# Safety and Efficacy Assessment of the Vertica® - A Radio Frequency Device for the Treatment Of Erectile Dysfunction (ED)

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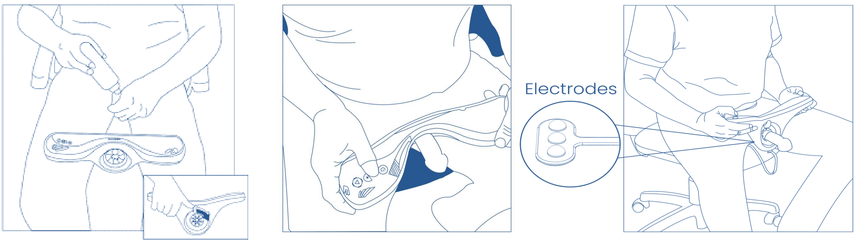
RING (15 MIN)

RING + PAD (15 MIN)

TOTAL OF 30 MIN TREATMENT




1) RF energy raises penile temperature, enhancing erectile response.
2) RF energy posits a direct structural and biochemical impact on tunical and corporal tissue, improving the tunical veno-occlusive mechanism.

## Study population:

- The study will recruit outpatient adult men ≥ 22 years of age, with mild to moderate ED reflected by the IIEF-EF score.

## Structure:

- The study is designed as a randomized, controlled, prospective, 6-month, double blind, study.

## Concurrent Control:

- A sham device with a non-therapeutic, low level, ineffective and superficially dispersed RF energy will be used in the control group.

## Study Duration:

- The study will be conducted for approximately ten months until all patients are enrolled and followed-up in the study.

## Study Objectives:

- Safety and efficacy of the VERTICA® device for treatment of ED.

Demographic data, medical history, concomitant medications and baseline clinical examinations.

Follow-ups: 1, 2, 3 and 6 months

Patients will be instructed to use the device:

3x / week for 4 weeks

2x / week for 4 weeks

1-2x/ week for 4 months

Patients will be instructed to attempt sexual activity at least 1x / week or 6 times a month

Enhancements in ED will be measured by comparing the scores of IIEF-EF, SEP, EHS, EDITS, and SHIM.

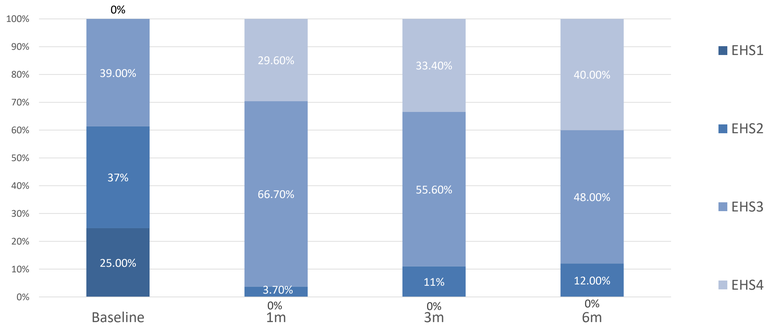



Figure 1: EHS Improvements in the Pilot Study

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