Informed Consent

I request and authorize Dr. _____ or designated person to perform the following procedure utilizing temperature controlled radio frequency technology.

Radio Frequency treatment of the vulvo-vaginal region:

_____Labia Minora
_____Labia Majora
_____Vagina and Perineum

Please initial each item:

_____The areas for treatment 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 and current conditions.

_____ The treatment will involve applying heat to the vulvar and vaginal tissues using radio frequency for therapeutic purposes.

_____ I am aware of the following possible experiences and/or risks associated with the procedure:

- Discomfort may be experienced during and/or after the treatment.
- Possibility of over treating, resulting in painful intercourse
- Some mild swelling and/or temporary redness may occur 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 (urinary tract, vaginal 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.

_____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

Informed Consent

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

_____ I consent to having clinical photographs taken before, during and after my procedure. I understand that these photographs are an important part of my medical record.

_____ 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, complications, as well as alternative methods of treatment have been fully explained to me by the physician or designated person 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.

_____ _____

Signature of Patient/Date

Signature of Provider / Date

_____

Signature of Witness/Date

THERMIva® Treatment Record

PATIENT INFORMATION

Patient Name: _____ Date of Birth: _____

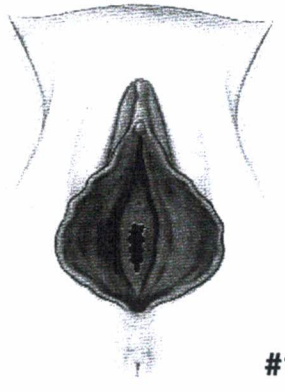
☐ Consent Signed ☐ Before Pictures Taken ☐ After Pictures Taken

Grounding Pad Location: _____

Date	TX #	Electrode Lot #	Grounding Pad Lot #	Area Treated	Set Temp	Max Temp Achieved	Total Time (min)	Max Vaginal Depth (cm)	Initials

OBSERVATIONS

Indicate treatment time per treatment area



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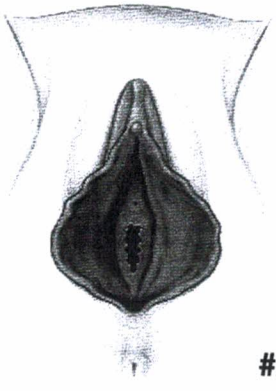

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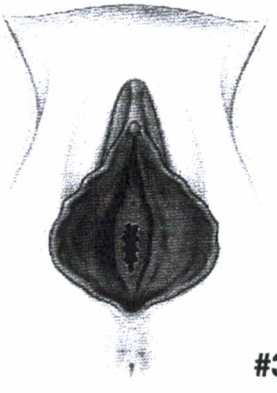

#3

Notes/Comments: _____

Notes/Comments: _____

Notes/Comments: _____

Provider (signature): _____ Title: _____

THERMIva® Post-Treatment Instructions

WHAT TO EXPECT

- If treated externally, skin may be slightly pink to red, swollen and warm to the touch for approximately one-hour post procedure
- Possibility of mild cramping, which should resolve in 24 hours
- Light spotting may occur immediately post procedure

ACTIVITY

- Resume normal physical and sexual activity, unless otherwise directed by your provider
- No restrictions on showering
- No restrictions on bathing, swimming or hot tubs (exception: if spotting or mild bleeding wait one day)

CALL YOUR DOCTOR

- Bleeding lasting longer than 24 hours,pain uncontrolled by over the counter medication, cramping lasting longer than 24 hours, fever > 101 degrees

FOLLOW UP APPOINTMENT

- One month after each treatment
- Next appointment: _____

I have read and understand the post-treatment instructions provided.

_____ _____

Signature of Patient Date

_____ _____

Signature of Witness Date