Cord Stimulators, Intrathecal Pumps (TECHNIQUES)

Last updated: September 2, 2023

SPINAL CORD (DORSAL COLUMN) STIMULATORS

References
1. "Spinal Cord Stimulation Implant Techniques" by Dr. Ryder Gwinn, Swedish Medical Center, Seattle, WA. Presented at Seattle Science Foundation's 2nd Annual Interventional Pain Management Fellows Course.
2. Nader "Neurosurgery Tricks of the Trade – Spine and Peripheral Nerves" (2014), ch. 67 (p. 312-315)
3. Medtronic - Spinal Cord Stimulator (Surgical Lead Implantation Guide) >>
4. St. Jude - Spinal Cord Stimulator >>

HISTORY

- SCS has been used as a modality to treat chronic pain since 1967 when Dr. Shealy implanted the first spinal cord stimulator in a terminally ill patient with bronchogenic carcinoma and right lower chest pain.

PHYSIOLOGY

- clinical application of SCS initially was inspired by the Gate Control Theory of pain: increased activity of large innocuous afferents presynaptically inhibits input to pain-transmitting projection neurons via inhibitory interneurons, as well as trigger supraspinal circuits that also modify spinal pain processing.

PARADIGMS & OUTCOME STUDIES

Classical Tonic Stimulation

- low-frequency stimulation; patient feels paresthesias (allows anatomical coverage mapping).

STUDIES

PROCESS study - SCS vs. Medical Management

Kumar K. "Spinal Cord Stimulation vs. Conventional Medical Management: A Prospective, Randomized, Controlled, Multicenter Study of Patients with Failed Back Surgery Syndrome (PROCESS Study)." Neuromodulation. 2005 Oct;8(4):213-8
Kumar K et al. Spinal cord stimulation versus conventional medical management for neuropathic pain: a multicentre randomised controlled trial in patients with failed back surgery syndrome. Pain 2007; 132 (1–2): 179 – 188

- 100 patients with Failed Back Surgery Syndrome (FBSS) and neuropathic pain in legs > back.
  - Randomized to medical management vs. MM plus SCS
- Primary outcome: 50% leg pain relief at 6 months.
  - 6 months:
    - At 6 months, 24 SCS patients (48 percent) and 4 CMM patients (9 percent) achieved at least 50 percent or more pain relief in the legs.
    - 73% MM patients requested to switch to SCS
    - 10% SCS patients requested to switch to MM
  - 24 months:
    - p<.001 improvements in pain, quality-of-life, and function outcomes.
    - 31% patients receiving an electrode experienced a device-related complication requiring additional surgery, they note.

PROMISE study

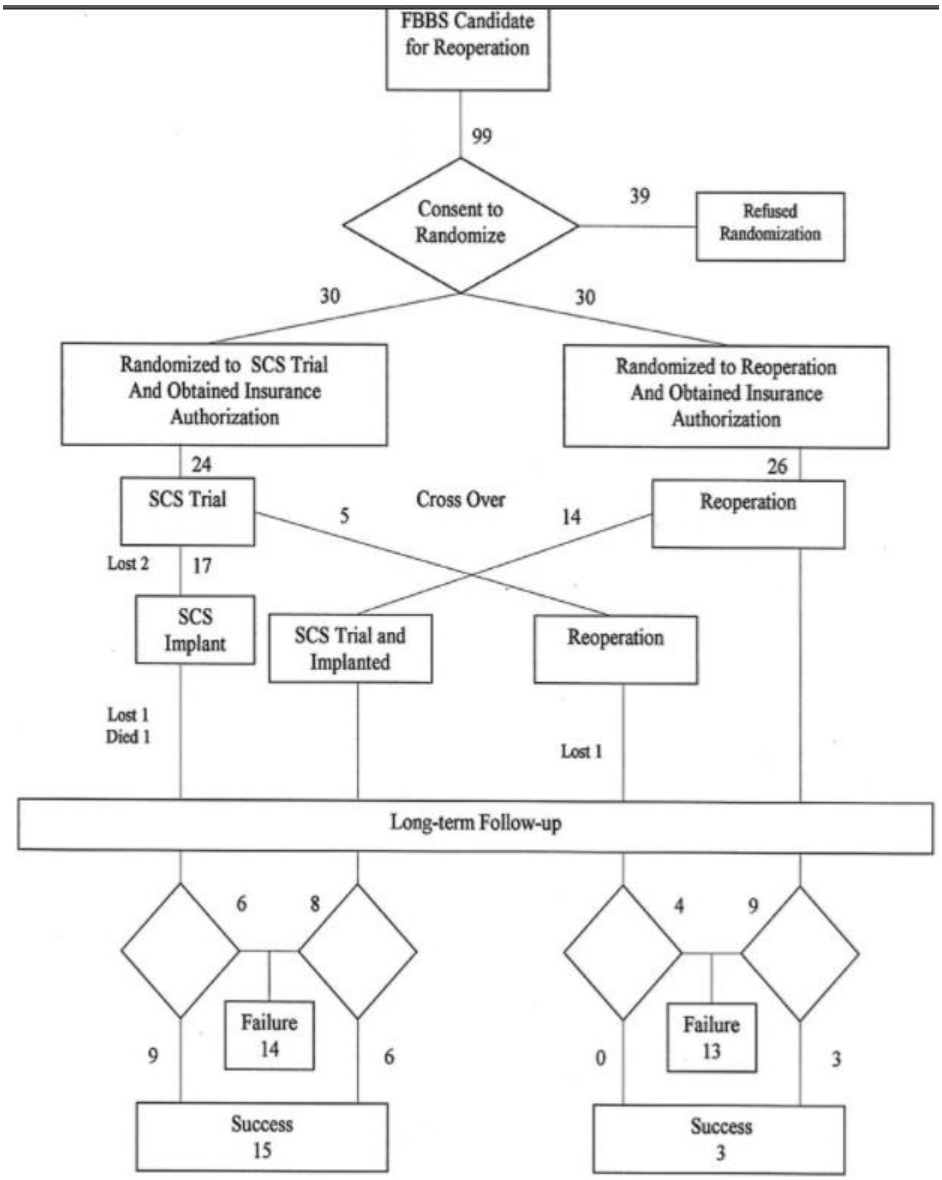
Rigoard P "Spinal cord stimulation for predominant low back pain in failed back surgery syndrome: study protocol for an international multicenter randomized controlled trial (PROMISE study)." Trials. 2013 Nov 7;14:376

Recruitment began in January 2013 and will continue until 2016

SCS vs. repeated surgery

Spinal cord stimulation versus repeated lumbosacral spine surgery for chronic pain: a randomized, controlled trial. North RB, Kidd DH, Farrokhi F, Piantadosi SA. Neurosurgery. 2005;56(1):98-106

Old trial (only 4-contact leads) – only surgical candidates (i.e. pathology is still seen after failed back surgery and patient is a good candidate either for repeat open surgery or SCS)



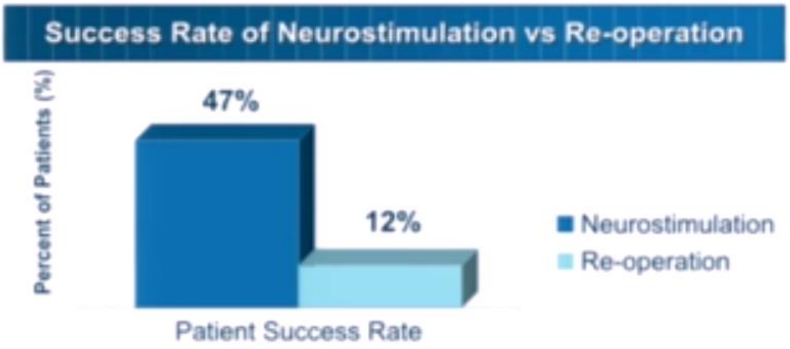


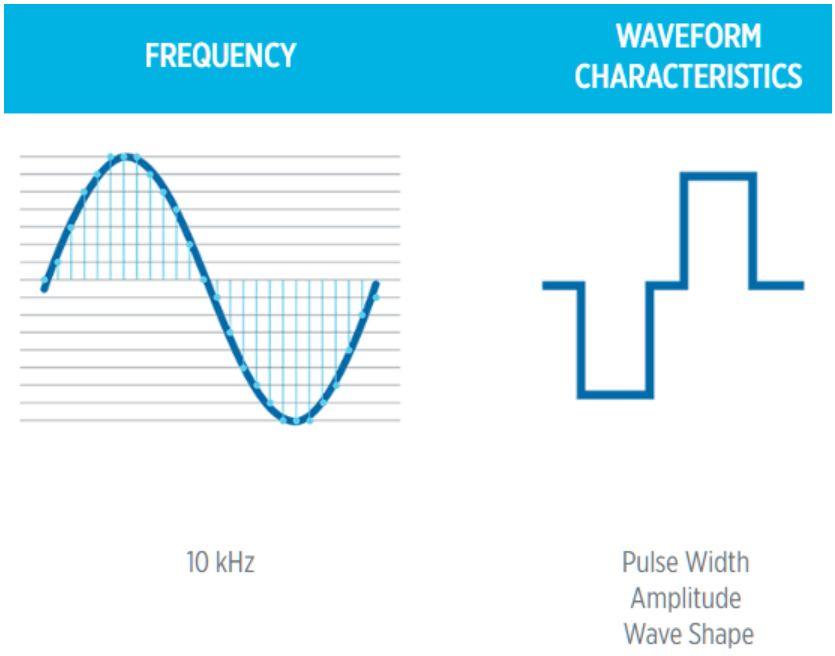
TABLE 5. Long-term outcomes of reoperation and spinal cord stimulation as randomized and as treated[a]

	Randomized	Crossover
Reoperation	12% (3/26)	0% (0/4)
Spinal cord stimulation	47% (9/19)	43% (6/14)

[a] Values are percentages and numbers of patients in each group.

HF10 (10K High Frequency) - Nevro

- **<u>proprietary HF10 therapy</u>**: high frequency (10 kHz), short-duration (30 msec), low-amplitude (1-5 mA) pulses - relieves ***back and leg*** *pain without causing constant paresthesias* (so no awake intraop testing is needed or available; for trial – implant and then test for 7 days)



vs. <u>traditional therapy</u>: low-frequency (40-60 Hz), longer duration (300-600 msec), and higher amplitude (4-9 mA) pulses.

- FDA approval in May 2015: a paresthesia-free therapy provided via high-frequency stimulation at 10-kHz (HF10 therapy).
- lead position is based on extensive empirical observation that most patients respond to stimulation application near T9/10, while allowing for patient variation by covering T8-T11.
  N.B. implant at T9/10!!!
- high drain on battery - only rechargeable battery that lasts 10 years under typical settings.

Proprietary programming algorithm developed over several years

STUDIES

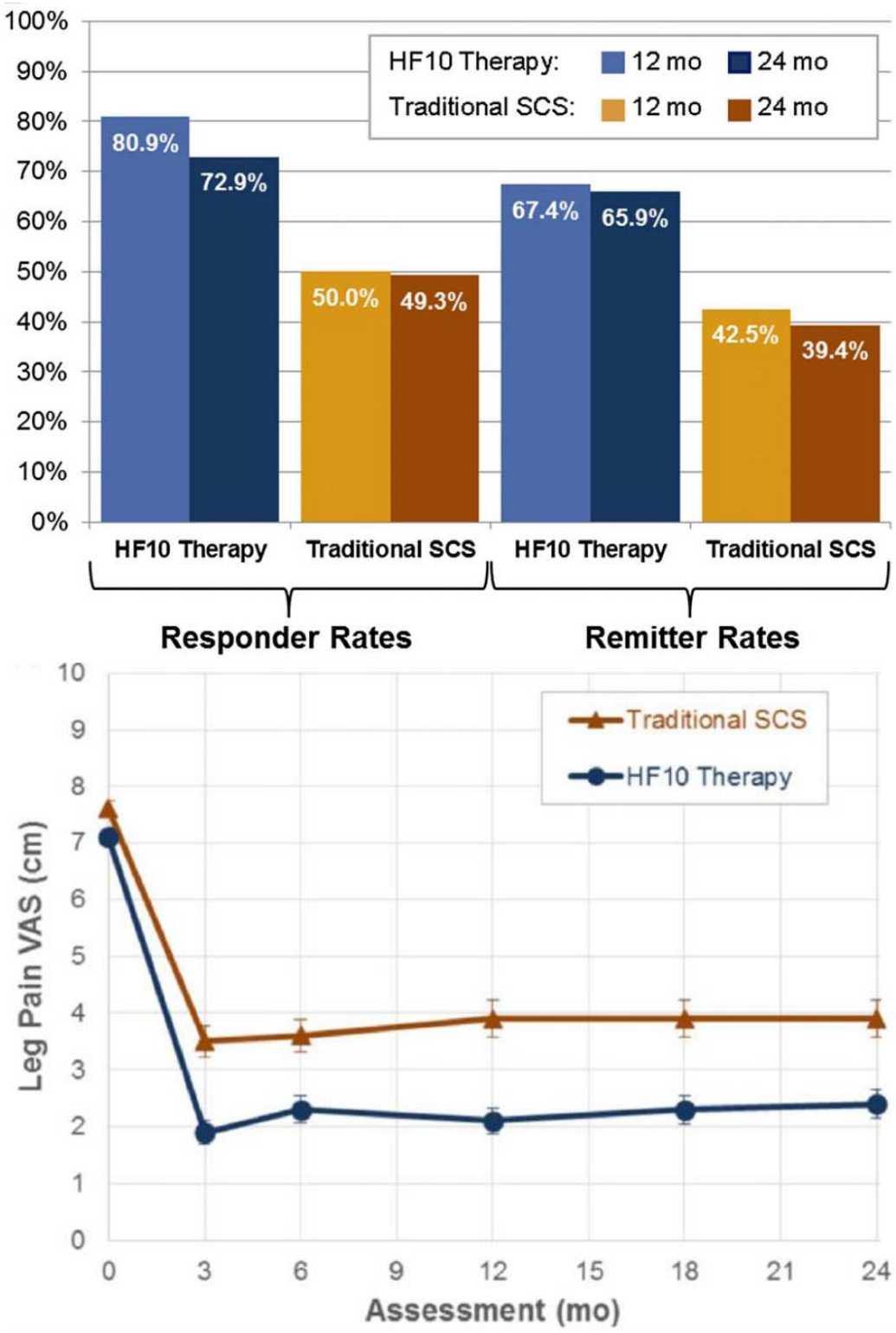
SENZA-RCT: Senza system (Nevro Corp.) vs. Precision Plus system (Boston Scientific)

- 10 kHz vs. traditional low-frequency (both systems consisted of two 8-contact leads and rechargeable IPG).

Kapural L, Yu C, Doust MW, Gliner BE, Vallejo R, Sitzman BT, Amirdelfan K, Morgan DM, Yearwood TL, Bundschu R, Yang T, Benyamin R, Burgher AH. "Comparison of 10-kHz High-Frequency and Traditional Low-Frequency Spinal Cord Stimulation for the Treatment of Chronic Back and Leg Pain: 24-Month Results From a Multicenter, Randomized, Controlled Pivotal Trial." Neurosurgery. 2016 Nov;79(5):667-677.

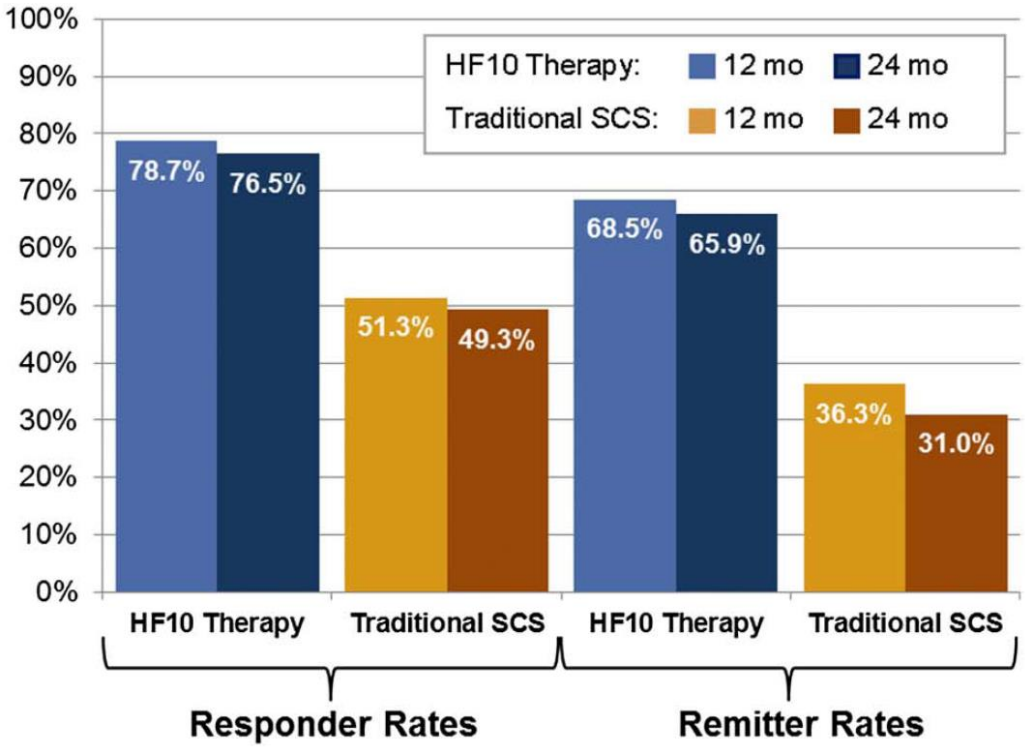
Leg pain – responder rate (> 50% pain decrease from preop):

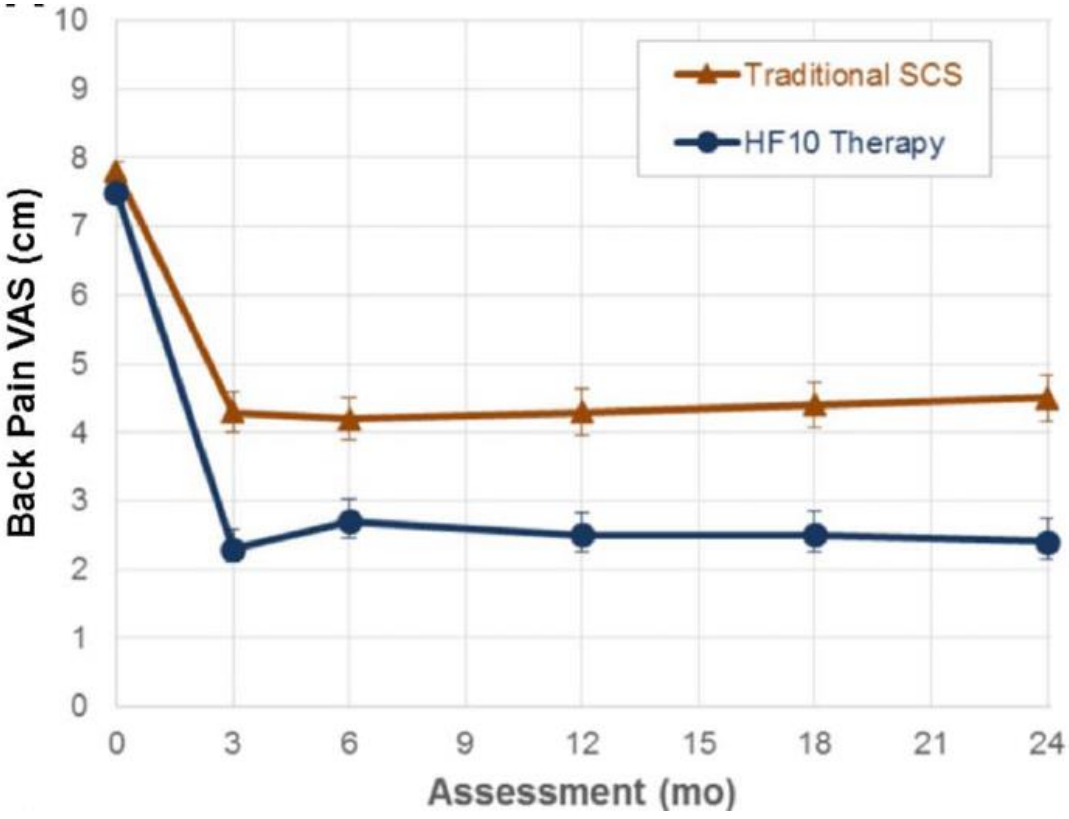
F/U	Traditional SCS	HF10	p value
3 mos	55.5%	83.1%	< 0.001
12 mos	50%	80.9%	
24 mos	49.3%	72.9%	< 0.001



Back pain – responder rate (> 50% pain decrease from preop):

F/U	Traditional SCS	HF10	p value
3 mos	43.8%	84.5%	< 0.001
12 mos	51.3%	78.7%	
24 mos	49.3%	76.5%	< 0.001





SENZA-PDN - 10 kHz SCS + CMM vs. CMM alone in the treatment of diabetic neuropathic limb pain

https://clinicaltrials.gov/ct2/show/NCT03228420

Inclusion:

1. Clinically diagnosed with diabetes & diabetic neuropathy resulting in lower limb pain.
2. Refractory to conservative treatments, including pregabalin or gabapentin and at least one other class of analgesic.
3. Symptomatic despite conservative therapy for ≥ 12 months
4. ≥ 5 out 10 cm on the pain VAS in the lower extremities.

5. Willing to undergo SCS placement percutaneous procedures.
6. Willing to participate in around 14 research visits over 24 months

Exclusion:

1. Lower limb amputation other than toes.
2. HbA1c > 10%
3. BMI > 45
4. Daily opioid dosage > 120 mg morphine equivalents.
5. Prior experience with SCS (includes failed trials)
6. Have an implanted drug pump or active implantable device such as pacemaker.
7. Other painful areas with VAS > 4 (such as PDN in hands)

Results – at 6 months:

Pain:

- 85% of participants reported pain relief > 50% (vs 5% in the CMM control arm, $p < 0.001$).
- average pain relief was 76% (% reduction of VAS from baseline) vs average worsening of 2% in the control arm.

Quality of Life:

- 92% of patients were either "satisfied" or "very satisfied" with 10 kHz SCS therapy vs 91% of CMM patients who were either "dissatisfied" or "very dissatisfied" with treatment.
- sleep disturbance due to pain in the 10 kHz SCS group was remarkably diminished.

Burst stimulation – Abbott / St. Jude

- does not generate paresthesias (possible to do placebo-controlled studies)

De Ridder D et al. Burst spinal cord stimulation for limb and back pain. World Neurosurg. 2013 Nov;80(5):642-649.e1. doi: 10.1016/j.wneu.2013.01.040. Epub 2013 Jan 12.

