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,

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_____

TELL US ABOUT YOURSELF

Please complete this form and bring it and this packet to your procedure.

Why are you having this procedure? _____

Do you take Warfarin (Coumadin)? ❑ Yes ❑ No ***Do you use oxygen at home?*** ❑ Yes ❑ No

Are you, or could you be, pregnant? ❑ Yes ❑ No

Do you smoke or use tobacco products? Amount_____ ***Do you drink alcohol?*** Amount_____

Do you use marijuana products? ❑ Yes ❑ No

Do you have any of the following medical conditions? If yes, please briefly explain.

❑ Yes ❑ No Diabetes _____

❑ Yes ❑ No High Blood Pressure _____

❑ Yes ❑ No Heart Disease _____

❑ Yes ❑ No Asthma/COPD _____

❑ Yes ❑ No Stroke _____

❑ Yes ❑ No Liver Problems _____

❑ Yes ❑ No Blood Clots _____

❑ Yes ❑ No Kidney Problems _____

❑ Yes ❑ No Sleep Apnea _____

❑ Yes ❑ No Other _____

Previous Surgeries:

Surgery/Approximate Date: Surgery/Approximate Date:

_____ _____

_____ _____

_____ _____

Please list any of your blood relatives with a history of colon cancer or colon polyps:

_____ _____

Previous Endoscopic Procedures:

Colonoscopy _____ Approximate Date: _____

Upper Endoscopy _____ Approximate Date: _____

Do you have a living will? ❑ Yes ❑ No ***Do you have a medical durable power of attorney?*** ❑ Yes ❑ No

Do you want any information regarding these? ❑ Yes ❑ No

_____ _____

Signature ***Date***

Health History has been reviewed by _____ ***RN*** ***Date*** _____ ***Time*** _____

Please complete medication form on back page.

MEDICATION FORM

Name: _____ Date: _____

ALLERGIES: _____

_____

At Skyline Endoscopy Center we understand that the safe management of your medications may be a challenge and we can provide assistance. In fact, it is something we take very seriously. We join with your physician in developing systems that assure that your next provider of care has full knowledge of your current medications. This allows safe administration of new drugs and avoiding duplication of drugs or dangerous drug interactions.

We call this "Reconciliation"…We think this is Important…and so should you!

You can help us by completing this form before you come to the Center. After your procedure is completed a copy of this form will be handed back to you with additional medications you received during your stay at the Center or that were prescribed for you on discharge.

PLEASE PRINT CLEARLY ANY MEDICATIONS YOU ARE TAKING—INCLUDING PRESCRIPTIONS, OVER THE COUNTER MEDICATIONS AND HERBALS

DRUG NAME	STRENGTH	HOW MANY TIMES A DAY	TAKE FOR WHAT PURPOSE

NEW INSTRUCTIONS/PRESCRIPTION(S) ADDED TODAY UPON DISCHARGE:

DURING YOUR VISIT YOU WERE GIVEN:

- ❑ PROPOFOL FOR SEDATION
- ❑ VERSED FOR SEDATION
- ❑ FENTANYL FOR DISCOMFORT
- ❑ CETACAINE SPRAY
- ❑ OTHER MEDICATIONS:

_____

_____

REVIEWED BY: _____

DATE: _____

INTERSTIM PROCEDURE PREP

Your physician has scheduled you for an InterStim® procedure. Please follow the instructions below.

