Frankston Pain Management **Suite 7, 20 Clarendon St, Frankston, Vic, 3199**
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Spinal Cord Stimulator Trial and Implant - Patient Information Consent and Request Form

Spinal cord stimulation (SCS) therapy has been used for over 30 years to treat pain. SCS works by delivering mild electrical impulses to the appropriate area of your spinal cord that may or may not produce a gentle tingling feeling (paraesthesia) to relieve pain.

Although stimulation may reduce your pain, it does not cure or eliminate the cause of your pain. A big advantage of SCS is that it is a reversible non-destructive procedure. The trial result is the best predictor of the 3 month outcome which is the best indicator of the result at 5 years and beyond. SCS helps 70-80% patients to become more active, have a better quality of life and reduce dependence on medications and other health care. Patients' responses to spinal cord stimulation (SCS) vary widely and some people don't obtain pain relief.

A retrospective review of 49 patients treated at Frankston Pain Management with 10 kHz SCS implant between 2012 and 2024, showed that at last follow up, 90% of patients reporting at least 50% pain relief with 10 kHz SCS. The majority of patients reported improvements in sleep quality (84.4%), function (83.0%), and reduced analgesic use (66.7%) at their most recent visit compared to pre-implantation. This real world clinic data is similar to published randomised controlled trials.

Indications
A successful trial of spinal cord stimulation.
SCS can treat pain that resists other treatment. SCS is an advanced alternative treatment used when other simpler standard treatments haven't worked. It can treat many different types of pain.

Pain type	Current Evidence for SCS	Level of Evidence
Neuropathic/Nerve pain	Persistent spinal pain syndromes Complex regional pain syndrome Painful diabetic neuropathy Post-surgical neuropathy Peripheral neuropathy/polyneuropathy Trigeminal neuralgia Post herpetic neuralgia	Strong evidence
Nociplastic pain/Sensitised nervous system	Widespread pain syndromes Fibromyalgia	Limited Evidence, get second opinion Good patient selection critical
Nociceptive pain and neuromuscular dysfunction	Mechanical and nociceptive axial low back pain	Minial efficacy of SCS, best mixed type Moderate evidence for restorative L2 neuromuscular electrical stimulation
Mixed Pain	Post surgical pain with neuropathic and nociceptive pain	Moderate evidence for benefit
Ischaemic Pain	Refractory angina, ischaemic limb pain	Evidence primarily observational
Emerging Indications	Pelvic and visceral pain. Eg interstitial cystitis	Good patient selection and auditing

Absolute Contraindications
Patient refusal
Spinal canal narrowing or unfavourable anatomy, not allowing safe lead placement
Active untreated infection
Severe thrombocytopenia or uncontrolled bleeding disorder
Untreated major psychiatric disorders or psychosis
Active, untreated substance use disorder

Relative contraindications
Symptoms unexplained by known pathology
Unrealistic expectations
Cognitive impairment and/or Inability to manage device
Severe obesity due to complexity and increased risk of device failure
High opioid use >90mg morphine equivalent or inability to reduce dose, due to poor outcome
Severe depresson
Other: immune suppression, spinal cord injury, obsessive compulsive disorder
Inadequate social support and poor coping skills
Non-engagement and poor compliance

RISKS of Spinal Cord Stimulation: (adapted from Eldabe 2015)
Common to all therapeutic and diagnostic procedures are the usual risks of surgery.

Rate	**Biologic Complications/Problems**
5-12%	Wound pain, pocket pain. (Usually resolves with further treatment)
<5%	No pain relief despite positive trial
<0.5%	Nerve damage, spinal cord injury, paralysis, loss of bladder / bowel / sexual function
<0.5%	Epidural bleed/haematoma (may need early spine surgery)
~1%	Spinal tap/dural puncture and postural head ache.
<1%	Wound haematoma/seroma over devices
<0.1%	Allergy to the device orcomponents
<0.2%	Skin Erosion
1-2% ?	Serious/deep infection/abscess (usually requiring system removal and early spine surgery)
2-4%	Superficial surgical site infection (usually settles with antibiotics)
?	Drug withdrawal symptoms whilst reducing/stopping strong (morphine-like) pain killers.
	Device Complications/Problems
5-15%	Lead migration/ fracture/high impedance (needing revision/replacement)
0-10%	Extension-related disconnection or misconnection (needing revision/replacement)
2-5%	Premature Pulse Generator (IPG) battery depletion, flipping and recharging difficulties
	Programming or Therapy-related complications
5-15%	Loss of paraesthesia, pain relief, tolerance over 10 years (reprogram or device removal)
5-15%	Painful stimulation or unpleasant paraesthesia (reprogram or device removal)
?	Hot/burning sensation while recharging IPG.

