

# Trial Information

A Prospective, Randomized Blinded Multicenter, Parallel Study Comparing Transdermal, Continuous Oxygen Delivery to Moist Wound Therapy (MWT) in the treatment of Diabetic Foot Ulcers

## **Study Population:**

Male and female patients 20-90 years of age with type 1 or type 2 diabetes mellitus with non-healing, full-thickness, University of Texas Classification of Diabetic Foot Ulcers Class IA diabetic foot ulcers of at least 4 weeks duration, but not greater than 52 weeks, measuring 1 -10 cm<sup>2</sup> in area

Qualifying subjects will be randomized with a 1:1 ratio (i.e., Active arm: Control arm) with two stratification factors. The stratification factors are used to ensure a balanced distribution of subjects with characteristics important to healing in the Active and Control arms. The active arm is a currently FDA Approved device called EpiFlo, small, silent, disposable, oxygen concentrator used in the treatment of chronic and acute wounds. The control arm will receive sham units with a look and feel of active units, but will not provide oxygen.

## **Goal:**

The primary objective of this study is to compare number of wounds closed on or at week 12 between subjects randomized to receive EPIFLO or MWT.

## **Lead Principal Investigator:**

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## **US Investigators:**

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## **Canadian Investigators**

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