



## **ThermiVa: Patient Consent for Treatment**

### **A. Purpose and Background**

- ThermiVa is a procedure developed to treat vaginal laxity, urinary leakage, stress incontinence, vaginal dryness, sexual dysfunction and orgasmic issues. This procedure utilizes temperature controlled radio frequency technology that treats the vulvo-vaginal region including the Labia Minora, Labia Majora, Vagina and Perineum.

### **B. Procedure**

- ThermiVa is an in-office, non-surgical procedure for labia and vaginal tightening. A radio frequency generator, powers a hand piece that tightens external and internal vulvovaginal tissue via a thermistor tip which is able to control heat delivered. The tip has gentle curves that provide comfort. The complete ThermiVa procedure includes 3 separate treatments over a period of 3 months. The procedure is comfortable and has little to no downtime other than the office appointments, and no anesthetics are required.

### **C. Risks/Discomfort**

- The risks associated with ThermiVa may include but are not limited to: Discomfort during and/or after the procedure, possibility of over treating resulting in painful intercourse, mild swelling and/or temporary redness following the procedure, potential for transient over-active bladder, injury to bowel and bladder. Scarring is rare, but is a possibility if the skin surface is disrupted. Although uncommon, burns can occur and may require additional care at my own expense. Infection is uncommon, but should it occur, treatment with antibiotics and/or surgical intervention may be required. Infection can further increase the risk of scarring. Proper wound care is important in the prevention of infection. If signs of infection such as pain, heat, blisters, or surrounding redness develop call the office immediately. I acknowledge that no guarantees are made concerning the risks, procedure, or outcome.

### **D. Benefits**

- ThermiVa is a comfortable in-office procedure which requires no preparation. The heat is delivered through a curved probe by moving it over the labia and inside the vaginal canal, it is described as feeling like a gentle warm massage. The benefits include: Labia Majora tightening, Vaginal Canal tightening, improvement of involuntary urinary leakage, increased vaginal moisture and improved orgasms.

### **E. Contraindications**

- While I understand this technology does not have any manufacturer declared contraindications, it is advised not to treat patients with the following conditions:
  - Cardiac devices such as AICD's (auxiliary internal cardiac devices such as defibrillators, mechanical valves, pacemakers).
  - Pregnancy
  - Active Sexually Transmitted Diseases
  - Current Urinary Tract Infection
- Your physician may suggest alternative treatment if you have any of the following conditions:
  - Greater than stage 2 pelvic organ prolapse
  - Recent vaginal surgery or fillers

**F. Consent to Procedure**

- The areas for treatment today have been reviewed with me today and I am in agreement. I have been thoroughly and completely advised regarding the objectives of the procedure. I understand that the practice of medicine and surgery is not an exact science and although these procedures are effective in most cases, no results have been guaranteed. I acknowledge that imperfections might ensue and that the operative result may not live up to my expectations. I understand that clinical results may vary based on many variables such as age, lifestyle, degree of laxity or dysfunction and current conditions.
- I understand that pregnancy is a contraindication for treatment, I am not currently pregnant or breastfeeding.
- The treatment will involve applying heat to the vulvar and vaginal tissues using radio frequency for therapeutic purposes.
- I consent to having clinical photographs taken before, during and after my treatment. I understand that these photographs are an important part of my medical record and are required for this procedure.
- In addition I consent to the use of these photographs, without my identity being revealed, for the education of future patients, professional clinical presentations and medical journals.
- The nature and effects of the procedure, the risks, the ramifications, and complications have been fully explained to me and I understand them. The benefits of the proposed procedure along with the probability of success have also been discussed with me. I have been given the opportunity to ask questions and have received satisfactory answers. I certify that I have read the above authorization and that I fully understand it.

**I elect to proceed with ThermiVa treatment.**

**Patient Name:** \_\_\_\_\_ **Date:** \_\_\_\_\_

***Patient Signature:*** \_\_\_\_\_

**Provider Signature:** \_\_\_\_\_