

Informed Consent Votiva by InMode Internal Vaginal and External Labial Treatment



Patient Name: _____

I duly authorize North Roswell Internal Medicine - Aesthetics trained 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 side -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)**.

InMode, the makers of Votiva/FormaV, 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 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 contact our office for immediate evaluation and treatment.
8. **Pigmentary changes:** you may experience lightening of the skin which may be temporary or permanent (hypopigmentation). You may experience temporary or permanent darkening of the skin (hyperpigmentation).

9. **Scarring:** the risk of this complication is minimal but can occur whenever the surface of the skin is disrupted. Strict adherence to all post-treatment instructions will minimize the possibility of this occurring.

10. **Allergic reactions:** it is possible to experience an allergic reaction to an anesthetic topical cream or oral medication.

11. **Herpes Eruption:** it is possible, even with antiviral prophylaxis, to experience a herpes eruption if you are an HSV carrier. Inform your doctor immediately if you experience pain, skin eruptions or blistering post-treatment so that the proper treatment can be initiated.

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 _____ (**patient initial**)
- I understand that treatment with Votiva involves a series of treatment, and the fee structure has been fully explained to me _____ (**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 _____ (**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 _____ (**patient initial**)
- I consent to the taking of photographs and authorize their anonymous use for the purpose of medical audit, education and promotion _____ (**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 _____ (**patient initial**)

Patient Signature _____ Date _____

Witness Signature _____ Date _____

