# V-Lase<sup>®</sup> Patient Informed Consent Form

Voluntarily request and authorize Dr. Babak Farzaneh or staff to perform the V-Lase<sup>®</sup> CO2 laser minimally invasive procedure for therapeutic purposes in the vulvovaginal area, an off label use of a FDA approved machine. SLIM Evolution CO2 lasers and related accessories have been cleared by FDA under 510(k)K063001 and K110984. The Slim Evolution family of CO2 lasers and delivery device accessories are indicated for use in surgical applications that require ablation, vaporization, excision, incision and coagulation of soft tissue in dermatology and plastic surgery, general surgery, gynecology, podiatry, dental and otorhinolaryngology.

- I hereby release Truecare Cosmetic Surgery & Med Spa, its staff, and any other participating health care providers from any and all liability for any adverse effects that may result from this treatment and related procedures.
- For the purpose of accurate medical record keeping I consent to having clinical close-up photographs taken before, during and after treatment of the anatomically involved area(s). I consent to the use of these photographs (without my identity being revealed) for professional educational and training purposes and for use in medical journals.
- I understand that the practice of medicine and surgery is not an exact science and no results for this minimally invasive procedure have been guaranteed. I acknowledge that the operative result may or not meet my expectations and are based on many variables such as age, lifestyle, and current medical condition.
- I am currently not pregnant (absolute treatment contraindication)
- I am aware of the following (recommended) treatment contraindications:
  - Experiencing undiagnosed painful sexual intercourse (this needs a workup prior to treatment to determine cause of pain)
  - POP (pelvic organ prolapse) beyond the hymen
  - Active or undiagnosed vulvovaginal infection (bacterial, viral, fungal) or STD at time of treatment
  - o Active or undiagnosed lesion of the vagina, cervix or external genitalia
  - Pre-cancer of the external genitalia or vagina
  - I understand and acknowledge that alternative methods of treatment have been fully explained and that multiple treatments (usually 3 but maybe more) and up to six months are usually required to achieve optimal results.
  - I have been given an opportunity to ask questions about my condition and treatment and by signing below I understand the information provided.
  - I understand of the risks included but not limited to infection, burning, bleeding, pain, painful, urination, painful intercourse, frequent urination, sense of urgency with urination, need for further procedures.
  - If any concern I understand that I may need to see a specialist, which may incur more cost not covered by insurance.



## V-Lase CO2 Laser

#### **Before treatment**

- Provide most recent Pap smear results during first appointment.
- Reschedule if on menstrual cycle.

#### After treatment

• No sexual intercourse for 1 day.

Next treatment in 1 month, annual maintenance.



### V-LASE WAIVER TO PRODUCE PROOF OF PAP SMEAR

I would like to proceed with V-Lase CO2 laser. I understand that this is an elective procedure for vaginal dystrophy which does not replace surgery. Standard protocol for Truecare Cosmetic Surgery & Med Spa is to have a normal pap smear within one year and no recent vaginal infection, pain, bleeding or odor that would require follow up with a GYN MD. In the event that I have had a normal pap smear within one year and I cannot produce documents; a liability waiver is necessary. I take full liability for the treatment and understand that Truecare Cosmetic Surgery & Med Spa is proceeding in good faith and I have had a normal pap smear. I also attest that I have not had any vaginal infection, pain, bleeding or odor within the last year.