Cover Letter:

All enclosed below documents are part of the clinical trial NCT03536819

Study Name: Radio-frequency rejuvenation for pelvic floor and vagina

Protocol No.: DO607404A

Document date: September 20, 2017

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Informed Consent Votiva/FormaV STUDY

Patient Name: _____ **STUDY ID #:**_____

STUDY TITLE: Radio-frequency rejuvenation for pelvic floor and vagina

PRINCIPLE INVESTIGATOR[redacted]
SUPERVISING PHYSICIAN:
PHYSICAL THERAPISTS:

STUDY SITE: 1.[redacted]

SPONSOR: InMode MD, Ltd, Yokneam, Israel

INTRODUCTION:

You are being asked to participate in a medical research study. Your participation is voluntary. To decide whether or not you want to be part of this research, the possible risks and benefits are outlined in this document. This consent form along with a thorough discussion with the treating provider constitute the informed consent process. This consent form also will describe the purpose of the study, protocols and schedule of visits. In addition, this form also explains how your medical information will be used, who will see it. As part of the study protocol, measurements and photographs will be taken. A separate consent for photographs will be administered.

This document may contain words that you are not familiar with. Please do not hesitate to ask for clarification and explanation of anything that you do not understand. Once you have reviewed this informed consent and have discussed it with your treating provider, you will be asked to initial areas and sign it if you choose to participate. You will be given a copy of the signed document for your records

BACKGROUND:

You are being asked to participate in this study because you suffer from symptoms related to pelvic floor relaxation syndrome or atrophic vaginitis, which include but are not limited to: pelvic floor laxity, decreased muscle contraction in the pelvic floor, urinary incontinence, sexual dysfunction, vaginal dryness, vaginal pruritis (itching). In order to qualify for enrollment in the

study, participants must have an evaluation by the Pelvic Floor Physical Therapists at [redacted] Institute. All participants must have a below average reading(30% below the norm) on initial assessment of internal or external pelvic floor contraction in order to be included in the study.

The device used in this study is Votiva by InMode. The applicator for treatment is the FormaV that uses radiofrequency energy to treat the vaginal canal and perineal area. Ultrasound gel is used to aid in the conduction of energy into the tissue. The tissue is not ablated nor is an open wound created. The Votiva system has been cleared by the United States Food and Drug Administration (FDA) for sexual dysfunction and pelvic floor relaxation.

PURPOSE:

The purpose of this study is to determine the effect of internal and external radiofrequency on the strength of internal and external pelvic floor structures as measured by active contraction. Further analysis of symptom improvement will be assessed via questionnaire and direct patient reporting.

EXCLUSIONS:

You may not participate if you have any of the following:

1. Internal defibrillator, pacemaker, bladder stimulator or any other implanted electrical device anywhere in the body.
2. Permanent metal implant in the treatment area
3. History of pelvic floor radiation
4. Current diagnosis of cancer
5. Severe concurrent conditions such as epilepsy, uncontrolled hypertension, liver or kidney disease
6. Previous vaginal treatment with any radiofrequency or CO2 device
7. Pregnancy or nursing
8. History of diseases stimulated by heat, such as recurrent herpes Simplex in the treatment area.
9. Poorly controlled endocrine disorders
10. Any active condition in the treatment area such as psoriasis, open wounds, infection
11. Any surgery in the treatment area in the last 3 months
12. Any condition not listed here, determined by the practitioner that may compromise the treatment.

PROTOCOL:

If you agree to participate in this study, you will be required to follow the treatment schedule as outlined in this section. Photographs will be taken before each treatment session and at the

[redacted]

designated follow-up intervals. These photos may be used by the Sponsor (InMode MD LTD) in the future for educational and marketing purposes. Your identity will never be disclosed. Agreement to company use of your photos is a pre-requisite for your participation in the study and you will have to sign a separate consent.

You will be given written post-care instructions after each treatment. Any side effect will be assessed and treated.

Patients will be randomized into one of 2 treatment groups.

Group 1 will be measured at the specific interval. No actual treatment will be administered during your treatment visit but the applicator will be applied in the same manner as the treatment group .

Group 2 will be measured and receive 2 FormaV treatments at the specified intervals.