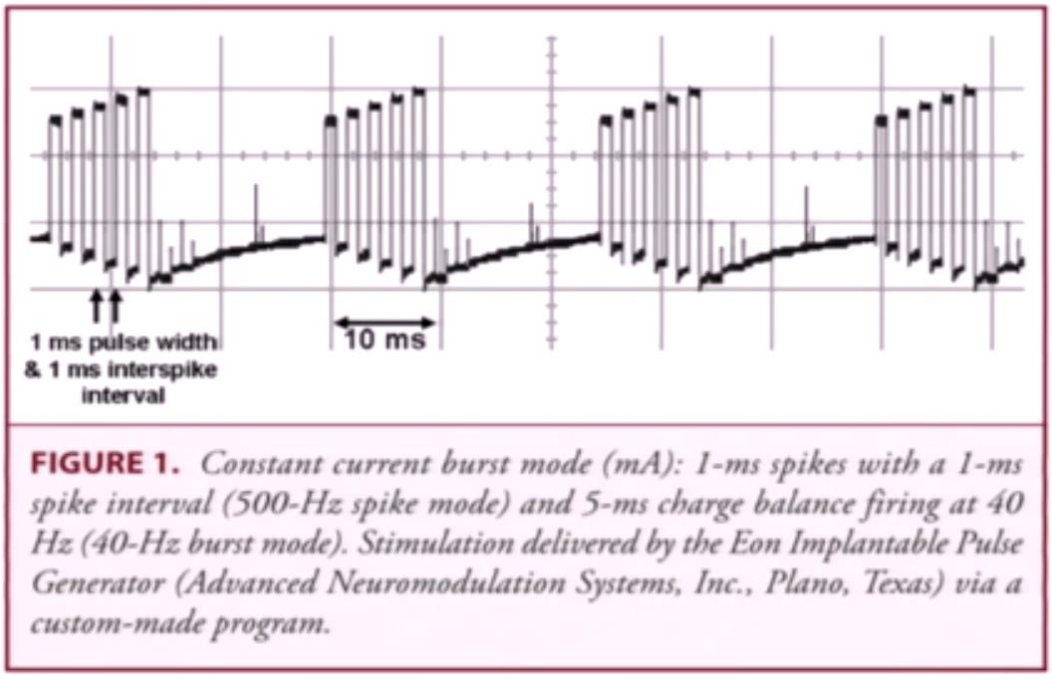
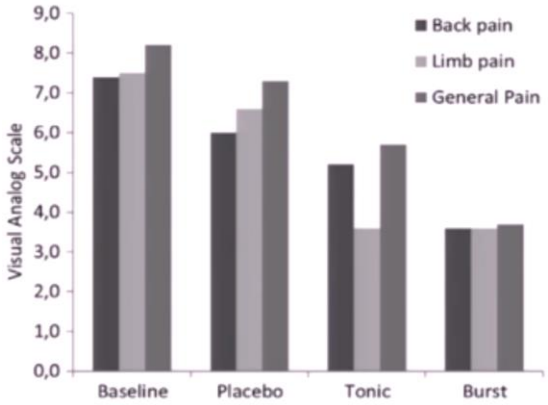
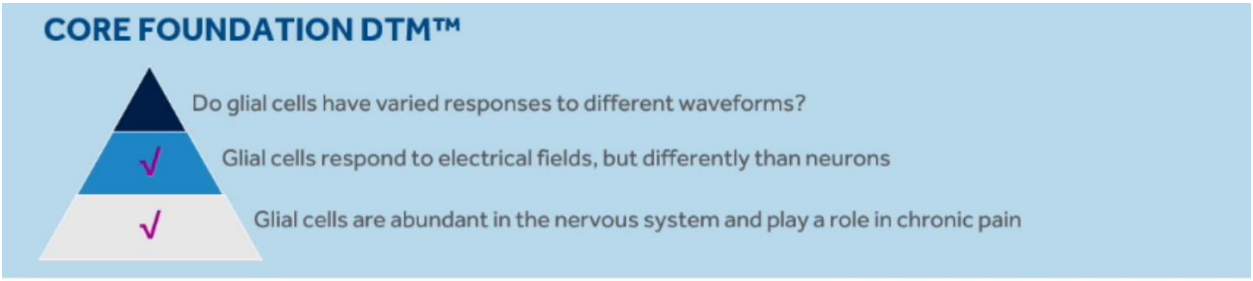


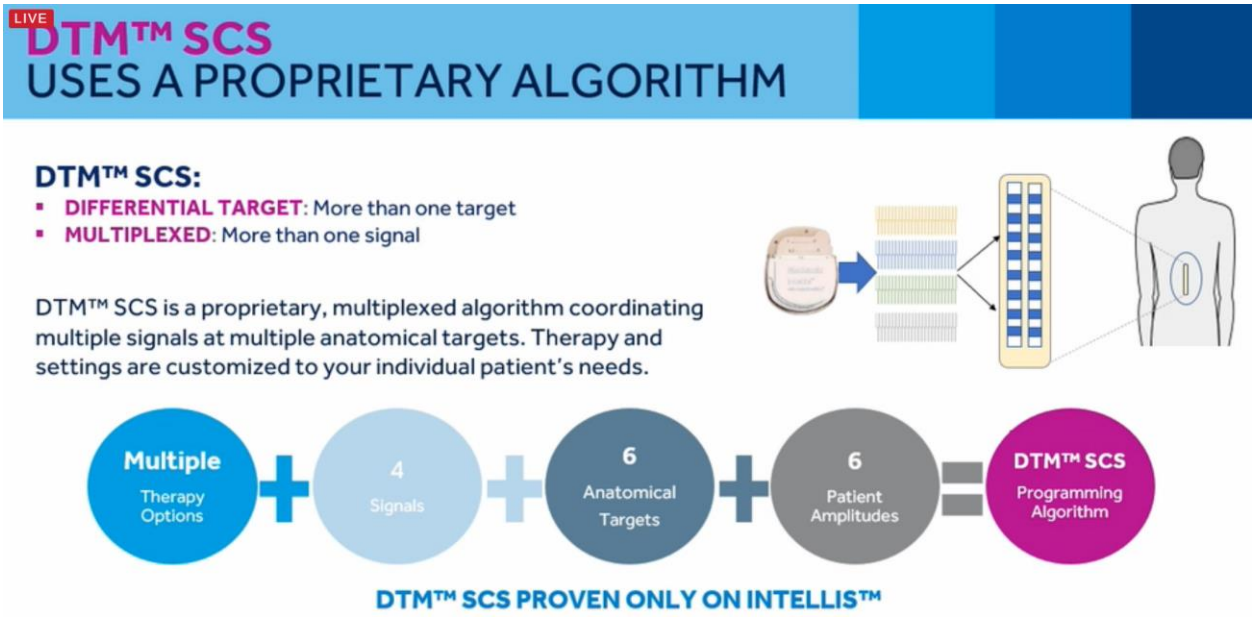
FIGURE 1. *Constant current burst mode (mA): 1-ms spikes with a 1-ms spike interval (500-Hz spike mode) and 5-ms charge balance firing at 40 Hz (40-Hz burst mode). Stimulation delivered by the Eon Implantable Pulse Generator (Advanced Neuromodulation Systems, Inc., Plano, Texas) via a custom-made program.*



DTM (Differential Target Multiplexed) - Medtronic

- Dr. Vallejo invention – algorithm with variation of waveform, frequency, amplitude, pulse width - targets ***glial cells***.
- patients may feel some paresthesias





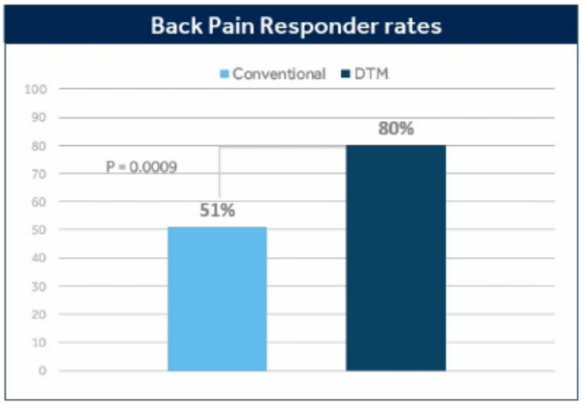
Clinical Studies

BACK PAIN RESPONDER RATE (≥ 50% REDUCTION IN PAIN)

51%
Responder Rate with **Conventional SCS**
Pain Relief at 3 Months

80%
Responder Rate with **DTM™ SCS**
Pain Relief at 3 Months

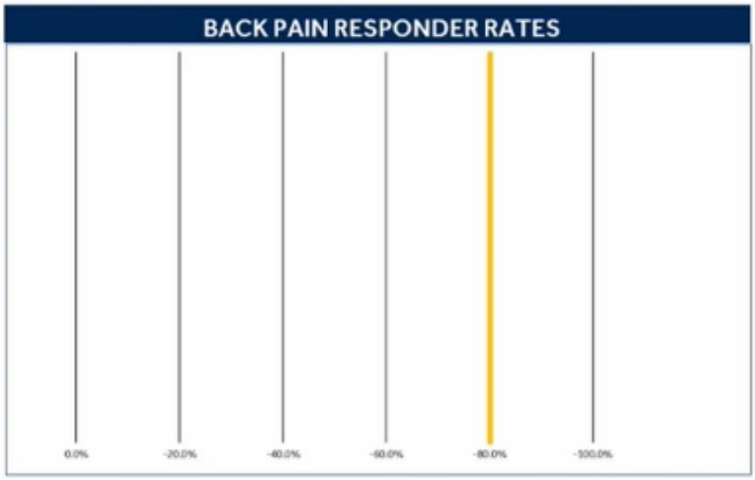
Statistically significant reduction in Low Back Pain at 3 Months (P= 0.0009) demonstrated DTM™ SCS was superior compared to Conventional SCS.



PROFOUND RESPONDERS (> 80% PAIN RELIEF)

28%
Profound responders with **Conventional SCS**

63%
Profound responders with **DTM™ SCS**



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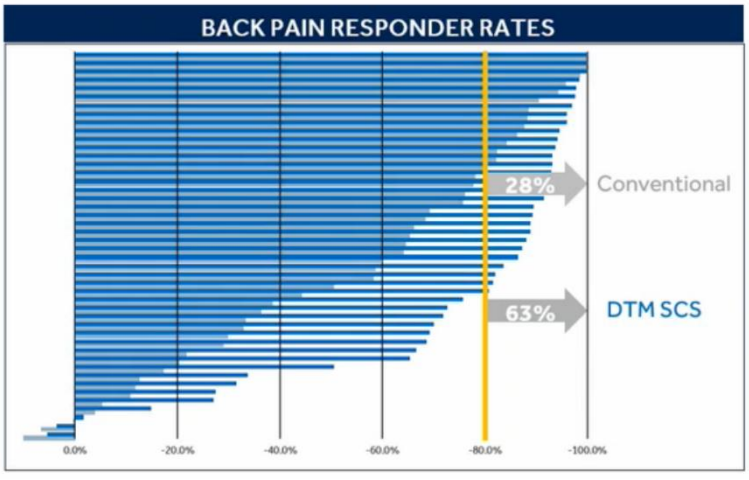
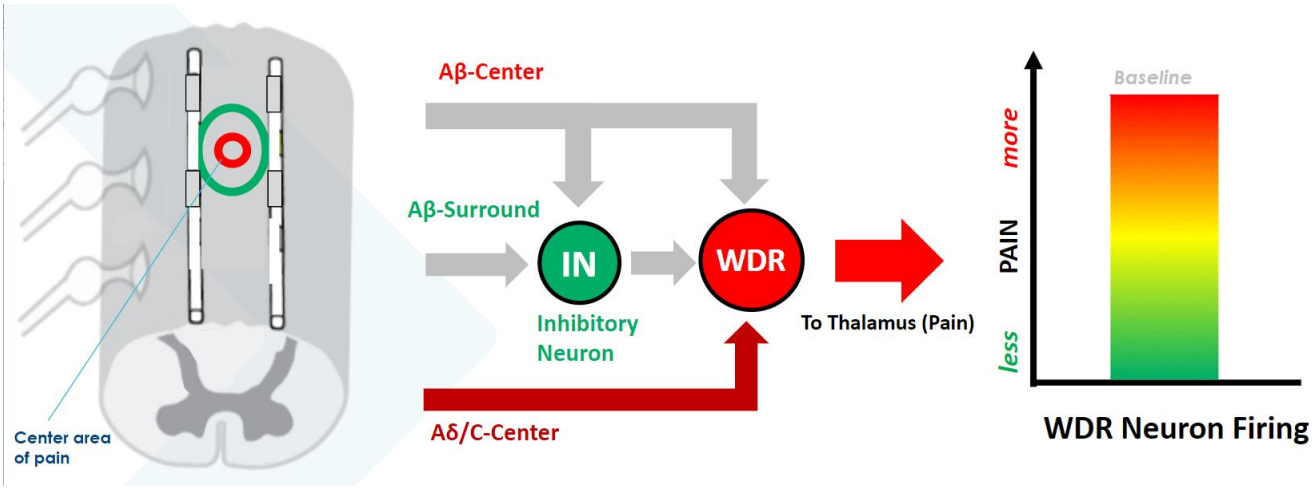
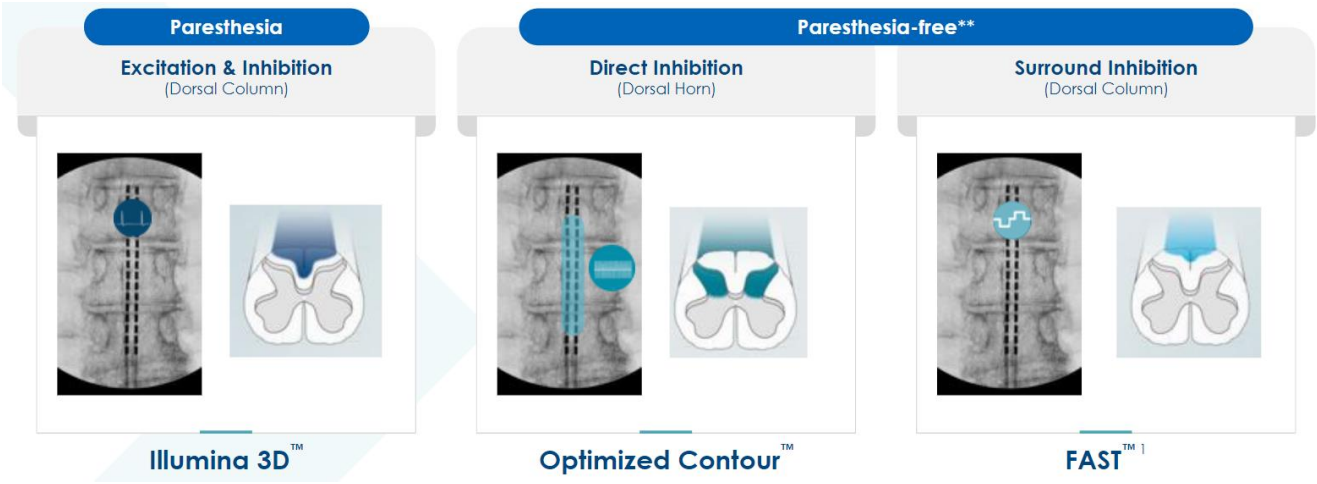


Surround Inhibition – WaveWriter (Boston Scientific)



"Donut pillow" for coccygeal pain.



Closed-loop – Saluda (Evoke system)

Hardware – see below >>

- all currently available commercial SCS systems still operate in a ***fixed-output stimulation (or open-loop) configuration*** (e.g. fixed frequency, fixed pulse width, fixed amplitude, and fixed pulse train) regardless of the neural activation of the spinal cord (SC) fibers;
  - these fixed-output systems do not account for the large variation of electrical field strength and, subsequently, volume of tissue stimulated that occurs because of changes in the distance between the electrode and SC from normal physiological activity (e.g. breathing and heartbeat) and movement - changes in stimulation strength lead to variable activation of the SC and, thus, variable inhibition of pain processing pathways.
- each suprathreshold stimulus elicits an evoked compound action potential (ECAP), which represents the sum of all single-fiber action potentials generated by the stimulus; ECAP is therefore a direct measure of SC activation and provides information on the fibers elicited by SCS, contributing to the therapeutic effect of stimulation.
- closed-loop SCS system that maintains stable SC activation via continuous ECAP measurement.
- **recording electrodes** for measuring the ECAP can be any 2 nonstimulating electrodes on either lead.
- ***ECAP elicited by the stimulation is sensed and processed*** by the stimulator to measure its amplitude → amplitude is used to drive a feedback loop that adjusts the stimulus current at each stimulus pulse to maintain near-constant SC activation.
- ECAP amplitude correlates with stimulation sensation intensity in a linear fashion, i.e. a higher ECAP amplitude results in an equal or stronger perceived stimulus sensation (never weaker).

- **therapeutic window** - range of ECAP amplitudes lying between the stimulus perception threshold and the maximum level of stimulation (discomfort threshold).

STUDIES

EVOKE study (NCT02924129) - closed-loop SCS vs. open-loop

- 134 participants, age 18-80 years, chronic intractable pain of the back and legs.
- closed-loop SCS system - Evoke System (Saluda Medica, Artarmon, Australia).
- closed-loop SCS had statistically superior overall back and leg pain relief with no increase in pain medications compared with open-loop SCS:
  - of those treated with closed-loop SCS, 83.1% (49/59) had at least 50% pain relief vs 61.0% (36 of 59) for those treated with open-loop SCS (P=.006).
  - for participants using opioid medications, use was reduced or eliminated for 55% (17/31) of participants treated with closed-loop SCS vs 40% (12/30) of those treated with open-loop SCS.
  - closed-loop system maintained spinal cord activation within the therapeutic window 95.2% of the time vs 47% of the time for open-loop SCS.

Avalon study - closed-loop SCS outcome at 12 months

- prospective, multicenter, single-arm study.
- at 12 months:
  - proportion of patients with ≥ 50% relief was 76.9% (back), 79.3% (leg), and 81.4% (overall).
  - proportion with ≥ 80% pain relief was 56.4% (back), 58.6% (leg), and 53.5% (overall).
  - 68.8% (22/32) eliminated or reduced their opioid intake.
  - ECAP measurements are possible long term and remain stable over a 12-mo period.
  - closed-loop SCS was able to maintain SC activation within a therapeutic window for 84.9% of the time - helps to avoid overstimulation discomfort as well as understimulation (suboptimal therapeutic delivery).

PATIENT INCLUSION CRITERIA, TRIALING

1. Intractable pain for > 3 months
2. Objective evidence of pathology
3. No untreated substance abuse
4. Mandatory psychological clearance - to examine factors such as patient expectations, psychosomatic components of the pain, and secondary gain motivation.
   20-30% patients later request SCS removal ("Does not work for me")!
5. Not pregnant
6. Satisfactory results from neurostimulation trial; most authors agree that screening trial with 50% pain relief warrants permanent implantation
   N.B. trial always has placebo effect, so permanent implant always does slightly worse – aim for 70% pain relief with trial plus definitive functional improvement (not just "reduced amount of pain pills")
   Indication for insurance purposes – at least 50% pain reduction.
   Indication for neurosurgeons – worthwhile pain reduction leading to functional improvement.
   - trial has to be for ≥ 2 days (e.g. some burst paradigm patients start to respond after 3 days of stimulation).

SMOKING

- SCS population has an estimated prevalence of smoking that is 2.5 times greater than that in the general population.

- American College of Surgeons advocates for 4-6 weeks of smoking cessation before surgery, particularly involving implanted materials, because a reduction in wound-related complications has been reported when patients quit four to eight weeks before surgery.
- tobacco users have worsened outcomes with SCS.

INDICATIONS

1) persistent spinal pain syndrome (it replaced the old term "failed back surgery syndrome") - recurrent back pain after multiple low back operations; Class I evidence demonstrating success of SCS over repeat spinal surgery in this population
2) radicular pain
3) painful peripheral neuropathy (e.g. inguinal pain after herniorrhaphy, diabetic polyneuropathy)
4) spinal arachnoiditis
5) complex regional pain syndrome I, II – effectiveness of SCS is greater for those treated within 12 months of diagnosis
6) traumatic nerve injury
7) postherpetic neuralgia
8) ischemic (vasculopathic) pain (e.g. angina)
9) peripheral stretch injuries pain
10) stump pain

CONTRAINDICATIONS

1. Nerve compression amenable to surgery causing a significant neurologic deficit
2. Gross instability of the spine
3. Inability of the patient to control the device
4. Poor surgical candidate
5. Infection (esp. systemic or near surgery site)

TARGET LOCATION & CLEARANCE

– check percutaneous trial results! (ideally middle of paddle will be where active electrode of trial lead was)

For arms – C4-7
For legs – T8-11 (for Nevro – it is 80-90% at T9-10 disc space, 10-20% contact next to T9-10)

- electrodes are placed into **posterior epidural space**.
- stimulation elicits tingling sensation (paresthesia) in corresponding dermatomes, with goal of stimulation paresthesia to ***fully cover painful area (or surround it)*** – the basis to do trial placement in awake patient.
- most rostral contact no more than several cord segments above most rostral level of pain.

N.B. to prevent cord injury, avoid inserting the paddle at vertebral levels where:

- thickness of the CSF layer is < 3 mm along the width/length of the lead
- thickness of the paddle allows < 1 mm of CSF clearance
- spinal canal is narrowed by focal stenosis or degenerated discs and cannot be surgically corrected to allow for 1 mm of clearance.

ELECTRODE CHOICE (perc lead vs. paddle)

specific products by vendor – see below >>

Both can be used for trial and for permanent implantation!

Coverage

Percutaneous leads have better rostro-caudal coverage** vs. **paddle leads** – better left-to-right coverage!

**up to 16 contacts per lead

Paddles have more columns of electrodes (vs. per leads – max 2 leads implanted)

Medtronic – 3 columns
Boston Scientific – 4 columns
St. Jude – 5 columns (but outside columns are not independent)

Spinal cord stimulation electrode design: prospective, randomized, controlled trial comparing percutaneous and laminectomy electrodes-part I: technical outcomes. North RB, Kidd DH, Olin JC, Sieracki JM. Neurosurgery. 2002 Aug;51(2):381-9

Old study (only 4-contact leads): **paddles** had better LBP coverage, larger area of pain coverage (67% vs. 47%), and only needed half of voltage used for perc* leads.

Energy

***Percutaneous leads** have no dorsal insulation – radial stimulation pattern with half of energy being wasted! Plus, **paddles** take more space – push contacts closer to dorsal columns.

Migration

Paddles – practically never migrate after implantation (vs. **perc leads** – higher revision rates but technology is getting better).

Implantation

Paddles – more risky surgical procedure.

GENERATORS

specific products by vendor – see below >>

Rechargeable – pocket must be no deeper than 1 cm (at least for Medtronic); last twice as long as non-rechargeables.

