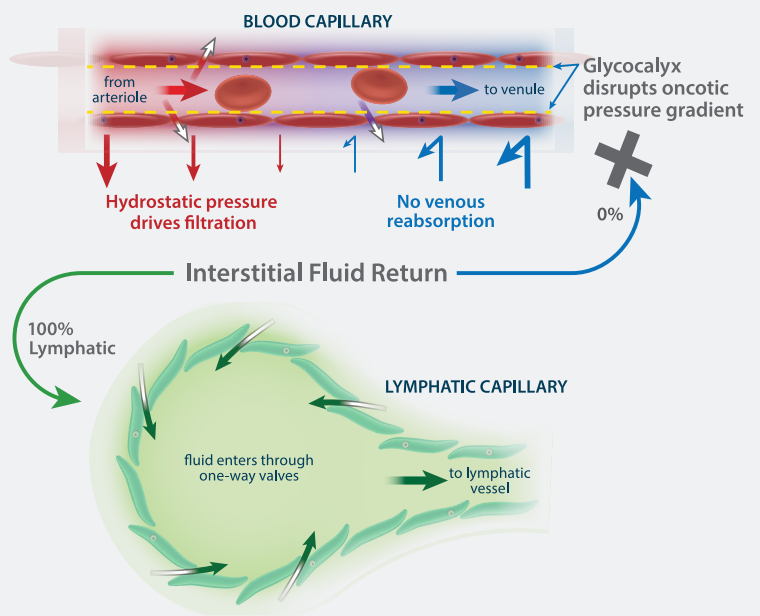
#### Classic model: now known to be incorrect.

Traditionally it was taught that 90% of interstitial fluid was reabsorbed by the venous system. This is now known to be incorrect.



#### Modern view: glycocalyx model.

Modern evidence shows the endothelial glycocalyx prevents venous reabsorption. Therefore, all chronic edema indicates an inadequacy or failure of lymphatic function.<sup>3,4</sup>



# Lymphedema secondary to CVI.

## **CVI-related lymphedema is a two-system failure that requires early detection and comprehensive treatment.**

Phlebolymphe­dema occurs when the excessive burden of capillary filtrate from venous hypertension overwhelms the lymphatics, leading to lymphatic hypertension and lymphatic damage. Just as CVI causes microangiopathic changes in the venous system, prolonged chronic edema can permanently damage the lymphatics,<sup>5</sup> paving the way for progressive infection and complications,<sup>6</sup> increased office visits, and costly treatments and hospitalizations.

Compression garments and appropriate endovenous or surgical interventions can reduce venous hypertension. However, phlebolymphe­dema requires early detection and comprehensive lymphatic therapy to reduce buildup of protein-rich edema and thereby lower risk of infection and inflammation.<sup>7</sup> Pneumatic compression devices (PCDs) can complement acute lymphatic therapy and improve patient self-care.



...clinical examination is adequate for diagnosing lymphedema and that all patients with chronic venous insufficiency (C3–C6) should be treated as lymphedema patients.<sup>8</sup>

### **2022 EXPERT CONSENSUS FOR LYMPHEDEMA DIAGNOSIS AND TREATMENT:<sup>8</sup>**

All patients with chronic venous insufficiency should be considered as lymphedema patients.

Regular use of compression garments reduces progression of lymphedema.

Pneumatic compression should be recommended for lymphedema patients.



Read the full consensus.

# Lymphedema secondary to CVI (phlebolymphe<sup>1</sup>edema).

## CHRONIC VENOUS DISEASE (CVD)

CLINICAL STAGE

## LYMPHATIC INVOLVEMENT SHOWN VIA FLUORESCENCE LYMPHATIC IMAGING<sup>1</sup>

**C0** No Clinical Signs

**C1** Telangiectasias or Reticular Veins

**C2** Varicose Veins



A healthy lymphatic system (right) allows lymph to enter lymphatic capillaries. In early stage venous disease, lymphatics manage the venous filtrate overload.

