



## Tactile Medical Announces Positive Clinical Trial Results in Lymphedema Patients Using Advanced Pneumatic Compression Device Therapy

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### Largest U.S. Prospective Clinical Trial Ever Conducted Demonstrated High Compliance with the Flexitouch® System and Significant Improvements Across Study Endpoints

MINNEAPOLIS, Sept. 25, 2024 (GLOBE NEWSWIRE) -- Tactile Systems Technology, Inc. ("Tactile Medical"; the "Company") (Nasdaq: TCMD), a medical technology company providing therapies for people with chronic disorders, today announced the publication of a new clinical study in the *Journal of Vascular Surgery, Venous and Lymphatic Disorders*. This study assessed outcomes associated with use of the Company's Flexitouch advanced pneumatic compression device (APCD) in Veterans with lower extremity lymphedema. Notably, this 52-week study represents the largest peer-reviewed, prospective, clinical trial investigating PCDs and lymphedema ever published in the United States.

The prospective, longitudinal, pragmatic study publication, titled "*Longitudinal assessment of health-related quality of life and clinical outcomes with at home advanced pneumatic compression treatment of lower extremity lymphedema*", was authored by Padberg et al. and included 179 Veterans across four participating VA medical centers. The primary outcome measures included disease-specific health-related quality of life (QoL) endpoints obtained at baseline and again at each of 12, 24, and 52 weeks. The secondary outcome measures assessed limb circumference, cellulitis events, skin quality, and therapy compliance over the course of 52 weeks. Among the patients included in the study, chronic venous insufficiency was the most common etiology of lymphedema (phlebolymphe'dema), presenting in approximately 63% of study participants. Further, mild lymphedema was the most common disease stage, presenting in 68% of patients.

The study demonstrated significant improvements in its primary endpoint of health-related and general quality of life measures. Specifically, Lymphedema Quality of Life (QoL) increased from 6.2 to 6.9, which includes improvements in function, appearance, symptoms, and emotion.

The secondary endpoint results demonstrated several statistically significant improvements, baseline to 52 weeks, with reductions in limb girth, cellulitis events, and skin hyperpigmentation. Among these results, the following were observed:

- Limb girth decreased by 1.4 cm
- Cellulitis events decreased from 21.4% to 6.1%
- Skin hyperpigmentation decreased from 75% of patients to 40%

There were additional improvements also noted in compliance and limb girth reduction which included:

- 92% patient compliance (defined as used for 5 to 7 days per week) with Flexitouch at 8 weeks and 72% patient compliance at 52 weeks
- 74% patient compliance with compression garments at 52 weeks, compared to 64% at baseline
- 6% limb girth reduction at 12 weeks in patients with moderate (stage 2) and severe (stage 3) lymphedema.

"We sincerely thank the clinical researchers, patients, and VA Medical Centers for advancing peer-reviewed evidence that supports clinical and patient benefits of our Flexitouch therapy," said Sheri Dodd, President and Chief Executive Officer of Tactile Medical. "Achieving these impressive study results, including outstanding compliance over a 1-year timeframe, validates the importance of APCD therapy outcomes and demonstrates a patient experience that supports strong adherence to therapy. We are proud to provide Veterans the at-home tools they need to improve their clinical symptoms and quality of life."

Full text of the study may be found online at: [https://www.jvsvenous.org/article/S2213-333X\(24\)00208-7/fulltext](https://www.jvsvenous.org/article/S2213-333X(24)00208-7/fulltext).

#### About Tactile Systems Technology, Inc. (DBA Tactile Medical)

Tactile Medical is a leader in developing and marketing at-home therapies for people suffering from underserved, chronic conditions including lymphedema, lipedema, chronic venous insufficiency and chronic pulmonary disease by helping them live better and care for themselves at home. Tactile Medical collaborates with clinicians to expand clinical evidence, raise awareness, increase access to care, reduce overall healthcare costs and improve the quality of life for tens of thousands of patients each year.

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