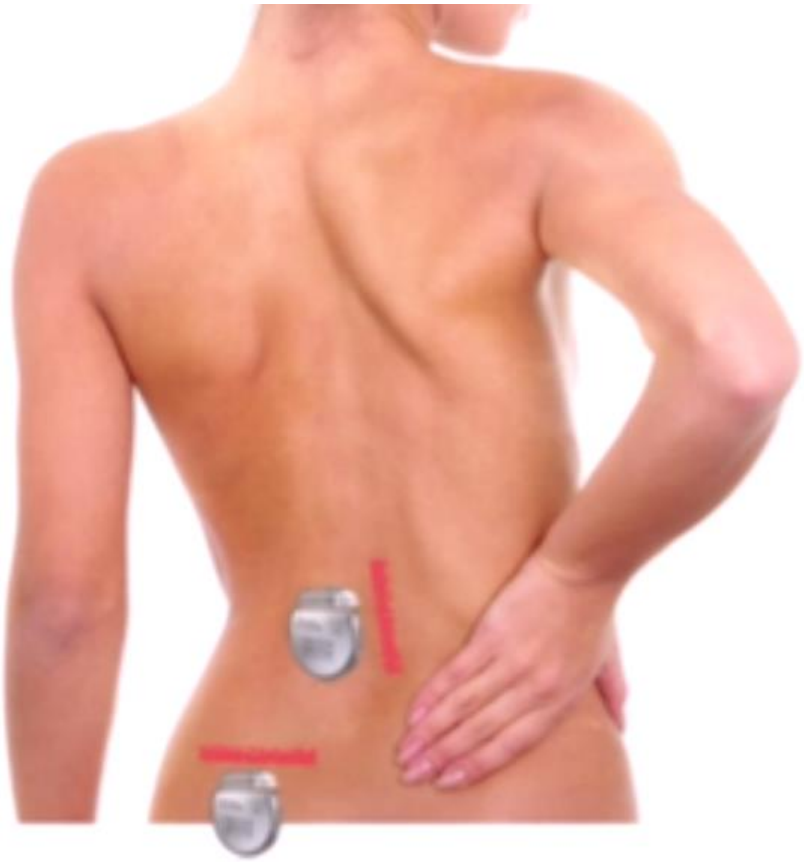
Non-rechargeable

IMPLANT LOCATION

- ask patient to tape dental floss box to the buttocks and ask to live with it for several days - to make sure belt and other equipment does not rub against the "battery"; in the morning of surgery patient will show the location which was selected as acceptable.
- generator placement subcutaneously:
  a) **flank area** above belt – shortest distance for leads, minimal IPG movement
  b) **upper buttock area** – enough tissue padding; mark incision with patient sitting in PACU (make sure incision is not under belt – will irritate and may erode through the skin; make also sure incision is not too low or patient will sit on generator)

c) **anterior abdominal wall** (subcostal flank area) – after stimulator leads are finally placed with patient in prone position → coil leads in spinal incision and temporarily staple skin → patient is repositioned to lateral decubitus.
d) **subclavicular**

N.B. verify generator position with patient preop!
There is no perfect place for IPG for all patients!



PATIENT COUNSELLING

- Discuss long term therapy with patient
- Discuss what type of system is best for pain needs and lifestyle
  - Percutaneous vs. Laminectomy Electrode
  - Rechargeable vs single cell
  - Location of battery
- This is designed to be a permanent implant, though it can be removed if absolutely necessary.

SURGICAL PROCEDURE

Absolutely necessary to review a thoracic spine MRI - to avoid cord injury by implanting in congenitally narrow thoracic canal!

- also review axial images at intended level – may anticipate difficulties of symmetric paddle placement!

Ratio of **trial : permanent** – 40% nationally (75-80% in expert hands)

PERCUTANEOUS LEADS

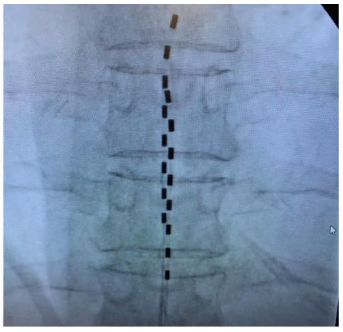
- trial for 3*-30 days.

*if response is obviously good, remove trial leads in 3 days to minimize epidural scar formation

- hardware:
  - 1 or 2 x8 contact percutaneous lead; Medtronic has choice of stylets – soft, stiff, steerable (has bent tip – directs lead advancement under fluoroscopy while rotating stylet hub)
  - external neurostimulator (ENS) with snap-lid connector cable
- anesthesia: MAC (PROPOFOL is best; second choice – PRECEDEX)
- position: prone on chest rolls or radiolucent Wilson frame, arms forward.
- target puncture – few levels below (e.g. skin entry at L1)
- using fluoroscopy, mark on skin interlaminar space (e.g. T11-12) – will be visual guide to insert needle.
- insert hollow 14G needle with stylet (bevel up) on one side of spinous process (paramedian) → using AP fluoro go with needle tip just under lamina (feel sudden give) → dorsal epidural space is verified with glass syringe (tap plunger with finger until sudden give - easy air injection without plunger going back) + sterile saline entry without resistance (drop saline into needle hub – negative epidural pressure draws saline in); make sure not to go intrathecally (no CSF is aspirated).
- percutaneous 8 contact electrode lead is advanced to desired level under live fluoroscopy.
- some experts insert 2 leads but that is rather difficult; some experts use percutaneous leads for permanent implantation– then need to insert second lead – usually from opposite side (sometimes, if difficult to steer lead, may insert second lead on same side parallel to first needle).
- stimulation - patient is reporting tingling area while surgeon moves lead until patient agrees with location.
- advance lead a little bit up than desired as lead tends to migrate caudally during needle withdrawal (withdraw needle while watching lead tip on live fluoro).
- tunnel lead subcutaneously using same Tuohy needle; secure lead to skin with few stitches, Tegaderm
  - St. Jude has wireless model – communicates with unit tapped to skin; patient adjusts stimulation using iPhone app.
  - some experts use ANCHORED ("BURIED") TRIAL if patient is highly likely to benefit from trial - make midline skin and subcutaneous tissue incision → secure lead to fascia; ***advantage*** – may leave permanently (***disadvantage*** – if patient does not like stimulation still needs to go to OR for lead retrieval; otherwise surgeon just can pull lead in office).
- before taking final XR (to be used for programming), ask patient flex and extend – leads always migrate caudally by 1-2 contacts (esp. obese patients):

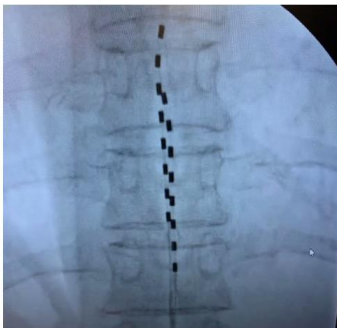
Pre-flexion

- Left lead tip at bottom of T7
- Right lead tip at top of T8



Post-flexion

- Left lead tip at T7/T8 disc space
- Right lead tip at mid-T8

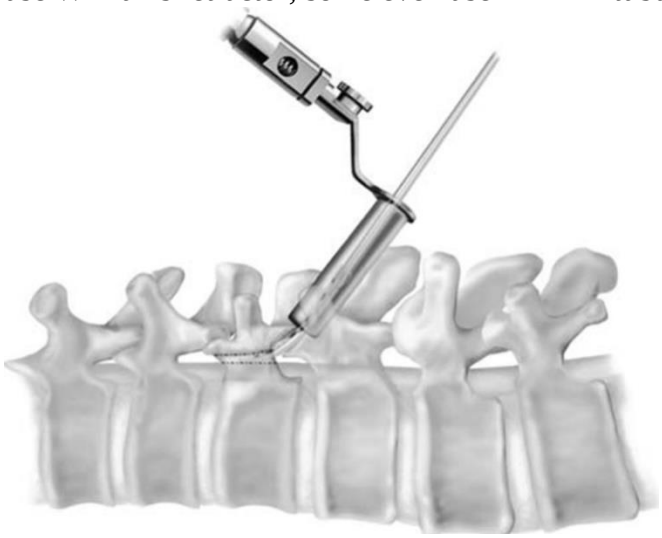


N.B. *stop blood thinners before trial hardware removal* - based on numerous series and case

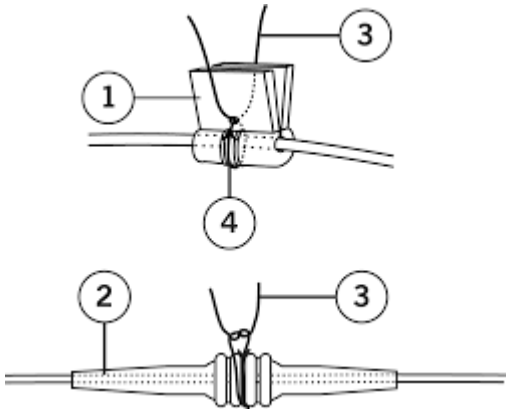
reports, placement and removal of SCS percutaneous leads in the presence of altered coagulation increases risk of epidural hematoma!

LAMINOTOMY PADDLE

- check MRI – make sure there is ≥ 3 mm anterior-posterior CSF cuff at intended level!
- anesthesia: general oral endotracheal.
- position: prone on chest rolls or radiolucent Wilson frame* with arms forward; if neck too extended, place head on horseshoe head holder.
  *Dr. Holloway thinks that Wilson frame makes paddle insertion more difficult.
- skin incision is really short.
- leave supraspinous ligament intact:
  1) serves as tension band
  2) will be used to suture anchors
- remove some of vertebral lamina (to make window for paddle insertion) – from inferior hemilaminotomy up to full laminectomy – extent dictated by patient anatomy and surgeon's choice.
- inferior hemilaminotomy – 1-2 levels below (e.g. if need paddle electrode to cover T9 vertebral body, perform inferior T10 hemilaminotomy – center incision around T10-11 disc space – best to check and measure on sagittal MRI knowing the length of paddle to be implanted and levels to cover from trial results).
  - use Williams retractor; some even use METRx tubular or Redmond retractors.



  - Nevro paddle always at T9-10, so plan T11 laminotomy (plan skin incision over T11-12 disc space); important - Nevro paddle is long (covers two full vertebral bodies) - try T12 laminotomy?
  - if stenosis at level of insertion, may insert retrogradely (hemilaminotomy 1-2 levels above target).
- optional: insert dummy paddle ("hockey stick") into dorsal epidural space (right on dura below epidural fat) and take XR → insert real paddle.
  N.B. if feel slightest resistance – STOP!
  - if trouble inserting, perform hemilaminotomy one level above (alternative - remove inferior part of spinous process and perform full inferior laminotomy; up to full laminectomy may be needed to expose intended paddle location, - in this case, some would secure paddle to dura with few dural stitches).
- stimulator leads are secured to edges of supra/interspinous ligament using special anchors and 2-0 silk (do not use polypropylene or monofilament suture because of possible damage to the anchor and lead)

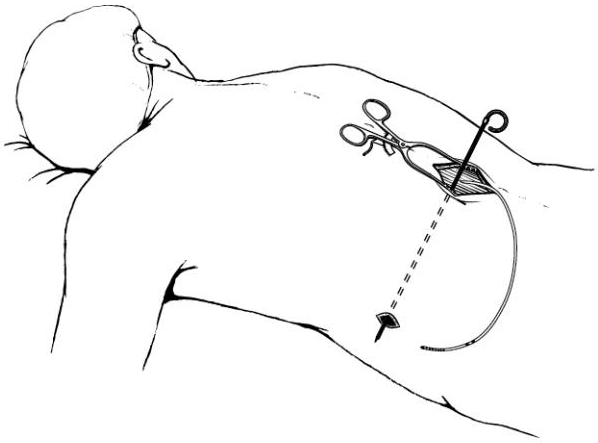


— Boston Scientific has anchors with screws to secure lead inside and special automatic suturing device (works well for small incisions).

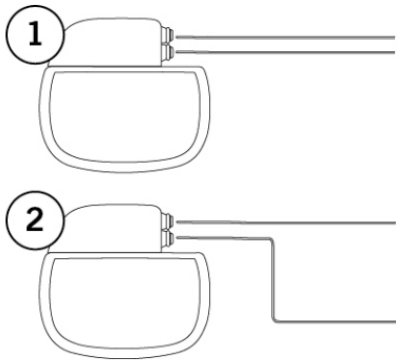
			
Mechanical Anchor	Click Anchor	Swift Lock	Twist Lock
Company	Boston Scientific	St. Jude Medical	Medtronic
FDA approved	2011	2010	1998
Material	Silicone	Hard Plastic	Hard Plastic
Ease of unlocking	+	+++	+
Damages lead	Not shown	Not shown	Shown by Kumar 2006
Cost	$375 a pair	$350 a pair	Included in lead kit

Credit: Reproduced with permission from Neurostimulation for the Treatment of Chronic Pain, Vol 1; 9781437722161

- leads are tunneled from spinal midline incision to generator pocket and connected to generator.



N.B. tunnel leads only after you coiled them in loop and secured anchors to fascia (hard to do that if leads already tunneled and twisted).
N.B. leads must be implanted adjacent to each other in the tunnel (nonadjacent leads have the possibility of creating a conduit for stray electromagnetic energy - theft detectors and metal screening devices - changes in perceived stimulation):



1. Correct
2. Incorrect

- connect to IPG
  N.B. exposure of the internal IPG contacts to body fluids or saline can cause corrosion and affect stimulation (if exposure occurs, clean the contacts with sterile deionized water or sterile water [not saline!] for irrigation and dry completely)
- generator is interrogated to make sure all impedances are within normal limits.
- generator is placed into pocket with leads folded underneath; secure generator in the position to the fascia with 2 anchoring stitches of 2-0 silk.
- fill incisions with vancomycin powder.
- do not use staples for skin - heats up with charging battery so reps delay turning on stimulation.

ELECTROPHYSIOLOGICAL ASSISTANCE

SSEP + EMG

Neurostimulation Appropriateness Consensus Committee (NACC) guidelines:
"***Confirmation of correct lead placement*** has been advocated with either **awake** intraoperative verbal confirmation of paresthesia coverage or use of neuromonitoring in **asleep** placement, such as EMG responses or SSEP collision testing."

- use implanted paddle contacts to stimulate at pulse width of 350 microseconds, frequency of 40 Hz, current gradually increasing from 1 to 5 mA.
- **SSEP** is monitored to find ***physiological midline of dorsal column*** – watch for SSEP response attenuation until complete flattening (current where clinical effect will be observed) – must be symmetric (or adjust paddle position left to right).
- further increasing current, watch for **EMG** changes (side effect*; current should be higher than for SSEP flattening).
  *but also can be used as SSEP substitute when registering CMAP in the myotomes corresponding to painful dermatomes

Nonawake vs Awake Placement of Spinal Cord Stimulators

Steven M Falowski, Ashwini Sharan, James McInerney, Darren Jacobs, Lalit Venkatesan, Filippo Agnesi. Nonawake vs Awake Placement of Spinal Cord Stimulators: A Prospective, Multicenter Study Comparing Safety and Efficacy. Neurosurgery, *Volume 84, Issue 1, January 2019, Pages 198–205*

- subjects were assigned to undergo asleep (n = 19) or awake (n = 11) SCS paddle implantations in a nonrandomized fashion.
- process for intraoperative programming differed between the groups: awake subjects participated by verbally reporting on pain-paresthesia overlap, while for asleep subjects, paresthesia location was inferred based on EMG monitoring.
- **operative time** was shorter for the asleep group (88.9 ± 51.2 min vs 125.2 ± 37.9; P = .018).

- at 6 wk postimplant, subjects in the asleep group had better **pain-paresthesia overlap** than the awake group (83.5% ± 19.8 coverage vs 46.6% ± 44.5; P = .05) and fewer **extraneous paresthesia** (16.7% ± 23.1 vs 71.2% ± 30.3; P < .001).
- both groups had equivalent **levels of pain relief** (more than 50%) after 6 and 24 wk of treatment.
- there were 2 **adverse events** in the asleep group compared to 6 in the awake group.

Asleep surgery becomes even more feasible with anatomical paddle placement paradigms where lateralization is even less important!

LAMINOTOMY PADDLE FOR TRIAL

- book two surgeries 7 days apart:
  1) implant paddle, connect to extension, externalize extension and connect it to external battery.
  2) either remove entire system or open incision, completely remove extensions (by pulling outwards) and implant internal battery (send cx, put vancomycin and tobramycin powder into wound).

BATTERY REPLACEMENT

- dead SCS battery (unable to test impedances) – may connect external extension and test impedances before opening new battery.

PADDLE EXPLANTATION

- most can be done as outpatient (careful with cervical SCS paddle removals!).
- some recommend using **IONM (SSEP and MEP)** to increase safety
- explant battery (IPG) first.
- careful using Bovie (even if IPG is explanted, it is still possible that monopolar electrocautery can conduct through the wires and should be used with caution).
- focus incision around the inferior point of the paddle.
- osseus overgrowth, scar formation, ligamentous hypertrophy are commonly encountered obstructing the paddle - ***may need laminotomy*** (at insertion level or above it).
- although rare, the lead can scar ventrally to the dura, necessitating complete exposure of the paddle for safe dissection off the dura.

  N.B. tension to remove the paddle without dissection can result in contacts that remain adhered to the scarred dura.

  N.B. certain paddle types are at risk for electrode contacts to disconnect during removal (may use fluoroscopy if in doubt).

SPECIAL SITUATIONS

EPIDURAL SCAR

- may insert ***retrograde*** (from above).
- may need ***skip laminotomies*** (leaving bars of lamina to keep paddle against the dura).

SPECIFIC PRODUCTS BY VENDORS

Cannot test impedances preop if battery is dead.
Normal impedances are < 2000.

	St. Jude Medical Protege	Medtronic Sensor SureScan	Boston Scientific Spectra	Nevro Senza
Number of Contacts	16	16	32	16
Independent Amplifiers	No	No	Yes	No
Positional Compensation	No	Yes	No	No
Device Warranty	7 yrs	5 yrs	5 yrs	5 yrs
High Frequency	1200*	1200	1200	10,000
MRI Compatability	Head/ Extremity	Brain/Body*	Brain*	Head/ Extremity

Dr. Ryder Gwinn

- ***independent amplifiers*** – each contact current can be adjusted individually – see Illumina 3D system (otherwise, all contacts get the same voltage and current depends on resistance at the particular contact)
- ***positional compensation***: Medtronic generators (RestoreSensor®) feel body position and may adjust stimulation parameters.
- ***warranty***: Boston Scientific maintains warranty for rechargeable batteries (price 30,000 USD) even if patient fails to charge properly.
- ***high frequency***: all companies have it (Nevro up to proprietary 10K); St. Jude has also "burst stimulation".

MEDTRONIC

GENERATORS

http://professional.medtronic.com/pt/neuro/scs/prod/index.htm#.UMmxkiBsLAQ

- some model have 1200 Hz (called "High output" regimen) – RestoreSensor, RestoreUltra

PrimeAdvanced (37702)
FDA Approval Date Jul 2006

Height	2.6 in (65 mm)
Width	1.9 in (49 mm)
Thickness	0.6 in (15 mm)
Volume	39 cc
Battery type	Non-Rechargeable
Expected Battery life	Depends on settings and use
Maximum Electrodes	16
Amplitude	0 - 10.5 V
Rate	2 - 130 Hz
Pulse Width	60 - 450 µsec
Groups	26
Programs	32
Implant Depth	≤ 4 cm

PrimeAdvanced SureScan MRI (97702)

FDA Approval Date Mar 2013

Height	2.6 in (65 mm)
Width	1.9 in (49 mm)
Thickness	0.6 in (15 mm)
Volume	39 cc
Battery type	Non-Rechargeable
Expected Battery life	Depends on settings and use
Maximum Electrodes	16
Amplitude	0 - 10.5 V
Rate	3 - 130 Hz
Pulse Width	60 - 450 µsec
Groups	26
Programs	32
Implant Depth	≤ 4 cm

RestoreSensor (37714)

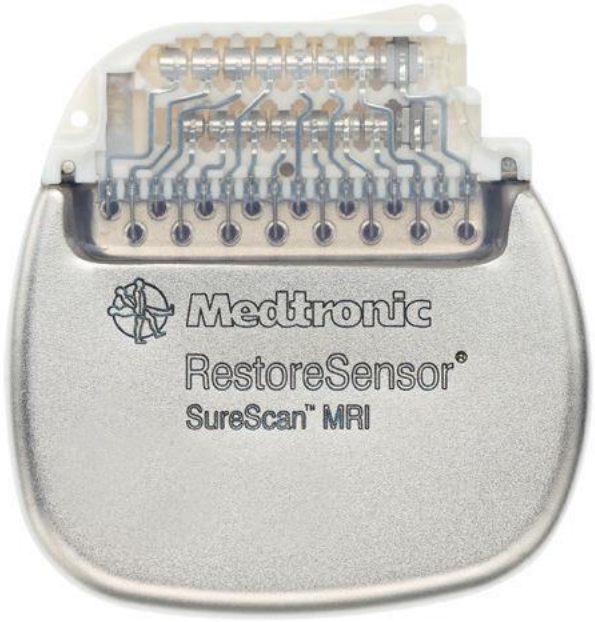
FDA Approval Date Nov 2011

Height	2.1 in (54 mm)
Width	2.1 in (54 mm)
Thickness	0.4 in (9 mm)
Volume	22 cc
Battery type	Rechargeable
Expected Battery life	9 years
Maximum Electrodes	16
Amplitude	0 - 10.5 V
Rate	2 - 1200 Hz
Pulse Width	60 - 1000 µsec
Groups	8
Programs	16
Implant Depth	≤ 1 cm

RestoreSensor SureScan MRI (97714)

FDA Approval Date Mar 2013

Height	54 mm (2.1 in)
Width	54 mm (2.1 in)
Thickness	9 mm (0.4 in)
Volume	22 cc
Battery type	Rechargeable
Expected Battery life	9 years
Maximum Electrodes	16
Amplitude	0 - 10.5 V
Rate	2 - 1200 Hz
Pulse Width	60 - 1000 msec
Groups	8
Programs	16
Implant Depth	≤ 1 cm



RestoreAdvanced (37713)
FDA Approval Date Jul 2006

Height	2.6 in (65 mm)
Width	1.9 in (49 mm)
Thickness	0.6 in (15 mm)
Volume	39 cc
Battery type	Rechargeable
Expected Battery life	9 years
Maximum Electrodes	16
Amplitude	0 - 10.5 V
Rate	2 - 130 Hz
Pulse Width	60 - 450 µsec
Groups	26
Programs	32
Implant Depth	≤ 1 cm

RestoreAdvanced SureScan MRI (97713)

FDA Approval Date Mar 2013

Height	2.6 in (65 mm)
Width	1.9 in (49 mm)
Thickness	0.6 in (15 mm)
Volume	39 cc
Battery type	Rechargeable
Expected Battery life	9 years
Maximum Electrodes	16
Amplitude	0 - 10.5 V
Rate	2 - 130 Hz
Pulse Width	60 - 450 µsec
Groups	26
Programs	32
Implant Depth	≤ 1 cm

Itrel 4 (37703)

