Informed Consent to Participate in Clinical Research Study

A DOUBLE-BLIND, SHAM CONTROLLED PROSPECTIVE PILOT STUDY OF URINARY STRESS INCONTINENCE AND URGENCY IN WOMEN AFTER 6 TREATMENTS WITH HIFEM TECHNOLOGY (BTL EMSELLA)

Sponsor:	**Irwin Goldstein, MD**
Protocol Number:	**SDSM-2018-02** **December 18, 2018**
Principal Investigator:	**Irwin Goldstein, MD** **San Diego Sexual Medicine, APC** **5555 Reservoir Drive, Suite 300** **San Diego, CA 92120**
24-Hour Telephone Number:	**(619) 265-8865**

This is a research study. You are being asked to take part in this study because you have stress urinary incontinence, urge incontinence or a mixture of the two. This study includes only individuals who voluntarily choose to participate. Please take your time to make your decision. Discuss it in confidence with your regular healthcare provider, friends and family if you want. Be sure to ask questions about anything you do not understand in this document.

WHAT IS THIS STUDY ABOUT?

The BTL EMSELLA is a device cleared by the Food and Drug Administration (FDA) for entirely non-invasive electromagnetic stimulation of pelvic floor musculature for the purpose of rehabilitation of weak pelvic muscles and restoration of neuromuscular control for the treatment of male and female urinary incontinence. Therapy using the BTL EMSELLA is an appropriate treatment for incontinence symptoms. High intensity focused electromagnetic (HIFEM) technology induces deep pelvic floor muscle contractions designed to deliver the equivalent of 11,200 Kegel exercises over 28 minutes, with the intention of increasing neuromuscular tone of the pelvic floor.

The investigational purpose of this study device is to examine the safety of the BLT EMSELLA as well as changes to your incontinence and to your sexual function.

This is a blinded study which means that neither you nor the study doctor will know if you are receiving the active HIFEM treatment or the sham treatment that delivers no muscle contractions. All enrolled subjects will be provided with the treatment:

- 2 out of 3 women will start active treatment at the second visit,
- and 1 out of 3 women will start sham treatment (control) at the second visit. You will then receive the active treatment starting at the tenth visit.

HOW LONG IS THIS STUDY? HOW MANY OTHER PEOPLE WILL BE IN THIS STUDY?

A total of 21 women will be enrolled in this study. More than 21 women may be screened in order to get 21 eligible women. You will be in the study for about 5-8 months, depending on whether you start treatment at visit 2 or 10. Participation requires approximately 9 visits if you receive active treatment at visit 2 or 17 visits if you receive sham (inactive treatment) at visit 10 to the clinic. Whether you are in the active treatment at visit 2 or visit 10 is chosen by chance, like flipping a coin.

WHAT IF NEW INFORMATION BECOMES AVAILABLE?

If new information in relation to the study device becomes available that may be relevant to the purpose and safety of the study and your willingness to continue participation in this study, you will be informed by the study healthcare provider.

WHAT WILL HAPPEN DURING THE STUDY?

If you agree to take part in this research study, you will be required to sign this informed consent form before any procedures take place.

STUDY PROCEDURES:

During the screening and, if you qualify and continue, during the study the following procedures will occur:

- Questions about your health, past surgeries, and medications you are taking including requests for your medical records
- Questionnaires to assess your incontinence and sexual function
- Height and weight will be measured
- Pregnancy test to ensure you are not pregnant while being treated
- Physical examination including assessment of your pelvic muscle strength by perineometer (a device that measures how hard your muscles can squeeze) as well as by a physical therapist.

The screening visit should take approximately one and a half hours. Each additional visit should take approximately one hour.

The study healthcare provider or representative will talk to you and give you a list of the things you must do to participate, such as:

- Pre-study medication: Any medications that you are currently taking (with some exceptions described below) can continue provided they do not change during the screening and treatment periods. You must inform the study healthcare provider if you need to change your medications once screening begins (especially if it is a medication for incontinence) through the end of the study. You must inform the study healthcare provider if you need to change your medications once screening begins through the end of the study.

- The following medications are prohibited from screening visit through the end of the study:
    - All forms of testosterone
    - Any investigational drug or medical device
    - Any drugs of abuse.

After screening, if you meet all eligibility criteria, you will be scheduled for your six study device appointments. Please inform the research personal if you have any plans to be unavailable during the treatment period.

