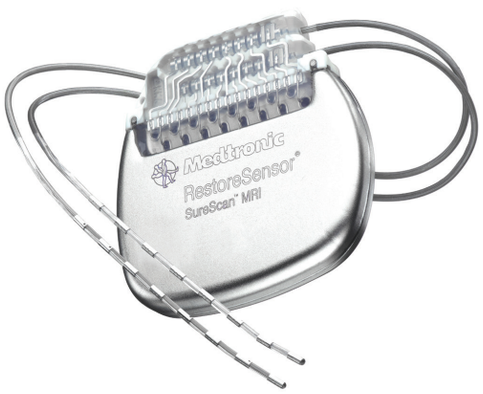
Medtronic

Spinal Cord Stimulation

FOR CHRONIC PAIN

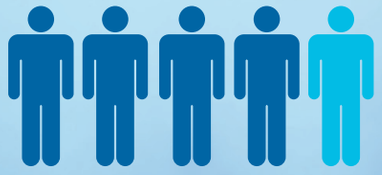
Move your patients

beyond the pain



Innovating for life.

Chronic pain is a widespread problem



1 in 5 Adults in Western Europe suffer from Chronic Pain*

31%
of all sufferers feel they "could not tolerate any more"

59%
have had pain for 2-15 years

19%
have lost their job

46%
of these patients suffer constant pain

*Chronic pain was defined as pain lasting more than 6 months, having pain during the last month, several times during the last week, and last experienced pain having an intensity of 5 or more on a Numeric Rating Scale[1]

Pathway of treatment

How do you choose the right patients for Medtronic Pain Therapies?

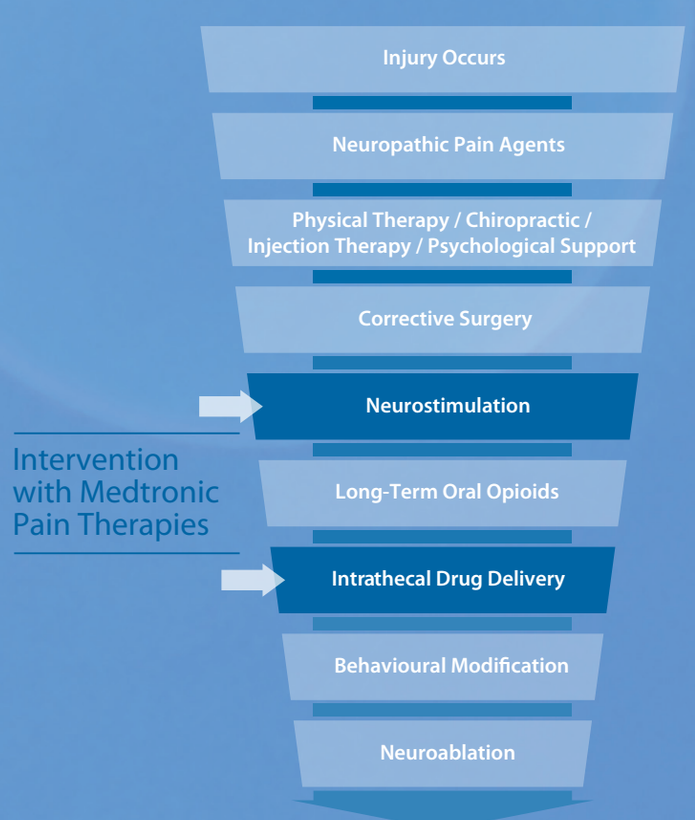
Chronic pain is a complex disease that is at the severe end of the chronic pain spectrum of pain intensity and duration, making management difficult

Indications for Medtronic Pain Therapies

Most prevalent indication

CRPS - Complex Regional Pain Syndrome	**FBSS - Failed Back Surgery Syndrome**	Intractable pain
Radiculopathies	Causalgia (CRPS Type II)	Axial somatic pain
Neuralgia	Phantom limb pain	Cancer pain
Angina pectoris	Postherpetic neuralgia	Osteoporosis pain
PVD - Peripheral Vascular Disease	Arachnoiditis	Chronic pancreatitis pain
Spinal Cord Stimulation (SCS)	**SCS, Intrathecal Drug Delivery (IDD). Peripheral Nerve field Stimulation (PNfS) for FBSS (in addition to SCS)**	**IDD Pump**

Neuromodulation Treatment Ladder[2]