FDA Approval Date May 2012

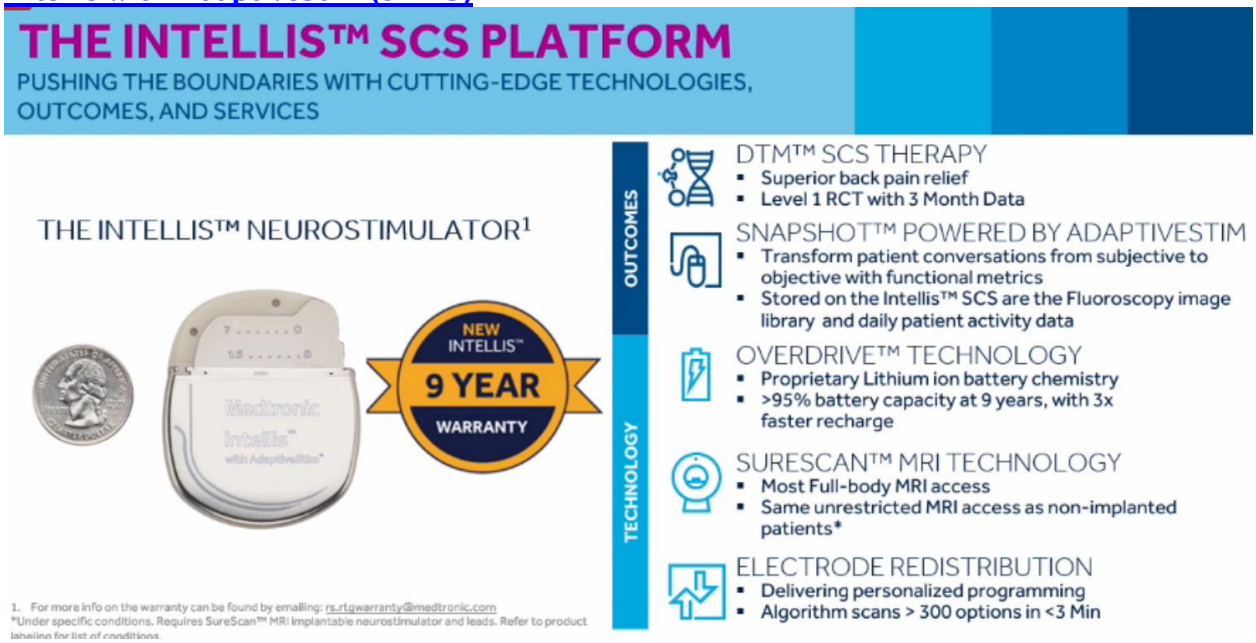
Height	2.2 in (55 mm)
Width	2.4 in (60 mm)
Thickness	0.4 in (11 mm)
Volume	28 cc
Battery type	Non-Rechargeable
Expected Battery life	Depends on settings and use
Maximum Electrodes	4
Amplitude	0 - 10.5 V
Rate	2 - 130 Hz
Pulse Width	60 - 450 µsec
Groups	1
Programs	1
Implant Depth	≤ 4 cm

RestoreUltra SureScan MRI (97712)

FDA Approval Date Mar 2013

Height	2.1 in (54 mm)
Width	2.1 in (54 mm)
Thickness	0.4 in (10 mm)
Volume	22 cc
Battery type	Rechargeable
Expected Battery life	9 years
Maximum Electrodes	16
Amplitude	0 - 10.5 V
Rate	2 - 1200 Hz
Pulse Width	60 - 1000 µsec
Groups	8
Programs	16
Implant Depth	≤ 1 cm

Intellis with AdaptiveStim (97715)



PADDLES

http://professional.medtronic.com/pt/neuro/scs/prod/index.htm#.UMmxkiBsLAQ

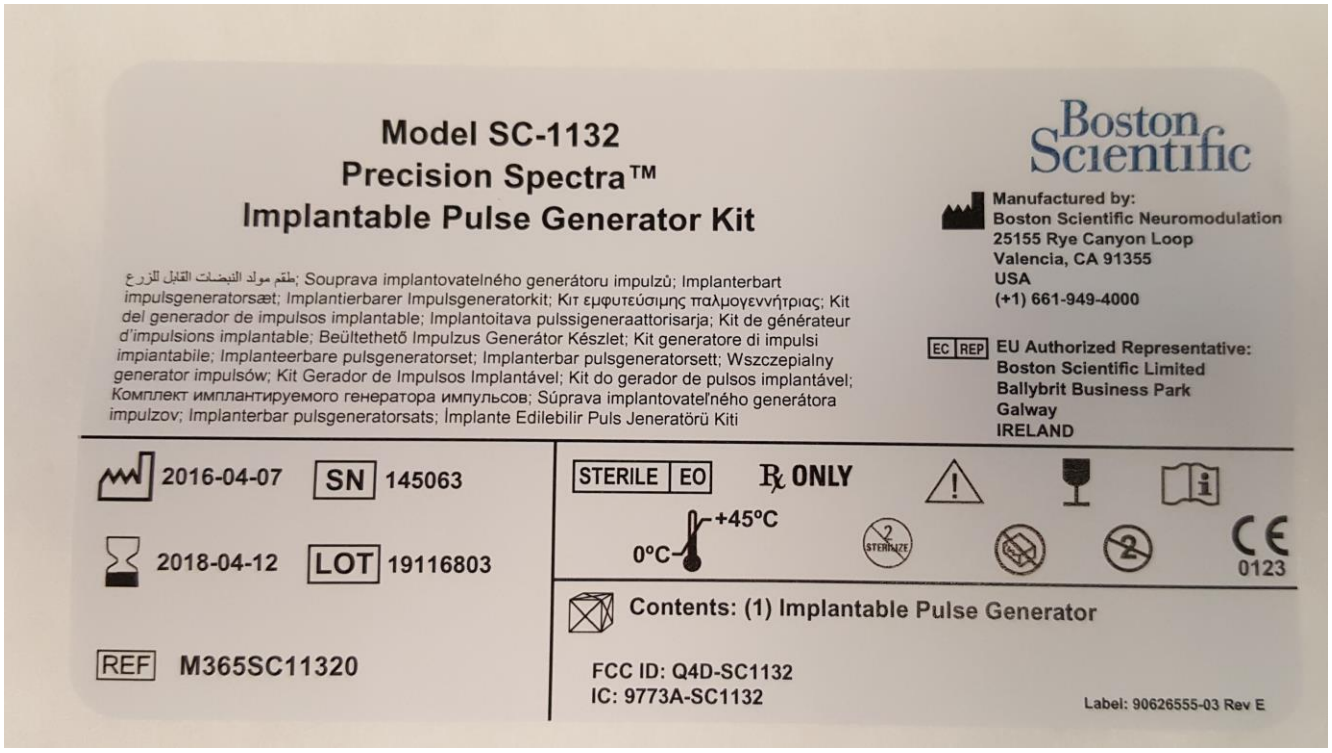
Specify (model 3998)

[Specify 5-6-5 (model 39565), Specify 2x8 (model 39286)]

Device Name	Specify 5-6-5
Lead Type	**Surgical**
Lead	
Length (cm)	30, 65
Diameter (mm)	1.3
Electrode	
Number	16
Shape	Rectangular
Length (mm)	4.0
Width (mm)	1.5
Individual Surface Area (mm)	6.0
Longitudinal Spacing: Edge to Edge (mm)	4.5
Lateral Spacing: Edge to Edge (mm)	1.0
Array Length (mm)	49.0
Array Width (mm)	7.5
Paddle	
Length (mm)	64.2
Width (mm)	10.0
Thickness (mm)	7.5

BOSTON SCIENTIFIC

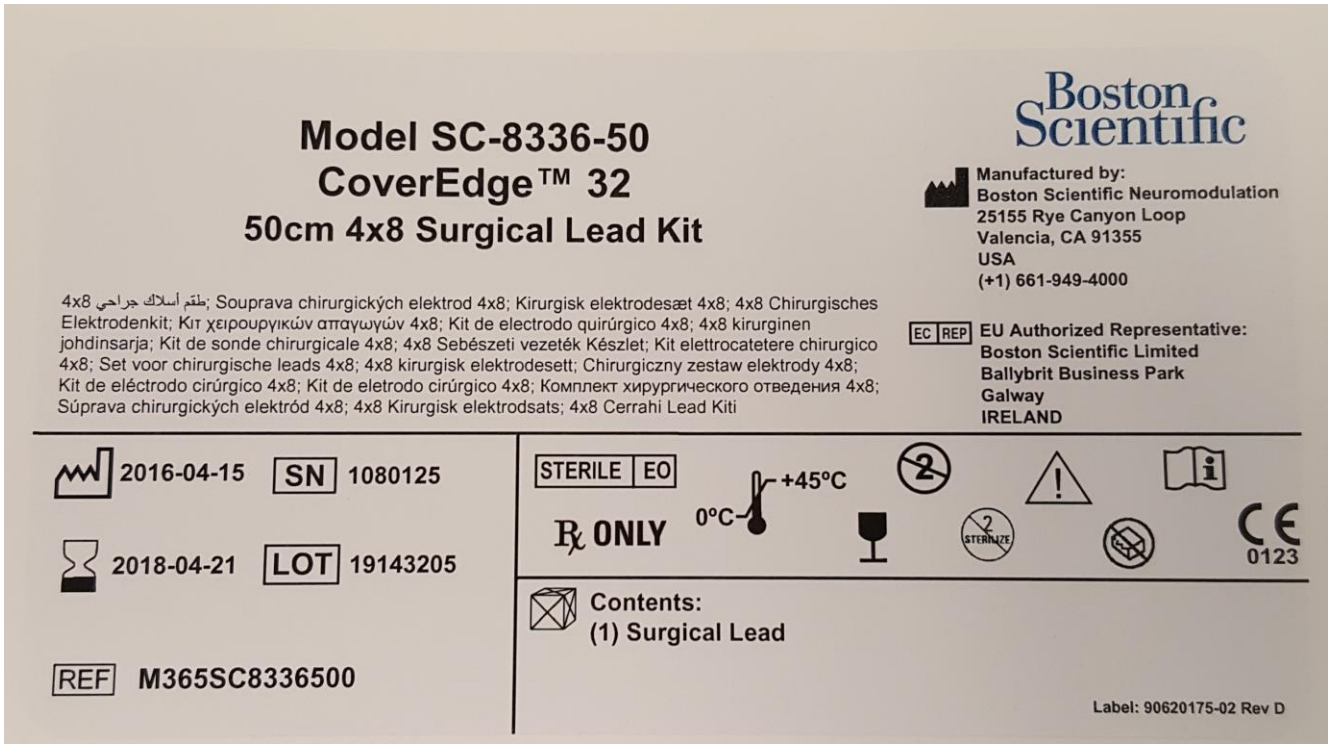
GENERATORS



WaveWriter Alpha™ SCS system and Fast-Acting Sub-perception Therapy (FAST™) – uses Surround Inhibition paradigm. see above >>

- full-body MRI-conditional portfolio.

PADDLES



Boston Scientific paddle has four leads!

ABBOTT (ex ST. JUDE)

Surgery mode – avoids interference with Bovie.

GENERATORS

<u>Nonrechargeable</u>

Proclaim 7 (model 3662), **Proclaim 5**; full body MRI compatible

- can stimulate between perc leads (distance ≤ 6 mm)

Proclaim XR - lasts up to 10 years at low-dose settings (0.6 mA, 500 Ohms, duty cycle 30s on/360s off)

- upgradeable technology that can deliver the latest advancements via software updates

Rechargeable of two types:

Protégé - no MRI

Protégé MRI - can have head and extremities MRI (not full body)

- rechargeables can go deepest - 2.25 cm deep.
- burst can go with nonrechargeable e.g. Proclaim.
- burst adjustments - can go up or down on amplitude (if overstim - pt feels tiredness as after marathon); cannot adjust frequency or pulse width.

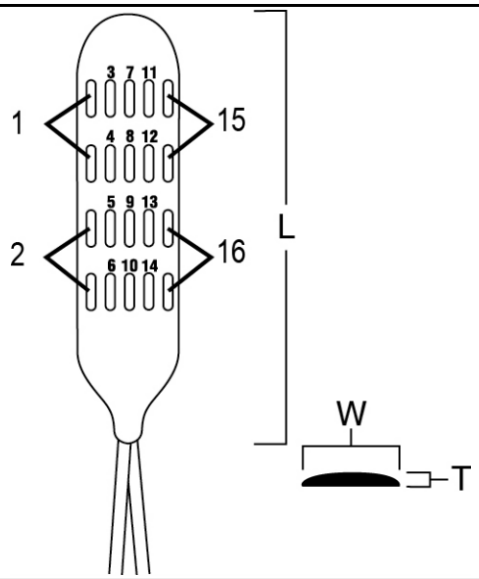
PADDLES

N.B. dummy paddle does not have a stiff handle to help navigate and open epidural space (so no real need to use dummy).

Component	Material
Electrodes and terminal end contacts	Platinum iridium
Paddle	Silicone
Insulation	Polycarbonate polyurethane
Lead blank	Silicone with 20% barium sulfate

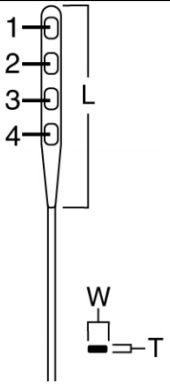
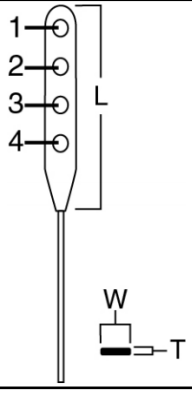
Penta

- only MRI conditional lead!
- 5x8 electrode paddle with two leads.
- paddle size 46x11x2 mm (25 mm electrode array length).

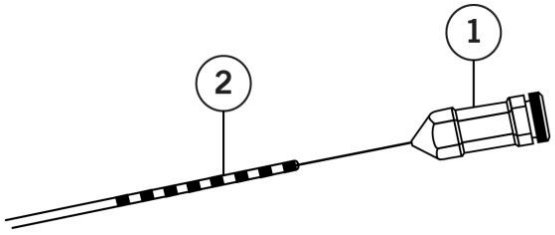
Description		Penta, 3 mm
Electrodes are shown facing down (anteriorly)		
Lead length and model	60 cm	3228
Lead diameter		1.4 mm
Electrodes		
Number		16
Configuration		5 columns of 4
Length		4 mm
Width		1 mm
Longitudinal spacing		3 mm
Lateral spacing		1 mm
Array length		25 mm
Array width		9 mm
Paddles		
Length (L, includes taper)		46 mm
Width (W)		11 mm
Thickness (T)		2 mm
Lead resistance (for all lengths)		< 10 ohms
Differentiation band signifies		Electrodes 1–8
MRI status*		
MR Conditional	Model	3228

* The butterfly anchor (Model 1105) and long anchor (Model 1106), which are included in the lead kit, are MR Conditional components.

Lamitrode S-4, Lamitrode 4

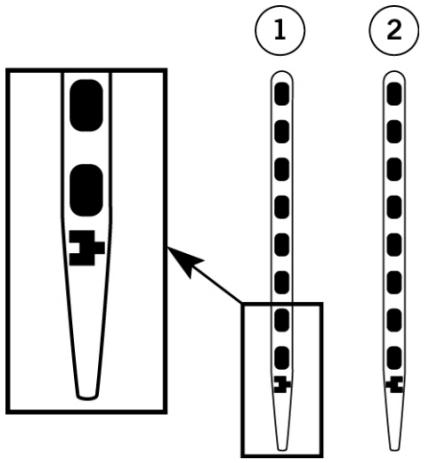
Description		Lamitrode S-4	Lamitrode 4
			
Lead length and model	30 cm	3243	—
	60 cm	3246	3240
	90 cm	3266	—
Lead diameter		1.4 mm	1.4 mm
Electrodes			
Number		4	4
Configuration		1 column of 4	1 column of 4
Length		4 mm	4 mm
Width		2.5 mm	4 mm
Longitudinal spacing		3 mm	6 mm
Array length		25 mm	35 mm
Array width		2.5 mm	4 mm
Paddles			
Length (L, includes taper)		39 mm	51 mm
Width (W)		4 mm	8 mm
Thickness (T)		1.8 mm	1.7 mm
Lead resistance (for all lengths)		< 10 ohms	< 10 ohms
MRI status		All models listed in this table are untested for MRI.	

- slimline design for enhanced maneuverability.
- S-4s feature **removable stylets** (straight and curved) that provide added stiffness to facilitate steering and control during lead placement.



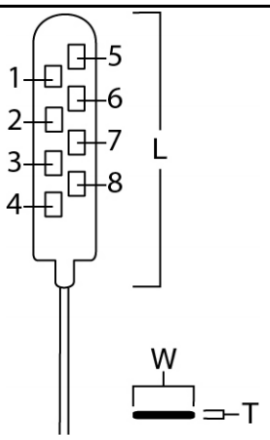
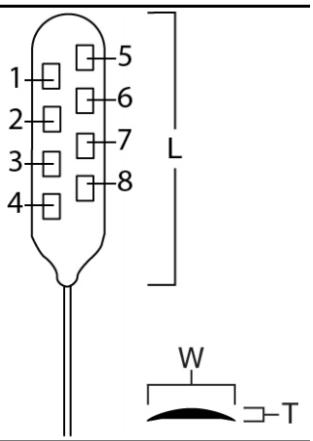
1. Stylet
2. Terminal end of lead

- feature an **indicator** that shows which direction the electrodes are facing. An anterior-posterior (AP) fluoroscopic view will allow you to see the directional indicator (see the following figure). If the indicator is pointing to the right in the AP view, the electrodes are facing anteriorly (toward the dura). If the indicator is pointing to the left, the electrodes are facing posteriorly (away from the dura):



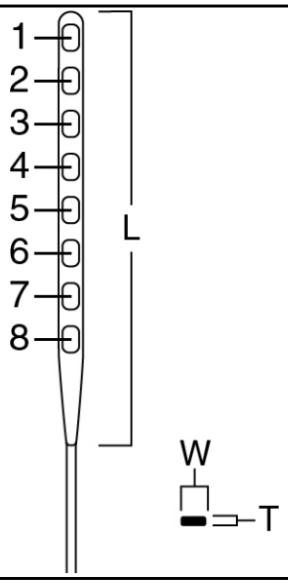
1. Anterior-facing electrodes (correct)
2. Posterior-facing electrodes (incorrect)

Lamitrode 44 and 44C

Description		Lamitrode 44	Lamitrode 44C
Electrodes are shown facing down (anteriorly)			
Lead length and model	60 cm	3244	3245
	90 cm	3262	—

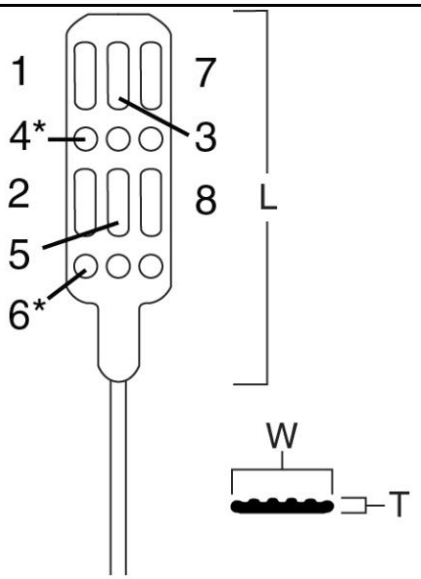
Lead diameter	1.4 mm	1.4 mm
Electrodes		
Number	8	8
Configuration	2 offset columns of 4	2 offset columns of 4
Length	4 mm	4 mm
Width	2.5 mm	2.5 mm
Longitudinal spacing	3 mm	3 mm
Lateral spacing	1 mm	2 mm
Array length	28 mm	28 mm
Array width	6 mm	7 mm
Paddles		
Length (L, includes taper)	51 mm	51 mm
Width (W)	10 mm	13 mm
Thickness (T)	1.7 mm	2 mm tapering to 0.4 mm
Lead resistance (for all lengths)	< 10 ohms	< 10 ohms
MRI status	All models listed in this table are untested for MRI.	

Lamitrode S-8

Description		Lamitrode S-8
		
Lead length and model	30 cm	3283
	60 cm	3286
	90 cm	3268

Lead diameter	1.4 mm
Electrodes	
Number	8
Configuration	1 column of 8
Length	4 mm
Width	2.5 mm
Longitudinal spacing	3 mm
Array length	53 mm
Array width	2.5 mm
Paddles	
Length (L, includes taper)	67 mm
Width (W)	4 mm
Thickness (T)	1.8 mm
Lead resistance (for all lengths)	< 10 ohms
MRI status	All models listed in this table are untested for MRI.

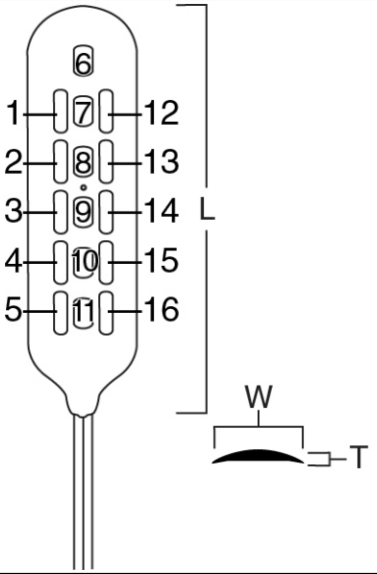
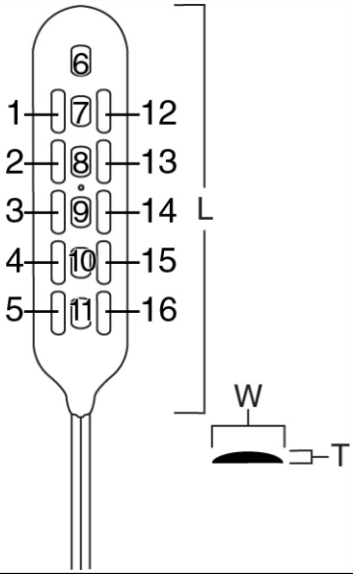
Lamitrode Exclaim – reports of difficulty with programming

Description	Exclaim
Electrodes are shown facing down (anteriorly)	
Lead length and model	60 cm 3224

* Electrode number includes all three button electrodes

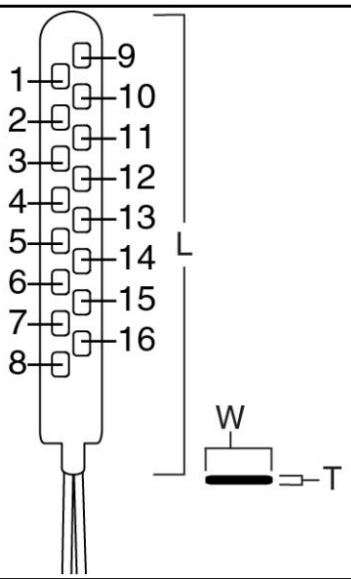
Lead diameter	1.4 mm
Electrodes	
Number	8
Configuration	3 columns with rows that alternate between rectangular and button electrodes
Length	Rectangular: 5.8 mm Button: 2.2 mm (diameter)
Width	Rectangular: 1.8 mm
Longitudinal spacing	1.6 mm
Lateral spacing	1 mm
Array length	21 mm
Array width	8 mm
Paddles	
Length (L, includes taper)	33 mm
Width (W)	9.5 mm
Thickness (T)	2 mm
Lead resistance (for all lengths)	< 10 ohms
MRI status	All models listed in this table are untested for MRI.