At the six visits following screening you will be asked about changes in your health or medication and have a treatment with the study device. You will be asked to remove any metal on your body from your waist down, and to take metal objects (e.g. keys) and electronics (e.g. cell phone) out of your pockets. You will remain fully clothed for this treatment. You will be asked to sit on the device and the height will be adjusted until your feet are on the floor and positioned at a right angle. The BTL EMSELLA will be turned on for you to adjust yourself on the device. Once you can feel that you are in the correct position, the treatment will be turned on and strength adjusted to be at the maximum you can tolerate. The strength may be increased as you sit until it is at 100%. You will have the treatment for 28 minutes at which time the device automatically shuts off. After completing visit 7, the last treatment of the first phase, you will complete incontinence and sexual function questionnaires.

At visit 8 you will have your first follow up visit with your height and weight measured, be asked about changes in your health or medication, have an examination of your pelvic muscle strength, and complete questionnaires about your incontinence and sexual function.

The visit 8 procedures will be repeated at visit 9 as well as a physical exam. The research staff will let you know at that time if you had received active treatment in which case your participation in the study is complete, or sham treatment. If you were assigned to sham, you will be asked to take another pregnancy test and if you still meet all the requirements for the study you will be able to start the active treatment (visit 10) either on that same day or another day based on schedule, as you will need to have to complete visits 10 and 11 in the same week. You will continue with active treatment for a total of six visits.

At visit 16 you will have your first follow up visit after active treatment with your height and weight measured, be asked about changes in your health or medication, have an examination of your pelvic muscle strength, and complete questionnaires about your incontinence and sexual function.

The visit 16 procedures will be repeated at visit 17 as well as a physical exam. This will be your final visit.

If you decide to stop your participation early, you will be asked to do the same procedures as in the last visit.

Please tell your regular health care providers and any emergency care providers that you are participating in this research study.

WHAT ARE THE RISKS AND DISCOMFORTS OF PARTICIPATING IN THIS STUDY?

The study device has been associated with the following risks: muscular pain, muscle spasm, joint or tendon pain, local skin redness, temporary increase of local circulation, increased sensitivity during intercourse. These are all temporary issues that can happen during or after the treatment.

There may be risks associated with this research that are currently unknown.

You can ask the study doctor for the package insert for this device or read more about it on the internet.

Notify your study healthcare provider if you have any unusual symptoms such as severe pain with urination.

Are there pregnancy risks?
Nothing will be put inside you, but you should not participate if you are pregnant, or within 3 months of having given birth. Discuss this with your study doctor if you have any questions about the risks or your contraception use if you are able to become pregnant.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, you may have improvement in your symptoms of stress urinary incontinence and/or urge incontinence. Your condition may stay the same or get worse.

WHAT, IF ANY, ARE THE ALTERNATIVES TO PARTICIPATING IN THIS STUDY?

There are alternative choices to treat your incontinence. You could choose to ask your healthcare provider for a prescription for medication or you could choose to work with a physical therapist or have sling surgery. You could also choose to pay for treatments with the study device without being in this clinical trial. Consult your study healthcare provider for more information on these options.

CONFIDENTIALITY

Your personal information will be kept confidential to the extent permitted by law. We cannot guarantee absolute confidentiality. By signing this document, you give permission to access your medical records, including after withdrawal, for data verification purposes.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as:

- The study staff and other researchers involved in the study
- The Food and Drug Administration (FDA)
- Aspire Independent Review Board (IRB)

The results from the study may be published for scientific purposes, but your identity will be kept confidential.

In the rare event that your information is required to be disclosed by law to another entity, privacy laws may not apply, and neither the Sponsor nor Aspire IRB can protect your information.

WHAT ARE THE COSTS?

There are no additional costs associated with being in this study. You are responsible for your regular health care while in this study. You will not have to pay for study visits or procedures that are part of the study.

INVESTIGATOR PAYMENT

The Sponsor is one of the study healthcare providers so your payment will cover the cost of conducting this study.

WILL YOU BE COMPENSATED DURING THE STUDY?

You will not be compensated for participating in and completing this research study.

WHAT HAPPENS IF YOU HAVE COMPLICATIONS OR ARE INJURED?

If you have serious side effects, complications or are injured because of participation in this study, please contact the study healthcare provider promptly. The study healthcare provider will provide any necessary medical treatment to help you promptly recover from the injury. If you require care outside of the study site your insurance will be billed for the medical treatment.

YOUR RIGHTS AS A RESEARCH SUBJECT

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to the study healthcare provider and your regular healthcare provider first.

YOUR RESPONSIBILITIES AS A RESEARCH SUBJECT

You will be asked to adhere to all instructions issued by the study healthcare provider and other study staff including the following:

1. Answer all medical questions completely and truthfully
2. Arrive at all study visits on time
3. Follow instructions provided by the study staff
4. Report any changes in your medications while on the study to the study healthcare provider or staff
5. Adhere to the instructions on prohibited medications

6. Inform your regular healthcare provider about your participation in this study

Should you not comply with instructions, the study healthcare provider may stop your study participation. Your study healthcare provider may also exclude you from this trial if he deems it beneficial for your health, or if you do not meet the study requirements.

