

FormaV -a safe and effective gentle thermal tissue remodeling for the vagina and vulva that provides uniform RF heating of the internal vaginal and external vulvar tissue. Numbing offered for external treatments.

Single treatment cost- 1350

Package of three treatments- 2650(one month apart)

Combined **FormaV** vaginal rejuvenation with **Morpheus** external vulvar rejuvenation- 1800

SAMPLE PATIENT INTAKE FORM

Personal Information			
[REDACTED]		[REDACTED]	
[REDACTED]		[REDACTED]	
[REDACTED]		[REDACTED]	
[REDACTED]		[REDACTED]	
[REDACTED]			
[REDACTED]	I II III IV V VI		

Gynecological History	
[REDACTED]	_____ (mm/dd/yy)
[REDACTED]	<input type="radio"/> Normal <input type="radio"/> Abnormal
[REDACTED]	<input type="radio"/> No <input type="radio"/> Yes, if so nature of diagnosis, treatment & follow up
[REDACTED]	_____ (mm/dd/yy)
[REDACTED]	

Medical History	
[REDACTED]	
[REDACTED]	
[REDACTED]	

CONTRAINDICATIONS:

- Vaginal or Pelvic area surgery within the last 12 months.
- Metal implants in the treatment area
- History of genital herpes
- Active lesions in the treatment area
- UTI
- Pelvic infection
- Active malignancy or cancer treatment within the last five years
- Melanoma history
- Dysplastic nevi in the treatment zone
- Pelvic lymph node dissection or poor lower lymphatic drainage
- Significant illness such as diabetes, cardiac disease, autoimmune disease
- History of epidermal or dermal disorders involving collagen or microvasculature
- Active electrical implant in any region of the body
- Pregnancy and nursing
- Diseases of the immune system such as HIV, AIDS or immunosuppressive med
- Diseases which may be stimulated by light at the wavelengths used
- Use of anticoagulants or history of bleeding disorders
- Any active condition in the treatment area, such as open lacerations, abrasions or lesions, psoriasis, eczema or rashes
- History of skin disorders, keloids, abnormal wound healing
- Surgical procedure in the treatment area within the last three months
- Tattoo in the treatment area
- History of Accutane use in the previous 6 months
- History of oral corticosteroid use in previous 6 months
- Excessively tanned skin in the treatment area from sun, sun-beds or tanning creams

Sample Informed Consent Votiva

Internal Vaginal and External Labial Treatment

Below is a **sample** Informed Consent Form for regular patients or for volunteer patients for training. Invasix/InMode provides these forms for demonstration only and does not accept any liability for their contents. It is essential that each clinic customize Consent Forms according to treatment procedure, local specific requirements and language.

Patient Name: _____

I duly authorize _____ and clinical staff to perform the Votiva treatment.

I understand the Votiva is used for the remodeling of the skin in the vaginal and vulvar regions and the external skin of the labia. I understand there is a possibility of short term effects such as pain, discomfort, reddening, blistering, scabbing, swelling, temporary bruising and temporary discoloration of the skin, as well as rare side effects such as scarring and permanent discoloration. This treatment has the potential to cause skin damage, so infection is possible. Infection is unlikely, but can be life threatening if it does occur and is left untreated. Signs and symptoms of infection are redness, fever, pain, pus and swelling. If infection occurs or you suspect you may be developing signs of infection, you should contact the doctor for immediate evaluation and treatment. These effects have been fully explained to me (____ patient initials).

Invasix/InMode has determined that the Votiva device used for the treatment of Vulvovaginal treatment is a non-significant risk device. The risks associated with use of the Votiva device have been demonstrated to be minimal and are limited to the skin surface. Potential risks include but are not limited to:

1. Twinge/Soreness (pain) – you may experience pain after the procedure. If you feel significant discomfort after the treatment, you may apply OTC pain relief to minimize that pain.
2. Swelling – the study treatments may cause swelling, which usually go away in one week or less.
3. Bruising – you may experience some temporary bruising in the treated area which will subside with healing.
4. Ecchymosis & Purpura – you may experience some temporary ecchymosis in the treated area which will subside with healing.
5. Blistering/Bullae – you may experience some temporary blistering/bullae in the treated area which will subside with healing.
6. Burn – you may experience burn in different degrees in the treated area which will subside with healing.
7. Infection – this treatment has the potential to cause skin damage, so infection is possible, including a urinary tract infection. Infection is unlikely, but can be life threatening if it does occur and is left untreated, signs and symptoms of infection are redness, fever, pain, pus and swelling. Should infection occur, you should contract the study doctor for immediate evaluation and treatment. Any antibiotics required for an infection will be provided by the study doctor.

It is important that you tell your doctor if you think you have experienced any of these side effects.

- I understand that clinical results may vary depending on individual factors, including but not limited to medical history, skin type, patient compliance with pre- and post-treatment instructions, and individual respond to treatment [REDACTED] (patient initial)
- I understand that treatment with Votiva involves a series of treatments and the fee structure has been fully explained to me [REDACTED] (patient initial)
- I certify that I have been fully informed of the nature and purpose of the procedure, expected outcomes and possible complication, and I understand that no guarantee can be given as to the final result obtained. I am fully aware that my condition is of an elective concern and that the decision to proceed is based solely on my expressed desire to do so [REDACTED] (patient initial)
- I confirm that I have informed the staff regarding any current or past medical condition, disease or medication taken and I confirm that I have had a normal and up-to-date PAP test [REDACTED] (patient initial)
- I consent to the taking of photographs and authorize their anonymous use for the purpose of medical audit, education and promotion [REDACTED] (patient initial)
- I certify that I have been given the opportunity to ask questions and that I have read and fully understand the contents of this consent form [REDACTED] (patient initial)

Patient Signature _____ Date _____

Witness Signature _____ Date _____

Sample Votiva Treatment Record

PATIENT NAME: _____ DOB: _____

TREATMENT: **FORMAV / FRACTORAV**

SKIN TYPE: I II III IV V VI