Lamitrode Tripole 16C and 16

Description		Tripole 16C	Tripole 16
Electrodes are shown facing down (anteriorly)			
Lead length and model	60 cm	3214	3219

Lead diameter	1.4 mm	1.4 mm
Electrodes		
Number	16	16
Configuration	1 center column with 2 offset columns on either side	1 center column with 2 offset columns on either side
Length	Center column: 4 mm Outer column: 6 mm	Center column: 4 mm Outer column: 6 mm
Width	Center column: 2.5 mm Outer column: 1.8 mm	Center column: 2.5 mm Outer column: 1.8 mm
Longitudinal spacing	Center column: 3 mm Outer column: 1 mm	Center column: 3 mm Outer column: 1 mm
Lateral spacing	1 mm	1 mm
Array length	40 mm	40 mm
Array width	8 mm	8 mm
Paddles		
Length (L, includes taper)	57 mm	57 mm
Width (W)	13 mm	10 mm
Thickness (T)	2 mm tapering to 0.4 mm	2 mm tapering to 0.4 mm
Lead resistance (for all lengths)	< 10 ohms	< 10 ohms
Differentiation band signifies	Not available	Electrodes 1–8
MRI status	All models listed in this table are untested for MRI.	

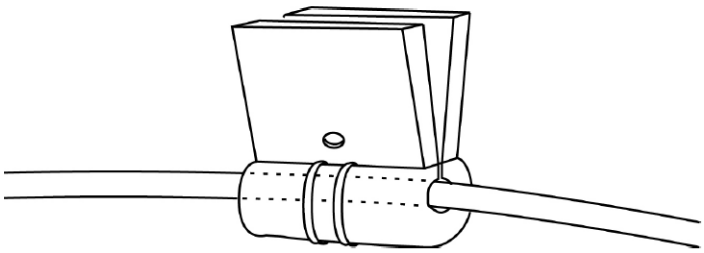
Lamitrode 88

Description		Lamitrode 88
Electrodes are shown facing down (anteriorly)		
Lead length and model	60 cm	3288

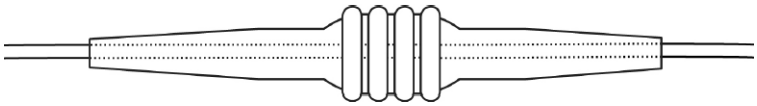
Lead diameter	1.4 mm
Electrodes	
Number	16
Configuration	2 offset columns of 8
Length	4 mm
Width	2.5 mm
Longitudinal spacing	3 mm
Lateral spacing	1 mm
Array length	56 mm
Array width	6 mm
Paddles	
Length (L, includes taper)	79 mm
Width (W)	10 mm
Thickness (T)	1.7 mm
Lead resistance (for all lengths)	< 5 ohms
Differentiation band signifies	Not available
MRI status	All models listed in this table are untested for MRI.

ANCHORS

Butterfly anchor



Long anchor



Nevro (SENZA systems)

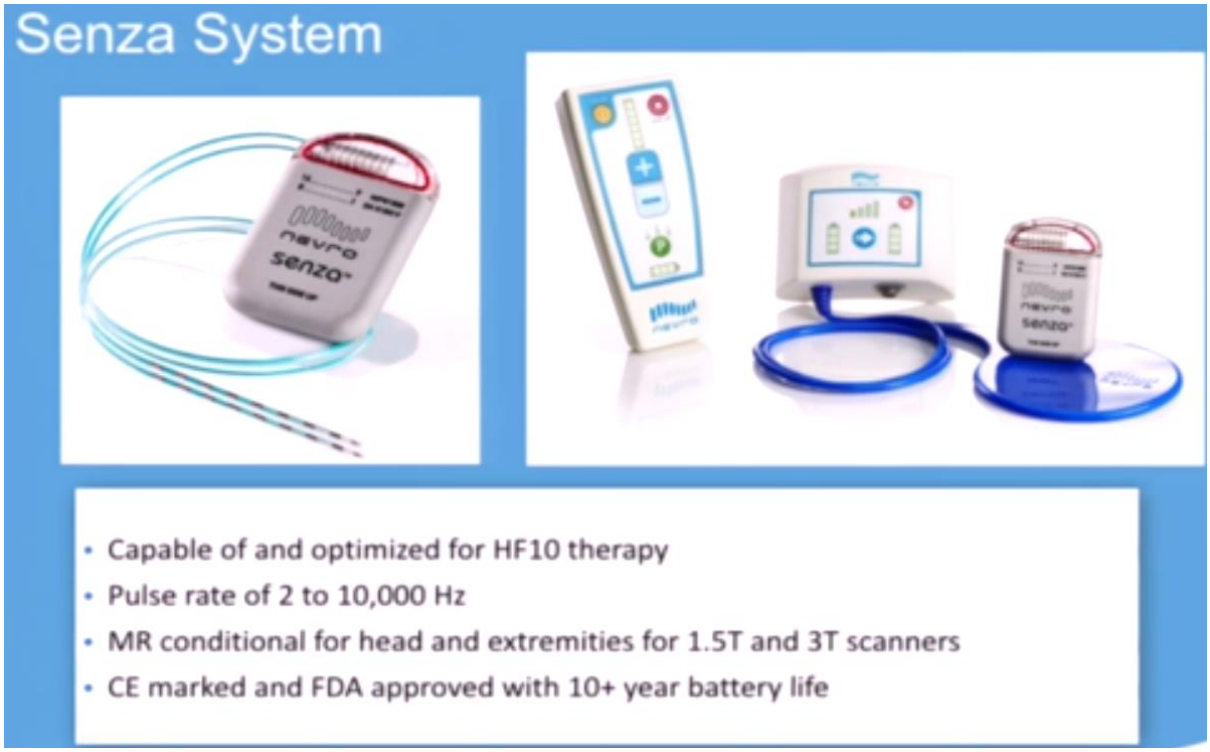
Uses HF10K paradigm – see above >>

1. Charge coil in IPG header permits safe, rapid charging without additional heating
2. IPG
3. Leads
4. Anchor

System type	Constant current
Frequency (Hz)	10,000
Maximum number of electrodes	16
MRI compatibility with percutaneous leads	1.5T and 3T; head and extremity
MRI compatibility with surgical leads	1.5T and 3T; head and extremity
Device battery life at 10 kHz (years)	10+
Average daily charging time (minutes)	45
Battery overdischarge protection	Yes
RF wireless range (inches)	60

- overstimulation makes legs feel tired (like after running marathon).

GENERATORS



- implantable pulse generator (Model Nos: NIPG1000 or NIPG1500)

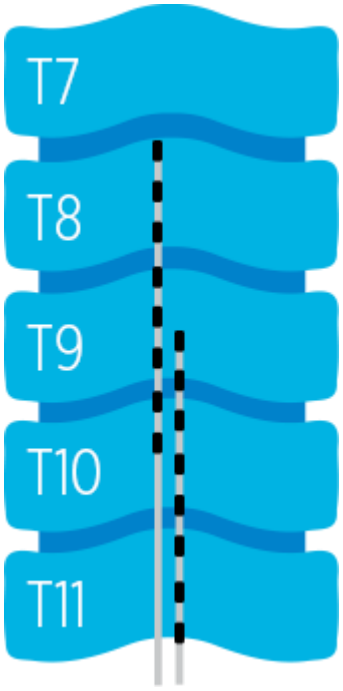
Senza II™ - FDA approved 2018-01-08
- smaller footprint IPG

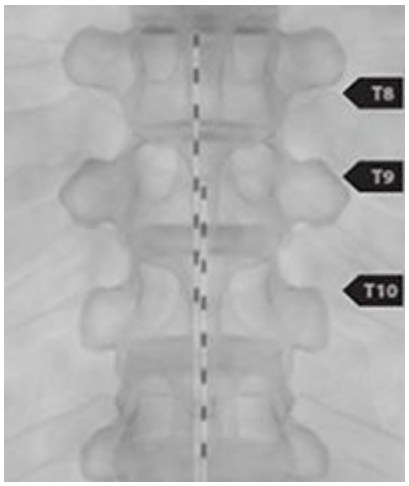
Senza Omnia™ - expanded versatility to remotely optimize patients with a data-driven programming approach informed by outcomes across 70k+ patients in HFX Cloud™

PERCUTANEOUS LEADS

percutaneous leads (Model No.: LEAD10x8-xxB)
surgical lead (LEAD3005-xx(B), LEAD3015-xx(B), LEAD3025-xx(B))
lead extensions (Model No.: LEAD2008-xxB)
lead anchors (Model No.: ACCK5xxx)
IPG Port plug (ACCK7000)

Anatomic lead placement - leads positioned consistently for all lower back and leg pain patients (no awake surgery for paresthesia mapping):





Lead Placement

Two leads are implanted as close to anatomical midline as possible

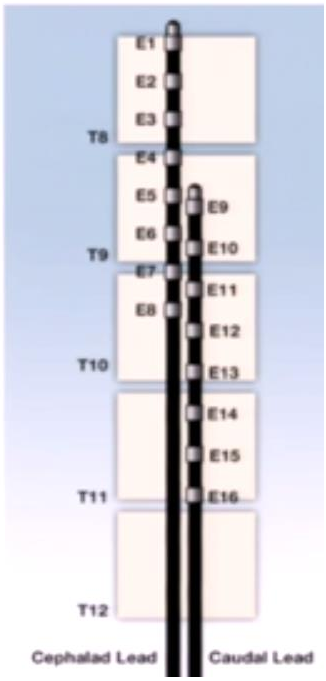
- ✓ Cephalad lead (top lead) is placed at Top of T8
- ✓ Caudal lead (bottom lead) is placed at Mid T9

Leads are implanted so contacts are staggered

- ✓ Double coverage over T9/10 disk space

Two leads to cover more vertebral space

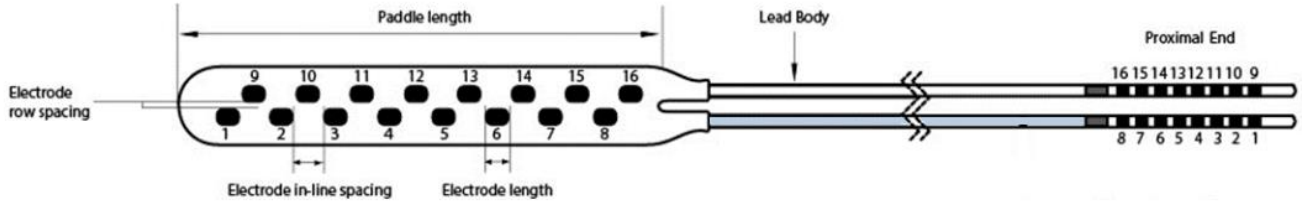
- ✓ More programming possibilities to account for patient variability



PADDLE

Surpass™ Surgical Lead

Nevro paddle is long - covers two levels so do T11 inferior laminotomy (paddle enters at inferior endplate of T11); T12 inferior laminotomy might be too much (but may consider PRN tunneling wires retrogradely to exit from underneath T12 lamina)!



One proximal leg is blue in color with connections to electrodes 1-8, while the other proximal leg is clear with connections to electrodes 9- 16.

Description	Model LEAD3005-xx*(B)	Model LEAD3015-xx*(B)	Model LEAD3025-xx*(B)
Connector	Octapolar, in-line	Octapolar, in-line	Octapolar, in-line
Shape	Contoured	Contoured	Contoured
Conductor resistance	<18 Ω	<18 Ω	<18 Ω
Length (includes paddle)	30 to 90 cm	30 to 90 cm	30 to 90 cm
Lead body diameter	1.3 mm	1.3 mm	1.3 mm
Distal end			
Number of electrodes	16	16	16
Electrode shape	Rectangular	Rectangular	Rectangular
Electrode size (width x length)	1.25 mm x 3.0 mm	1.25 mm x 3.0 mm	1.25 mm x 3.0 mm
Electrode stimulating area	6.75 mm²	6.75 mm²	6.75 mm²
Electrode span	57.4 mm	64.6 mm	71.9 mm
Electrode spacing (edge to edge)			
in-line spacing	4.25 mm	4.25 mm	4.25 mm
row spacing	1.0 mm	1.0 mm	1.0 mm
Paddle length	64 mm	71 mm	79 mm
Paddle width	10 mm	10 mm	10 mm
Paddle thickness	2.0 mm	2.0 mm	2.0 mm

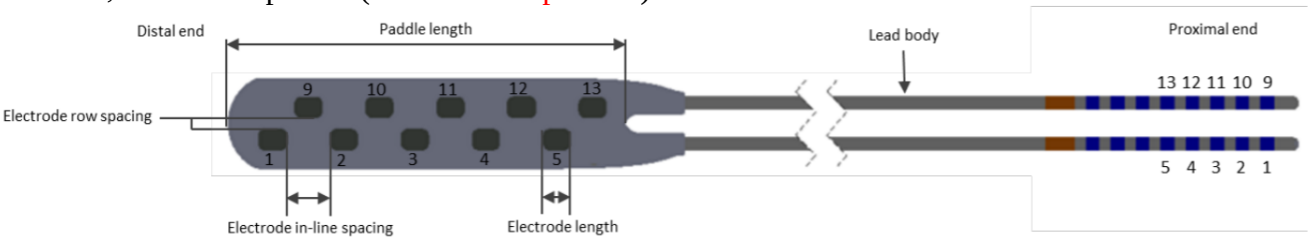
* xx represents the overall lead length

List of tissue contacting materials

Component	Material
Lead	
Electrodes	Platinum-iridium
Electrode paddle	Silicone rubber
Insulation	Polyurethane
Proximal connector	MP35N
Lead Anchors	Silicone rubber

Surpass-C™ Surgical Lead

- smaller, 10-contact paddle (not MRI compatible!)



Description	Model LEAD2005-xx*(B)
Connector	Octapolar, in-line
Shape	Contoured
Conductor resistance	<18 Ω
Length (includes paddle)	30 to 90 cm
Lead body diameter	1.3 mm
Distal end	
Number of electrodes	10
Electrode shape	Rectangular
Electrode size (width x length)	1.25 mm x 3.0 mm
Electrode stimulating area	6.75 mm²
Electrode span	35.6 mm
Electrode spacing (edge to edge)	
in-line spacing	4.25 mm
row spacing	1.0 mm
Paddle length	40.4 mm
Paddle width	9.0 mm
Paddle thickness	1.8 mm

* xx represents the overall lead length 30-90cm.
[a] All measurements represent nominal values

List of tissue contacting materials

Component	Material
Lead	
Electrodes	Platinum-iridium
Electrode paddle	Silicone rubber
Insulation	Polyurethane
Lead Anchors	Silicone rubber

STIMWAVE (FREEDOM-4 SCS SYSTEM)

http://www.stimwave.com/

- externally worn power source to power device.

SALUDA MEDICAL (EVOKE SCS SYSTEM)

- consists of a rechargeable external closed-loop stimulator (eCLS), implantable closed-loop stimulator (CLS), two 12-contact percutaneous leads.

NUVECTRA (ALGOVITA system)

Company filed for bankruptcy in October 2019

- some reports that Abbott batteries may work with Nuvectra leads (recommendation to do externalization trial first to see if different paradigm is helping; may also consider rechargeable IPG to have paresthesia mapping opportunity). Boston Scientific batteries do not accept Nuvectra leads.

- rechargeable IPG with 24 independent current sources.

- wireless Pocket Programmer, a color icon-based charging system, and on-screen battery status indicators.

POSTOP

- discharge home 4-6 hours* postop (some patients stay overnight as they are on chronic opioids and pain control is an issue).

*observation time for spinal epidural hematoma / cord ischemia (some experts keep overnight for this reason)

DRESSING, BATHING, REGIMEN

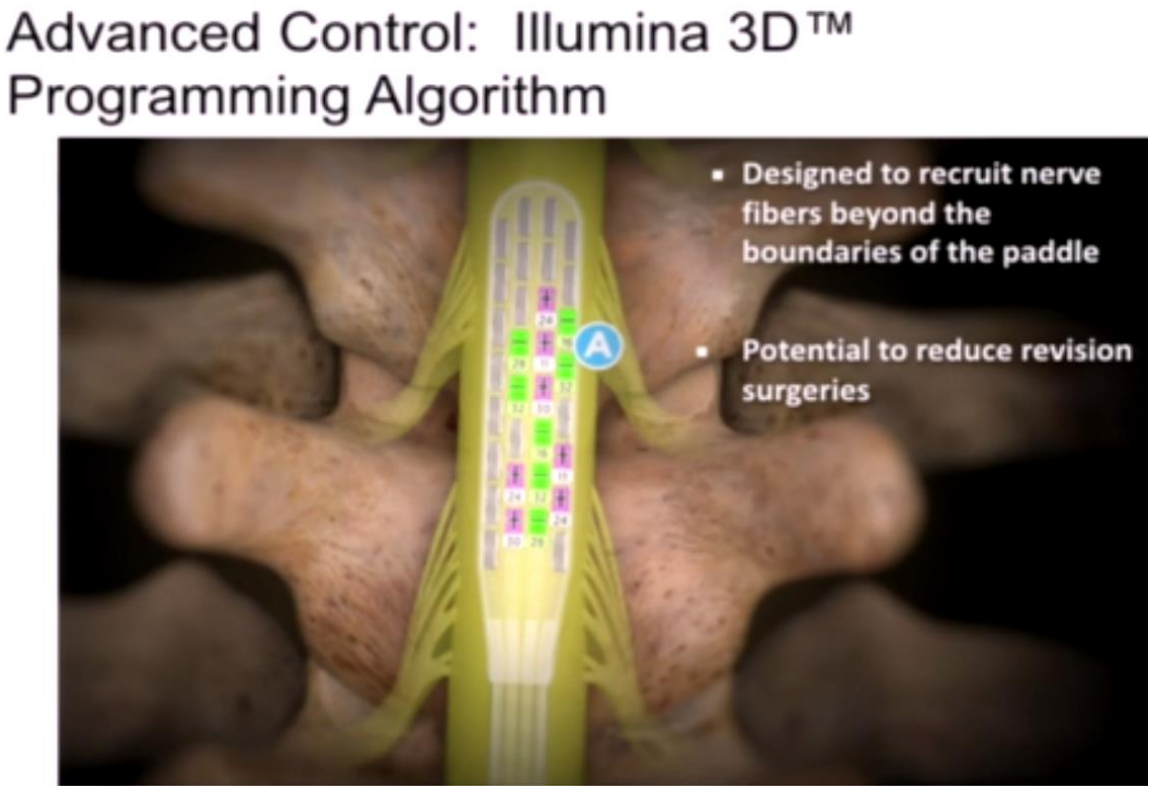
- if Tegaderm covers incision – let patients shower any time; remove Tegaderm on POD3; no immersing wounds for 6 weeks (or until completely healed).
- aggressive bending, twisting, or lifting weights should be avoided especially during the first 6 weeks post implant.
- no diving deeper than 10 m.

PROGRAMMING

Medial contacts – for axial pain.

- contact mapping is done in PACU.
- stimulation is turned on at 2 weeks when surgical pain has subsided (vs. after battery replacement surgery – stimulation is turned on in OR or in PACU); some experts turn on device on POD2.
- weeks of testing (various pulse widths, frequencies, amplitudes) before successful stimulation parameters are established.
- SCS can produce at least 50% pain relief (i.e. success) in 50-60% patients, and reduce use of more medications; with proper follow-up care, these results can be maintained.
- change in paresthesia corresponding to change in posture is normal and seldom causes a problem.

Boston Scientific has advanced programming – e.g. allows to surround cathode by anodes – limits unpleasant lateral current spread into roots:



FAILED STIMULATION

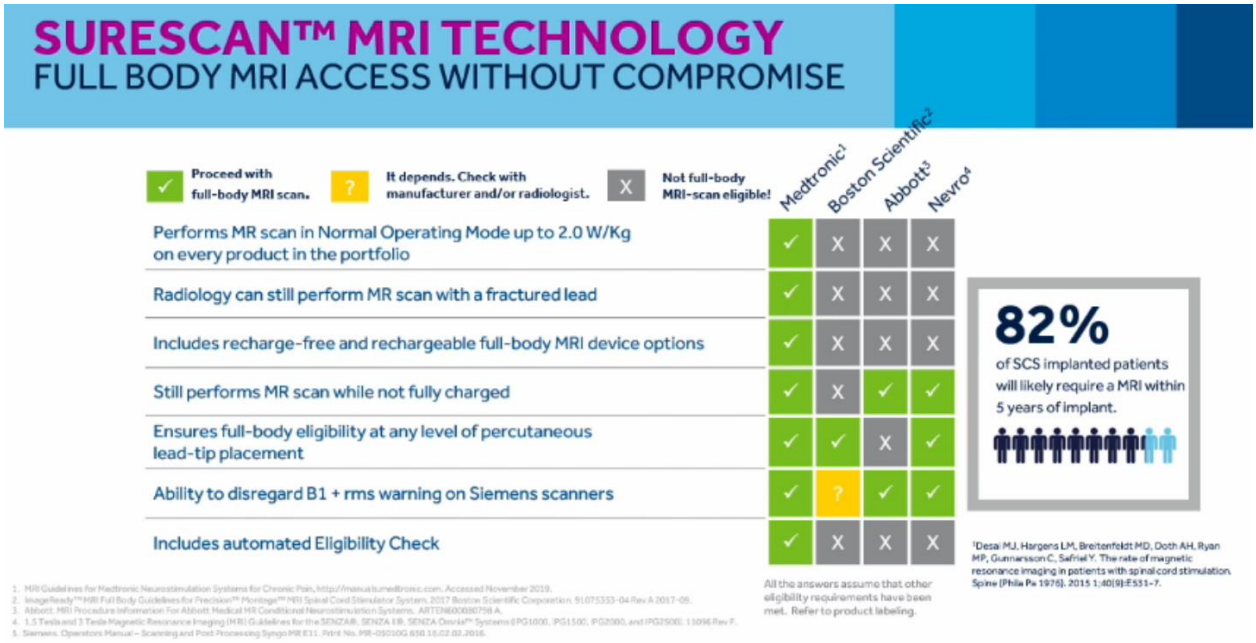
Check if paresthesias are covering the pain area:

a) **yes** - the patient is nonresponder.
b) **no** - the error of selecting incorrect implantation level - worth considering revision surgery.

20-25% explant rate over a 5-yr period.

MRI-compatibility

All manufacturers make systems with at least head MRI compatibility: also see above >>
No abandoned leads (no battery) are compatible with MRI – risk of spinal cord damage with induced electrical currents!



