



## VIVEVE CONSENT FORM

Please read the following information carefully and discuss any questions you may have with your physician.

### IT HAS BEEN EXPLAINED TO ME THAT:

- The Viveve® System delivers a low amount of radiofrequency energy to the tissue inside the vagina near the opening. While there is no downtime, the tissue may be tender from the treatment. Therefore, I understand it is important to follow my doctor's timeline for refraining from intercourse or insertion of tampons.
- The results vary from person to person given the amount of tissue laxity and my body's own natural response to the treatment.
- I may not start to feel a difference until approximately one month after treatment and that the results may build gradually in the months following.
- This non-surgical treatment is not intended to provide the same results as a surgical procedure.
- The device, while FDA cleared for safety and efficacy in general surgery and electrocoagulation and hemostasis, is being performed for off-label use. Although clinical trials have been conducted and proved positive for vaginal laxity, the FDA has not yet cleared this treatment for the conditions being addressed today.
- Based on clinical experience with the Viveve System, as well as theoretical assessments, the following risks or discomforts may be experienced during or following treatment: pain or discomfort during procedure related to warmth/heat and/or cold in the designated treated area; transient vulvar or vaginal inflammation and/or swelling; transient vaginal discharge; transient vulvar and or vaginal erythema/redness; transient pelvic pain or pelvic discomfort; transient allergic reaction or hypersensitivity in the vulvar and or vaginal region to any component of the device; altered sensation that may be focal or transient, manifested as numbness or tingling in the vulvar and or vaginal pelvic region; excessive vaginal tightness resulting in interference with sexual activity; and, damage to the urinary bladder and/or urethra.

### MANY FACTORS CONTRIBUTE TO SEXUAL SATISFACTION:

- I understand that increased friction resulting from tightening of the vaginal opening is one of many factors contributing to sexual satisfaction.

### RELEASE FROM RESPONSIBILITY:

I understand and agree on behalf of myself, my dependents, heirs, administrators, legal representatives, and assigns, to release and hold harmless Viveve, and any and all associates, employees, agents and representatives thereof, from any and all liability for illness, injuries, or death, and for any losses or damages relating thereto, however occurring, in relation to my consultation with and/or treatment by Viveve. Without limitation, I understand and agree that neither Florida Center for Hormones and Wellness Viveve, nor any associates, employees, agents or representatives thereof, is liable for any direct, indirect, consequential, or incidental damage, injury, death, loss, delay, or inconvenience of any kind which may be occasioned by reason of any act or omission, including, without limitation, any willful or negligent act or failure to act, or breach of contract. I further recognize and understand that there are certain inherent risks associated with surgical and medical procedures and I assume full responsibility for any personal injury to myself and further release Viveve for any injury, loss or damage arising from this procedure.

I have read and understand all the information presented to me. I consent to the Geneveve by Viveve treatment.

\_\_\_\_\_  
Patient Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Patient Name (Printed)

\_\_\_\_\_  
Witness Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Witness Name (Printed)