Official Title

A non-randomized, open-label study to evaluate the safety and effectiveness of Koya active wearable compression technology for treating lower limb lymphedema

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Study Title	A non-randomized, open-label study to evaluate the safety and effectiveness of Koya active wearable compression technology for treating lower limb lymphedema
Study Objective	To demonstrate that the Koya active wearable compression technology is safe and effective for use
Clinical Hypothesis	1. The Koya wearable device improves quality of life (LYMQOL®) in subjects with lower extremity edema as measured by the difference between pre-use and post-use of the device 2. The Koya wearable device is safe for use as assessed by adverse events 3. The Koya active wearable compression device maintains or reduces swelling in patients with lower extremity edema as measured by the difference between pre-use and post-use of the device
Subject Population	Up to 50 subjects will be enrolled.
Investigational Materials	● The Koya wearable device is a smart calibrated active gradient pressure full-leg compression garment that is segmental and programmable, and applies controlled sequential pressure from the distal to proximal-end of the limb in a cyclic manner. These patterns are similar to advanced pneumatic compression devices, which are known to produce safe, well-regulated compression. ● A controller with a rechargeable battery that powers the limb garment
Study Design **Structure** **Number of Sites** **Duration** **Control**	 Non-randomized, open-label pilot study Up to six (6) sites. The duration of subject participation is approximately four (4) months None
Visit Schedule	Subjects will be seen at the screening visit, day 0, day 7, and week 4, week 8 and week 12
Clinical Parameters	● LYMQOL Survey Index ● Sequential Circumference using Tape Measure ● Photography of the lower limb
Primary Endpoints	● LYMQOL Index
Secondary Endpoints	● Lower Limb Volume ● Adverse Event ● Adherence (exploratory)
Key Inclusion Criteria (not a complete list)	● Males and females ≥ 18 years of age ● Willing to sign the informed consent and deemed capable of following the study protocol ● Subjects must have a diagnosis of primary or secondary unilateral lower extremity edema

	● At the time of initial evaluation, individuals must be at least 3 months post surgery, chemotherapy and/or radiation treatment for cancer if applicable.
Key Exclusion Criteria (not a complete list)	● Individuals with a history or presence of a systemic disorder or condition that could place the subject at increased risk from sequential compression therapy ● Inability or unwillingness to participate in all aspects of study protocol and/or inability to provide informed consent ● Subjects with exam results that would prevent safe and effective use of the study device (cellulitis, open-wounds, healing-wounds, etc.) ● Subjects must not have any diagnosed cognitive or physical impairment that would interfere with use of the device ● Diagnosis of lipedema ● Diagnosis of active or recurrent cancer (< 3 months since completion of chemotherapy, radiation therapy or primary surgery for the cancer) ● Diagnosis of Acute infection (in the last four weeks) ● Diagnosis of acute thrombophlebitis (in last 6 months) ● Diagnosis of pulmonary embolism or deep vein thrombosis within the previous 6 months ● Diagnosis of pulmonary edema ● Diagnosis of congestive heart failure (uncontrolled) ● Diagnosis of chronic kidney disease with acute renal failure ● Diagnosis of epilepsy ● Subjects with poorly controlled asthma ● Any condition where increased venous and lymphatic return is undesirable ● Women who are pregnant, planning a pregnancy or nursing at study entry ● Participation in any clinical trial of an investigational substance or device during the past 30 days