Medtronic systems that have:

1) **stimulators** with "SureScan™ MRI" logo (e.g. RestoreAdvanced, RestoreUltra, RestoreSensor, PrimeAdvanced)
2) **lead** with "Vectris®" logo
3) **anchors** with "Injex®" logo

- are MRI compatible to 1.5T

Boston Scientific – only head MRI (plus, paddle has to be bellow T6).

Nevro: battery and leads are compatible with full body MRI (important to turn off device before MRI and check impedances).
No abandoned leads (no battery) are compatible with MRI.
Battery without leads is OK for MRI.

Abbott
Nonrechargeable Proclaim: full body MRI compatible
No abandoned leads (no battery) are compatible with MRI.
Rechargeable of two types:
Protégé - no MRI
Protégé MRI - can have head and extremities MRI (not full body)

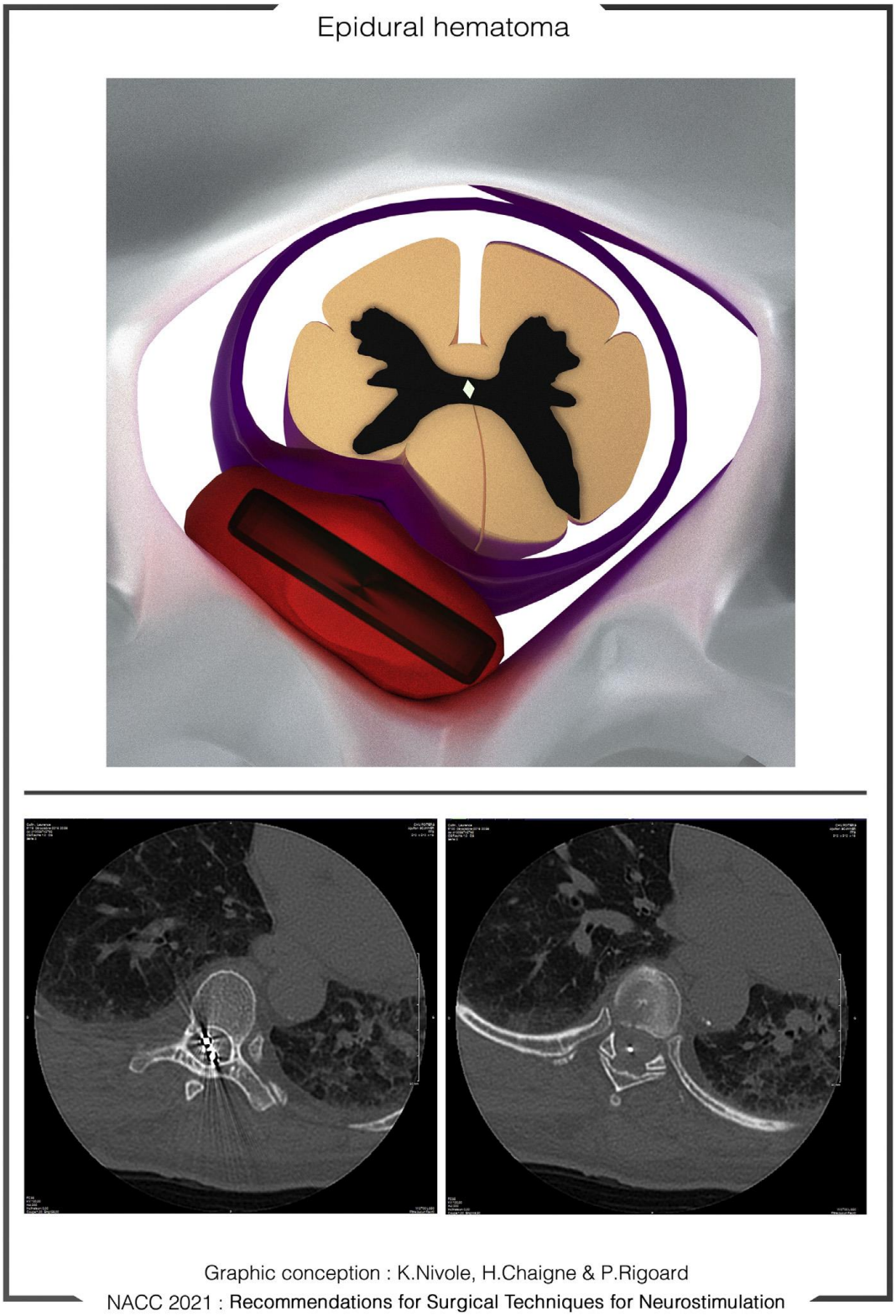
COMPLICATIONS, ADVERSE EFFECTS

- up to one-third of patients will experience a complication, the vast majority of which are minor.
- severe neurologic complications, including paralysis, occur in < 1%.
- complications occurring within the first 3 months are surgery related – infection, seroma and hematoma.
- complications occurring after 3 months are usually technical (hardware failure).

1) **epidural hematoma**, **spinal cord compression** with paralysis, weakness, clumsiness, numbness, or pain below the level of the implant
    - incidence of SCI: 2.35% for percutaneous leads and 1.71% for paddle leads.

N.B. spinal cord dysfunction may manifest hours after procedure – due to cord ischemia, epidural hematoma – rationale for postop observation (6 hours, up to overnight)

2) **infection** (2.45%) – see detailed recommendations by NACC p. Op120 >>
3) cerebrospinal fluid (CSF) leakage
4) skin erosion
5) persistent pain at the electrode site or IPG site
6) stimulation in unwanted places (such as radicular stimulation of the chest wall – esp. if paddle sits asymmetrically)
7) allergic or rejection response to implant materials
8) hardware failure with undesirable changes in stimulation - paddle migration (6-13%), lead fracture (1-9%), high impedance (2.8%), generator malfunction (3-6%) and early battery failure (1-2%)



SPINAL CORD (DORSAL COLUMN) STIMULATORS - CERVICAL

- may want burst (St. Jude) or HF10 (Nevro) so patient won't have paresthesias in hands.
- anatomical location:
    a) anatomical midline
    b) within intervertebral foramen (cervical dorsal root ganglion stimulation).
    c) far lateral (trigeminal tract, nucleus caudalis) - to treat headache and facial pain.

- spinal cord is closest to the posterior dura between C3 to C7.
- relatively small spinal canal and epidural space compensate for increased cervical range of movement - rates of lead movement and migration are similar to SCS leads in other areas.

CONTRAINDICATIONS

- previous laminectomies – dorsal epidural space scarring (may try levels above, including retrograde C1-2 technique).
- canal stenosis - not an absolute contraindication – can be resolved with decompression.

PREOP IMAGING

- MRI (or CT-myelogram).
- no current imaging technique can give useful information about the presence of epidural fibrosis.

PERCUTANEOUS TRIAL

- pt awake, prone on radiolucent horseshoe for head
- pillows for torso
- arms side by side
- try fluoro before draping - AP and lateral.
- sedate.
- prep and drape.
- clip one mosquito clamp on the left side of neck (for side orientation on images).
- fluoro AP to check entry points (e.g. L1-2).
- local anesthetic.
- Tuohy or curved tipped Coudé needle with glass syringe at 30 degrees, paramedian.
- advance lead on AP fluoro.

    N.B. use lead with steering tip guidewire!

- when at C3-4 check with lateral fluoro for dorsal position (final positions usually are C2-6).
- leave guidewire in and start the second wire (should be easier as it follows path of first lead).
- leads should stagger to get better sup-inf coverage.
- pull guidewires.
- test for paresthesias - make sure able to cover painful area completely.
- sedate patient.
- place purse strings Nylon 2-0

- pull Tuohy needle while monitoring contacts under AP fluoro.
- tie roman sandal nylon around leads.
- final X-ray and print images (keep hard copies in my folder)
- BioPatch, Tegaderms
- connect external battery
- battery goes into pouch and gets sealed and glued to body
- phase 2 recovery
- Percocet 30 tabs
- trial duration is 3-10 days.
- cervical leads have been reported to have higher migration rates (than thoracic leads).

PERMANENT IMPLANT

- consider intraoperative **neuromonitoring** if operating under general anesthesia.
- on chest rolls.
- pin the head → **neck flexed** to open interlaminar spaces and eliminate cervical lordosis.
- arms tucked at sides.
- may leave more generous strain relief loop.
- it is advisable to place the lead and paddle at C1-C3 to avoid cord compression (paddle needs additional clearance to allow for flexion and extension of the neck).

Retrograde suboccipital approach (via C1-2 interspace)

- minimal to no bone removal.
- option for patients who are likely to benefit from high cervical paddle electrode placement.
- elevated risk of revisions or removal, mainly due to high impedances and positional changes.

IPG site

- upper limit outside of the range of motion of the scapula.
- lower limit below the belt line.
- usually – flank area.
- tunneling to the anterior chest wall over the trapezius has also been described.

SPECIFIC VENDORS

ABBOTT

- paddles for cervical placement: Penta

DORSAL ROOT GANGLION STIMULATION

ACCURATE trial

- dorsal root ganglion stimulation is a neuromodulation therapy used for chronic neuropathic pain.
- typically, patients are awakened intraoperatively to confirm adequate dorsal placement.
- neuromonitoring can be used in an asleep patient to assure proper positioning of the dorsal root ganglion electrode in the dorsal foramen by generating somatosensory evoked potential responses in the absence of electromyogram responses.

- entry – 2 levels below of target neuroforamen.

S. JUDE

Axium™ Neurostimulator System

CERVICAL

- cervical DRG trial is recommended only after failure of SCS trial.
- in cervical spine, transverse processes form a bony canal through which the DRG is positioned, outside of the spinal canal. The vertebral artery bisects this canal through the transverse foramen, ventral to the DRG. As such, the semirigid introducer sheath should not be advanced beyond the medial pedicular border because entering the bony canal raises the risk of vascular injury. The canal and nerve slope ventrolaterally, and thus lead position in the lateral fluoroscopic view may be ventral to the posterior vertebral border. In addition, a review of preoperative imaging is required given the space-occupying sheath. Cervical DRG-S should be avoided in cases of moderate to severe stenosis caudad to the target foramen.

Intrathecal (Drug Delivery) Pumps, s. Targeted Drug Delivery

- implanted, programmable pump and catheter release prescribed amounts of medication directly into the intrathecal space (bypassing BBB) = lower doses, minimized systemic side effects, no risk of drug misuse.

CONTRAINDICATIONS

1) infection (meningitis, ventriculitis, skin infection, bacteremia, and septicemia)
2) insufficient body size
3) spinal anomalies
4) drugs with preservatives, drug formulations with pH ≤ 3
5) general CI to surgery (such as coagulopathy).

PREOP

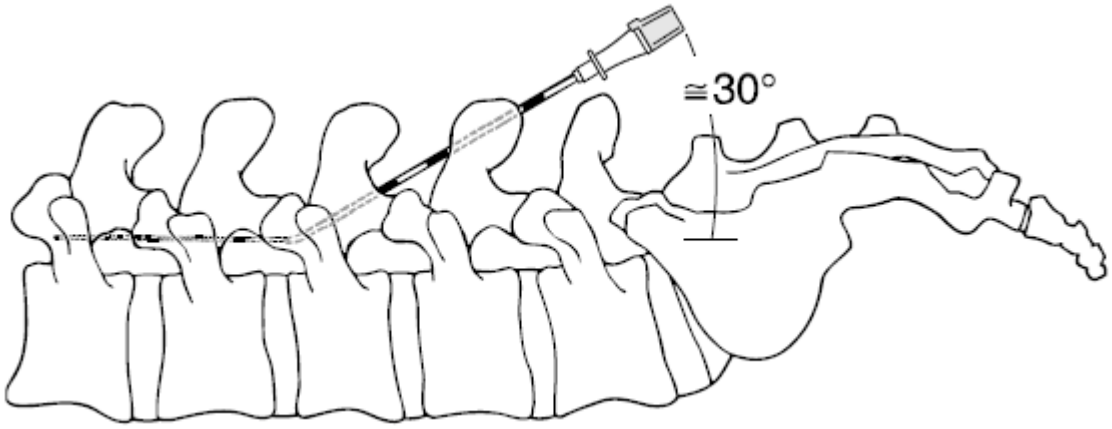
- stop anticoagulants / antiplatelets preop
- choose ***pump implantation side*** with the patient (right side is most common, esp. if anticipate G-tube need).
- prophylactic **antibiotic**
- general anesthesia is preferable.
- C-arm fluoroscopy.

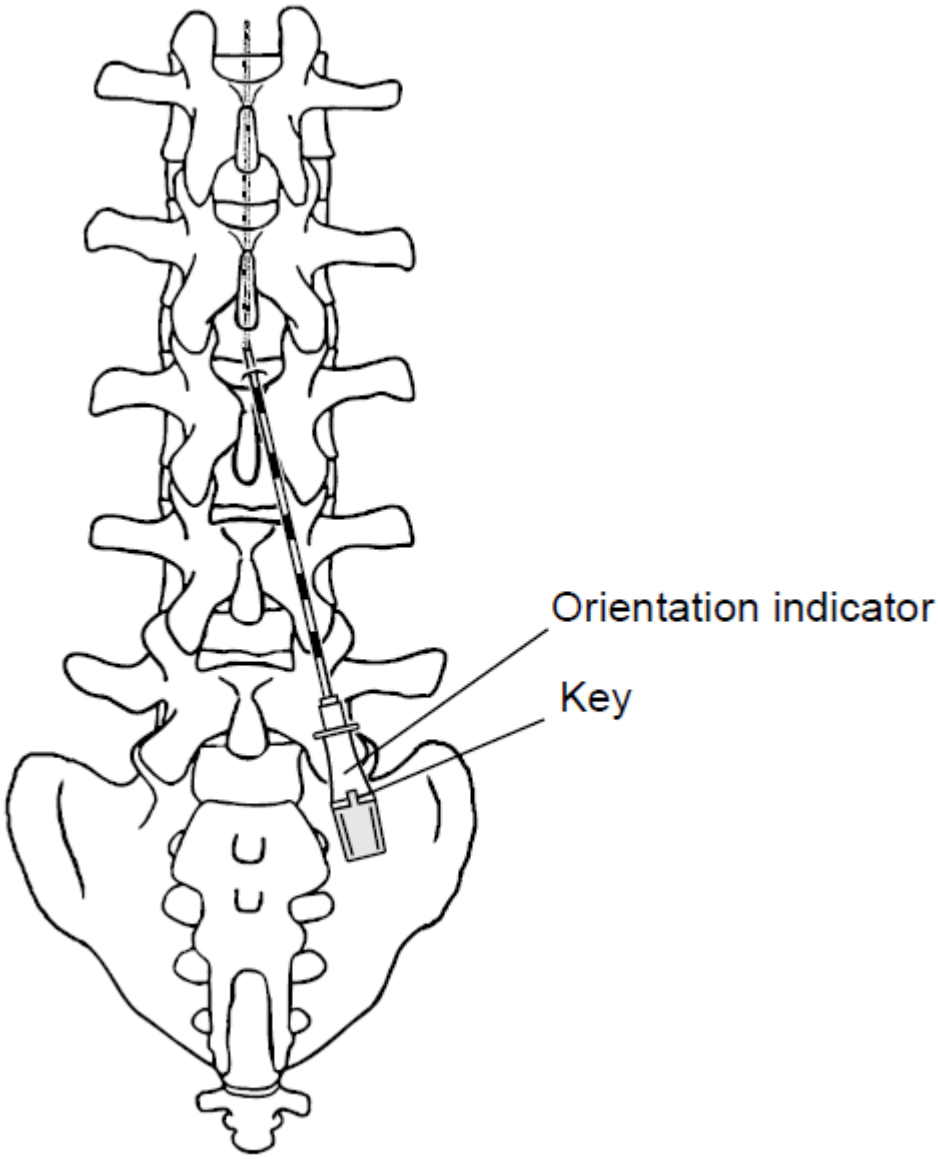
NEW SYSTEM IMPLANTATION

LUMBAR PORTION

Caution: If catheter must be retracted during positioning, *do not withdraw catheter through introducer Tuohy needle* - needle tip can damage catheter, requiring additional surgery to repair or replace catheter. Withdraw needle and catheter together. Then, carefully retract catheter from introducer needle. Begin procedure again.

- patient in lateral decubitus position on bean bag.
- use radiolucent spine table (flat top) – so fluoroscopy is easy to navigate (consider rotating the table in the way that is easy for fluoroscopy to go in from the patient's back side, otherwise arms get in the way).
- intrathecal catheter is inserted at mid-lumbar region: midline skin incision over L4-5.
- lowest catheter complication rate - **paramedian oblique approach** - insert needle into intrathecal space at shallow angle (approximately equal to 30-45°) - entry point of Tuohy needle into skin (or fascia, if needle insertion is performed through open incision) should be parallel to vertebral lamina, approximately 1 to 1.5 vertebral levels below interlaminar space selected for dural puncture and 1-2 cm lateral to midline on side of intended pump pocket:





- needle is introduced with the bevel parallel to the axis of the spine and therefore to the dural fibers; when the needle enters into the lumbar cistern, it is rotated so that the opening is directed cephalad.
- ***catheter is advanced under fluoroscopy*** (!!!) to lower thoracic spine;
    - receptors for back pain are at Th9-10
    - receptors for spasticity are at T10-11 for patients with spastic diplegia and C7-T4 for those with spastic quadriparesis;
    - catheter has to be dorsal to spinal cord! (in case needed to treat granuloma)
      N.B. consensus is to place catheter tip as close to pain level as possible to minimize drug dilution!
- place 2-0 silk purse string stitch on thoracolumbar fascia around catheter while needle is still in place (this way won't damage catheter).
- needle is backed off; withdraw stylet from catheter.
  N.B. catheter is vaguely radiopaque so it is visible as long as metal stylet is in (if need to see the catheter after stylet is out – inject undiluted Omnipaque into catheter using 24G needle; some experts always inject Omnipaque to verify intrathecal position)
  N.B. use fluoroscopy in **subtraction mode** (otherwise, hard to see Omnipaque cloud coming out catheter tip!)

ABDOMINAL PORTION

- abdominal* incision – horizontal subcostal – make sure pump will not be *rubbing against ribs or pelvic bone* (at least 2-3 fingerbreadths below the rib margin); make sure incision will not be above access ports.

  *infraclavicular region is an alternative site
- minimum of 20 cm away from another programmable device to minimize telemetry interference and incorrect or incomplete programming.
- pump must be placed at a depth of **no more than 2.5 cm beneath the skin**
- pump is placed on fascia (or subfascially in most children and thin patients).
- contour tunneler to patient's flank shape and tunnel subcutaneously from abdomen towards lumbar area (occasionally need one interim incision); most commonly tunneler exits at lumbar incision too close to skin surface so keep it in mind while guiding tunneler.
- place anchoring tabs on the catheter and tunnel catheter towards the abdomen.

Pump is primed (to displace factory water filling in reservoir with drug solution) on Mayo stand.

— ***aspirate all fluid from the new pump*** (until air bubbles no longer appear in the syringe); may need more than one syringe – pull needle out with each syringe (never disconnect syringe from inserted needle - negative pressure will suck air into pump; if that happens, will need to aspirate it).

— some sterile water remains, so you may rinse reservoir with drug solution to increase drug concentration:

Pump reservoir capacity	Filling without rinsing	Rinsing with 3 mL of drug	Rinsing with 10 mL of drug
8637-20	93%	98%	99%
8637-40	97%	99%	100%

— inject drug solution full volume into pump.

— 0.14 or 0.3 mL of internal pump tubing remains unfilled - possible actions:

a) prime internal tubing on the table ("back table prime" s. "pre-implant pump prime") - takes 12-19 mins wait time but is safer; program pump to bolus intrathecal catheter (it happens inside the patient).

b) aspirate intrathecal catheter completely (so it fills with CSF), connect pump to catheter – program pump to bolus both internal tubing and intrathecal catheter - it all happens inside the patient so no wait time in OR.

— Medtronic recommends ***monitoring patients*** after any priming bolus procedure:

a) **opioids**: monitor with pulse oximetry for a minimum of 24 hours

b) **baclofen**: monitor for a minimum of 8 hours or until they demonstrate stable neurological, respiratory and cardiac function.

c) **ziconotide**: there are no labeling guidelines (published guidance recommends an overnight admission).

- connect catheter by leaving strain-relief coil in lumbar incision
- test connector points for integrity:
  - — see if can aspirate CSF from catheter access port
  - — then attempt to inject CSF back while rubber-shod clamp is placed distally on catheter (watch for any leaks).
- implant pump with refill "nipple" facing towards midline (e.g. at "3 o'clock" if implanting on the right side); place 1-2 anchoring stitches to the fascia with 2-0 silk.

  N.B. keep the refill port within 2.5 cm of the skin surface
  - — in obese patients, the subcutaneous tissue superficial to the pocket may be too thick, requiring resection of a layer of fat - this maneuver is preferable to making the pocket more superficial to begin with because the pump cannot be reliably anchored to subcutaneous fat to prevent flipping.
- any excess catheter is looped beneath the pump, so that it is not punctured or lacerated during pump refills.

PUMP ACCESS NEEDLES

- currently available Medtronic pumps accept only a 24 gauge needle in the **catheter access port**, whereas **refills** should only be done with a 22 gauge noncoring needle – although this prevents direct injection refill drug into the catheter (and subarachnoid space), injection into the pump pocket is still possible.
- for catheter access, do not use < 10 mL syringes.

Pocket fill - the improper injection into the subcutaneous tissue, which includes the pump pocket, during a pump access procedure.

- can result in significant tissue damage, drug underdose or overdose.

PUMP REPLACEMENT

- do not flush old IT catheter – it will give high medication bolus IT; rather aspirate old IT catheter (either using catheter access port with 24G needle or attaching tuberculin 1 mL syringe [without needle] to the disconnected catheter tip).
- if pump is ERI and was just refilled, aspirate drug from old pump and inject into new pump (saves expensive drug).
- pump priming – *see above >>*
- restart at previous rate (long term maintenance rates for baclofen range 12-2003 µg/d)

N.B. pump does not detect catheter occlusion; so if patient has signs of drug withdrawal (with otherwise normally working pump) / increasing requirement for drug lately - do catheter dye study preop.

- if electively replacing pump and unable to aspirate from catheter + no fluid in pocket + no signs of drug withdrawal (or withdrawal due to dead pump or stalled pump motor) → assume "dry intrathecal space" and leave catheter unrevised; prime pump on the table → postop monitor for continuous withdrawal (if yes, take back to replace catheter).
- if able to aspirate only part of catheter (i.e. not a full volume of catheter), prime pump on the table → postop monitor for continuous withdrawal until the segment of catheter gets refilled with medication (one can calculate how many hours it will take = how long to observe the patient).

Elective pump replacement – disconnect pump and watch catheter:

a) fluid is passively dripping → ***aspirate*** catheter → implant pump and ***prime pump in vivo***.
b) no fluid is coming out → ***prime pump on table*** → implant pump (this saves from admission in the case if only part of catheter can be aspirated. i.e. rather spend < 20 mins in OR priming on the table than admitting the patient for observation).

