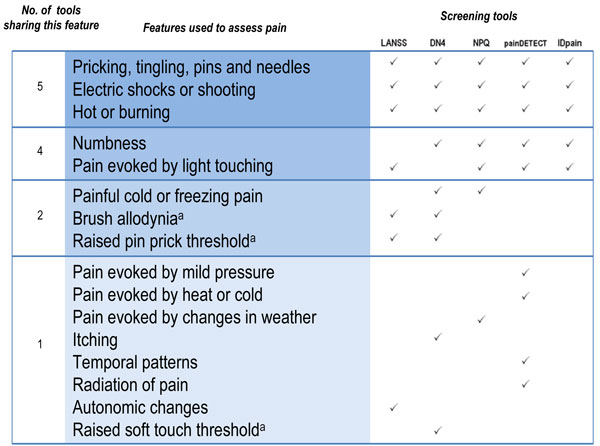
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DR TIM GRICE

INFORMATION SHEET and CONSENT for Implantation of Dorsal Root Ganglion Spinal Cord Stimulator

There are a number of different types of pain people can suffer during their life. They are: a. Nerve pain (neuropathic), b. internal organ pain (visceral), c. tissue pain (nociceptive), and often there is a combination of these pain types (Mixed pain) present. People suffer neuropathic pain for a number of reasons.

Neuropathic pain has a number of distinct symptoms that help in its diagnosis.

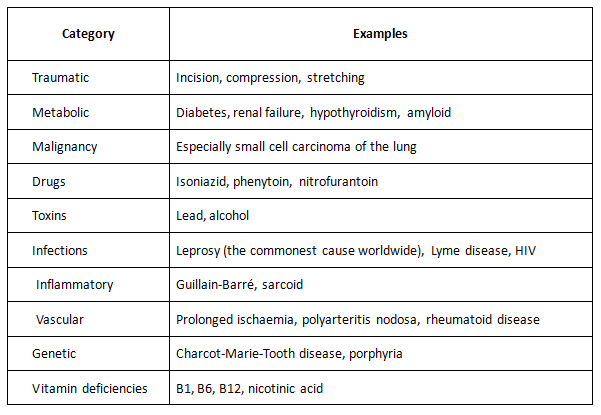
**Why Do Dorsal Root Ganglion (DRG) Spinal Cord Stimulation SCS (Indications)?**

DRG spinal cord stimulation is one type of treatment used for neuropathic pain. When the neuropathic pain is located in a focal area, which comes from specific nerve roots of the spinal cord; it is sometimes possible to target that area of pain. The target is the Dorsal Root Ganglion as it leaves the spinal cord and forms the individual nerves that travel throughout the body. If this nerve carry’s the pain signals to the brain it can be disrupted by electrical signals at this level to give pain relief.

There are 2 steps in using DRG Spinal Cord Stimulation for the treatment of neuropathic pain. The first step is the trial of the DRG Stimulator for 7 -10 days after it is inserted via a needle through the skin onto the DRG. This is completed in an operating theatre under sedation. The patient is often woken up after the insertion of the leads to test that they are in the correct position in order to maximise that chances of a successful trial. The patient is educated before the trial and monitored during the trial and the trail is reviewed at its conclusion to consider its success. Sometimes the trial is repeated if there were technical issues that could be improved in order to give better results.

**Causes of Neuropathic Pain**

There are many causes of neuropathic pain. The treatment of the pain is combined with the treatment of the underlying cause where possible. A list of the more common causes of neuropathic pain is listed below.

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**Indications for a Trial of Dorsal Root Ganglion Stimulation**

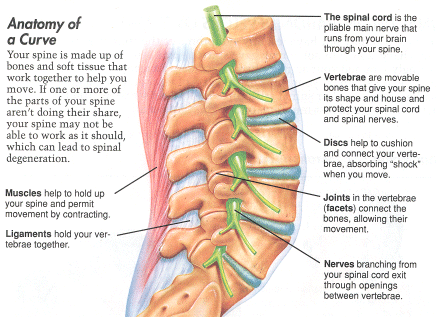
## Complex Regional Pain Syndrome-Also known as CRPS, this is a collection of localized pain conditions occurring after a trauma. The pain is concentrated primarily in the extremities and can result in significant limitations to personal mobility.

## Failed Back Surgery Syndrome-After invasive back operations, patients may develop FBSS. Scar tissue which forms around a nerve root after surgery may cause a number of pain conditions in the back.