PROTOCOL:

If you agree to participate in this study, you will be required to follow the treatment schedule as outlined in this section. Photographs will be taken before each treatment session and at the designated follow-up intervals. These photos may be used by the Sponsor (InMode MD LTD) in the future for educational and marketing purposes. Your identity will never be disclosed. Agreement to company use of your photos is a pre-requisite for your participation in the study and you will have to sign a separate consent.

You will be given written post-care instructions after each treatment. Any side effect will be assessed and treated.

First visit: This visit is to be scheduled with [redacted] for a review of your complete medical history, review of study protocols, inclusion and exclusion criteria review and a physical exam will be performed. Pre-procedure questionnaires will be completed at this time. A recent pap smear and gynecological exam must be completed within 30days of beginning the treatment. Photographs will be taken at this time.

Second visit: This visit is to be scheduled with a [redacted]. This visit will be billed to your insurance. A complete pelvic floor assessment will be performed including but not limited to the following: measurement of internal and external pelvic floor contraction, measurement of vaginal canal length and diameter, measurement of the introitus, and length of the labia majora and minora. This visit will confirm inclusion criteria based on measurements. You will be instructed to shave prior to any treatments.

Third visit: The Forma V treatment will be next and done by [redacted]. This visit comprises of internal and external radiofrequency application with FormaV. Photos will be taken post treatment.

Fourth visit: This will occur 8 weeks from the Forma V treatment and be scheduled with a pelvic floor physical therapist at [redacted]. Measurements will be recorded.

[redacted]

Fifth visit: This visit also has to occur at 8 weeks after the first FormaV treatment and will be with [redacted]. This visit must occur after the 4th visit. Photographs will be taken and the second FormaV treatment will be performed.

Sixth visit: This will occur 8 weeks from the second FormaV treatment and will be scheduled with a pelvic floor physical therapist at [redacted]. Measurements will be recorded.

Seventh visit: This visit also has to occur at 8 weeks and will be with [redacted]. This visit must occur after the 4th visit. Photographs will be taken. This will be the last visit for the study purposes.

RISKS AND BENEFITS:

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. In rare circumstances, scar formation after a burn is possible.
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 contract the study doctor for immediate evaluation and treatment. Any antibiotics required for an infection will be provided by the study doctor.

8. Scarring- This treatment has the potential to cause tissue damage and theoretically scar formation can occur.

It is important that you tell your doctor if you think you have experienced any of these side effects. You will be informed of any new findings that develop during the course of this study.

PREGNANCY AND BIRTH CONTROL:

If you are pregnant, planning to become pregnant or are breast-feeding, you may not participate in this study. This treatment may have unknown risks to a pregnant woman, an embryo, fetus or breast feeding infant.

If during the study period you become pregnant, you must notifiy the study provider immediately. You will no longer receive treatments and your participation in the study will be ended.

ALTERNATIVE TREATMENT:

You do not have to participate in this study to receive treatment for pelvic floor relaxation or sexual dysfunction. You may receive treatments without participating in the study. You may also utilize other methods of treatment including but not limited to Pelvic floor physical therapy, CO2 treatment, other radiofrequency treatments.

COST:

There will be no cost to you for the office visits and study treatments. Your insurance will be billed for the pelvic floor assessment and pelvic floor physical therapy. In the event you do not have insurance, you will not be excluded from the study. The sponsor will pay all cost incurred that are not covered by insurance.

COMPENSATION:

You will not receive any monetary compensation for your participation.

COMPENSATION FOR RESEARCH RELATED INJURY:

In the event of a research-related injury, the sponsor of the study will pay for reasonable costs of medical treatment, except for the costs covered by your medical insurance. The sponsor has no plans to provide any other form of compensation. By signing this form, you will not give up your rights in the event of negligence by any provider participating in this study.

VOLUNTARY PARTICIPATION WITHDRAWL:

At any time during the study period, you may voluntarily withdraw from the study for any reason without penalty. There are no known medical consequences or risks if you choose to withdraw.

You may be discontinued from the study at any time by the provider, sponsor or Sterling IRB for the following reasons, including but not limited to:

a. A severe side effect
b. The study is terminated
c. Your failure to comply with study-related instructions
d. The study provider determines it is in your best interest to terminate participation.