Financial Considerations
The direct medical and hospital costs may include out-of-pocket gaps for your planned treatment. In addition, please note the possible extra costs for pathology, radiology, recovery (eg rehabilitation) and bills from other medical specialists to anticipate and prevent unexpected problems for your safety. Your ability to work during the trial and for 2-6 weeks after implanting a permanent device is reduced, which may cause a loss of income for those who are self-employed or don't have enough sick leave. The cost of complications are difficult to quantify in terms of financial consequences to patients and families. Although most adverse events are self-limited and resolve, severe complications, while rare, may require surgery/procedures, prolonged hospital stay, more time off work than expected and unexpected dependency on family or carers, which may impact on loan repayments and other commitments.

Informed Consent
Get informed!
Please **read** supplied patient information.
Please **watch** the video patient information: https://www.painaustralia.org.au/spinal-cord-stimulation
Please **read**: https://www.painaustralia.org.au/static/uploads/files/spinal-cord-stimulator-consumer-experience-report.pdf
Check http://www.fpmx.com.au/solutions.html#treatment-procedures and
Check company websites http://www.fpmx.com.au/patients.html#useful-links **for more information**.
Speak with a patient ambassador who has a stimulator implanted for a similar problem
Speak with the stimulator technician to learn how to live with and manage your device.
Ensure your questions and concerns have been answered, be aware of the benefits, limitations and risks

PREPARATION:
Please start weaning your pain killers in the 2-3 weeks leading upto your stim trial, to avoid withdrawal symptoms during the trial. Please make a plan to achieve this with your doctor.
Please have your teeth checked by a dentist and any necessary work done BEFORE your surgery.
Please see your GP to make sure you are in the best possible health
Please stop smoking to improve wound healing
Ladies if you may be pregnant, please tell your doctor ASAP.
Please have nothing to eat for 6 hours and nothing to drink for 2 hours before the procedure.
Please take your normal medications with a sip of water.
Please obtain specific instructions, if you are taking 'blood thinners' (eg warfarin or clopidodrel), insulin or other diabetic medications.

PROCEDURE:
The procedure is usually done in two stages with a 2-4 week trial with tunneled leads, followed if successful, by the implantation of a permanent system.

You will receive twilight sedation, the area will be cleaned with antiseptic and local anaesthetic will be injected to numb the area. Temporary leads are inserted in the operating theatre using x-ray guidance between the backbone and spinal cord (epidural space). The leads will be tunnelled to a convenient location and secured to skin and connected to an external pulse generator.

The stimulator technician will setup the device in recovery, adjust and optimise stimulation regulary during the trial. You will usually be seen in the clinic twice weekly to check your progress and wounds.

We will consider the trial successful if stimulation improves function, sleep, activity, sitting, standing and walking tolerances, reduces medication usage and pain.

After a successful trial, permanent leads will be inserted into to the epidural space in the target area, anchored to prevent movement and tunneled under your skin to a surgically implanted pulse generator also placed under the skin. The location of which depends on your area of pain, body size and type of device. The wounds will be sutured with an absorbable sutures and covered with strips and sterile dressings. The dressings should be removed and replaced if wet within first 2-3 days or 7 days.