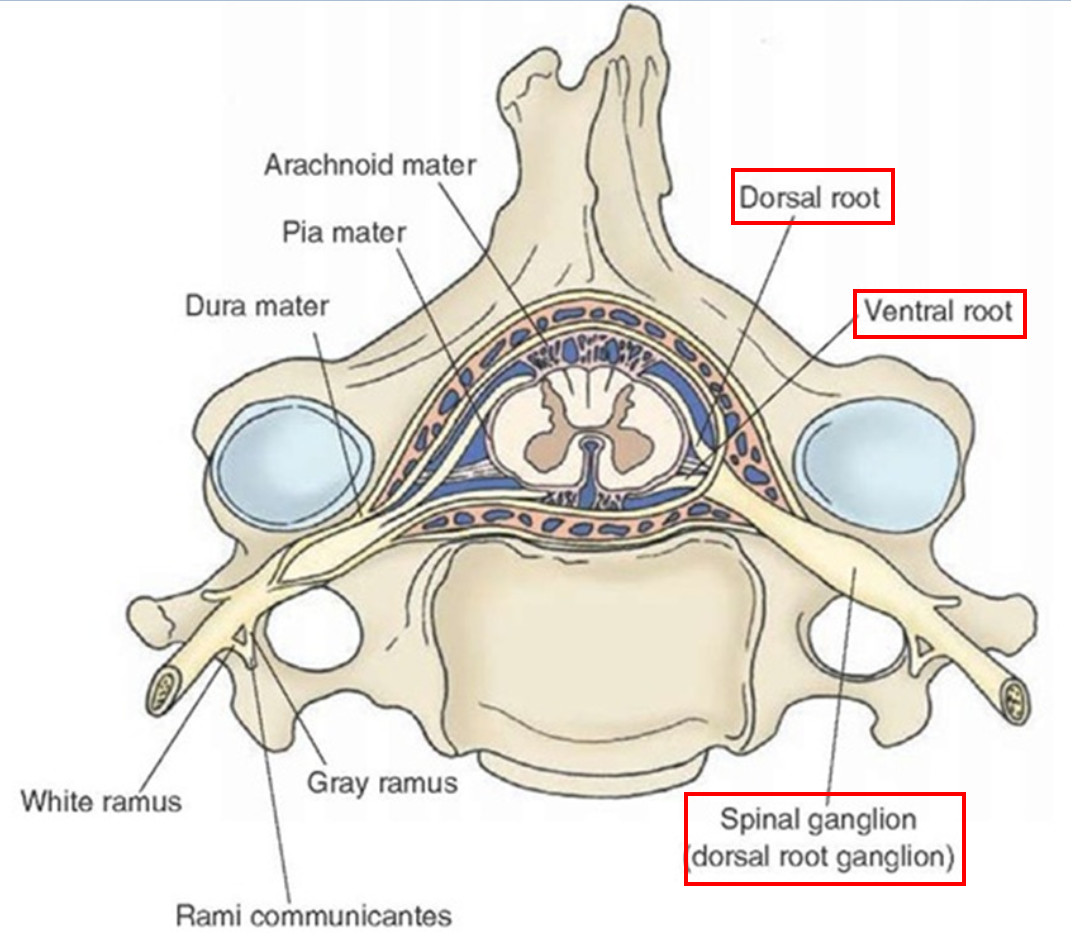
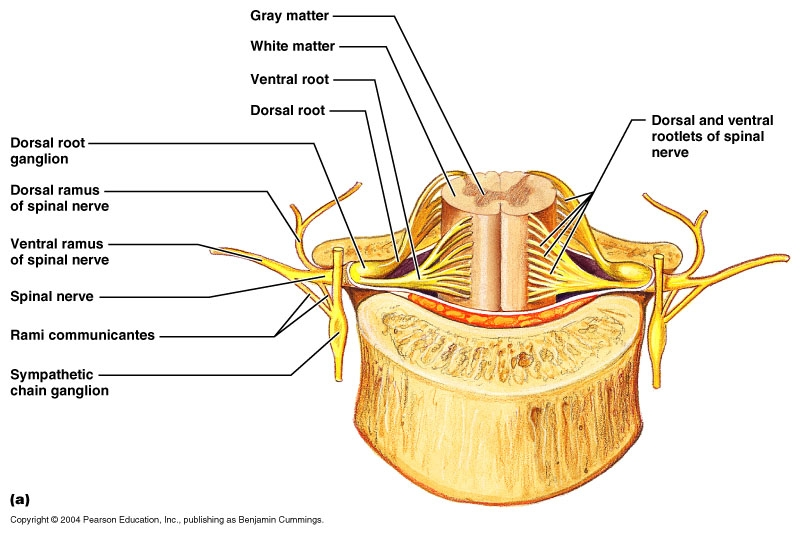
## Phantom Pain-Phantom pain is pain associated with a missing or amputated limb and can begin days to months after amputation. Phantom pain can vary in severity and frequency and can become chronic.

