ABOUT YOUR INTERSTIM TRIAL

Dear Patient:

Your physician has referred you for an InterStim® trial. The purpose of this letter is to familiarize you with the nature of the procedure, its benefits and its risks. What follows is absolutely essential for you to know, so please read this carefully. We consider your understanding of this material to be so important that we will ask you to sign this letter acknowledging you have read and understood this information. If you have any questions please contact us by phone (970-663-2159) before the procedure so we can discuss your concerns with you.

What is InterStim® therapy? Medical researchers have known for over 30 years that the sacral nerves control all the functions of the pelvis and its organs. Electrical impulses travel from the brain to the organs and muscles in the pelvis via the sacral nerves. These impulses are responsible for urinary and fecal elimination, muscle coordination, reproductive organs and the genitals.

InterStim® placement has 2 stages. Dr. North will perform Stage 1, the InterStim® Trial. This will determine if InterStim® is beneficial for you. Stage 2 is the permanent implant (placed by a local provider).

Stage 1: InterStim® Trial

InterStim® is unique in that a test stimulation is performed to assess the effectiveness of the therapy prior to placing a permanent implant. InterStim® trial procedure is performed in the outpatient setting under local anesthetic and mild sedation, if needed. Small wires are placed with the help of a needle through the skin without making any incisions. The temporary lead is plugged into a temporary stimulator that can be worn on the waistband either inside or outside of the clothing. The InterStim® temporary stimulator is used for about one week to assess the results of the stimulation.

After approximately seven days, you will return to the office with your stool/fecal incontinence diary. The pre and post diaries will be compared and Dr. North will review the results with you and your family. If the test was a success, you may elect to have the Interstim® Implanted Stimulator placed (Stage 2). This simple procedure is done in the hospital on an outpatient basis.

How does InterStim® work? Scientists have discovered that the exquisite coordination of organs and muscles in the pelvis necessary for normal, pain free function can become disrupted by any number of events. For example, child birth, hysterectomies, bowel and bladder surgeries, prostate surgeries, genetic predisposition or almost any other pelvic event can be an insult to the sacral nerves. The insult may lead to faulty nerve impulses traversing the nerves causing pelvic floor dysfunction, fecal incontinence, urgency, frequency and pelvic pain.



The mild stimulation provided by the InterStim® stimulator serves to connect the communication signals to the sacral nerves and thereby improving anal sphincter function and bowel incontinence. Although we are recommending this for your fecal incontinence, patients frequently experience improvement in urinary frequency, urge incontinence and several other ailments.

Is it safe? The gentle stimulation required to correct faulty sacral nerve communications is introduced in the tissues just under the skin over the sacrum (tailbone) through a small wire (also called a lead). The technology is similar to that of cardiac pacing and has been proven safe during the last 15 years of use on an international scale. Not a single patient has ever suffered a non-reversible health consequence as a result of InterStim® sacral nerve stimulation, and the treatment is reversible should the patient decide not to continue with the therapy for any reason.

Please contact us at 970-663-2159, if you would like to discuss any of this further. You will, of course, have an opportunity to speak to us immediately before the procedure.

Sincerely Yours,

Continos

Crystal M. North, DO

By signing here, you certify that you have read and understood the contents of this letter. If you have questions, please do not sign this until we have answered them for you.

Name	Date
Name	Date

