



## VOTIVA INFORMED CONSENT

**Patient Name:** \_\_\_\_\_

**I authorize \_\_\_\_\_ and clinical staff to perform the Votiva treatment.**

I understand that 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 the 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. Twinges/Soreness (pain) - you may experience pain after the procedure. If you feel significant discomfort after treatment you may apply OTC pain relief to minimize this pain.
2. Swelling – the treatments may cause swelling, which usually goes away in one week or less.
3. Bruising – you may experience 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 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. 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 your doctor for immediate evaluation and treatment.

**It is important to 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 response to treatment \_\_\_\_\_ (patient initials).
- I understand that treatment with Votiva involves a series of treatments and the fee structure has been fully explained to me \_\_\_\_\_ (patient initials).
- I certify that I have been fully informed of the nature and purpose of the procedure, expected outcomes and possible complications, 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 initials).
- 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 initials).
- I consent to the taking of photographs and authorize their use for the purpose of documentation in my patient record \_\_\_\_\_ (patient initials).
- I certify that I have been given opportunity to ask questions and that I have read and fully understand the contents of this consent form \_\_\_\_\_ (patient initials).

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

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