What is a SCS?

A spinal cord stimulator is a specialised medical device that is designed to be implanted in the epidural space to provide electrical stimulation (neuromodulation) of the spinal cord for chronic pain.

Australian Pain Management Association:

"A spinal cord stimulator (neurostimulator) is an electrical device positioned near the spine which delivers a pulsed current to the spinal cord which interrupts the pain signals being sent to the brain. The device is implanted under your skin and has a hand held control which allows the patient to change the intensity, within the limits set by the specialist until s/he is getting the desired electrical current to reduce the pain being felt by approx. 50%.

Initially, you will be given a trial procedure with an external SCS for up to two weeks so the patient and specialist can assess the benefit of the SCS before it is implanted. This stage is totally reversible. The SCS implant can then be performed with day surgery which is also reversible if necessary."

Ref: https://www.painmanagement.org.au/2014-09-11-13-35-53/2014-09-11-13-36-47/180-spinal-cord-stimulation.html

How does it work?

The device works by creating an electric field and creating stimulation essentially interrupting (or modulating) chronic pain signals at the spinal cord and central nervous system.

What type of pain does the SCS work for?

Typically, chronic neuropathic pain and conditions like Fail Back Surgery Syndrome, and Complex Regional Pain Syndrome are ideal candidates for SCS. Phantom limb pain can also be effectively treated in some cases.

What type of pain does the SCS not work for?

Pain types like acute pain, arthritis, mechanical/joint pain, bone pain, nociceptive pain generally does not respond well to SCS. Some mixed pathologies with a combined neuropathic element have some clinical response.

Australian Pain Management Association:

Clinical patient selection criteria are applied to each individual. There needs to be an explanation for the pain even if imaging isn't able to verify the cause eg FBSS. Patients will have often attended a multi-disciplinary pain clinic so that recommended psychological and physical therapies have been tried and continue to be used. Patient outcomes are improved when SCS is used in conjunction with active ongoing self-management of pain. Medication may also still be needed but often is reduced."

Ref: https://www.painmanagement.org.au/2014-09-11-13-35-53/2014-09-11-13-36-47/180-spinal-cord-stimulation.html

What is reprogramming and how is this organised?

- Reprogramming can be booked via the clinic who can contact the appropriate Stimwave representative to provide ongoing support or the patient can contact the Stimwave representative directly.
- Reprogramming is always done at the clinic and the patients' physician is provided a summary of the session for the patient's case file.
- Stimwave aims to operate under the direction of each treating physicians' preferences.

What scans can/can't a patient have? MRI, Xray, CT, SPECT, Ultrasound etc.

See below included in contraindications, precautions and warnings

What precautions are there with other surgical procedures?

See below included in contraindications, precautions and warnings

How long does the internal battery last? What to do at EOL?

- Stimwave has no internal battery. That is one of the key benefits of wireless pain relief is that upgrades and changes to the external power source are very easy to upgrade and maintain. External batteries have a warranty of 2years.
- Your local Stimwave representative will ensure that therapy is maintained and any replacement batteries are provided as required.

Who to contact if they need further information?

- Their local Stimwave representative
- Additionally, the Stimwave website has relevant information but please note the needs to be disclaimer that in Australia Stimwave is only TGA approved for SCS and the website is US based and does reference off label use like PNS and DRG)

Where can a GP learn more about the device?

GPs can access the Stimwave clinical portal if they are directed to the contact their local Stimwave representative

What can a patient travel through airport?

- Upon implantation with a permanent Stimwave device. A patient identification card will be provided to the patient stating they have a medically implanted device they can provide to airport security.
- Patients can place their external Wearable Antenna Assembly in the tub for scanning and walk through the metal detector or bio-scanner.
- Additionally, airline policies for use of implantable medical systems and electronic equipment during flights should be followed. Refer all questions to airline personnel.

What to do if any of the equipment associated with device stops working?

If any of the equipment stops working, please contact your local Stimwave representative who can assist with troubleshooting and/or replacement

What precautions are there with other surgical procedures?