Your participation in this study may be ended if the study is stopped for any reason. If your participation in the study is ended before you complete all the visits, you will be asked to visit the study center to have some final tests done.

WHOM TO CALL IF YOU HAVE QUESTIONS

For questions, concerns or complaints about the study or a research-related injury, contact Dr. Irwin Goldstein, 619-265-8865.

This research is being overseen by Aspire Independent Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at 1-877-366-5414 (toll free) if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

Although Aspire IRB has approved the information provided in this informed consent form and has granted approval for the investigator to conduct the study this does not mean Aspire has approved your participation in the study. You must evaluate the information in this informed consent form for yourself and decide whether or not you wish to participate.

PRIMARY HEALTHCARE PROVIDER / SPECIALIST NOTIFICATION OPTION

Please indicate below whether you want us to notify your primary healthcare provider or your specialist of your participation in this study.

_____ Yes, I want the study healthcare provider to inform my primary healthcare provider/specialist of my participation in this study.

_____ No, I do not want the study healthcare provider to inform my primary healthcare provider/specialist of my participation in this study.

_____ I do not have a primary healthcare provider/specialist.

_____ The study healthcare provider is my primary healthcare provider/specialist.

SIGNATURE AND CONSENT TO BE IN THE STUDY

Your signature below means that you have read the above information about this study and have had a chance to ask questions to help you understand what you will do and that you agree to participate in this study. Your signature also means that you have been told that you can change your mind later if you want to. You will be given a signed and dated copy of this agreement. By signing this consent form you are not giving up any of your legal rights.

_____ _____/_____

SIGNATURE OF SUBJECT DATE

_____

PRINTED NAME OF SUBJECT

I confirm that a copy of this consent form has been given to this person to read and that this person has been told about the study. The contents of the consent form describing the study has been discussed with this person. All questions have been answered to her satisfaction. I have watched this person sign the consent form.

_____ _____/_____

SIGNATURE OF PERSON OBTAINING CONSENT DATE

_____

PRINTED NAME OF PERSON OBTAINING CONSENT

Name of Study: **A Double-Blind Sham Controlled Prospective Pilot Study of Urinary Stress Incontinence and Urgency in Women after 6 Treatments with HIFEM Technology (BTL EMSELLA)**

Principal Investigator: Irwin Goldstein, MD
IRB Study Number: SDSM-2018-02

What is private health information?
State and federal privacy laws protect the use and release of your private health information.

Private health information is any information that can be traced back to you. We need your authorization (permission) to use your private health information in this research study. If you decide to give your permission to participate in the study, you must sign this form as well as the Consent Form. If you refuse to give permission, you will not be able to be in this research. The private health information that we will use and share for this study includes:

- your past and present health information (medical records)
- research records
- records about phone calls made as part of this research
- information obtained during this research, such as laboratory and other test results
- information that could be used to identify you

Your personal health information will be used to carry out the research, to review records on the information collected in this study, to check how the study was carried out, or for other uses permitted by law.

Who else will see my information?
If you give your permission and sign this form you are allowing the Principal Investigator and the research team to share your Personal Health Information with:

- All groups that work with the investigators, including government agencies such as the Food and Drug Administration. These organizations and their representatives may see your Personal Health Information. They may not copy or take it from your medical records unless permitted or required by law.
- The Aspire IRB committee that reviews research to help protect people who join research studies.

Once we have shared your information we cannot be sure that it will stay private. If ***you share*** your information with people outside the research team, it will no longer be private. Your name will not be used in any report that is written.

How long will you use and share my information?
This permission to release your Personal Health Information expires 50 years from when you sign this authorization unless you revoke it sooner. Research reports can be used forever.

What if I change my mind about sharing my research information?
You can cancel your permission at any time. You can do this in two ways. You can write to the researcher or you can ask someone on the research team to give you a form to fill out to cancel your permission. If you cancel your permission, you may no longer be in the research study. You may want to ask someone on the research team if canceling will affect your medical treatment. If you cancel, information that was already collected and disclosed about you may continue to be used. Also, if the law requires it, the sponsor and government agencies may continue to look at your medical records to review the quality or safety of the study.

Do I have the right to see and copy my research information?
You can see your research information that is also being used for your health care. Some research information may not be available to you because of the design of the study or because the tests have nothing to do with your health care. You can talk to your study healthcare provider about this.

If you agree to share your information please sign this form below. You will be given a copy of this form.

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I agree to share my information as described in this form

_____

Sign your name Date

_____

Print your name

If you have questions or concerns about your privacy and the use of your personal medical information, please contact your research healthcare provider at the phone number in the Informed Consent form.