

Scott & White Hospital & Clinics Clinical Research at Scott & White

Please complete this form for each of your studies that are currently enrolling subjects. This information will be used to create a web page available for viewing by the general public. Please use lay terminology as in the consent form. The information should be complete and accurately describe your studies.

Study Title: Prospective, Multicenter, Randomized, Parallel-Group Trial, Comparing the Safety and Efficacy of InterStim® Therapy to Standard Medical Therapy for Subjects with Symptoms of Overactive Bladder (Medtronic InSite UI protocol #1634 and Medtronic InSite UF protocol #1635)

Project ID#: 70885

Department: Urology

Sponsor: Medtronic, Inc.

1. Provide a brief synopsis of the study (purpose of the study from abstract, consent form, or protocol using lay terminology):

Condition(s):	Treatment(s):
overactive bladder with symptoms of: urinary urge incontinence or urinary urgency-frequency	InterStim® Therapy or Standard Medical Therapy (medication)

The purpose of this research study is to:

- compare the InterStim® Therapy system to using only medicine for overactive bladder.
- to learn more about how safe a part of the InterStim® system is (the tined lead) when used over a long period of time.
- to measure how your symptoms of overactive bladder affect your daily living.
- to learn more about how InterStim® Therapy may affect bowel function (stool), sexual function, mental depression, and pain in the pelvic area.
- to compare the costs to patients who have the InterStim® Therapy system with those who have medicine only for overactive bladder.
- to find out which symptoms might be helped the most by using InterStim® Therapy.

2. Who is eligible to participate in the study (basic qualifications such as age, gender, etc.)?

Age: 18 and older

Gender: Males and Females

To participate in the study subjects must meet all of the following inclusion criteria**:

- Have a **diagnosis of overactive bladder** including *urinary urge incontinence* **OR** *urinary urgency-frequency*
- Be able to consent to participate by signing the Informed Consent
- Be willing and able to attend visits and comply with the study protocol including adequate operation of equipment
- Have failed or are not a candidate for more conservative treatment (e.g. pelvic floor training, biofeedback, behavioral modification)
- Have failed or could not tolerate (stopped taking medication due to lack of efficacy or intolerable side effects) at least one anticholinergic or antimuscarinic medication **AND** have at least one anticholinergic or antimuscarinic medication not yet attempted

- Have been on current regimen of overactive bladder medications or have not been on any overactive bladder medications, for at least 4 weeks prior to medication discontinuation for the baseline diary

**Exclusion criteria apply to eligibility as well. Discuss qualifications with the study coordinator.

3. What may be involved/required for subject participation (visits, tests, and/or logs, etc.)?

Depending on your symptoms you will be in either the urinary urge incontinence group or urgency-frequency group.

You will then be assigned to 1 of 2 groups:

- The InterStim[®] Therapy group
- The medicine only group

If you are assigned to the InterStim[®] Therapy group, you will have a test to see if InterStim[®] therapy might be helpful to you. If you have a positive test, your doctor will implant the InterStim[®] Therapy system, and you will be in the study for 5 years. Follow-up visits will be completed at months 3, 6, 12, 24, 36, 48 and 60. At each follow-up visit, a physical examination (with the exception of month 3) will be conducted and voiding diaries, quality of life questionnaires, X-ray (with the exception of months 3 and 6) and economic data (through month 12 only) will be collected.

If you are assigned to the InterStim[®] Therapy group and you have a negative test, your doctor will not implant the InterStim[®] Therapy system, and you will be in the study for 12 months. You will be allowed to take medicine for your overactive bladder. Follow-up visits will be completed at months 3, 6 and 12.

If you are assigned to the medicine only group, you will remain in that group for 6 months, and then you will have the chance to have the test to see if InterStim[®] therapy might be helpful to you. If you have a positive test, your doctor will implant the InterStim[®] Therapy system, and you will be in the study for 5 more years. Follow-up visits will be completed at months 3 and 6 (also at 12, 24, 36, 48 and 60 if you have the InterStim[®] Therapy system implanted). At each follow-up visit, a physical examination (with the exception of month 3) will be conducted and voiding diaries, quality of life questionnaires, X-ray (with the exception of months 3 and 6) and economic data (through month 12 only) will be collected.

4. Contact Information:

Coordinator: Jennifer Gibbons-Ramirez, CCRP

Title: Clinical Research Coordinator

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