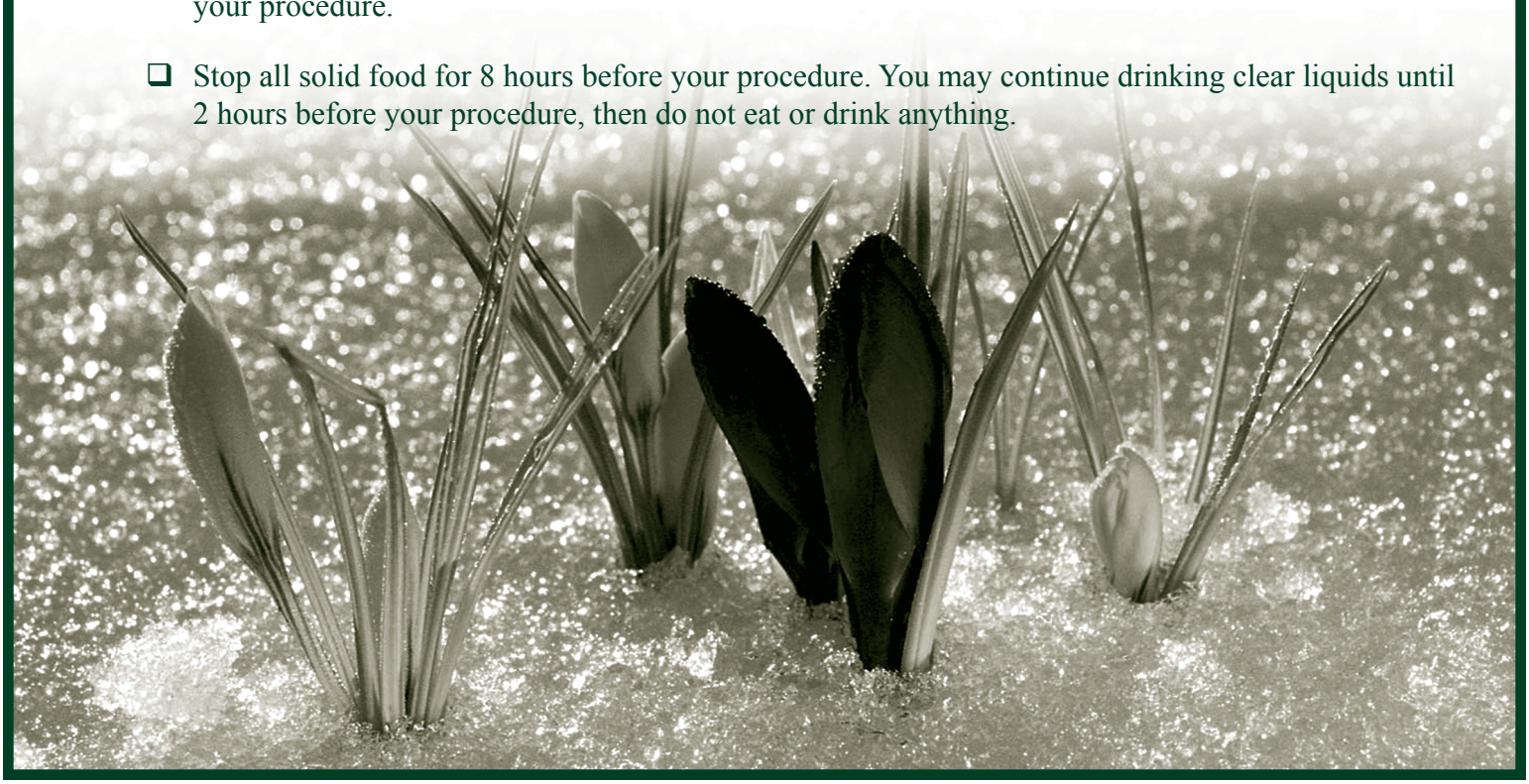
- ❑ If you need to cancel or reschedule your procedure for any reason, please call the Endoscopy Scheduler at 970-663-2159 at least 48 hours prior to your procedure.
- ❑ **Completely fill out the "TELL US ABOUT YOURSELF" and "MEDICATION FORM" in your packet. Bring the completed forms and your packet with you the day of your exam.**

General Information:

- ❑ Document your stools and incontinence episodes using the diary sheets provided (Bowel Symptom Tracker). Please provide at least 6 days of information.
- ❑ No aspirin or other blood thinning medications should be taken for seven days prior to the procedure. If you are taking blood thinners, please call Dr. North's office at 970-669-5432 if you have questions.
- ❑ Do not eat or drink anything for 2 hours before your procedure. (Take **nothing** by mouth for these 2 hours.)
- ❑ Follow the instructions given to you by Dr. North.
- ❑ Bring a photo ID and insurance card(s).
- ❑ If you do not receive sedation, you will be able to drive yourself home.

If you receive sedation:

- ❑ Make arrangements to have a responsible adult drive you home. Public transportation is not allowed unless you have an adult to accompany you. Your driver should plan to stay at the facility during your procedure.
- ❑ Stop all solid food for 8 hours before your procedure. You may continue drinking clear liquids until 2 hours before your procedure, then do not eat or drink anything.



