 

Family First Health Center PC

Physical Address: 333 N Maple Suite 105

Mailing Address: PO Box 218

Sutherland, NE 69165

308-386-4799

**Medical Profile/Informed Consent Form**

**Votiva**

Personal Information

**Home Phone:**

**Email:**

**Employment:**

**Address:**

**Date of Birth:**

**Name:**

**Would you like to be added to our email list?**

**Cell Phone:**

Fitzpatrick Skin Type: I II III IV V VI **Follow us on Facebook at Family First Health Center.**

Health Questionnaire

**Previous burns or injuries to face (or area we are treating) – Details:**

**Previous Cosmetic Treatments – Details:**

**Medicine Intolerance – Details:**

**Medication(s) – Details:**

**Hospitalization / surgeries – Details:**

**Existing or recent illness – Details:**

Gynecological History

Last PAP: (mm/dd/yy)

PAP Results: Normal Abnormal

History of Abnormal PAP smears? NO

YES, if so nature of diagnosis, treatment & follow up

Last Menstrual Period: (mm/dd/yy)

Reasons & Goals for treatment:

HSV History Y / N ?

Herpes simplex cold sores vagnal herpes

Medicine Intolerance – Details:

Medications:

**CONTRAINDICATIONS:**

o Surgery in the treatment area within the last 12 months.

o Implants in the treatment area

o History of herpes. Patients with history of diseases stimulated by heat

 such as recurrent Herpes Simplex in the treatment area, may be treated only

 following a prophylactic regimen.

o UTI

o Current or history of skin cancer and genital area cancer, or current

 condition of any other type of cancer, or pre-malignant moles.

o Significant poorly controlled illness such as diabetes, cardiac disease

 autoimmune disease

o History of epidermal or dermal disorders involving collagen or

 microvasculature (lichen sclerosis)

o Active electrical implant in any region of the body

o Pregnancy and nursing

o Diseases of the immune system such as HIV, AIDS or an immunosuppressive

 medications (like MS meds, certain Rheumatoid meds)

o Use of anticoagulants or history of bleeding disorders

o Any active condition in the treatment area, such as open

 lacerations,infection, abrasions or lesions, psoriasis, eczema or rashes

o History of skin disorders, keloids, abnormal would healing

o Tattoo in the treatment area

o History of Accutane use in the previous 6 months

o Having received treatment with light, laser, RF, or other devices in the

 treated area within 2-3 weeks for non-ablative procedures, and 6-12 weeks

 for ablative fractional laser resurfacing (according to treatment severity)

 prior to treatment, except special recommendations.

o Use of non-steroidal anti-inflammatory drugs (NSAIDS, e.g., ibuprofen-

 containing agents) one week before and after each treatment session, as per

 the practitioner’s discretion.

o Excessively tanned skin in the treatment area from sun, sun-beds or tanning

 creams

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 you tell your practitioner if you think you have experienced any 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 treatments 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)

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Patient Signature / Date Practitioner/Assistant Signature

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Patient Name (Print) Practitioner /Assistant Name (Print)

Or person authorized to sign for patient

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Witness Signature / Date