## Groin Pain-Surgeries in the abdominal area, such as Cesarean sections, inguinal hernia surgeries or appendectomies, can result in groin pain. This can be a temporary or chronic condition. If you are experiencing chronic pain and would like to learn more about the Spinal Modulation System, please contact your physician. Together, you can determine if this therapy could be beneficial for you.

**Anatomy of the Spine**

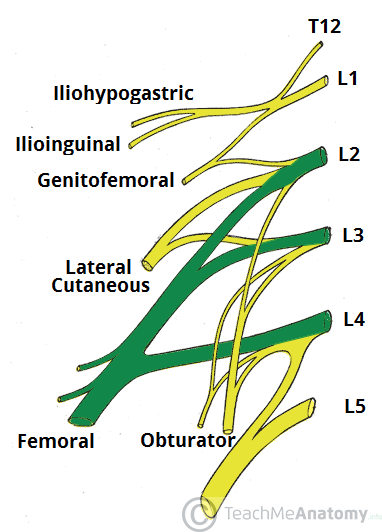
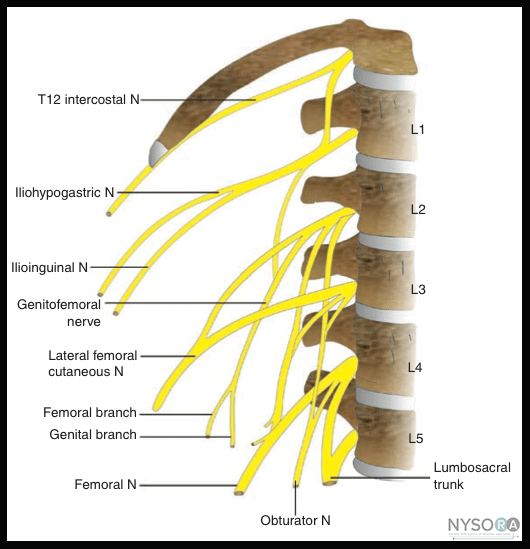
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**Anatomy of the Dorsal Root Ganglion**

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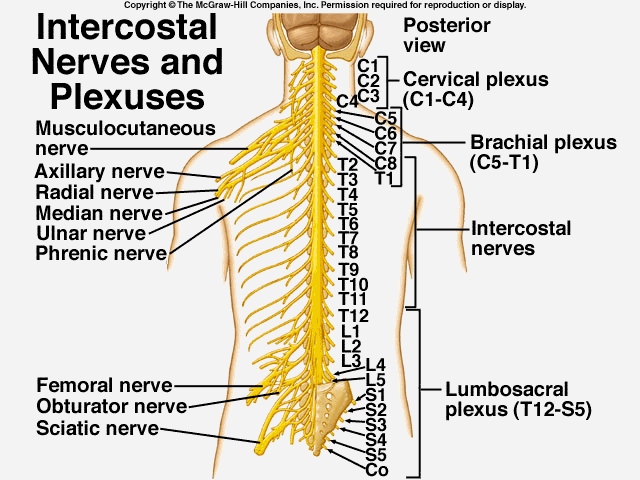
All of the nerves in the body are formed from the nerve roots after they leave the spinal cord. For example the left femoral nerve, that innervates the anterior thigh, is formed from the Left L2, L3, and L4 nerve roots. Once the nerve, and therefore the nerve root that is carrying the pain signals has been identified; the associated DRG can be targeted as a site to inhibit the pain signals. Often, there are multiple DRG that are targeted and therefore multiple DRG levels are treated during the trial.

