Are there any risks or inconveniences involved?

The procedure may or may not help your symptoms. There is always a possibility of unforeseeable risks. You will be closely monitored by the study doctors for any side effects throughout the course of the study. Precautions will be taken to prevent harmful side effects. Should side effects occur during the study, they are expected to be temporary and mild and will not require medical treatment. These temporary effects might include mild local swelling or redness in the area where the procedure is applied, or small bruising under the skin, some temporary tingling or numbness feeling in the procedure area. All of these side effects would be expected to be mild and resolve spontaneously. You will be asked to report any unusual event to your study doctor.

Will I have to pay to participate in this study?

Neither you nor your insurance company will be expected to pay for any of these procedures or tests that are required as part of this research study. You are still responsible for the costs of your usual on-going medical care, including procedures, and non-study medications that your study doctor or regular doctor requires during the study period, as part of your usual medical care.

About Medispec

As a leading designer and manufacturer, Medispec has delivered shock wave devices (which are acoustic-wave devices) to the worldwide medical community for over a decade in the fields of Urology for the treatment of kidney stones, Orthopedic for the treatment of heel spurs and more recently in Cardiology. Using our application expertise and experience, we strive to deliver high tech shock wave medical devices while providing advanced, high quality product that complies with the worldwide standards of today's marketplace. Medispec has a proven track record of delivering high performance Shock Wave devices to many renowned international institutions and continuously researching for new ways to improve patients' lives using shock wave therapy. Medispec's unique products give patients access to quality care –

When they need it, Where they need it.

To learn more, please Contact Us at
(855) 778-2345

or Visit Us at
www.medispec.com

MEDISPEC

Investigational Device. NOT approved by FDA for sale in USA
For more infromation, please consult your study doctor

MEDISPEC

A new clinical trial for Erectile Dysfunction

Evaluation of Extracorporeal Acoustic Wave Therapy for Erectile Dysfunction

Join the trial today!

- ✓ Non invasive
- ✓ Drug free
- ✓ Fast and pain-free treatments

OR-5-X203

Welcome to Medispec's new clinical trial designed to potentially improve your current sexual life. The goal of this study is to evaluate a different and novel approach towards the treatment of Erectile Dysfunction.

Let's start by answering a few questions that are probably on your mind.

Why would I join this particular clinical study?

The goal of this study is to evaluate a new procedure option using Medispec's Omnispec ED1000 device designed specifically for Erectile Dysfunction.

You should know that the Omnispec Model ED1000 device; used in this study is considered investigational, meaning it has still not been approved by the Food and Drug Administration (FDA) for routine clinical use in the United States. However FDA has allowed the use of this device in this research study.

How does this procedure work?

The Omnispec Model ED1000 device delivers low energy intensity sound waves to 5 procedure areas in the penis. Procedure is non-invasive, meaning that it does not penetrate through the skin; and may improve the blood flow in the penis, thereby contributing to improved erections in men.

For more information about how the device operates, please refer to the study doctor.

Am I eligable to participate in this study? How can I join?

If you are having Erectile Dysfunction due to impaired blood flow to your penis and you have experienced a positive reaction to medications that improve the blood flow to the penis, you are eligible to apply for participation in this clinical trial. Please refer to the study doctor to learn if you are eligible for participating in this trial.

How long will this study take?

If you agree to participate in this study and are found eligible by the study doctor, you will undergo a set of preliminary evaluations before entering the study. When these evaluations are completed, you will be scheduled to receive 12 study sessions within a time period of 9 weeks and will also be invited to the clinic for follow up visits at 1, 6 and 12 months post your last procedure. Each visit to the clinic will last approximately 20-30 minutes.

What does this study involve?

You should know that this clinical trial is a double-blind, placebo-controlled trial, meaning that 2/3 of participants will receive the investigational procedure, while 1/3 will receive a dummy version (placebo) . If you join the study, you will be randomly assigned to either the active or the inactive investigative procedure. You will have 2/3 chance of receiving active procedure and a 1/3 chance of receiving inactive (placebo) procedure. The Omnispec™ Model ED1000 placebo device is the same device as the Omnispec™ Model ED1000 active device, but will not provide the same sound waves.

All participants that happen to receive the placebo (inactive) procedure, will be given the opportunity of receiving the 12 active procedure sessions, once this study is complete. Even if you receive the active procedure it may not help your symptoms. In such case you will not be entitled to receive an additional procedure.

For more information about the study plan, please contact the study doctor at your respective clinic.

Standard Care

Some of the study procedures might be done as part of your standard care, even if you do not take part in this research study. The study doctor or a member of the study staff can answer any questions you may have about the procedures that are part of your standard care.