

## LYMPHEDEMA TREATMENT

The goals of lymphedema therapy are to reduce limb volume, swelling and re-accumulation of fluid to prevent infection and reduce both the physical and psychological discomfort.

The most commonly used approach to treatment is called “complete decongestive therapy”, or CDT, which consists of 2 phases:

PHASE 1

Decongestion: consists of professional manual lymphatic drainage (MLD), compression bandaging, exercise therapy and skin and nail care.

PHASE 2

Maintenance: may include daily self-MLD, wear of medical compression garments, night time wear of multi-layer compression bandaging, therapeutic exercise and skin and nail care.

A research study is a scientific study that evaluates the safety and effectiveness of medical treatments, drugs or devices.

Sometimes research studies are conducted to obtain approval by the regulatory agencies. Other times, studies are conducted to obtain more information about how medical care can be improved as is the case with this research study.

## CLINICAL RESEARCH OVERVIEW

The therapies and devices being used in this study have already been approved by the regulatory agencies. The purpose of this study is to evaluate the performance of two different pneumatic compression devices (PCD's) for the management of chronic lymphedema in the leg(s).

Your participation in this, or any research study, is always optional and voluntary. You can decide to discontinue participation at any time.

## LIVING WITH LYMPHEDEMA

## ABOUT LYMPHEDEMA

Lymphedema has many causes, one of which is a blockage in, or damage to, your lymphatic system, preventing lymph fluid from draining. This fluid begins to build up and cause swelling that can lead to the enlargement of your limb(s), pain and hardening of the affected tissue (fibrosis).

**Lymphedema is a chronic condition that cannot be cured, but with effective treatment you can manage the symptoms, minimize infections and improve your overall quality of life.**

### There are 3 Stages of Lymphedema:

- Stage 1** Mild, limb is almost at normal size and skin is in “pitting” stage
- Stage 2** Moderate, limb is always swollen and affected skin is firm and “non-pitting”
- Stage 3** Severe, skin is hard and will only slightly respond to pitting pressure. Without treatment swelling is irreversible and risk of infection increases.

## LYMPHEDEMA TREATMENT OPPORTUNITY

Physicians are conducting a clinical research study for people with lower extremity lymphedema. This study will evaluate the performance of two different pneumatic compression devices (PCD’s) for the management of chronic lymphedema in legs. A PCD is used to assist in controlling limb volume and to simulate and potentially replace self-MLD.

If you were diagnosed with secondary Stage 2 or 3 lower extremity lymphedema you may qualify to participate.



**To learn more about this study, please contact:**  
(Site Information)

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## RESEARCH STUDY TREATMENT

If you choose to participate in this clinical research study, you will use a pneumatic compression device every day in addition to continuing your routine daily care for lymphedema.

### Study Devices

- Flexitouch® System**  
Consists of a controller and a set of therapy garments that are applied to the leg and lower abdomen. Delivers therapy by continuous sequential inflate/deflate cycles in two phases.
- Flowtron Hydroven FPR™**  
Consists of a sequential pneumatic compressor that attaches to garments for treatment of the arms or legs. The garment contains three compression chambers.