**Nerve Roots for the Groin and Leg**



Other areas that are often targeted include the nerves to the groin (ilioinguinal and Genitofemoral) and the nerves to the ribs (intercostal nerves)

**Nerves to the Thorax Targeted during DRG Trial**

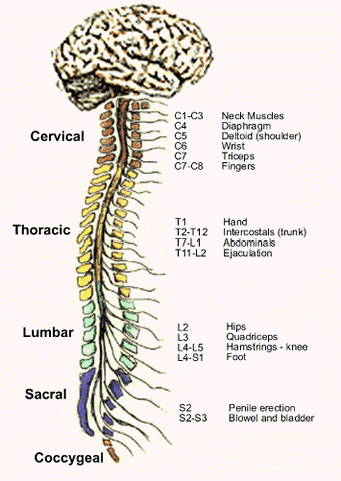


**What is involved in a DRG Spinal Cord Implantation?**

Before implantation all patients would have undergone a successful DRG trial.. The implantation involves a 1-2 hour procedure in which you are initially sedated and later are woken up in order to give feedback. Using techniques similar to a spinal injection or nerve block, the procedure includes the following steps:

**Before the Implantation**

1. You will have a scheduled appointment with a Representative from St Jude
2. They will meet you in clinic and conduct at least one session on
   1. Pain assessment
   2. Pain distribution
   3. Education as to how the DRG Trial will occur
   4. Familiarization with the equipment which will be used as part of the trial
   5. Discussion on how the success of the trial will be measured
   6. Answer any questions regarding the technical aspects of the Trial
3. You will then have an appointment with the Pain Specialist to
   1. Discuss any further questions regarding the implantation
   2. Obtain informed consent regarding the Trial
   3. Book in a date for the implantation.

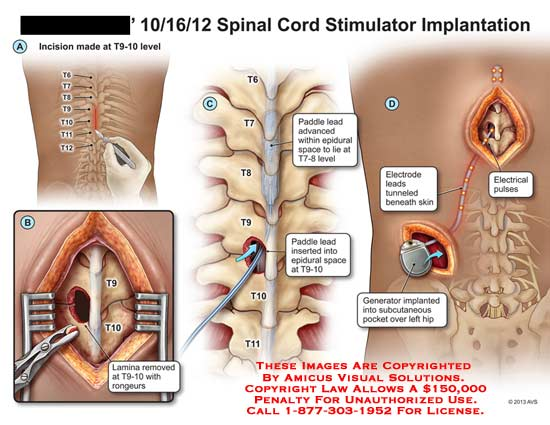
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**On the day of booking your procedure, please advise staff if you are –**

* Taking blood thinners (especially warfarin and clopidogrel)
* Diabetic
* Pregnant, or any chance of being pregnant
* Allergic to:
  + Shellfish
  + Steroids
  + Local anaesthetics
  + Iodine
  + Betadine
  + Chlorhexidine
* Unwell or have an infection

**When you are admitted to Hospital for the Implantation**

* PLEASE TAKE all you normal medications with a SMALL amount of water (except Blood Thinner Medications which should have been discussed and ceased a number of days prior to the Trial)
* DO NOT eat or drink (for 6 hours before your procedure),
* After arriving you will need to complete the necessary paperwork.
* You will then change into a hospital gown,
* The Pain Specialist, the Anaesthetist, and the Stimulator Representative prior to going into Theatre will review you. They will answer any questions you may have prior to the Trial.



**In the Operating Theatre**

1. A small drip will be inserted into one of your veins,
2. You will be given mild/moderate sedation, to allow the next few steps to be completed without any movement
3. Your heart rate and blood pressure will be monitored throughout the procedure
4. Your skin is prepared with alcoholic chlorhexadine solution to sterilise the skin and you are given intravenous (IV) antibiotics
5. Local anaesthetic will be injected into the area where the needles will be placed into the back
6. The needles are inserted through the skin into the Epidural space (the layer just outside the spinal cord) under X-Ray guidance.
7. Small leads are then inserted through he needles and positioned around the DRG at the correct levels under X-Ray guidance.
8. You are then woken up and the leads are tested to check they are in the correct position. This involves you communicating with the technical staff as to whether you can feel any stimulation in the same area you normally feel your pain.
9. The leads may need to be moved while you are awake. This may cause some mild to moderate discomfort.
10. Once the correct position of the leads has been confirmed you are once again sedated and the rest of the procedure is completed.
11. This involves removal of the needles and making an incision and implanting and securing the leads position with anchors and sutures. An incision is then made in the buttocks region and the leads are “burrowed under the skin to this position. The IPG (Battery and impulse machine which is contained in one metal case) is implanted under the skin. The wounds are then closed and dressings applied.
12. You are then taken to recovery to wake up slowly
13. Once you are discharged from recovery area, the Pain Specialist, and also the DRG Representative who will program the system on the ward will review you.
14. You will normally stay in hospital for one to four days on IV antibiotics and then
15. discharged and followed up in clinic