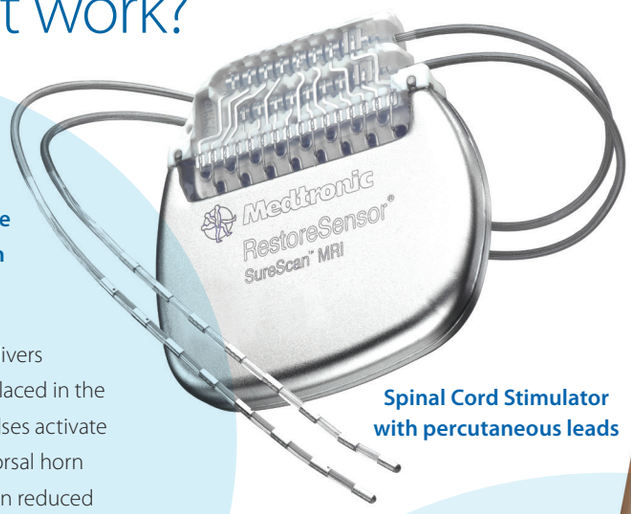
Move your patients Beyond the Pain

What is Spinal Cord Stimulation? How does it work?

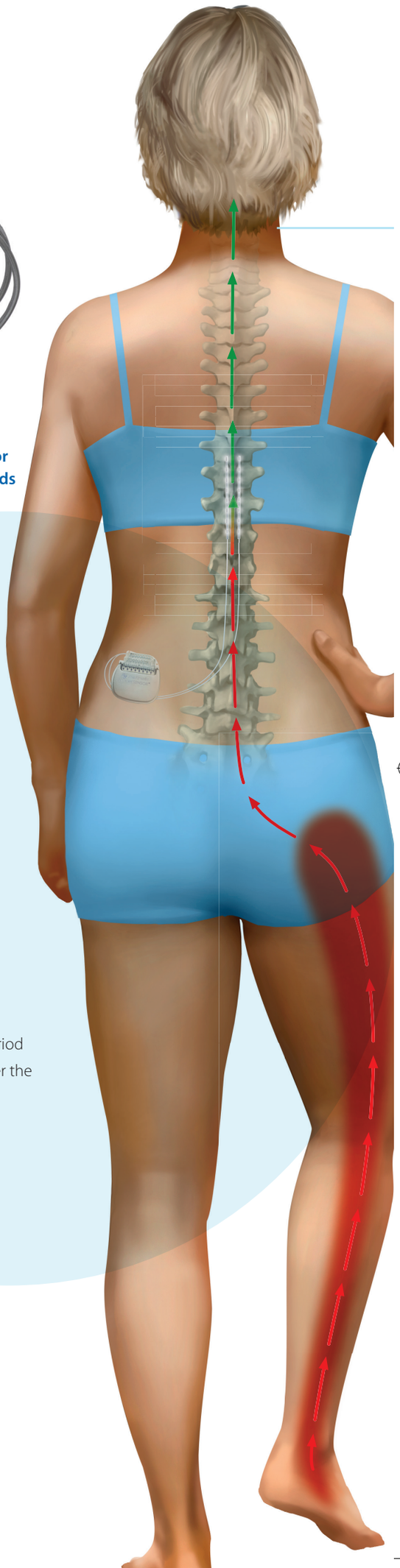
Medtronic Spinal Cord Stimulation may help provide chronic pain patients with an alternative therapy option:

Spinal Cord Stimulation (SCS) delivers electrical pulses via electrodes placed in the epidural space. The electrical pulses activate pain inhibiting neurons in the dorsal horn of the spinal cord, which results in reduced perception of pain.[3]

The stimulation also induces a tingling sensation (paraesthesia) in the area from which the pain originated, and the surrounding area.[3]

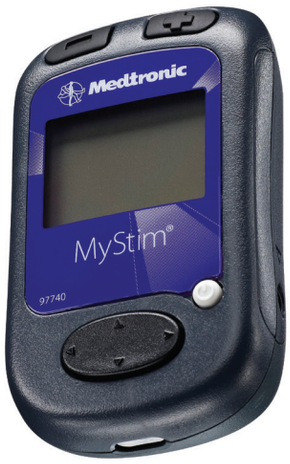


Spinal Cord Stimulator with percutaneous leads



Summary of Spinal Cord Stimulation Process technique:

- The technique is usually performed under local anaesthesia
- The leads are implanted in the epidural space
- The Spinal Cord Stimulator is placed in the abdominal wall or buttocks
- The physician adjusts Spinal Cord Stimulation externally with a physician wireless handheld programmer
- Patient undergoes less invasive trial period lasting 1-4 weeks to determine whether the therapy is right for them



The MyStim™ Patient Programmer

The handheld programmer enables patients to adjust stimulation delivered by the implanted device, through selecting and adjusting appropriate settings. Simplifies MRI eligibility with digital pre-screening.

