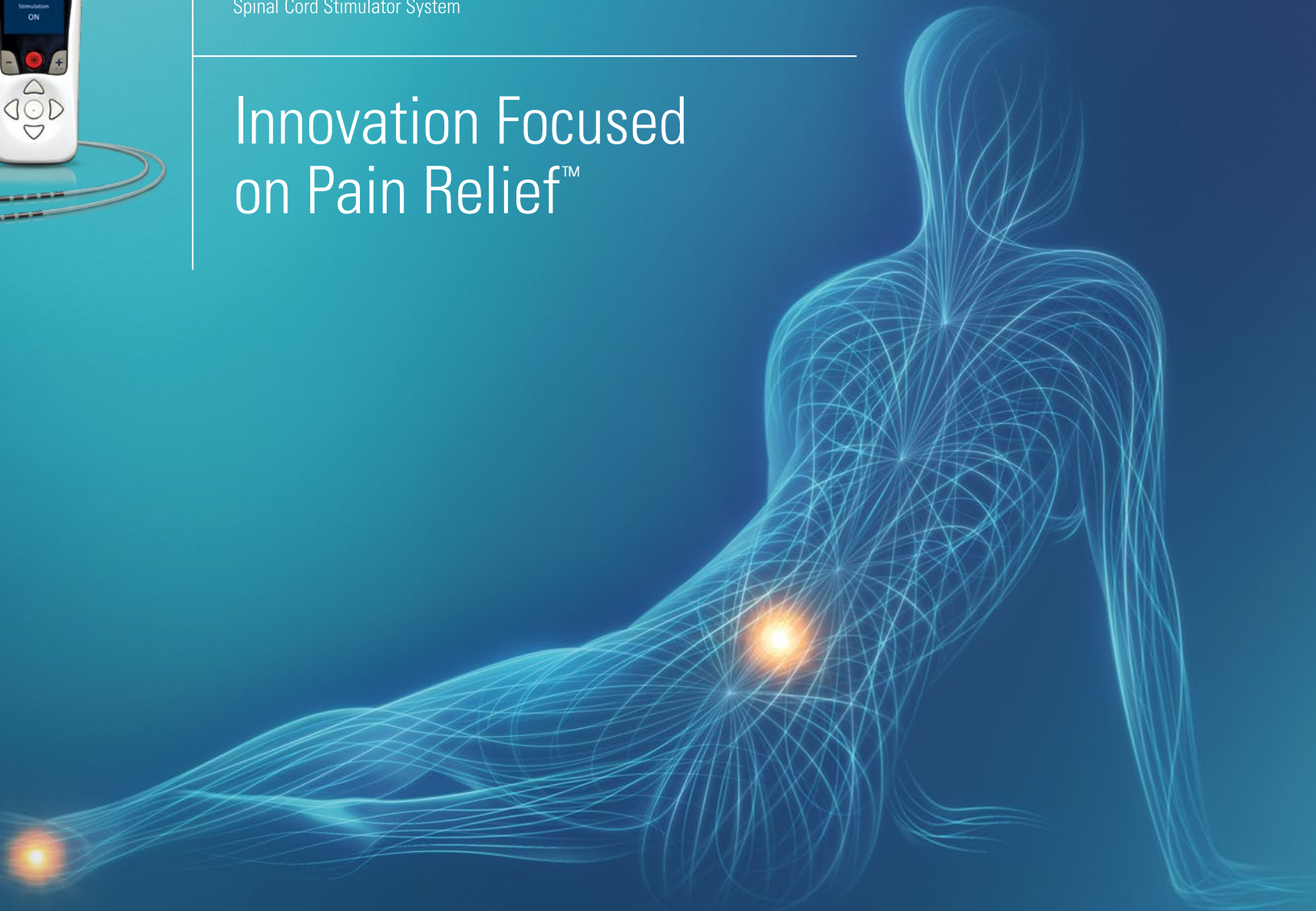


PRECISION
SPECTRA™
Spinal Cord Stimulator System

Boston
Scientific

Innovation Focused
on Pain Relief™



TREATING PAIN IS COMPLEX. MAKING IT SIMPLE IS OUR MISSION.

It all started with the launch of the Precision™ Spinal Cord Stimulator (SCS) System. As the world's first system with 16 dedicated power sources, a rechargeable battery, and innovative programming software, we advanced the world of SCS. While Precision was ahead of its time, we knew we were just getting started.

