



## **Tactile Medical Announces New Clinical Publication Highlighting the Role of Chronic Venous Insufficiency in Causing Lower Extremity Lymphedema**

February 13, 2020

**Researchers concluded that Chronic Venous Insufficiency, not cancer-related therapy, may be the most common cause of Lower Extremity Lymphedema in the United States, with an estimated prevalence of 16 million individuals**

MINNEAPOLIS, Feb. 13, 2020 (GLOBE NEWSWIRE) -- Tactile Systems Technology, Inc. ("Tactile Medical") (Nasdaq: TCMD), a medical technology company focused on developing medical devices for the treatment of chronic diseases at home, today announced the publication of a new clinical study demonstrating the prevalence of chronic venous insufficiency-related lymphedema ("CVI-related lymphedema," also known as "Phlebolymphe'dema"). While cancer-related lymphedema remains a significant causal factor, the results of the study provide further support for the view espoused by some experts and accumulating evidence that phlebolymphe'dema, not cancer, may be the leading cause of lower extremity lymphedema in the U.S. today.

The study, titled *The clinical characteristics of lower extremity lymphedema in 440 patients*, was a 3-year, single-center retrospective cohort study conducted by Steven M. Dean, DO\* et al. and e-published in the *Journal of Vascular Surgery: Venous and Lymphatic Disorders*. The purpose of this study was to retrospectively document the prevalence and manifestations of the four most commonly encountered causes of lower extremity lymphedema in 440 patients who presented to an oncology-affiliated physical therapy lymphedema center in a large urban academic medical center.

Despite a likely referral bias favoring the cancer population, researchers found that chronic venous insufficiency was the most common cause of lymphedema, responsible for 41.8% of lower extremity lymphedema cases, followed by cancer-related lymphedema (33.9%), primary lymphedema (12.5%) and lipedema with secondary lymphedema (11.8%). Based on these findings they concluded that chronic venous insufficiency, not cancer-related therapy, may be the most common cause of lower extremity lymphedema in the U.S.

In a 2016 study, Rasmussen et al.<sup>1</sup> provided insight into the lymphatic connection to CVI. Using near-infrared fluorescence lymphatic imaging (NIRFLI), they showed lymphatic dysfunction in CVI patients with very early stages of the disease, and certainly when the patient exhibited changes to the visible dermal (skin) layer. Dean et al. suggest that the prevalence of lymphedema due to CVI is approximately 16 million in the United States alone, based on prior literature estimating that 5% of the population has some skin changes associated with CVI.

"The clinical literature has continually cited a U.S. lymphedema prevalence at between 3 to 5 million," said lead author Steven M. Dean. "That citation is based solely on 2003 data generated in Europe by Moffatt et al.<sup>2, 3</sup> Since many in the medical community believed that it significantly underestimates the number, it is gratifying to be able to now support significance for a broader patient population." Whereas cancer is probably responsible for nearly 4 million U.S. patients, the phlebolymphe'dema population is likely four times greater. This understanding should inform the medical community to notice the manifestations of venous hypertension earlier in the disease process and address them, helping millions of patients improve their symptoms, potentially saving valuable healthcare resources.

"The findings of this study highlight the potentially large, underdiagnosed and underserved patient population living with phlebolymphe'dema, and the need for increased awareness of this condition across the medical community," said Gerald R. Mattys, Chief Executive Officer of Tactile Medical. "Tactile Medical is uniquely positioned to serve these patients, as prior research has demonstrated that management of phlebolymphe'dema with our Flexitouch system is associated with significant health and economic benefits, even in comparison to treatment with other forms of therapy."<sup>4</sup>

The study is available with open access and may be found online at: <https://doi.org/10.1016/j.jvs.2019.11.014>

\*Steven M. Dean, DO is a member of the Tactile Medical Scientific Advisory Board and their physician speakers bureau.

### References:

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2. Moffatt CJ, Franks PJ, Doherty DC, Williams AF, Badger C, Jeffs E, Bosanquet N, Mortimer PS. Lymphoedema: an underestimated health problem. *QJ Med* 2003; 96(10): 731-738.
3. Stout NL, Weiss R, Feldman JL, Stewart BR, Armer JM, Cormier JN, Shih Y-CT. A systematic review of care delivery models and economic analyses in lymphedema: health policy impact (2004-2011). *Lymphology* 2013; 46 (1), 27-41
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### About Tactile Medical

Tactile Medical is a leader in developing and marketing at-home therapy devices that treat chronic swelling conditions such as lymphedema and chronic venous insufficiency. Tactile Medical's Mission is to help people suffering from chronic diseases live better and care for themselves at home. The Company's unique offering includes advanced, clinically proven pneumatic compression devices, as well as continuity of care services provided

by a national network of product specialists and trainers, reimbursement experts, patient advocates and clinicians. This combination of products and services ensures that tens of thousands of patients annually receive the at-home treatment necessary to better manage their chronic conditions. Tactile Medical takes pride in the fact that our solutions help increase clinical efficacy, reduce overall healthcare costs and improve the quality of life for patients with chronic conditions.

**Legal Notice Regarding Forward-Looking Statements:**

This release contains forward-looking statements. Forward-looking statements are generally identifiable by the use of words like “may,” “will,” “should,” “could,” “expect,” “anticipate,” “estimate,” “believe,” “intend,” “continue,” “confident,” “outlook,” “guidance,” “project,” “goals,” “plans,” “look forward” or “commit” or the negative of these words or other variations on these words or comparable terminology. The reader is cautioned not to put undue reliance on these forward-looking statements, as these statements are subject to numerous factors and uncertainties outside of the Company’s control that can make such statements untrue, including, but not limited to, the adequacy of the Company’s liquidity to pursue its business objectives; the Company’s ability to obtain reimbursement from third party payers for its products; loss or retirement of key executives, including prior to identifying a successor; the Company’s Chief Executive Officer transition, including disruptions and uncertainties related thereto, the Company’s ability to appoint a successor with the desired level of experience and expertise in a timely matter, the potential impact on the Company’s business and future strategic direction resulting from the transition to a new Chief Executive Officer and the Company’s ability to retain other key members of senior management; adverse economic conditions or intense competition; loss of a key supplier; entry of new competitors and products; adverse federal, state and local government regulation; technological obsolescence of the Company’s products; technical problems with the Company’s research and products; the Company’s ability to expand its business through strategic acquisitions; the Company’s ability to integrate acquisitions and related businesses; price increases for supplies and components; the effects of current and future U.S. and foreign trade policy and tariff actions; or the inability to carry out research, development and commercialization plans. In addition, other factors that could cause actual results to differ materially are discussed in the Company’s filings with the SEC. Investors and security holders are urged to read these documents free of charge on the SEC’s website at <http://www.sec.gov>. The Company undertakes no obligation to publicly update or revise its forward-looking statements as a result of new information, future events or otherwise.

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Source: Tactile Systems Technology, Inc.