DURING THE TRIAL/SCREENING PERIOD:
You will be encouraged to have day leave, go home and do your normal activities to 'road test' the SCS for pain relief during the usual 2-4 week trial.
It is however important to AVOID over activity and extreme movements.
DO NOT use monkey bars or lift items weighing more than 3 kg.
DO NOT over twist, bend or stretch your body at the waist/neck. (depending on your SCS location)
DO NOT shower (you may 'dry wash' the essentials)

POST IMPLANTATION:
After implantation surgery the neurostimulator is programmed by a qualified technician to control your pain. When you go home you will take a hand-held programmer that lets you "fine-tune" the stimulation for your own needs. It may take several sessions of programming in the doctor's office to obtain the best possible pain relief. Please follow your prescribed activity plan and progressively resume your desired activities as tolerated. It is usually safe to return to sedentary work in 2 weeks, more vigorous activities in 4 weeks and most people wanting to work have found and returned to work within 4-6 months.

WARNINGS:
DO NOT drive or operate dangerous equipment if you feel stimulation, to avoid the risk of sudden stimulation surges.
Report pain, swelling, redness, wound leakage. These symptoms may indicate infection.
Report unexpected changes in stimulation, painful sensations (turn device OFF)
MRI scans can be conditionally performed, for some indications, on most modern spinal cord stimulators
MRI scans are contra-indicated on incompatible or faulty devices.
Avoid ultrasound examinations or short-wave diathermy within 10cm of the IPG (neurostimulator).

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SPINAL CORD STIMULATION TREATMENT REQUEST AND CONSENT

I _____
Given Names Surname

request and consent to the insertion of spinal cord stimulation (SCS) electrodes and a trial of stimulation to control my pain. I confirm that my Doctor has provided me with adequate information:

1. About my medical condition, its consequences, prognosis and chance of recovery, alternate possible treatments such as nerve blocks, strong pain killers and surgery for this condition.

2. That there is no guarantee that SCS will improve my pain control, quality of life, solve my personal or family problems. Sometimes adequate pain relief is not possible.

3. The risks and hazards in continuing in my present condition without treatment and the possible risks and hazards related to the proposed surgery and anaesthesia. I understand that common to all therapeutic and diagnostic procedures is the chance of infection, blood clots in veins and lungs, allergic reactions, haemorrhage/bleeding and death. I am also aware that the following hazards may occur: *Worse pain, no pain relief, nerve damage, spinal cord injury, paralysis, loss of bladder / bowel / sexual function, numbness, unwanted, inadequate or painful stimulation, spinal tap and postural head ache, equipment failure or lead migration needing reprograming or revision, erosion through skin, superficial or serious deep infection may require system removal. I also understand that I may experience drug withdrawal symptoms whilst reducing/stopping any strong (morphine-like) pain killers.*

4. To help me actively manage my own pain, participate if requested in a pain management program, attend all medical and like appointments and comply with reasonable treatment requests.

5. To have a family member or friend present while the risks and benefits of spinal cord stimulation were explained to me and that my questions have been answered to my satisfaction.

6. I have read the attached and suggested extra information on the SCS lead insertion, trial stimulation and implantation of a permanent device.

7. About the possible risk of rare severe complications and potential impact on financial stability (including repayments for loans, mortgage, educational responsibility), the need for ongoing treatment, further interventions or surgery, and prolonged recovery in physical and mental health have been discussed.

8. After considering the above information, I request the insertion of spinal cord stimulating electrode(s) and a period of trial stimulation.

Dated _____ Signed _____

Relationship to patient (if other than self) _____

In the presence of _____ Signature of Witness _____
(name of witness)
confirm that the benefits and the known risks of spinal cord stimulation were adequately explained.

Confirmation

I _____
(name of doctor)
have explained to the patient / person legally responsible for the patient, the nature and effects of spinal cord stimulation. In my opinion, He / she understood this explanation.