CATHETER DYE STUDY

Indications – suspected catheter occlusion (pump does not detect catheter occlusion):

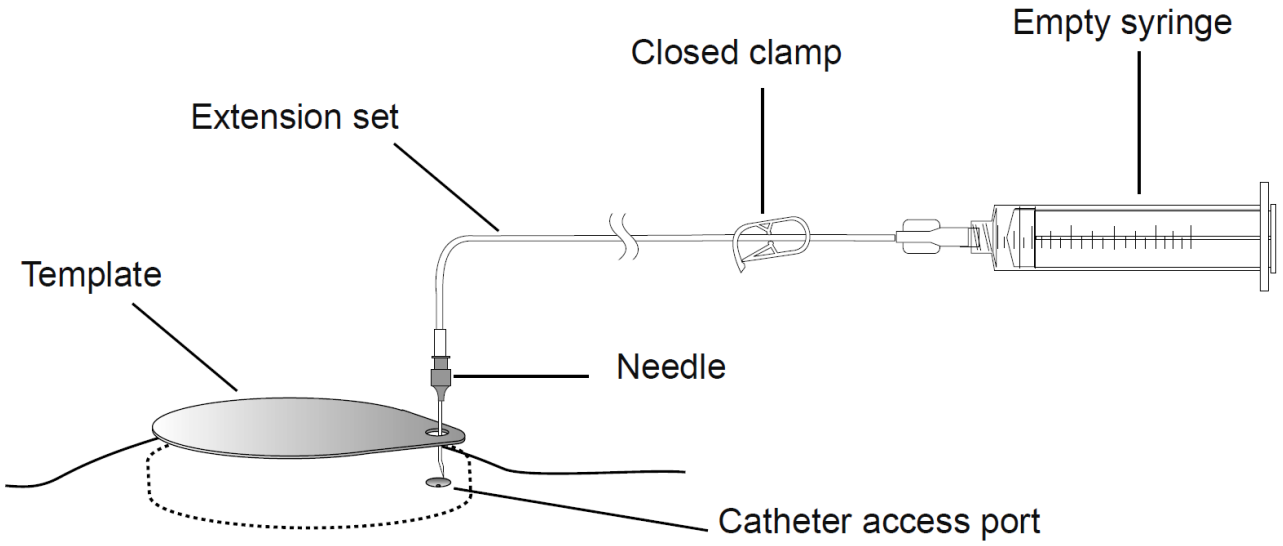
a) patient has signs of drug withdrawal
b) patient has been on steady dosing for years and then increasing requirement for drug lately (maybe partial catheter obstruction and not getting full drug dose; tolerance for baclofen is uncommon).

- otherwise, dye study before routine replacement is not needed (although some people would do if it is ≥ 3rd pump replacement - to verify that old catheter is still intact) - if it is positive or negative,

still would do just pump replacement (if unable to aspirate from catheter, it might has been just "dry" thecal space - implant new pump and watch patient for baclofen withdrawal symptoms).

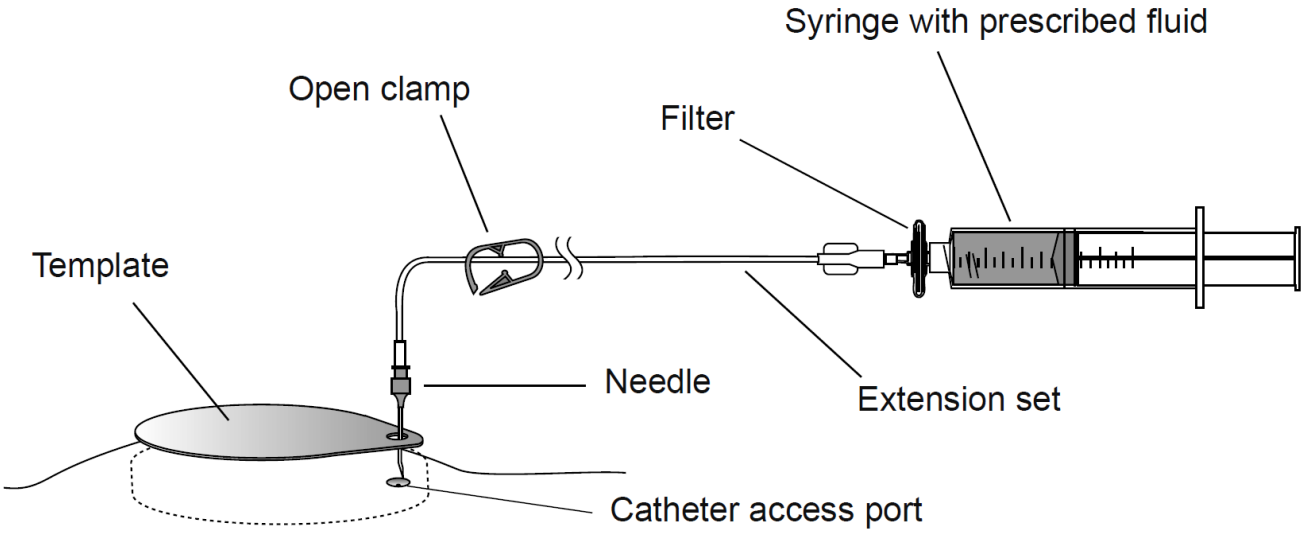
Technique

- ***access***: close the clamp and insert the needle into the catheter access port:



- ***aspirate***:
  a) if cannot aspirate from catheter → post for catheter replacement
  b) if can aspirate, then aspirate full catheter volume (recommendation is to aspirate 1-2 mL) → proceed with dye injection to verify catheter integrity and intrathecal delivery.
- ***injection****:
  - close clamp
  - replace aspiration syringe with Omnipaque syringe (always use a bacterial-retentive 0.22 micron filter when injecting through the catheter access port)
  - open clamp and inject at max 5 mL/min.

  *N.B. never inject before aspirating catheter volume or else will bolus medication!!! (i.e. if cannot aspirate, then cannot do dye study).



  - after injection may flush catheter with preservative-free saline.
  - if catheter was found intact, program to prime catheter to resume drug delivery.

SYSTEM EXPLANTATION DUE TO INFECTION

- start antibiotics and titrate IT baclofen rate down slowly (e.g. decrease daily rate in half over the next few days) – explant when ready – this way minimizes chances of baclofen withdrawal (cf. sudden explantation).

COMPLICATIONS

Hardware erosion
Catheter occlusion (3.62%)
Catheter dislodgement from intrathecal space (3.26%)
Catheter break/cut (2.32%)
Catheter kink (1.72%)

Infection (3%); usually requires removal of the hardware, although intrathecal antibiotics delivered by pump can sometimes successfully treat an infection of CSF.

CSF leaks – treatment: bed rest, epidural blood patch at the catheter entry site, insertion of lumbar drain, or rarely, open exploration and insertion of a purse-string suture and fibrin glue around the catheter exit site.

Overinfusion (0.12%)

Drug Overinfusion – Emergency Procedure:
1) for opioids: 0.4-2.0 mg NALOXONE IV; repeat PRN q2-3mins (or start IVI); if no response is observed after 10 mg of naloxone, the diagnosis of narcotic-induced toxicity should be questioned.
2) empty pump reservoir with noncoring 22G needle to stop drug flow (record amount withdrawn).
3) withdraw 30-40 mL* of CSF through the catheter access port (or by LP) to reduce CSF drug concentration

*alternative: 20 mL of CSF is withdrawn and replaced with 20 mL of a 5% dextrose–0.25% normal saline 2 or 3 times.

Motor Stalls (2.07%)

- Medtronic response: "Intrathecal pump failure is relatively rare but they do occur. Usually, failing pumps will start to stall and then will restart spontaneously. This process can occur intermittently over several days. The stalling period(s) can last for a few hours or a few days. While the pump is stalled, the patient gets little or no drug and when the pump recovers, the usual dose resumes. A stalling pump should be surgically replaced as soon as this can be arranged."
- until the pump restarts, the patient is at risk for drug withdrawal.

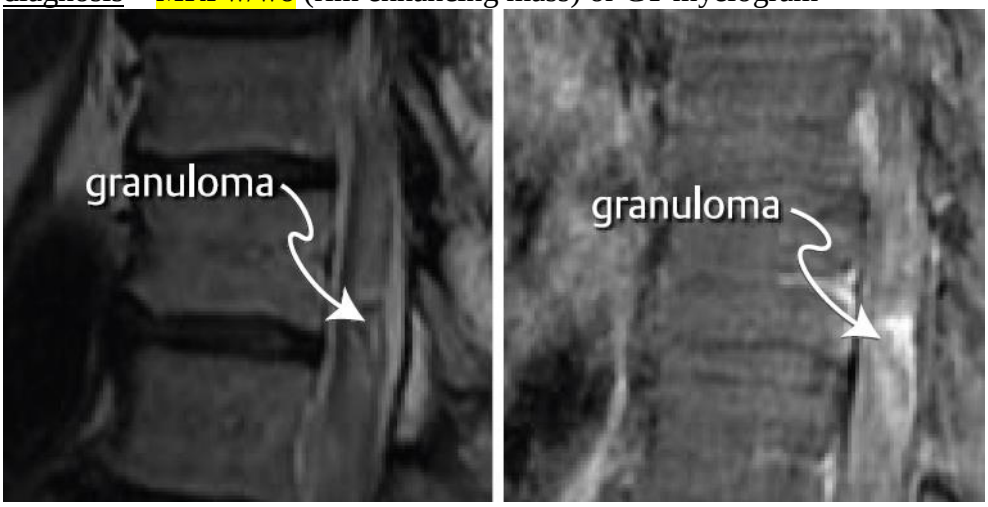
Baclofen withdrawal may result in death – see p. Mov3 >>

Catheter-associated inflammatory mass (catheter tip granuloma) at the tip of implanted catheter

- arise from arachnoid – composed of macrophages, plasma cells, eosinophils and lymphocytes.
- usually intradural extramedullary (rarely may be extradural or intramedullary).
- typically sterile (although infectious cases have been described).
- associated with all known intrathecal medicines (esp. MORPHINE)
- risk factors - *high doses and concentrations* (+ low flow, CSF flow disruptions) of opioids, use of pharmacy compounded analgesic *admixtures*.
  - no relation to catheter material or location have been identified.

- previous recommendations to place catheter tip below conus have not proven to be clinically significant.

- preventative measures: dorsal placement of catheters: larger CSF space, granuloma formation would be easier to treat surgically
- incidence: 0.1–5% of intrathecal drug systems.
- clinically: need for rapid dose escalation (due to decreasing opioid delivery, not due to opioid tolerance) + mass effect (new radicular pain, esp. at catheter tip level, myelopathy).
  - average time for development after initiation of infusion therapy is 39.5 ± 13.5 months.
- diagnosis – MRI w/wo (rim enhancing mass) or CT myelogram



- treatment:
  a) **asymptomatic** (incidentally discovered granuloma):
     1) reduce drug concentration
     2) use bolus dosing (instead of continuous infusion)
     3) switch to another opioid (e.g. lipophilic) or to ZICONOTIDE
     4) pull catheter down 2-3 cm.
     - one study demonstrated almost 50% reduction in relative risk of granuloma formation by reducing morphine dose and concentration from recommended maximum of 15 mg/day and 20 mg/mL to 10 mg/day and 15 mg/mL.

  b) **symptomatic mass effect** → catheter removal (granuloma will auto-absorb) in awake patient: if paresthesias appear, stop → surgical removal.
     Board answer: if cord compression, do not pull catheter down but do open resection (be careful if stuck to cord – do not aim for gross total resection)

BACLOFEN (LIORESAL®, GABLOFEN®)

Facts about systemic baclofen – see p. Mov3 >>

- first intrathecal baclofen (ITB) administration in adults was reported by Penn and Kroin in 1984.

40 mL – 3600 USD

PHARMACOKINETICS

- baclofen IT dose is less than 1% of that delivered orally - reduces the principal side effect of sedation (virtually no baclofen infused intrathecally is detectable in the systemic circulation).
- patients are very sensitive to small changes in microdoses of baclofen!
- dosage equivalents: *oral* : *intrathecal* = 1000 : 1 or **100 : 1**
  N.B. there is no direct conversion from intrathecal to oral or intravenous dosing of baclofen - dose must be titrated to achieve relief of withdrawal symptoms
- baclofen is stable in CSF and does not become metabolized.

- baclofen must travel from CSF to the spinal cord receptors - distance of 2-5 mm - very slow process (45-60-minute delay from the time that a bolus dose is injected until spasticity is reduced); after the receptors have been reached, diffusion back to CSF is equally slow (single bolus dose may reduce spasticity for 4-12 hours; its maximal effect occurs when the level in CSF has decreased to almost zero - cord tissue acts as a reservoir after it is loaded).

Lumbar-cisternal concentration gradient 4:1 * is established along the neuraxis during baclofen infusion.

*based upon simultaneous CSF sampling via cisternal and lumbar tap in 5 patients receiving continuous baclofen infusion at the lumbar level at doses associated with therapeutic efficacy; the interpatient variability was great; the *gradient was not altered by position*.

- upper extremity spasticity can be treated, particularly when the catheter tip is placed at the high thoracic or even cervical level.

PHARMACODYNAMICS

ITB's site of action:

Spasticity - in superficial layers of the spinal cord (Rexed layers I, II), where it in essence replaces deficient GABA that is not released by descending inhibitory axons.

Dystonia - at a cortical level, where it inhibits the premotor and supplementary motor cortex, regions that are excessively stimulated in patients with dystonia:

(1) in dystonia, bolus ITB doses often cause no appreciable change within 4 hours (changes that are seen when treating spasticity);
(2) continuous ITB infusions often take 24 to 48 hours to decrease dystonia, long enough for baclofen to ascend and enter CSF over the cerebral convexities;
(3) higher catheter tips, which should result in higher intracranial CSF baclofen levels, are associated with a greater reduction in dystonia scores.

- intraventricular baclofen infusion has been described to treat dystonic CP (dystonia may respond to intraventricular baclofen at lower doses than needed with intrathecal administration, but insufficient data are available to confirm this observation).

INDICATIONS

- spasticity* from:

5) cerebral palsy (*spastic* CP responds better than *dystonic* CP; *choreoathetoid* CP practically does not respond).
6) TBI (wait at least one year after the injury before consideration of long term ITB therapy)
7) SCI (unresponsive to oral baclofen therapy)
8) MS
9) stroke

*Ashworth scores of ≥ 3

- "reducing spasticity" per se is not a therapeutic goal.
- appropriate goals - increasing range of motion, facilitating care, slowing the development of contractures, and decreasing painful muscle spasms.
- ITB is rarely administered with the intent of improving gait in patients with CP who have spastic diplegia:
  - young ambulatory patients with spastic diplegia are best treated with lumbar rhizotomies,
  - nonambulatory / minimally ambulatory patients with spastic quadriparesis are better treated with ITB.

PREOP TRIAL

- bolus 50* µg of baclofen infused via LP.
  *careful – overdose was reported in a sensitive adult patient after receiving a 25 µg intrathecal bolus
- PT evaluates before and after trail – every 2 hrs for 8 hrs total (Ashworth score improvement by 1 point is positive trial).**
  **if the initial response is less than desired, a second bolus injection (75 µg) may be administered 24 hours after the first; if the response is still inadequate, a final bolus screening dose of 100 µg may be administered 24 hours later.
- onset of action is 30-60 min after an intrathecal bolus; peak effect is seen at 4 hours after dosing and effects may last 4-8 hours.
  N.B. sometimes too much of leg muscle relaxation has deleterious effect on ambulation (patient uses stiff legs to support body weight).

SCALE	FINDING
ASHWORTH SCALE	
1	Normal muscle tone
2	Slight increase in resistance "Catch" with movement
3	Moderately increased resistance
4	Markedly increased resistance
5	No range of motion
MODIFIED ASHWORTH SCALE	
0	Normal muscle tone
1	Slight increase in resistance "Catch" with movement
1+	Catch, plus minimal resistance through a range of motion
2	More marked increase but limb easily flexed
3	Considerable increase in tone through range of motion
4	Affected part rigid

NEW SYSTEM

- usual start – 500 µg/mL in 20 or 40 mL pump (during refills may increase concentration to 2000 µg/mL).
- intraop pump is programmed to ***start delivering at low rate***, e.g. 50 µg/d (screening dose that gave a positive effect should be doubled and administered over a 24-hour period, unless the efficacy of the bolus dose was maintained for > 8 hours, in which case the starting daily dose should be the screening dose delivered over a 24-hour period. No dose increases should be given in the first 24 hours).
- postop continue usual home PO doses of baclofen (PMNR will wean it off during follow up).
- traumatic SCI patients require higher baclofen doses than MS patients.
- half-life of an ITB bolus is 4-5 hours, so approximately 24 hours is required to achieve a steady-state concentration after a change in infusion dosage.

COMPLICATIONS

Baclofen withdrawal may result in death → oral baclofen, IV benzodiazepines, LP injection of baclofen, pump system revision, report to pump manufacturer. see p. Mov3 >>

Baclofen overdose may result in coma → no antidote, aspirate drug from pump reservoir, aspirate CSF 30-40 mL. see p. Mov3 >>

N.B. seizures have been reported both - during overdose and with withdrawal from baclofen!

- 5% of patients become **refractory** to increasing doses. H: treat in hospital with "drug holiday" - gradual reduction of IT baclofen over a 2-4 week period and switching to alternative methods of spasticity management; after the "drug holiday," IT baclofen may be restarted at the initial continuous infusion dose.

- effect of ITB on seizures: Bounaguro et al. evaluated seizures in 150 children undergoing ITB therapy, 40% of whom had seizures before ITB; after ITB therapy, seizures decreased in 13% and increased in 2% of the children who had seizures before ITB; in children who had no seizures before ITB, only 1 child had a first seizure after ITB.

PAIN MEDICATIONS

INDICATIONS

Refractory pain – cancer and noncancer.

N.B. oncological indications do not require intrathecal trial!

Requirements

1) inadequate pain relief and/or intolerable side effects from systemic opioid therapy
2) objective evidence of pathology
3) psychological clearance - to examine factors such as patient expectations, psychosomatic components of the pain, and secondary gain motivation
4) no untreated substance abuse
5) sufficient body size to accept the bulk and weight of the pump
6) clear therapy goals and realistic expectations
7) no contraindications to surgery
8) favorable response to the screening test
9) life expectancy > 3 months
10) for cancer patients: visual analog scale (VAS) of ≥ 5, despite 200 mg/day* of oral morphine (or the analgesic equivalent)

*200 mg oral morphine or equivalent was used as enrollment criterion in a pivotal randomized clinical trial and has since been referenced as a criterion.

Smith TJ et al. Randomized clinical trial of an implantable drug delivery system compared with comprehensive medical management for refractory cancer pain: impact on pain, drug-related toxicity, and survival. J Clin Oncol. 2002;20(19):4040-4049.

MEDICATIONS

Infumorph® - preservative-free MORPHINE sulfate sterile solution (max. 25 mg/mL).
40 mL – 2200 USD

Prialt® - preservative-free ZICONOTIDE sterile solution (max. 100 mcg/mL).

CLONIDINE – off label

BUPIVACAINE – off label

HYDROMORPHONE – off label

NEW SYSTEM

- implant pump filled with saline (to prevent overdose) and start on minimal rate (to prevent catheter clogging).
- PMNR will refill with opioid in a month and will titrate.

Medtronic optional myPTM™ programmer allows patient-activated, bolus dosing of morphine (within physician set parameters) to control unpredictable pain, and decrease intake of supplemental oral opioids.

PMT = Personal Therapy Manger

OUTCOMES

National Outcomes Registry for Low Back Pain

Deer T et al. Intrathecal drug delivery for treatment of chronic low back pain; report from the National Outcomes Registry for Low Back Pain. Pain Med. 2004;5(1):6-13.

- significant improvement in back and leg pain at 6 and 12 months ($p < 0.001$) compared to baseline.
- 87% of patients rated their quality of life as fair to excellent.
- 66% of patients successfully reduced their disability at 12 months.
- 90% of patients would recommend therapy to a family member or friend.

Chronic noncancer pain

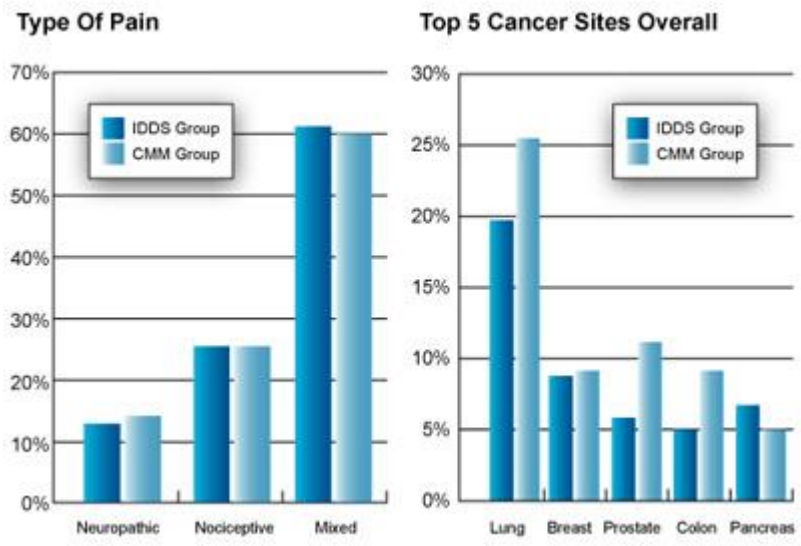
Roberts LJ et al. Outcome of intrathecal opioids in chronic noncancer pain. Eur J Pain. 2001;5(4):353-361.

- 60% mean pain relief after 6 months.
- 74% of patients reported increased activity levels.
- 88% of patients were satisfied with intrathecal therapy.
- significant reduction in oral medication intake ($p < 0.0001$)

Cancer pain

Smith TJ et al. Randomized clinical trial of an implantable drug delivery system compared with comprehensive medical management for refractory cancer pain: impact on pain, drug-related toxicity, and survival. J Clin Oncol. 2002;20:4040-4049.

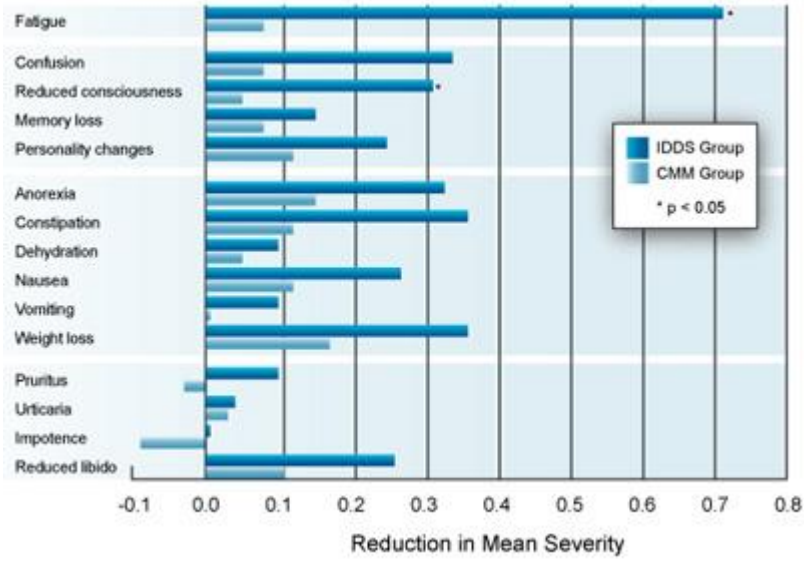
- prospective, multicenter, randomized clinical trial
- 200 patients with ***refractory cancer pain*** (VAS pain score ≥ 5 despite 200 mg/day of oral morphine or its equivalent, or lower doses with intolerable side effects)
- comprehensive medical management (CMM) arm (n=100) vs. intrathecal drug delivery (IDDS) plus CMM arm (n=100).
- SynchroMed™ programmable infusion system.