Government recommendations for SCS patient selection

NICE TAG 159 provides recommendation of patient selection[4]

Spinal cord stimulation **is recommended** as a treatment option for adults with **chronic pain of neuropathic origin** who:

- Continue to experience chronic pain (measuring at least 50mm on a 0–100mm visual analogue scale) for at least 6 months despite standard treatments
- Who have had a successful trial of stimulation as part of the assessment by a specialist team

British Pain Society Recommendations

Good indications for SCS (likely to respond)[5]	Neuropathic pain in leg or arm following lumbar or cervical spine surgery (FBSS/FNSS)
	Complex regional pain syndrome (CRPS)
	Neuropathic pain secondary to peripheral nerve damage
	Pain associated with peripheral vascular disease
	Refractory angina pectoris (RAP)
	Brachial plexopathy: traumatic (partial, not avulsion), post-irradiation
Intermediate indications for SCS (may respond) [5]	Amputation pain (stump pain responds better than phantom pain)
	Axial pain following spinal surgery
	Intercostal neuralgia, such as post-thoracotomy or post-herpetic neuralgia
	Pain associated with spinal cord damage
	(other peripheral neuropathic pain syndromes, such as those following trauma may respond)

HAS recommendations for Spinal Cord Stimulation[6]

- Patient with chronic, neuropathic pain
- Post-surgical pain (sciatica, lumbar-radicular pain, cruralgia)
- Persistent for at least one year
- Resistant to other conventional medical management
- No contraindications: psychological, surgical, or environmental

German S3 Guideline for Spinal Cord Stimulation for treatment of Chronic Pain[7]

Chronic Back and Leg Pain / FBSS – **Strong Recommendation**
Primarily for predominant radicular pain. Patient must fail conservative treatments. Exclusion criteria – psychological contraindications.

CRPS Type I – **Strong Recommendation**

After unsuccessful multimodal conservative treatment. Patients should be treated with epidural spinal cord stimulation while maintaining intense physical treatment

FBSS is the primary indication
recommended
by European Governments and organisations for Spinal Cord Stimulation

Spinal Cord Stimulation Evidence

The supporting evidence for Spinal Cord Stimulation

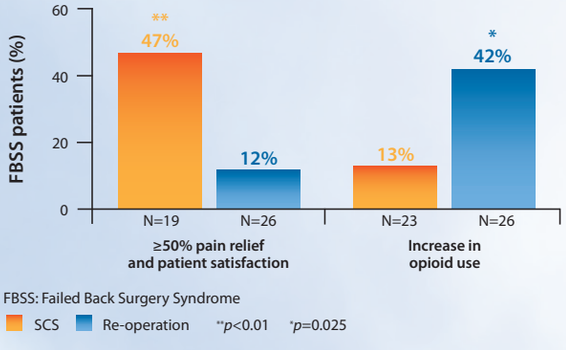
SCS is clinally proven to:

- Provide effective pain relief (≥50%) that is sustained long term[8-11]
- Decrease the use of opiate analgesics[8,11]
- Improve quality of life[9-13] and functional ability[9,11-13]
- Be well tolerated[11,14]
- Provide patient satisfaction[9]

Spinal Cord Stimulation provides effective **long-term pain relief** and patient satisfaction and reduces the need for opiate analgesics

1. After a mean follow-up of 3 years:

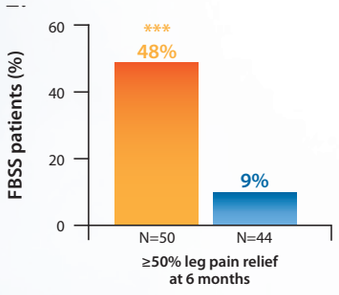
- ≥50% pain relief and patient satisfaction in more FBSS patients than re-operation patients (47% **vs.** 12%; p<0.01)[8]
- More patients in the re-operation group increased their opioid use (42% **vs.** 13%; p=0.025)[8]



FBSS: Failed Back Surgery Syndrome
SCS Re-operation **p<0.01 *p=0.025

2. At 6-month follow-up:

- Adding spinal cord stimulation to CMM was more effective than CMM alone at providing ≥50% leg pain relief (48% **vs.** 9%; p<0.001) (PROCESS Study)[9]