Dated this _____ day of _____ 20 ___ Signature of Doctor _____

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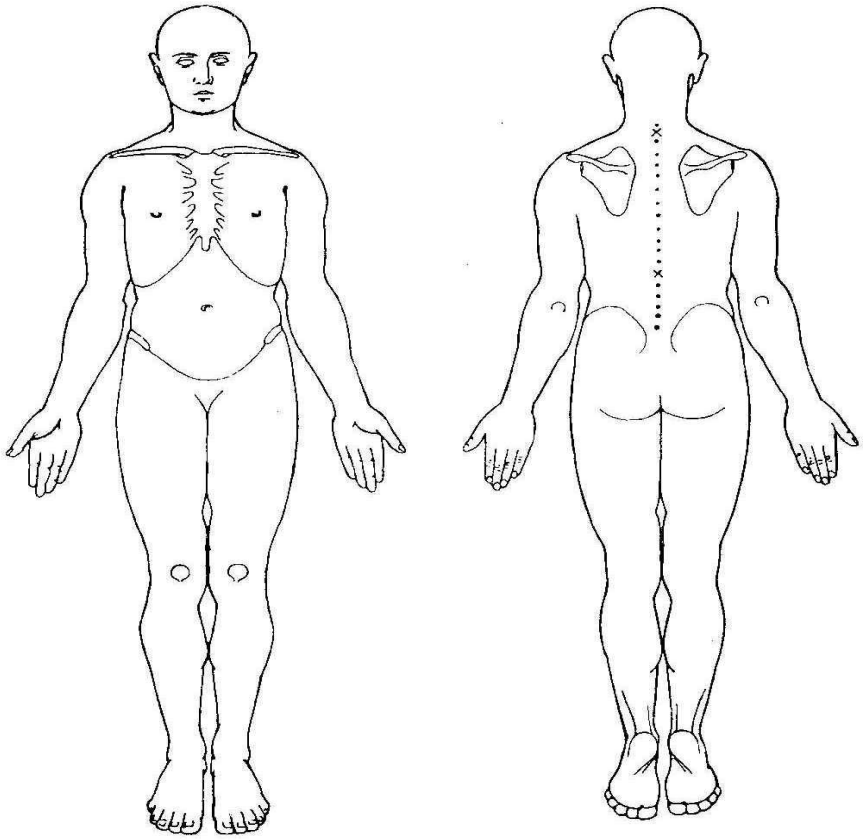
SCS/PNS Trial Record

Patient Name: _____ Date: _____

1 Mark the area on the attached diagram where you usually feel pain



3. During the Trial did you accomplish your goals? (answer yes or no)

Program	Medication	Goal 1	Goal 2	Goal 3	Goal 4	Goal 5
	Analgesic Use*					
A						
B						
C						
D						
E						
F						

*Analgesic Drug Use Key:	Other Drugs Use (list) : nil=0, occasional=1, regular=2
0 = none	Valium/Diazepam etc:
1 = Simple eg paracetamol, aspirin, NSAID	
2 = Occasional oral codeine ± above	
3 = Occasional oral morphine, oxycodone etc	
4 = Regular non-injection narcotics	
5 = Regular injected narcotics	

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SCS Discharge Instructions

To help reduce lead movement and subsequent loss of stimulation, it is very important that you follow these activity precautions. Even small movements in the lead can produce significant changes in stimulation.

Immediately after the procedure:
- Stay in bed for 2 hours. You will need to use a bottle / bed pan during this period of bed rest.
- Raise the bed head about 20 degrees for the first post-operative night to stabilise your spine.
- Don't over stretch, reach, bend or twist. Log roll in/out of bed, DO NOT use monkey bars.
- No showers or bathes during SCS trial and for 24 hours after permanent implant. Keep wound dry for 1 week.

For the next 2-3 days after surgery:
- Walk for brief periods keeping your back as straight as possible to prevent lead movement.

For 6-8 weeks following surgery:
- Use Physiotherapy After Spinal Cord Stimulation instruction sheet to gradually increase activity
- Avoid strenuous activities and

DO
- Sleep with a firm mattress which equally supports your legs and back.
- Check temperature 4 times per day with a thermometer and report any fever above 38ºC.
- Apply ice/cold packs at incisional sites to reduce bruising, swelling and discomfort for 2-3 days after your surgery. Expect some oozing from wound but report excessive or bright red bleeding.
- After implantation keep wounds dry, protect while showering and no tub bathes for at least 2 weeks.
- Follow your physician's recommendations regarding recommencing sexual activity.
- Obtain approval from your physician before having your spine manipulated by a chiropractor or physician (the manipulation may disrupt the position of the lead).
- Move your body without twisting by moving your shoulders and hips at the same time with a "log-rolling" movement. While in the hospital, you may need to ask the nurse to help you do this.
- Build up your physical strength by walking for brief periods of time each day or engaging in a physical therapy program per your physician's instructions.