**C3** Edema (Pitting)



Lymphatics are unable to accommodate excess venous filtrate so swelling occurs.<sup>3</sup>

**C4: Edema (Non-pitting)**

**C4a: Pigmentation or Eczema**

**C4b: Lipodermatosclerosis or Atrophie Blanche**

**C4c: Corona Phlebectatica**

**C4**



Prolonged excess venous filtrate overburdens lymphatics causing protein buildup and permanent damage and/or obstruction.

Exaggerated immune reactions such as stasis eczema and dermatitis are indicative of compromised lymphatic immunity. Dermal backflow follows hemosiderin staining.<sup>1</sup>

Chronic inflammation and fibrosis are indicative of a buildup of proteins that the lymphatics are unable to clear due to obstruction. Fibrosis indicates protein-rich buildup from lymphatic obstruction regardless of swelling. Corona phlebectatica is recognized as a predictor of venous ulcer with risk profile similar to other stages.

**C5** Healed Venous Ulcer

**C6** Active Venous Ulcer

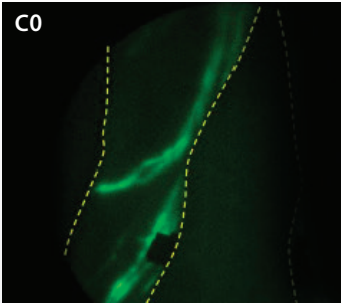
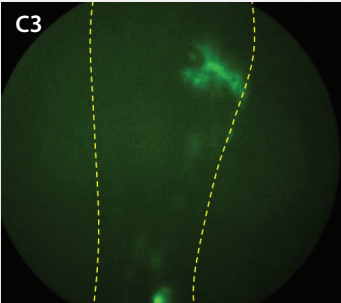
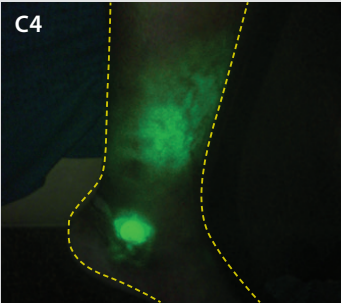
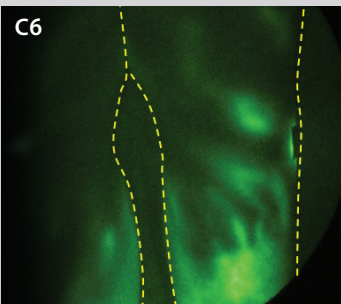


Scar tissue disrupts lymphatic drainage.

Open wound disrupts superficial lymphatics and lymphatic drainage from the ulcers.

**LYMPHATIC CHANGES ARE PRESENT IN EARLY CLINICAL STAGES OF CHRONIC VENOUS DISEASE**

In biopsies, patients with CVI show structural lymphatic changes, including collapsed lumens and disturbance of lumen-opening filaments, resulting in reduced function.<sup>5</sup> This chart illustrates how lymphatics can be impacted at each clinical stage of the Comprehensive Classification System for Chronic Venous Disorders (CEAP):<sup>9</sup>

NEAR INFRARED		LYMPHEDEMA (LE) CLINICAL STAGE	
Water and flow through lymphatics are able to		<b>Stage 0</b>	<b>Latent</b> No clinical signs.
filtrate,		<b>CONSIDERED LYMPHEDEMA — PCD TREATMENT RECOMMENDED<sup>8</sup></b>	
tics, resulting in dysfunction. <sup>3</sup>		<b>Stage 1</b>	<b>Spontaneously Reversible Pitting Edema</b> Soft swelling (i.e., sock line) that progresses throughout the day but may resolve overnight or with other conservative measures including compression, elevation, or exercise.
and allergic contact immune function. <sup>6</sup>		<b>Stage 2</b>	<b>Irreversible Non-pitting Edema</b> Early stage 2 presents with soft pitting edema which does not resolve with elevation or conservative treatment. As it progresses, patients may present with skin hardening/fibrosis, and increased risk of infection/cellulitis.  Symptoms may also present as deepened skin folds, fibrosis, scaling or hyperkeratosis, hyperpigmentation.  <i>Left unmanaged, lymphedema can progress to:</i>
uildup of fluid and insufficiency or failure. insufficiency, ized as a leading er C4 skin changes. <sup>10</sup>		<b>Stage 3</b>	<b>Lymphostatic Elephantiasis</b> Extensive and/or disfiguring fibrotic swelling, blistering and ulcerations, lymphorrhea, hyperkeratosis, papillomas and recurrent infections.
h fluid leaks			