CONTRAINDICATIONS

Poor surgical risks – Spinal cord stimulators should not be used on patients who are poor surgical risks or patients with multiple illnesses or active general infections. This includes patients who need anticoagulation therapy that cannot be temporarily halted to accommodate the implantation procedure.

Pregnancy – Safety and effectiveness of the Freedom SCS System for use during pregnancy and nursing have not been established.

Inability to operate System – Spinal cord stimulators should not be used on patients who are unable to understand or operate the System.

Exposure to short-wave, microwave, or ultrasound diathermy – Patients with the device should not have shortwave diathermy, microwave diathermy or therapeutic ultrasound diathermy. The energy from diathermy can be transferred through the device and potentially cause tissue damage, resulting in severe injury.

Occupational exposure to high levels of non-ionizing radiation that may interfere with therapy – Patients who regularly work in environments with elevated levels of non-ionizing radiation should not be implanted with the device. The energy in high-level areas can be transferred through the device and cause tissue damage, resulting in severe injury. Examples of environments having high level nonionizing radiation includes the following: o Radio or cell phone transmission stations o Facilities using radiofrequency heat sealers or heaters o Electric power infrastructure controlled environments (i.e. step down transformers or high voltage power lines)

Implanted cardiac systems – Patients who have implanted cardiac systems should not use the Freedom SCS System. Electrical pulses from the device may interact with the sensing operation of an implanted cardiac system, causing inappropriate responses.

WARNINGS

If you suspect that equipment is interfering with device function:
Move the equipment or object away from the patient.
Remove the external transmitter (Wearable Antenna Assembly (WAA)) from the vicinity of the patient.

Electromagnetic interference (EMI) – EMI is a field of energy generated by equipment found in the home, work, medical or public environments. EMI that is very strong can interfere with System. The device includes features that provide protection from EMI. Most electrical device and magnets encountered in a normal day will not affect the operation of the System. However, strong sources of EMI could result in the following:

- Serious patient injury resulting from heating of the implanted device and damage to surrounding tissue.
- System damage, resulting in a loss of, or change in, symptom control and requiring additional surgery.
- Operational changes to the WAA. This may cause either external device to turn on, turn off, or to reset to factory settings. If this occurs, the WAA need to be reprogrammed.
- Unexpected changes in stimulation, causing a momentary increase in stimulation or intermittent stimulation. Some patients have described as a jolting or shocking sensation. Although the unexpected change in stimulation could feel uncomfortable, it does not damage the device or cause a patient direct injury. In rare cases, as a result of the unexpected changes in stimulation, patients have fallen down and been injured.

Computed Tomography (CT) Scanning – Safety has not been established for CT scanning of patients with an implanted stimulator. X-rays from the scan could cause unintended shocks or malfunctions of the stimulator. The CT operator should use CT scout views to determine if implanted medical devices are present and their location relative to the programmed scan range. For CT procedures in which the device is in or immediately adjacent to the programmed scan range, the operator should:

- Remove the WAA from the CT scan range.
- Minimize X-ray exposure to the implanted device by:
- Using the lowest possible X-ray tube current consistent with obtaining the required image quality.
- Making sure that the X-ray beam does not dwell over the device for more than a few seconds.
- After CT scanning directly over the implanted device:
- Place WAA and turn on stimulation.
- Check for proper stimulation and that indicator lights are operating as expected.
- Shut off WAA if it is suspected that it is not functioning properly.

Radiofrequency (RF) ablation – Safety has not been established for radiofrequency (RF) ablation in patients with a device. RF ablation can cause heating of the stimulator that results in tissue damage.

Radiofrequency Identification (RFID) Emitters - Theft detectors, electronic article surveillance (EAS) systems, and radiofrequency identification systems – Tests have been performed with an array of simulated RFID emitter systems, and have demonstrated that the Freedom PSC System (implanted device and WAA) can be affected by separation distances between the Freedom SCS System and the RFID emitter of less than 3m (~10 ft.). More powerful RFID

Emitters might cause effect at farther distances. RFID emitters can be hidden or portable and not obvious to the Stimwave user. Any RFID emitter may temporarily interrupt stimulation, or cause elevated levels of stimulation. It is recommended that if a patient feels a change in stimulation near a potential RFID emitter, they promptly move away from the area and remove the WAA from the body. When possible, it is best to avoid RFID emitters or remove the WAA while passing near RFID emitters. Patients with an implanted device should inform the attendant who may be able to assist them in bypassing any RFID emitter. If unavoidable, the patient should walk through the RFID emitter and promptly move away from the area. Patients should not lean on scanners or linger in the area of RFID emitters.