DO NOT:
- Shower, tub bath or swim during the trial and do not shower for 24 hours after permanent implant.
- Stretch your arms over your head with the device turned on (It causes increased stimulation).
- Bend, twist, stretch, or lift more than 3 kilograms.
- Sleep on your stomach; sleep on your back or side instead.
- Climb too many stairs (ie., when you feel tired, stop climbing stairs)
- Sit too long in a chair (ie., when you feel tired, stop sitting).
- Drive for several weeks or per your physician's instructions to reduce the risk of abrupt movements or shifts in position that increase the risk of lead movement.
- Operate motor vehicles, power tools or equipment while your stimulator is on. Turn the stimulator off to reduce risks associated with sudden sensation changes.

Emergency Contact
If you have any questions, concerns or problems, call (03) 9770 0522 during office hours. If the problem is urgent, attend the nearest Hospital Emergency Department.

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Physiotherapy After Spinal Cord Stimulation (SCS)

Gentle graded land activity and physiotherapy are to begin once the procedural pain from implanting your spinal cord stimulator has settled. (Hydrotherapy can be undertaken once the wound has fully healed)

Learning to activate the deep muscles of the abdomen and low back area (core) that support the spine can be done nearly immediately without putting stress on the implanted stimulator, lead(s) or wound; no lifting, twisting, reaching, bending or stretching are required.

These core muscles, when activated, work like an internal brace that helps to support the spine. After the stimulator is implanted, activating these muscles may feel different because there is less pain. It is recommended that you consult a physiotherapist before starting any core exercise program.

The phases of rehabilitation after SCS outlined below are to be read in conjunction with the **SCS Discharge Instruction** leaflet.

Reminders:
No Monkey bars, **Avoid** over stretching/reaching/bending, **Lift** less than 2.5kg for first 6 weeks.

Post-operative: typically 3-7days
Gentle exercises for the ankle and leg to improve circulation including assisted walking.
Education on how to log-roll in and out of bed, reach, stretch and bend **safely,** to prevent lead movement.
Start basic trunk stabilisation exercises under supervision
Home Exercises after discharge: **Standing Heel Raises** (3 sets of 10 reps), **Mini Squats** (10 squats) (Keep your back straight, bend at the hips and knee only), **Marching on the Spot (**1-2 minutes at a time, rest as needed), **Step up and Step downs** on a small step (10 times). Do home exercises 2-3 times day.

Recovering at home: 1-5 weeks
Schedule an appointment with your physiotherapist who will assist with the following:

- General conditioning exercises for the lower extremity,
- Upper extremity exercises below shoulder height,
- Structured walking as per your specialist's advice, and
- Review your home exercise and activity program.

Ongoing rehabilitation: 6 weeks onwards
Further physiotherapy will usually not be required until after 6 weeks when the restrictions outlined by your specialist have been lifted. This time allows scar tissue to form around the electrodes and wires in order to keep them in place before doing any significant movements with your trunk and back. Your specialist will advise when it is appropriate for the restrictions to be lifted for you.

During this phase you will:

- Undergo structured pool program if applicable (**DON'T** take the remote into pool!)
- Continue advanced trunk stabilising exercises
- Improve general conditioning

After approximately 8 weeks, you will be able to increase your activity level and start to resume more of your normal activities. Your physiotherapist will advance your core strengthening exercises at this time so that you are doing challenging exercises that progress your strength and endurance without undue stress on the trouble spot. They will also advise you on returning to your regular daily work and leisure activities. Cardiovascular exercise in the pool may also be suggested but should not be done until the wounds have healed and your specialist has given clearance. Spinal cord stimulators should be **turned off** before entering a swimming **pool** above waist height, while **driving** or using **machines** unless advised otherwise.

Participating in more stressful cardiovascular activities such as jogging, weightlifting or regular sport will need to be discussed with your specialist to ensure they are appropriate for you. Contact sports and activities with sudden movement (eg singles tennis or squash) increase the risk of lead movement and should be avoided.

Funny or inconsistent stimulation sensations may indicate some lead movement and the need for further discussion with your specialist and programmer.

Should your pain flare up, you may need to seek follow-up with your programmer, physiotherapist or pain specialist until the pain settles.