CMM: Conventional Medical Management
FBSS: Failed Back Surgery Syndrome
SCS + CMM CMM ***p<0.001

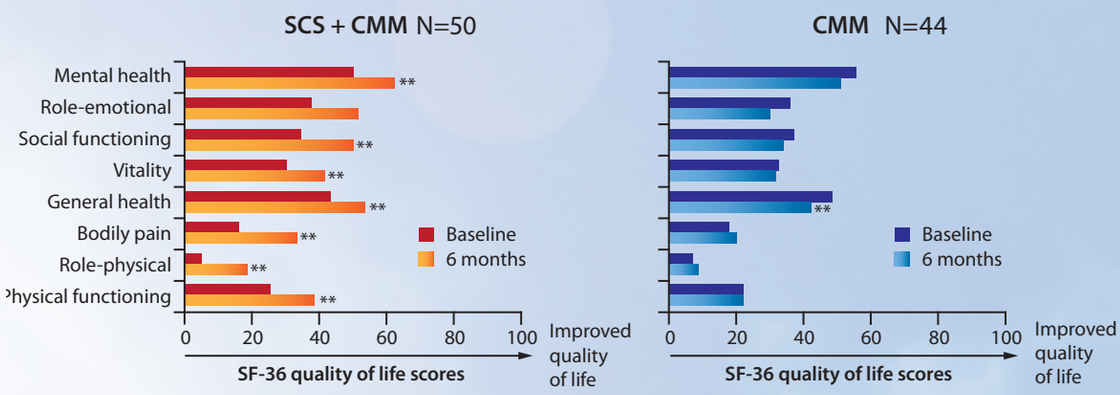
Current European guidelines support the use of spinal cord stimulation:

"…spinal cord stimulation (SCS) is efficacious in failed back surgery syndrome (FBSS)"[16]

Spinal Cord Stimulation improves quality of life

At 6-month follow-up:

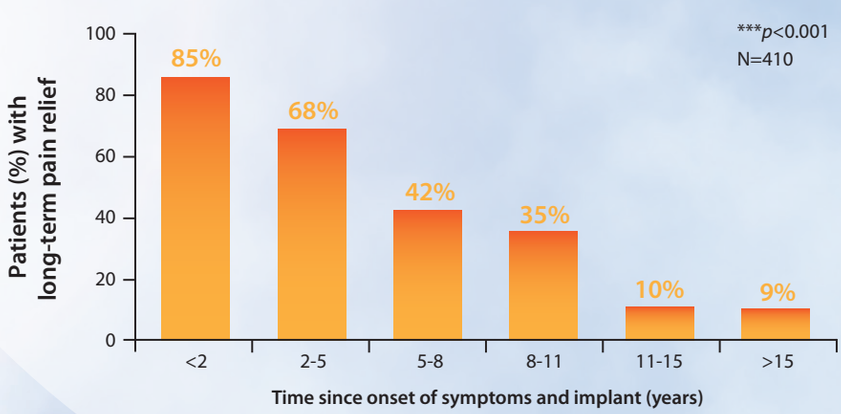
- Spinal cord stimulation plus CMM improved scores in 7 out of 8 health-related quality of life domains ($p<0.01$); CMM alone did not improve quality of life and the 'general health' domain actually worsened ($p<0.01$) (PROCESS Study)[9]



**$p<0.01$ CMM: Conventional Medical Management

Time to treatment

85% success rate in patients treated with spinal cord stimulation within 2 years of onset of chronic pain syndrome; only 9% success rate if treated more than 15 years after onset of symptoms following onset of chronic pain syndrome ($p<0.001$)[15]



