



### ***Vitalia Consent Form***

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

I hereby permit a Gunn Dermatology to perform the Vitalia Procedure:

The procedure has been explained to me and I have been told the reasons for the procedure.

The risks of the procedure have also been explained to me. In addition, I have been told that the procedure may not have the results that I expect. I understand that in addition to the risks described to me about this procedure there are additional risks that may occur with any surgical or medical procedure. I am aware that the practice of medicine and surgery is not an exact science, and that I have not been given any guarantees about the results of this procedure. I have had enough time to discuss my condition and treatment with my healthcare providers and all of my questions have been answered to my satisfaction. I have enough information to make an informed decision and I agree to have the procedure. The Vitalia System delivers a low amount of radio frequency energy to the tissue inside the vagina near the opening. While there is no downtime, the tissue may be tender from the treatment. 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. I further understand that it is not possible to guarantee or give assurance of a successful result.

#### **Risks:**

- 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

I understand and agree that Vitalia does not make any claims whatsoever, expressed or implied, regarding effects or outcomes of the analysis or therapies provided, and shall not be liable for the same. I certify that I sought the treatment of Vitalia solely in my personal capacity, and do not represent any governmental agency, law firm, attorney, or investigator. I am not involved in a lawsuit nor am I gathering information for a potential lawsuit.

***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.

***Contraindications:***

- I am not pregnant. I do not have an autoimmune disease. I am not diabetic. I do not have herpes simplex.
- I do not have a cut, wound, or infected skin on the area to be treated.
- I am not on local, oral, or systemic anesthetic agents.
- I do not have any embedded electronic devices.
- I do not have an embedded pacemaker or implantable cardioverter defibrillator (ICD), the client's cardiologist must be consulted prior to treatment.
- I am not allergic to adhesives, such as glues on medical tape.
- I am not allergic to gold, such as the metallic covering of the TempSure handpieces.
- I am not allergic to corn, such as the corn derivative ingredient in Parker Aquasonic Gel.
- I do not have nerve insensitivity to heat in the treatment area.

- I do not have severe laxity or sagging that causes redundant folds of tissue or hanging skin in the area to be treated.
- I have not used Accutane (Isotretinoin) six to twelve months prior to treatment, as this can thin the skin and make it brittle.

***RELEASE FROM RESPONSIBILITY:***

I understand and agree on behalf of myself, my dependents, heirs, administrators, legal representatives, and assigns, to release and hold harmless Vitalia, 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 Vitalia. Without limitation, I understand and agree that neither Vitalia, 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 Vitalia 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 Vitalia treatment.

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