WHAT TO EXPECT AFTER YOUR INTERSTIM PROCEDURE

Dear Patient:

Please follow these guidelines to ensure the best possible outcome after your procedure:

- ✔ Start documenting your incontinence/stooling again in the diary (Bowl Symptom Tracker), just as you did prior to the procedure. Bring this with you to the next office appointment.
- ✔ Take Tylenol for pain if needed.
- ✔ Dressings over the lead wires should not be removed.
- ✔ Do not shower or soak in a bath. Please only sponge off, or use wet wipes to clean.
- ✔ Keep the next doctor's appointment. We will remove the leads at that time.
- ✔ Limit exercise and excessive bending at the waist.

Report the following to Dr. North:

- ✔ Signs of infection: fever over 101 degrees; redness, tenderness or swelling at the site; foul smelling yellow drainage from the site (a small amount of drainage is normal).
- ✔ If you have any questions regarding these instructions, your medications, or allowed activities, please call 970-669-5432.

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INTERSTIM PROCEDURE CONSENT FORM

CONSENT FOR PROCEDURE

SKYLINE ENDOSCOPY CENTER

PERCUTANEOUS IMPLANTATION OF NEUROSTIMULATOR ELECTRODES

Patient: _____

1. PROCEDURE AND ALTERNATIVES: I (patient or authorized representative) authorize Dr. North to perform procedure: Percutaneous Implantation of Neurostimulator Electrodes.This procedure involves putting a small needle into the sacrum in the vicinity of the nerves that control my bowel function. A thin lead will be inserted through the needle and connected to a battery operated device that will provide stimulation of the nerves.

I understand the reason for the procedure is: Testing to determine if stimulation through temporary leads will reduce or eliminate bowel symptoms / fecal incontinence.

2. RISKS: This authorization is given with the understanding that any procedure involves some risks and hazards. The more common risks include: infection, bleeding, nerve injury, allergic reactions, pain in the area of procedure, no relief of bowel symptoms / incontinence.

3. SEDATION / ANESTHESIA: This procedure will be done under local anesthesia (injection of local anesthetic / numbing medication in the area of the procedure). A small dose of IV sedation (Versed) may be administered for my additional comfort. I consent to the use of such analgesia and sedation as considered necessary by Dr. North.

4. I understand that no guarantee or assurance has been made as to the results of the procedure and that it may not relieve the condition of bowel symptoms/fecal incontinence.

NOTE: IF YOU HAVE ANY QUESTIONS ABOUT THE PROCEDURE, OR THE RISKS OR CONSEQUENCES ASSOCIATED WITH IT, TALK WITH YOUR PHYSICIAN. YOU MAY WITHDRAW THE CONSENT FOR THIS PROCEDURE AT ANY TIME PRIOR TO ITS PERFORMANCE. DO NOT SIGN THIS CONSENT UNLESS YOU HAVE READ AND UNDERSTAND THIS FORM.

_____ _____

Patient / Authorized Representative **Date and Time**

_____

Relationship of Authorized Representative

PHYSICIAN DECLARATION: I have discussed the procedure, risks, complications, consequences, and alternatives with the patient or patient's representative, and to the best of my knowledge, the patient or patient's representative understands this information and consents to the proposed procedure.

_____

Physician's Signature

NOTICE OF PATIENT RIGHTS & RESPONSIBILITIES

PATIENT RIGHTS

Decision Making

You or your representative have the right to:

- Be informed before care is given or discontinued whenever possible.
- Receive accurate and current information regarding your health status in terms you can understand.
- Participate in planning for your treatment, care and discharge recommendations.
- Receive an explanation of proposed procedures or treatments, including risks, serious side effects and treatment alternatives, including request for second opinion.
- Participate in managing your pain effectively.
- Receive emergency care or transfer to a higher level of care (hospital), if necessary, with a full explanation of your medical need for transfer. No wait for insurance authorization will be required and no financial penalty will be imposed.
- Have persons of your choice promptly notified of hospital admission.
- Accept, refuse or discontinue a treatment or drug, to the extent permitted by law, and be informed of the consequences of such refusal.
- Accept, refuse or withdraw from clinical research.
- Accept, refuse or withdraw from diagnostic or therapeutic procedures.
- Choose or change your healthcare provider.

