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Crabapple Medical Center PC
PRIMARY CARE & GERIATRICS
Care with Compassion

VOTIVA INFORMED CONSENT

PATIENT NAME _____

TREATMENT SITES _____

I DULY AUTHORIZE _____ TO PERFORM THE VOTIVA (FORMA-
V/FRACTORA-V)

I understand that the Votiva is an RF device used for remodeling of the tissue. It has been explained to me that although RF vaginal treatments has been very effective there is no guarantee that I will benefit from this treatment. I understand the most common side effects and complications from this treatment are the following:

1. **Pain:** you may experience pain during or after the procedure. If you feel significant discomfort after the treatment, you may use over the counter pain medications after the procedure.
2. **Swelling:** there may be swelling in the treatment areas after the treatment which can last up to one week in duration.
3. **Bruising:** you may experience temporary bruising in the treated area which will subside with healing.
4. **Ecchymosis & Purpura:** you may experience some temporary bruising or purple discoloration in the treatment area which will subside with healing.
5. **Blistering / Bullae:** you may experience some temporary blistering / bullae in the treatment area which will subside with healing.
6. **Burn:** you may experience a burn which can be mild, moderate or severe to different degrees in the treatment area. Minor burns generally heal without difficulty but more severe burns, though rare, can lead to scarring, sensory or pigmentary changes.
7. **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).
8. **Scarring:** the risk of this complication is minimal, but it can occur whenever the surface of the skin is disrupted. Strict adherence to all post-operative instructions will minimize the possibility of this occurring.
9. **Allergic reactions:** it is possible to experience an allergic reaction to an anesthetic, topical cream or oral medication.
10. **Herpes Eruption:** it is possible, even with antiviral prophylaxis, to experience a herpes

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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.

11. **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 your doctor for immediate evaluation and treatment.

It is important that you tell your doctor if you experience any of these side effects. I understand that clinical results may vary depending on individual factors, including but limited to medical history, skin type, patient compliance with pre/post treatment instructions, and individual response to treatment.

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 give as to the final result obtained. I am fully aware that my condition is of cosmetic concern and that the decision to proceed is based solely on my expressed desire to do so.

I confirm that I have informed the staff regarding any current or past medical condition, disease or medication taken. I confirm that I have had an up-to-date normal PAP test and that I have communicated these results.

I consent to the taking of photographs and authorize their anonymous use for the purpose of medical audit, education, and promotion.

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 Signature: _____ Date: _____

Witness Signature: _____ Date: _____

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).

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 contact 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 _____ (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)

Patient Signature: _____ Date: _____

Witness Signature: _____ Date: _____

Personal Information	
NAME:	HOME PHONE:
ADDRESS:	WORK/MOBILE:
CITY:	PROVINCE/STATE:
ZIP CODE:	DATE OF BIRTH:
REFERRED BY:	GENDER:

Skin Type Assessment	
FITZPATRICK SKIN TYPE: I II III IV V VI	ETHNICITY:
LAST EXPOSED TO UV (SUN OR TANNING BED)	
PASSIVE TAN? YES/NO	SELF-TANNING LOTION

Medical History			
PACEMAKER/DEFIBRILLATOR:		ACTIVE SKIN INFECTION (E.G. PSORIASIS, ECZEMA)	
METAL IMPLANTS		SKIN DISORDERS (E.G. KELOIDS, ABNORMAL WOUND HEALING)	
CURRENT OR HISTORY OF SKIN CANCER/OTHER CANCER/PRE- MAGLIGNANT MOLES		HISTORY OF BLEEDING DISORDERS	
SEVERE CONCURRENT MEDICAL CONDITIONS (E.G. CARDIAC)		USE OF MEDICATION/ HERBSINDUCING PHOTOSENSITIVITY	
PREGNANCY AND NURSING		FACIAL LASER RESURFACING / DEEP CHEMICAL PEELING, LAST 3 MONTHS	
IMPAIRED IMMUNE SYSTEM		NEEDLE EPILATION, WAXING OR TWEEZING, LAST 6 MONTHS	
DISEASES STIMULATED BY HEAT (E.G. HERPES SIMPLEX)		TANNED SKIN	

DISEASES STIMULATED BY LIGHT (E.G LUPUS, PORPHYRIA, EPILEPSY)		TATTOO OR PERMANENT MAKEUP	
ENDOCRINE DISORDERS (E.G. DIABETES, PCOS)		INJECTIONS/FILLERS	
SURGICAL PROCEDURES			
List any medications taken			
List any allergies			
Detail any medical condition			
Other considerations			

Gynecological History			
LAST PAP:		PAP RESULTS:	
LAST MENSTRUAL PERIOD:			
ANY HISTORY OF ABNORMAL PAP SMEARS?	YES / NO	INDICATIONS FOR TREATMENT	