CONFIDENTIALITY AND AUTHORIZATION TO USE AND DISCLOSE PERONAL HEALTH INFORMATION:

A federal regulation called the "Health Insurance Portability and Accountability Act" (HIPAA), describes how your personal health information may be used, disclosed, and made accessible to you. This privacy rule is designed to protect the confidentiality of your personal health information.

This study can be performed only by collecting and using your personal health information. Your study records will be kept as confidential as possible under local, state, and federal laws. You will be assigned a study identifier which will not include any personal information. Personnel from the following organizations may examine your study records: the sponsor (InModeMD Ltd.), personnel associated with this study, regulatory agencies, such as the Food and Drug Administration (FDA) and those in foreign governments, and Sterling Institutional Review Board (IRB). Because of the number of individuals who may see your records, absolute confidentiality cannot be assured.

Personal health information that may be used and disclosed includes that which is obtained to determine your eligibility to participate and that which is collected from the procedures that are carried out. It may identify you by name, address, telephone number, Social Security number, study number, date of birth, or other identifiers. Once the information is disclosed, it is possible that it may be re-disclosed, at which time it may no longer be protected by federal regulations, but may be by state laws. If the final study data are prepared for publication and other reports, your identity will not be revealed. Under these federal privacy regulations, you have the right to see and copy any of the information gathered about you, until your study records are no longer kept by the study provider. However, it may not be available until the study has been completed.

You may, by written notice to the study provider, cancel your authorization to use or disclose your personal information at any time. If you withdraw your authorization, the information

collected up to that time may still be used to preserve the scientific integrity of the study. By signing this consent form, you authorize these uses and disclosures of your personal information. If you do not authorize these uses and disclosures, you will not be able to participate in the study. This authorization does not have an expiration date.

The results of the study, including your information, may also be presented at meetings or in articles written about the study (publications). If the results of the study (including your research or health information) are published, your identity will remain confidential.

CONTACTS:

If you experience a study-related problem, or if you have any questions at any time about the study, contact the physician or physician assistant at the center who performed your treatment. The contact information for all of the providers involved in this study are listed on the 1st page of this consent document.

If you have questions regarding your rights as a research participant, or if you have questions, concerns, complaints about the research, would like information, or would like to offer input, you may contact the Sterling Institutional Review Board Regulatory Department, 6300 Powers Ferry Road, Suite 600-351, Atlanta, Georgia 30339 (mailing address) at telephone number 1-888-636-1062 (toll free).

Sterling IRB is a committee that has reviewed this research study to help ensure that your rights and welfare as a research participant are protected and that the study will be carried out in an ethical manner. Review and approval of this study by the Sterling IRB is not an endorsement of the study or its outcome.

RESEARCH PARTICIPATION INFORMATION:

You can obtain information about participating in research studies from a number of sources. A few are:

- Center for Information and Study on Clinical Research Participation (CISCRP): www.ciscrp.org
- Food and Drug Administration (FDA): www.fda.gov
- Office for Human Research Protections (OHRP): www.hhs.gov/ohrp
- National Institute of Health: clinical trials.gov
- National Cancer Institute: www.nci.nih.gov
- CenterWatch: www.centerwatch.com
- Various large university websites
- Various associations and societies concerned with specific diseases websites.

PHOTOGRAPHY CONSENT:

Photographs will be taken of your vagina as a requirement for participating in this study. These photographs may not be used without your written consent. Your face and name will not be disclosed, but this does not guarantee anonymity. By initialing below, you give your permission to use photographs of your vagina, which are to be taken during this study, for the purposes of professional publications, training, education, or sales. You will automatically be withdrawn from the study should you choose not to give your consent at this time.

You may cancel or withdraw your photography consent at any time during or after your participation in this study. You must do so in writing and submit that withdrawal of consent to the study doctor.

STATEMENT:

I agree to have photographs taken as a part of this study as described in this paragraph.

Participant's initials_____

CONSENT:

I have read the Participant Informed Consent Form and Authorization to Use and Disclose Medical Information and I agree to participate voluntarily in this study. I give my permission to the study doctor to use and disclose my protected health information as described in this consent form.

- 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)
- In 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)
- I will receive a signed copy of this form, which has 8 pages.
- I have not waived any of my legal rights by signing this document.

_____
Participant's Name (printed)

_____ _____
Participant's Signature Date

_____ _____
Person Conducting Consent Process Signature Date

_____ _____
Study Doctor's Signature Date