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**After Discharge**

1. You will be discharged with oral antibiotics and where necessary, painkillers.
2. Please take all of your normal pain killing medications so we can evaluate the effectiveness of the without any other changes in your treatment.
3. You will be under regular review by
   1. The Pain Specialist to see if there are any procedural complications such as infection, and for dressing changes if necessary.
   2. The Representative from the Spinal Cord Stimulator Company for program review and monitoring of efficacy of the device at reducing the pain



This procedure is usually safe and uneventful. However, as with any procedure there is always a small degree of risk.

**Common Complications**

* Continuing pain (no benefit)
* Minor bleeding in the area where the Leads were inserted
* Bruising in the area where the leads were inserted
* Temporary weakness or numbness from the local anaesthetic or leads inserted
* Brief increased pain that may fluctuate in intensity
* Skin irritation or numbness

**More Serious Side Effects**

* Infection at the Lead insertion site or in the epidural space where the leads are positioned
* Permanent nerve injury including, weakness, numbness and neuropathic pain
* Allergy to the anaesthetic or antibiotic used in the sedation or as part of the procedure
* Increase of any pre-existing medical condition such as cardiac conditions
* Bruising around the area from needle trauma

Please discuss with your doctor any other questions you may have about this procedure or this information sheet. If you agree to have the procedure, you will be asked to sign a consent form.

**If you notice:**

Any swelling from the site,

Any bleeding from the site, or

Have any other concerns

Contact your

General Practitioner,

Queensland Pain Doctor Rooms,

or the Emergency Department of your local hospital.

Dr Tim Grice

Specialist Pain Medicine Physician

Queensland Pain Doctor

Suite 4, Level 4

123 Nerang St

Southport, QLD 4215

Phone: 07 5532 0468

Fax: 07 5528 3850

Email: **admin@qpdr.com.au**

**CONSENT**

**I have had time to read and I understand the information and instructions provided to me regarding the Dorsal Root Ganglion Spinal Cord Stimulator Trial, Complications and the post-procedural care.**

**Common but Mild Complications** include: Continuing pain (no benefit), Minor bleeding in the area where the Leads were inserted, Bruising in the area where the leads were inserted, Temporary weakness or numbness from the local anaesthetic or leads inserted, Brief increased pain that may fluctuate in intensity, Skin irritation or numbness. Scarring **More Serious but Far Less Common Side Effects include:** Short Term or No relief from the procedure, Infection at the Lead insertion site or in the epidural space where the leads are positioned which may require the device being removed**,** Permanent nerve injury including, weakness, numbness and neuropathic pain**,** Allergy to the anaesthetic or antibiotic used in the sedation or as part of the procedure, Damage to the surrounding structures including blood vessels Increase of any pre-existing medical condition such as cardiac conditions, Bruising around the area from needle trauma. Increased cancer risk due the X-ray exposure during the operation. Eye injury from lying face down, Death from the procedure is possible but extremely rare

**I understand that I have the right at any stage to change my mind even after I have signed this document.**

**I have had time to ask any questions and raise any concerns I have regarding this procedure and its risks with Dr Tim Grice.**

**I understand that there are alternatives to this procedure including, no treatment, medication and psychological support and physical therapy.**

**I understand and agree to any emergency treatment required due to or as part of this procedure.**

**I understand and agree that a blood sample may be taken from me for testing if a staff member is exposed to my blood during the procedure**

**I believe that all my questions have been discussed and answered to my satisfaction.**

**I understand that I will not be able to have an MRI (magnetic Resonance Imaging) scan after the implantation of this device and bending twisting and lifting are restricted for 3 months post procedure to prevent lead movement.**

**I understand that there is a chance that not all of my pain will be treated by this device and that I may later develop pain that is not treated by the device and require other treatment options**

**I understand that this may not work permanently and further adjustment or surgery may occasionally be necessary**

**I consent to this procedure with sedation**

Patient Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_

Patient Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Doctor Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Doctor Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

CONTACT DETAILS

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