Electromagnetic field devices – Patient avoidance of the following equipment is advised:

- Antenna or citizen band (CB) radio or ham radio
- Electric arc welding equipment
- Electric induction heaters used in industry to bend plastic 8 English
- Electric steel furnaces
- High-power amateur transmitters
- High-voltage areas (safe if outside the fenced area)
- Linear power amplifiers
- Microwave transmitters (safe if outside the fenced area)
- Perfusion systems
- Resistance welders
- Television and radio towers (safe if outside the fenced area)

EMI from these devices can cause heating of the stimulator that may result in tissue damage.

Psychotherapeutic procedures – Safety has not been established for psychotherapeutic procedures using equipment that generates electromagnetic interference (e.g., electroconvulsive therapy, transcranial magnetic stimulation) in patients who have spinal cord stimulators. Psychotherapeutic procedures can cause heating of the stimulator that may result in tissue damage.

Other medical procedures – EMI from the following medical procedures is unlikely to affect the device:

- Diagnostic ultrasound (e.g., carotid scan, Doppler studies)
- Diagnostic x-rays or fluoroscopy
- Magnetoencephalography (MEG)
- Positron emission tomography (PET) scans
- Therapeutic magnets (e.g., magnetic mattresses, blankets, wrist wraps, elbow wraps) – Keep magnet at least 25 cm (10 in) away from the device site. Magnetic fields will generally not affect the device. EMI from these procedures can cause heating of the stimulator that may result in tissue damage.

Device fracture – If the insulation is ruptured or pierced due to extensive forces, unexpected changes in stimulation could result.

PRECAUTIONS

High-output ultrasonics / lithotripsy – Use of high-output ultrasonics or lithotripsy is not recommended and may result in damage to the device. If lithotripsy must be used, the beam should not be focused within 15 cm (6 in) of the stimulator.

Bone growth stimulators – Keep external magnetic field bone growth stimulator coils 45 cm (18 in) away from the device. When using either an implantable or external bone growth stimulator, ensure that both the bone stimulator and spinal cord stimulation system are working as intended. Bone growth stimulators could cause damage to the stimulator or intermittent/increased stimulation.

Dental drills and ultrasonic probes – Remove the WAA from the body. Keep the drill or probe 15 cm (6 in) away from the stimulator. Use of dental drills or ultrasonic probes could result in damage to the stimulator.

Electrolysis – Remove the WAA from the body. Keep the electrolysis wand at least 15 cm (6 in) away from the stimulator. Use of electrolysis could cause damage to the stimulator.

Laser procedures – Remove the WAA from the body. Keep the laser directed away from the stimulator. Use of lasers could cause damage to the stimulator.

Radiation therapy – Do not direct high radiation sources such as cobalt 60 or gamma radiation near the device. Use of radiation therapy could cause damage to the stimulator. If radiation therapy is required, place shielding over the area where the stimulator is located to help prevent radiation damage.
Transcutaneous electrical nerve stimulation – Do not place transcutaneous electrical nerve stimulation (TENS) electrodes so that the TENS current passes over any part of the stimulator. Use of TENS could cause the device to have intermittent/increased stimulation.

Medical tests and procedures – Before undergoing medical tests or procedures, patients should consult with the clinician to determine if the procedure will cause damage to the patient or the device.

Physician instructions – The patient should follow therapy instructions established by the clinician. Failure to do so may cause the therapy to be less effective in providing pain relief.

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Please note disclaimer re the Stimwave website is US based and may contain off-label information re the of Peripheral Nerve stimulation and Dorsal Root Ganglion stimulation.