# The Nimbl™ system.

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## Patients to consider for Nimbl may have one or more of the following:

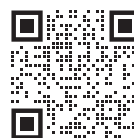
- Lymphedema, including secondary CVI (C3+) who haven't responded to conservative treatments
- No history or clinical presentation of truncal swelling
- Skin changes, fibrosis, and/or ulceration below the knee (C4–C6)



The Nimbl (E0651) is a non-programmable (basic) pneumatic compression device that delivers effective treatment with a small, light, and compact controller designed for improved patient experience. Nimbl's gentle and unique inflation sequencing directs lymphatic fluid away from the affected area toward healthy, functioning regions of the body where it can be naturally absorbed and eliminated.

### Vascular Patient Insights Survey<sup>11</sup>

Pneumatic compression leads in patient satisfaction, perceived effectiveness and price value when compared to other treatments, including compression, manual lymphatic drainage and more.



Need help documenting PCD criteria? Download our documentation guide here.

### *Journal of Vascular Surgery*: Data indicates conservative therapy plus simple pneumatic compression device reduces costs.<sup>12</sup>

- 39% reduction of total lymphedema and sequelae-related costs

# The Flexitouch® Plus system.

## Patients to consider for Flexitouch Plus may have one or more of the following:

- Lymphedema of any etiology or idiopathic, including secondary to CVI (C3+) of the lower extremity who has tried and failed conservative treatment
- A history or clinical presentation of truncal swelling, with or without a history of radiation and/or lymph node dissection to the abdominal or pelvic region
- Skin changes, fibrosis, and/or ulceration of lower extremity with truncal involvement (C4–C6)
- Skin integrity and pain indicate the need for a customizable sequential treatment



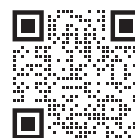
The **Flexitouch Plus** (E0652) is a programmable (advanced) pneumatic compression device system that is clinically proven to stimulate the lymphatic system. The unique design of the pneumatic chambers sequentially inflate and deflate, creating a gentle wave-like application of pressure to stimulate the movement of lymphatic fluid and direct it toward properly functioning areas of the body.

### *Journal of the American Medical Association Dermatology: At-home Flexitouch treatment improves health outcomes and reduces costs.*<sup>13a,13b</sup>

- 75% reduction in rate of cellulitis episodes
- 40% reduction in rate of outpatient hospital visits
- 36% reduction in rate of lymphedema-related costs per patient

### *Journal of Vascular Surgery: Evidence supporting optimal treatment of phlebolymphe<sup>12</sup>*

- 69% reduction vs. conservative therapy alone
- 85% reduction vs. simple lymphedema PCDs
- 53% reduction vs. other advanced lymphedema PCDs



Learn more about how the Flexitouch is backed by the most extensive body of clinical evidence of any PCD on the market.

## OUR SUPPORT NEVER ENDS

Tactile Medical is committed to improving your patients' quality of life, which shows in our end-to-end customer support. Only we provide a national network of Patient Education Consultants to ensure effective at-home product use, patient advocates to streamline insurance claims, and a local representative to assist with your needs.

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Individual results may vary.

**Indications/contraindications:** Indications, contraindications, warnings, and instructions for use can be found in the product labeling supplied with each device.

**Caution:** Federal (U.S.) law restricts this device to sale by or on the order of a licensed healthcare practitioner.

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Patient photos courtesy of Dr. Tony Gasparis or patient photo consent on file at Tactile Medical.

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