Earlier intervention with spinal cord stimulation improves treatment outcomes

References

1. Breivik H, European Journal of Pain 10 287–333 (2006).
2. Stamatos JM, Live Your Life Pain Free, October 2005.
3. Meyerson BA., Linderoth B et al., Mode of action of spinal cord stimulation in neuropathic pain. J Pain Symptom Manage; 31: S6–S12 (2006).
4. Nice Recommendation: http://www.nice.org.uk/guidance/TA159.
5. http://www.britishpainsociety.org/book_scs_main.pdf
6. Haute Autorité de Santé. Evaluation des systèmes implantables de neurostimulation médullaire. Service d'évaluation des dispositifs. Saint-Denis La Plaine : HAS ; 2014.
7. AWMF S3 Leitlinie: Epidurale Rückenmarkstimulation zur Therapie chronischer Schmerzen, Stand 07/2013; Online: http://www.awmf.org/leitlinien/detail/ll/008-023.html.
8. North RB., Kidd DH., Farrokhi F, et al. Spinal cord stimulation versus repeated lumbosacral spine surgery for chronic pain: a randomized, controlled trial. Neurosurg; 56: 98–106 (2005).
9. Kumar K., Taylor RS., Jacques L, et al., Spinal cord stimulation versus conventional medical management for neuropathic pain: a multicenter randomised controlled trial in patients with failed back surgery syndrome. Pain; 132: 179–188. (2007).
10. Kemler MA., De Vet HCW., Barendse GAM et al., The effect of spinal cord stimulation in patients with chronic reflex sympathetic dystrophy: two years' follow-up of the randomized controlled trial. Ann Neurol; 55: 13–18 (2004).
11. Taylor RS, Spinal cord stimulation in Complex Regional Pain Syndrome and Refractory Neuropathic Back and Leg Pain/Failed Back Surgery Syndrome: results of a systematic review and meta-analysis. J Pain Symptom Manage; 31: S13–S19 (2006).
12. Yu W., Maru F., Edner M, et al., Spinal cord stimulation for refractory angina pectoris: a retrospective analysis of efficacy and cost-benefit. Coronary Artery Disease; 15: 31–37 (2004).
13. Ubbink DT., Vermeulen H., Spincemaille GHJJ et al Systematic review and meta-analysis of controlled trials assessing spinal cord stimulation for inoperable critical leg ischaemia. Br J Surg; 91: 948–955 (2004).
14. Cameron T, Safety and efficacy of spinal cord stimulation for the treatment of chronic pain – a 20 year literature review. J Neurosurg Spine; 100: 254–267 (2004).
15. Kumar K., Hunter G., Demeria D et al., Spinal cord stimulation in treatment of chronic benign pain: challenges in treatment planning and present status, a 22-year experience. Neurosurgery; 58: 481–496 (2006).
16. Cruccu G., Aziz TZ., Garcia-Larrea L et al., EFNS guidelines on neurostimulation therapy for neuropathic pain. Eur J Neurol; 14: 952–970 (2007).
17. Sator-Katzenschlager S, Subcutaneous Target Stimulation (STS) in Chronic Noncancer Pain: A Nationwide Retrospective Study. Pain Practice; 10 (4): 279-286 2010.
18. Verrills P, Peripheral Nerve Stimulation: A Treatment for Chronic Low Back Pain and Failed Back Surgery Syndrome. Neuromodulation; 12 (1): 68-75 2009.
19. Lamer TJ, Treatment of cancer-related pain: when early administered medications fail. Maye Clin Proc; 69:473–480 (1994).
20. Medtronic Indications, drug stability, and emergency procedures SynchroMed® and IsoMed® manual
21. Erdine S., de Andrés S et al., Drug delivery systems. Pain Practice; 6: 51–57 (2006).
22. Deer T., Chapple., Classen A et al., Intrathecal drug delivery for treatment of chronic low back pain: report from the National Outcomes Registry for Low Back Pain. Pain Med; 5: 6–13 (2004).
23. Roberts LJ., Finch PM., Gouke CR et al., Outcome of intrathecal opioids in chronic non-cancer pain. Eur J Pain; 5: 353–361 (2001).
24. Ilias W., Polain Ie., Buchser E et al.,Intrathecal pain management with patient-controlled analgesia: 12-month study with the personal therapy manager. Presented at the 4th World Congress of the World Institute of Pain (WIP), Budapest, Hungary, September 25–28 2007 (2007).
25. Schultz D., Webster L., Kosek P.,Dar U., Tan Y., Sun M et al., Medtronic advanced pain therapy using neurostimulation for chronic pain. Clinical Summary, 2011. M221494A006. . Sensor-driven, position-adaptive spinal cord stimulation for chronic pain. Pain Physician. 15:1-12 2012.
26. Data compiled from Truven Health Analytics, Inc., MarketScan® Commercial Claims and Encounters Database, 2009 & 2010, based on MR Scan rates for patients with SCS indications of CRPS and chronic back and leg pain, including FBSS.
27. Bernstein CA, Spinal cord stimulation in conjunction with peripheral nerve field stimulation for the treatment of low back and leg pain: a case series. Neuromodulation; 11: 116-123 2008.
28. Hamm-Faber T.E., Aukes H.A., de Loos F., Gültuna Iet al., Subcutaneous Stimulation as an Additional Therapy to Spinal Cord Stimulation for the Treatment of Lower Limb Pain and/or Back Pain: A Feasibility Study. Neuromodulation 2012; 15(2):108-117 doi: 10.1111/j.1525-1403.2011.00393.x. Epub 2011 Sep 21 2011.