Equality of Care

You have the right to:

- Respectful treatment, which recognizes and maintains your dignity and personal values without discrimination on the basis of race, color, national origin, sex, age or disability.
- Accurate information about the facility where services are received and the name, credentials and job function of health care personnel involved in your care.
- Interpreters and/or special equipment to assist with language needs.
- Information on how to obtain auxiliary aids or services should these be required.
- Information about continuing healthcare requirements following discharge, including how to access care after hours.

Confidentiality and Privacy

You have the right to:

- Personal privacy and care in a safe setting free from abuse, harassment, discrimination or reprisal.
- Sharing of personal information only among those who are involved in your care.
- Confidentiality of your medical and billing records.
- Notification of privacy practices.
- Notification of breach of unsecured personal health information.

Grievance Process

You, or your representative, have the right to:

- Fair and objective review of any complaint you have regarding care received from healthcare providers/personnel, without fear of reprisal.
- Submit a formal complaint either verbally or in writing as shown below. You will receive a written notice of decision within 15 business days from the date the complaint was made known to the Center.

Administrator of ASC serving as Compliance Officer: 970-541-2582

Colorado Department of Health: 303-692-2904 or email: hfdintake@cdphe.state.co.us

Department of Registry Agency: 303-894-7800 or http://www.dora.state.co.us/medical/complaints.html

CMS Ombudsman: 1-800-MEDICARE (1-800-633-4227) or http://www.medicare.gov/claims-and-appeals/medicare-rights/get-help/ombudsman.html

Office of Inspector General: 800-447-8477 or https://www.oig.hhs.gov/hotlineoperations, or US Department of Health & Human Services, Attn: OIG Hotline Operations, P.O.BOX 23489, Washington D.C. 20026

Office of Civil Rights: https://www2.ed.gov/about/offices/list/ocr/docs/howto.html

Advance Directives

You have the right to know that:

- You may provide a Living Will and/or Medical Power of Attorney.
- It is Skyline Endoscopy Center's policy, regardless of the contents of any advance directive or instructions from a healthcare surrogate, that if a life threatening condition should occur during your treatment at this facility, we will initiate resuscitative or other stabilizing measures and transfer you via ambulance to an acute care hospital for further evaluation.

Access to Medical Records

You have the right to:

- Speak privately with health care providers knowing that your health care information is secure.
- Review and/or receive a copy of your Medical Records (including electronic format), within 30 days by secure transmission, upon written request.

Seclusion and Restraints

You have the right to:

- Be free from seclusion or restraint for behavioral management unless medically necessary to protect your physical safety or the safety of others.

Billing

You have the right to:

- Information specific to fees for services and payment policies, prior to the date of service.
- Payment privacy when you choose to opt out of insurance coverage, in accordance with federal regulations.

PATIENT RESPONSIBILITIES

Providing Information

You have the responsibility to:

- Provide accurate and complete information about present problems, past illnesses, hospitalizations, current use of prescribed or OTC medications, current use of nutritional supplemental products, and other health-related matters.
- Report perceived risks in your care and unexpected changes in your condition.
- Provide an Advance Directive, if you have one.
- Provide accurate and updated demographic and contact information for insurance and billing.

Involvement

You have the responsibility to:

- Participate in your plan of care and follow the recommended treatment plan.
- Ensure you have a designated responsible adult to provide transportation and assist with your care for 4-6 hours after your procedure.

Respect and Consideration

You have the responsibility to:

- Act in a respectful and considerate manner toward healthcare providers, other patients, and visitors; physical or verbal threats or conduct, which are disruptive to business operations, will not be tolerated.
- Be respectful of the possessions or property of others, as well as the facility property.
- Assist in keeping noise levels and the number of visitors to a minimum.

Insurance Billing

You have the responsibility to:

- Know the extent of your insurance coverage.
- Know your insurance requirements including pre-authorization, deductibles and co-payments. Deductible amounts owed and copayments are expected at time of service.
- Call the billing office with questions or concerns regarding your bill.
- Fulfill your financial obligations as promptly as possible.

Drs. Langer, North, Sears, Strong and Caufield have a financial ownership in Skyline Endoscopy Center.