- at 4 weeks, 60.6% of IDDS patients, compared to 41.7% of CMM patients, had their pain scores reduced from moderate-severe to mild (VAS < 4):

Study Parameter	Randomized to IDDS + CMM	Randomized to CMM	P Values
≥ 20% reduction in Pain VAS or equal VAS with ≥ 20% reduction in mean toxicity score	84.5% (n = 60/71)	70.8% (n = 51/72)	0.05
≥ 20% reduction in both Pain VAS and Toxicity	57.7% (n = 41/71)	37.5% (n = 27/72)	0.02
Mean VAS pain score	Reduced 51.5%	Reduced 39.1%	0.055
Mean composite toxicity criteria (CTC) scores	Reduced 50.3%	Reduced 17.1%	=.004

- all of the measured opioid side effects were reduced more in the IDDS group than in the CMM group (statistically significantly ($p < 0.05$) for fatigue and reduced consciousness):



- Smith et al. study of a similar design in 2005 confirmed these results

  Smith TJ et al. An implantable drug delivery system (IDDS) for refractory cancer pain provides sustained pain control, less drug-related toxicity, and possibly better survival compared with comprehensive medical management (CMM). Ann. Oncol. 2005;16(5):825-833.

SPECIFIC PRODUCTS (MEDTRONIC)

Worldwide statistics

7,975 patients (9,713 pumps, aggregate 23,643 years of follow up) (by October 31, 2017):

- 57.6% - for non-malignant pain
- 21.9% - for spasticity
- 18.2% - for malignant pain

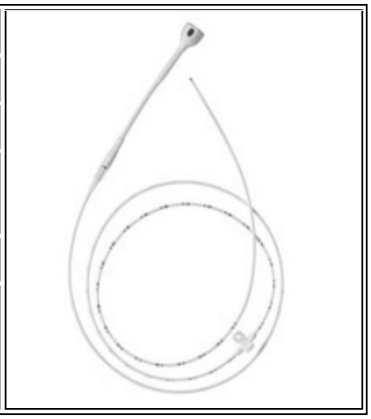
CATHETERS

8709 (InDura)
8711 (InDura)

8709SC (InDura 1P) w/ sutureless connector

FDA approval - Mar 2006

Total Length	89 cm
Outer diameter (spinal segment)	1.4 mm (4.2 French)
Inner Diameter (spinal segment)	0.53 mm
Catheter Tip Description	Closed tip, radiopaque, titanium with 6 side holes
Catheter Volume	0.0022 mL/cm
Trimmable Segments	Pump end



8731SC (w/ sutureless connector)

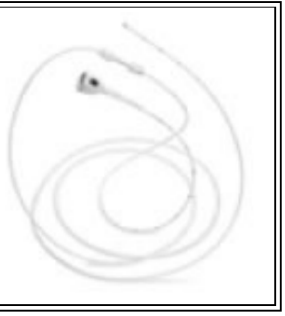
FDA approval - Mar 2006

Differences from 8709SC:

- Total Length 104.1 cm
- Catheter Tip Description - closed with 6 side holes
- Trimmable Segments - spinal and pump end

8780 (Ascenda)

FDA approval – Sept 2012

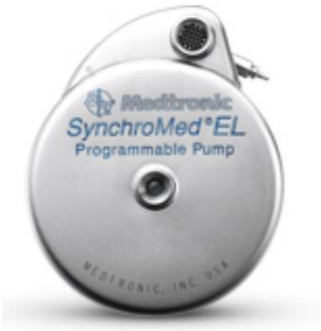
Total Length	114 cm	
Outer diameter (spinal segment)	1.2 mm (4.0 French)	
Inner Diameter (spinal segment)	0.5 mm	
Catheter Tip Description	Closed with 6 side holes	
Catheter Volume	0.0022 mL/cm	
Trimmable Segments	Connector end of the spinal segment	

8781 (Ascenda)
FDA approval – Sept 2012

Total Length	140 cm	
Outer diameter (spinal segment)	1.2 mm (4.0 French)	
Inner Diameter (spinal segment)	0.5 mm	
Catheter Tip Description	Closed with 6 side holes	
Catheter Volume	0.0022 mL/cm	
Trimmable Segments	Catheter connector ends of the spinal and pump segments	

PUMPS

SynchroMed - discontinued
SynchroMed EL – discontinued (FDA approved in 1999)



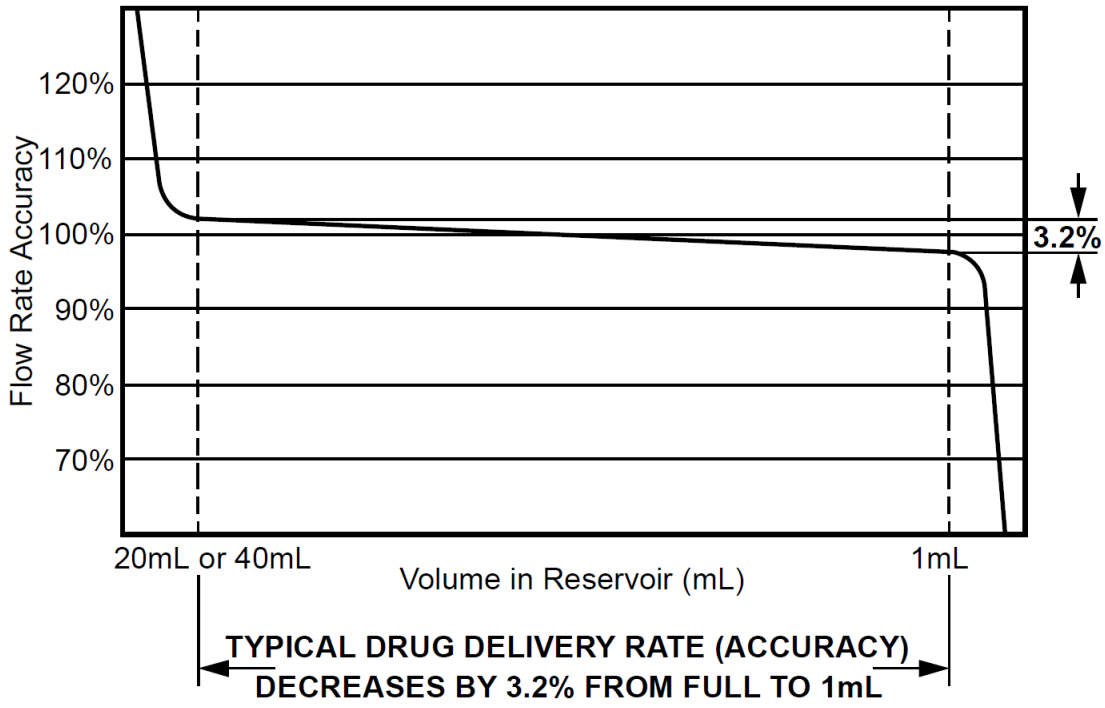
SynchroMed II (models 8637-20 and 8637-40) – FDA approved Sept 2003
- 20 or 40 mL (usable volume is the reservoir volume minus 1 mL)
- shipped filled with sterile water flowing at 0.006 mL/day.

Programmable flow rate:
minimal - 0.048 mL/day (0.006 mL/day nontherapeutic*)
maximum - 24 mL/day
*infuse preservative-free saline at minimum flow rate if therapy is discontinued for an extended period of time to avoid system damage.

- **Clinical Drug Infusion Accuracy** = observed drug volume / calculated drug volume

Time from implant	Completed subjects	Mean ± standard deviation	95% Confidence interval	Median	Range (min – max)
6 Months	N= 65	1.01 ± 0.05	1.00 – 1.03	1.01	(0.88 – 1.24)
12 Months	N= 54	1.01 ± 0.04	1.00 – 1.02	1.00	(0.91 – 1.10)

  - data shows at 95% confidence, 95% of the pumps have a flow rate accuracy of ± 8.8% of the programmed flow rate (50% of the pumps have a flow rate accuracy of ± 4.8%).
- flow rate of the pump varies slightly with the volume of fluid in the pump reservoir - flow rate decreases gradually as the reservoir empties and approaches 1 mL* (between 1 mL and 0 mL, the pump flow rate decreases rapidly then stops) - the pump should be refilled prior to reaching 1 mL
  *on average, the flow rate decreases by about 3.2% as the volume is reduced from full to a volume of 1 mL.



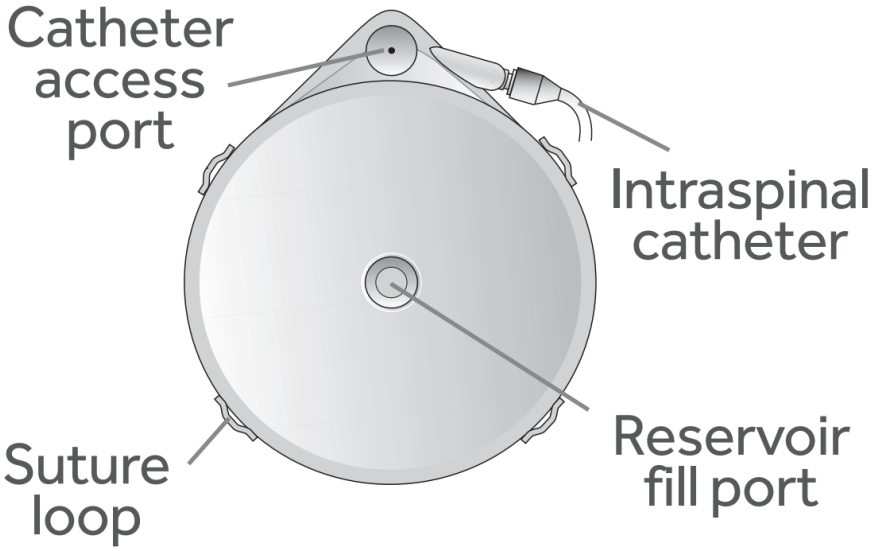
	8637-20	8637-40
Pump		
Thickness (including septum)	19.6 mm	26.1 mm
Weight (empty/full)	146/166 g	152/192 g
Displacement volume	88 mL	118 mL
Diameter (including CAP)	87.5 mm	87.5 mm
Pump reservoir		
Volume	20.0 mL	40.0 mL
Residual volume[b]	1.4 mL	1.4 mL
Fill volume at shipping from manufacturing	17.5 mL	37.5 mL
Reservoir fill port		
Septum puncture life	500 punctures	500 punctures
Catheter access port		
Septum puncture life	100 punctures	100 punctures
Flow rate		
Maximum programmable[c]	24 mL/day	24 mL/day
Minimum programmable[c]	0.048 mL/day	0.048 mL/day
Stopped pump maximum leakage	0.030 mL/day	0.030 mL/day
Bacterial retentive filter		
Pore size	0.22 µm (micron)	0.22 µm (micron)
Power source		
Battery	Lithium / carbon monofluoride - silver vanadium oxide	Lithium / carbon monofluoride - silver vanadium oxide
Longevity	Rate dependent (Figure 3)	Rate dependent (Figure 3)
Radiopaque identifier	NGP	NGV
Reservoir pressure	20.68 kPa to 34.75 kPa	20.68 kPa to 34.75 kPa

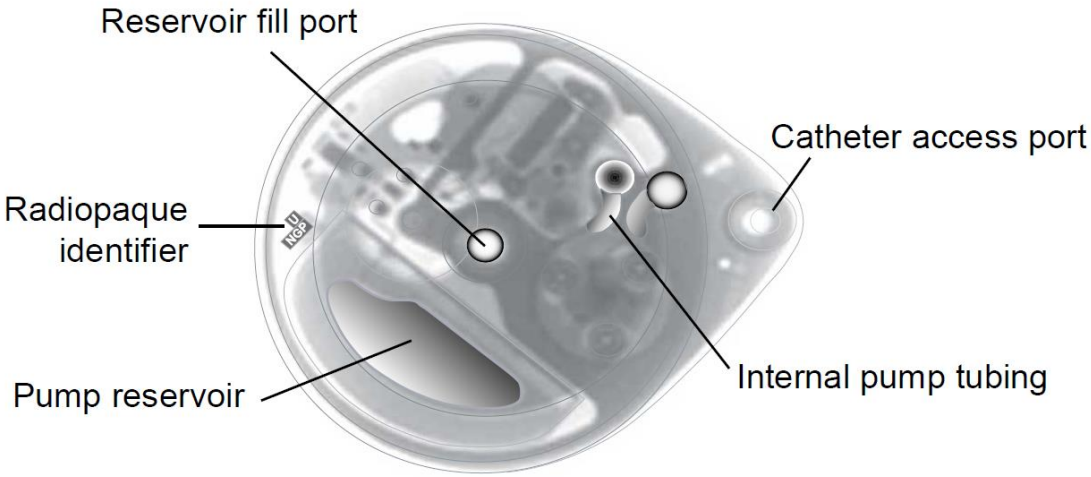
[a] All measurements are approximate.

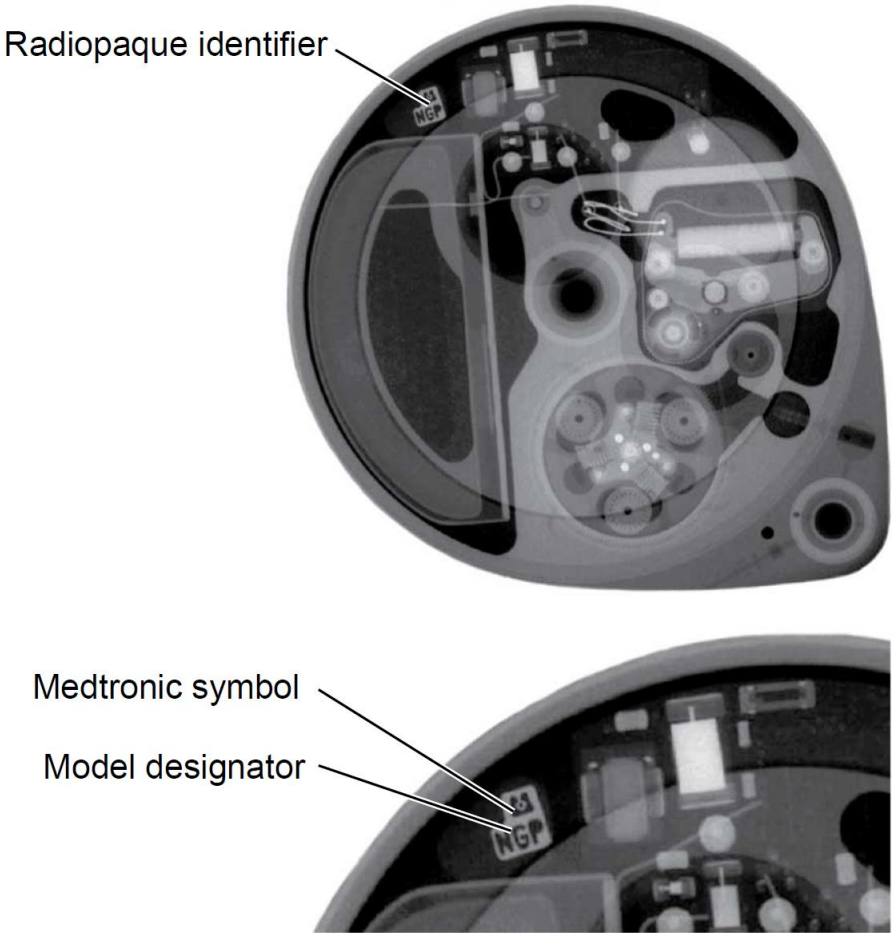
[b] Testing ensures that the residual volume is 1.4 mL ± 1.0 mL. Data shows at 95% confidence, 99% of 20.0 mL pumps have a residual volume between 1.15-1.76 mL and that 40.0 mL pumps have a residual volume between 0.83-1.64 mL.

[c] Actual limits depend on pump calibration constant and selected infusion mode.

Component	Material	Material contacts human tissue	Material contacts drug
Pump			
Exterior	Titanium	Yes	No
Reservoir	Titanium	No	Yes
Reservoir valve	Titanium	No	Yes
Tubing	Silicone rubber	No	Yes
Reservoir fill port septum	Silicone rubber	Yes	Yes
Catheter access port septum	Silicone rubber	Yes	Yes
Catheter port	Titanium	Yes	Yes
Bacterial retentive filter	Polyvinylidene fluoride	No	Yes
Suture loops	Titanium	Yes	No
Propellant	Inert gas	No	No
Needles	Stainless steel	Yes	Yes

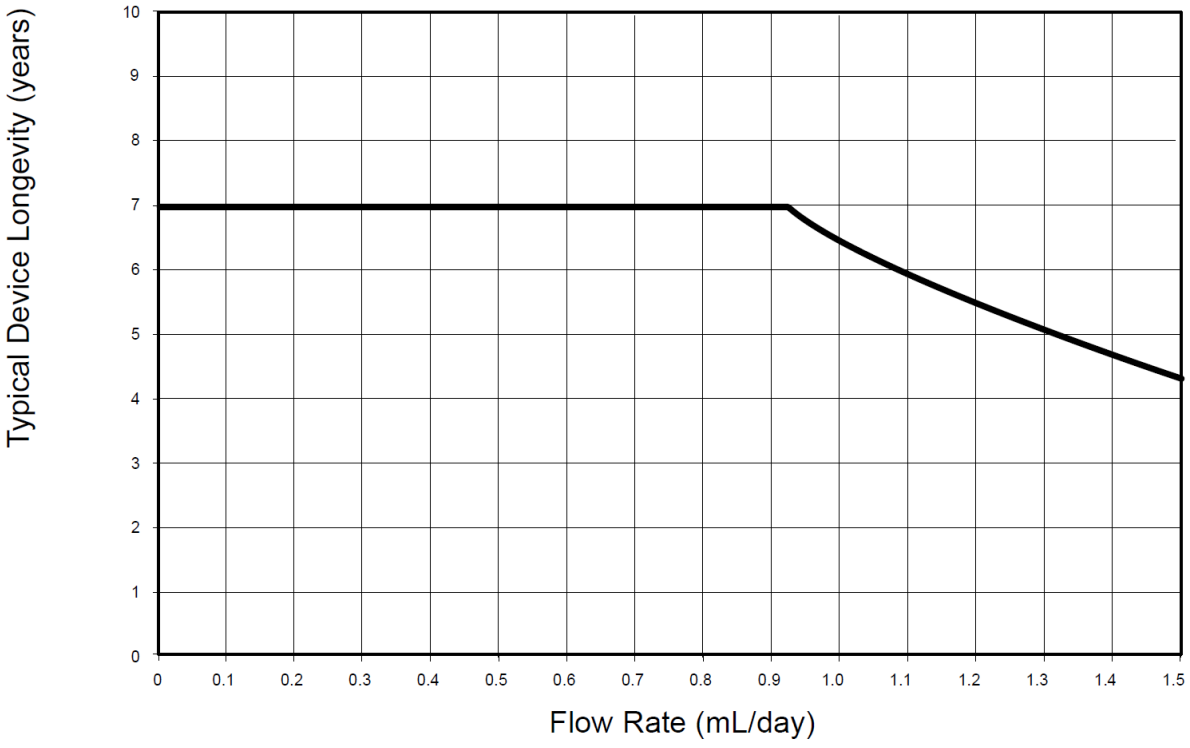

Catheter access port
Intraspinal catheter
Reservoir fill port
Suture loop


Reservoir fill port
Catheter access port
Radiopaque identifier
Internal pump tubing
Pump reservoir



BATTERY LIFE

- expected battery life is a function of flow rate (expect maximum 7 years):



- when ERI is reached it starts beeping (pump also beeps if motor stalls) - pump continues to operate within specifications for 90 days.

- EOS activation indicates the pump has reached the end of its service life - the pump stops, but telemetry is available until the pump battery is depleted.

POSTOPERATIVE

BOVIE

- not sensitive to Bovie (just cautious not to melt the catheter).

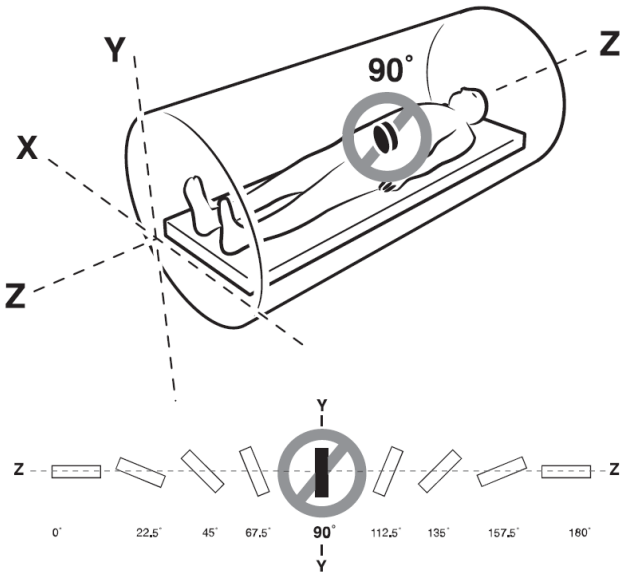
MRI

- SynchroMed II pumps are full body MRI compatible up to 3T (magnet will stall the motor [pump beeps two-tone alarm] but 20 minutes* after MRI the motor will automatically restart).

*rarely, motor recovery may take up to 24 hrs

Potential for permanent motor stall

- 90° alignment of an implanted pump with the z axis of horizontal, closed-bore MRI scanners can cause MRI induced demagnetization of the internal pump motor magnets, which can result in permanent, nonrecoverable stoppage of the pump (SynchroMed II pump performance has not been established using other types of MRI scanners such as open-sided or standing MRI):



RESOURCES (INTRATHECAL PUMPS)

H. Richard Winn "**Youmans** Neurological Surgery" 6th ed. (2011), Chapter 226 (Intrathecal Baclofen Therapy for Cerebral Palsy), Chapter 91 (Management of Spasticity by Central Nervous System Infusion Techniques)

Medtronic materials:

Intrathecal Drug Delivery:
http://professional.medtronic.com/pt/neuro/idd/edu/index.htm#.UHObw2JsLAQ
Intrathecal Baclofen Therapy: >>
http://professional.medtronic.com/pt/neuro/itb/prod/index.htm