* Patients receiving PNS (or in combination with SCS[27,28]) experienced chronic back pain relief [17,18,27,28], improvement in functional disability,[28] and reduction in medication intake.[17,18,28] In the study by Verrils[18] (N=13), 54% of the chronic low back pain patients achieved at least 50% pain relief.

According to a retrospective study performed by Sator-Katzenschlager[17] (N=111 of which 66 patient have chronic low back pain with or without leg pain), the average back pain score in the group of FBSS patients with chronic back pain and persistent radicular pain (n=37) was 8.0 ± 1.4 before implantation and decreased significantly to 3.3 ± 2.1. (p<0.0001) after 3 months. **A reduction of 59%.

***In the same study of Sator-Katzenschlager[17], patients with local axial back pain (N=29) significantly decreased their back pain from 8.3 ± 0.9 before implantation to 4.2 ± 2.2 3 months after implantation. (p<0.001) **A reduction of 49%.**

Important safety information

NEUROSTIMULATION SYSTEMS FOR PAIN THERAPY

Brief Summary: Product manuals must be reviewed prior to use for detailed disclosure. Indications: Neurostimulation for Spinal Cord Stimulation (SCS) – Medtronic SCS neurostimulation system is indicated for SCS as an aid in the management of chronic, intractable pain of the trunk and/or limbs, peripheral vascular disease, or intractable angina pectoris. Neurostimulation for Peripheral Nerve Stimulation (PNS) – A Medtronic PNS neurostimulation system is indicated for PNS as an aid in the management of chronic, intractable pain of the trunk and/or limbs. Contraindications: Diathermy – Do not use shortwave diathermy, microwave or therapeutic ultrasound diathermy (all now referred to as diathermy) on patients implanted with a neurostimulation system. Energy from diathermy can be transferred through the implanted system and cause tissue damage at the locations of the implanted electrodes, resulting in severe injury or death. Warnings: Sources of strong electromagnetic interference (eg, defibrillation, diathermy, electrocautery, MRI, RF ablation, and therapeutic ultrasound) can interact with the neurostimulation system, resulting in serious patient injury or death. These and other sources of EMI can also result in system damage, operational changes to the neurostimulator or unexpected changes in stimulation. Rupture or piercing of the neurostimulator can result in severe burns. An implanted cardiac device (eg, pacemaker, defibrillator) may damage a neurostimulator, and the electrical pulses from the neurostimulator may result in an inappropriate response of the cardiac device. Patients treated for intractable angina pectoris should be educated on the signs and symptoms of myocardial infarction and should seek medical attention immediately if signs and symptoms develop. Precautions: The safety and effectiveness of this therapy has not been established for pediatric use (patients under the age of 18), pregnancy, unborn fetus, or delivery. Patients should be detoxified from narcotics prior to lead placement. Clinicians and patients should follow programming guidelines and precautions provided in product manuals. Patients should avoid activities that may put undue stress on the implanted neurostimulation system components. Patients should not scuba dive below 10 meters of water or enter hyperbaric chambers above 2.0 atmosphere absolute (ATA). Electromagnetic interference, postural changes, and other activities may cause shocking or jolting. Adverse Events: Adverse events may include: undesirable change in stimulation described by some patients as uncomfortable, jolting or shocking; hematoma, epidural hemorrhage, paralysis, seroma, CSF leakage, infection, erosion, allergic response, hardware malfunction or migration, pain at implant site, loss of pain relief, chest wall stimulation, and surgical risks.

Summary

Medtronic Pain Therapies have been in use for over 40 years

More than 400,000 patients worldwide have benefited from Medtronic Pain Therapies

Minimally invasive, reversible, and patients begin with a trial period to determine whether they will respond to the therapy

Procedures are widely reimbursed and recommended in Europe

Therapies are backed by evidence including multiple level 1 RCTs

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Europe
. Medtronic International Trading Sàrl
Route du Molliau 31
Case postale
CH-1131 Tolochenaz
www.medtronic.eu
Tel: +41 (0)21 802 70 00
Fax: +41 (0)21 802 79 00

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