Our vision was to define the future of SCS by providing more pain relief to a broader spectrum of patients. That was the guiding principle in the development of our next-generation system.

The result is a highly innovative system that we've engineered to give you what matters most: more coverage than ever before, an entirely new level of flexibility, and advanced control for delivering stimulation in ways never before possible.

Innovation Focused on Pain Relief.™
Precision Spectra™ SCS System.

COVERAGE. FLEXIBILITY. ADVANCED CONTROL.

The world's first SCS system with 32 contacts and 32 dedicated power sources, the Precision Spectra™ SCS System is designed to provide unprecedented **COVERAGE** of the spinal cord.

Four ports and an unrivaled percutaneous lead portfolio give you more **FLEXIBILITY** designed to treat your patient's pain, both now and in the future.

Guided by our next-generation 3D programming algorithm, Precision Spectra is engineered to provide **ADVANCED CONTROL** for delivering stimulation in ways never before possible.

Designed for more coverage, more flexibility, and advanced control, Precision Spectra is engineered to provide more pain relief to a broader spectrum of patients.



COVERAGE

THE WORLD'S FIRST SCS SYSTEM WITH **32 CONTACTS AND 32 DEDICATED POWER SOURCES**, THE PRECISION SPECTRA™ SYSTEM IS DESIGNED TO PROVIDE UNPRECEDENTED COVERAGE OF THE SPINAL CORD.

More coverage → Designed for more pain relief

Pain relief starts with pain coverage. In a key study, Richard North, MD, found a strong relationship between pain coverage (paresthesia overlap) and pain relief.¹ And more coverage is what the Precision Spectra System is designed to provide.



Same small size.
Twice the power sources.

Clinical study results may not necessarily be indicative of clinical performance. Results in other studies may vary.

32 contacts and 32 dedicated power sources

With twice the contacts and 32 dedicated power sources, the Precision Spectra™ System lets you cover more of the spinal cord than ever before.

Seamless coverage for precise targeting

Two Infinion™ 16 Leads driven by 32 dedicated power sources provide seamless mediolateral and rostrocaudal coverage over three vertebral levels.^{2,3,4}

Clinical study results may not necessarily be indicative of clinical performance. Results in other studies may vary.

A Central Point of Stimulation (CPS) is the focal point of the stimulation field on the dorsal column. Fractionalizing current in 1% increments between two tightly spaced contacts provides 100 CPS. Single source systems or widely spaced contacts provide 3 CPS between adjacent contacts.²

CPS Calculations:

Image A: 8 CPS x 3 CPS = 24 CPS.

Image B: 15 CPS x 3 CPS = 45 CPS.

700 CPS x 100 CPS = 70,000 CPS.

Image C: 1,500 CPS x 100 CPS = 150,000 CPS.

COMPUTATIONAL MODELING METHODS

A volume conductor model of the low-thoracic spinal cord was created, and electric fields were calculated using ANSYS, a finite element modeling tool. The volume of activation (VOA) and the central point of the VOA were computed and are depicted in these figures.

Only cathodes applied on single or adjacent contacts were used in these models.

Computational modeling may not necessarily be indicative of clinical performance.

BEFORE PRECISION SPECTRA: TRADEOFFS

Coverage gaps with two widely spaced 8-contact leads.^{3,5}

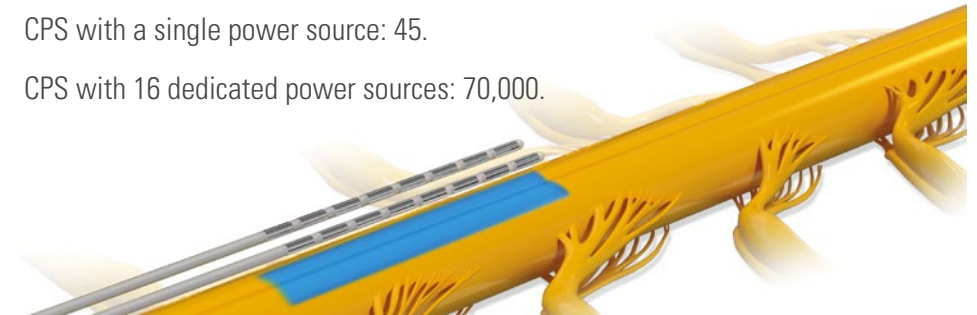
Central Points of Stimulation (CPS) with a single power source: 24.



Seamless coverage with less vertebral span.^{3,5,6}

CPS with a single power source: 45.

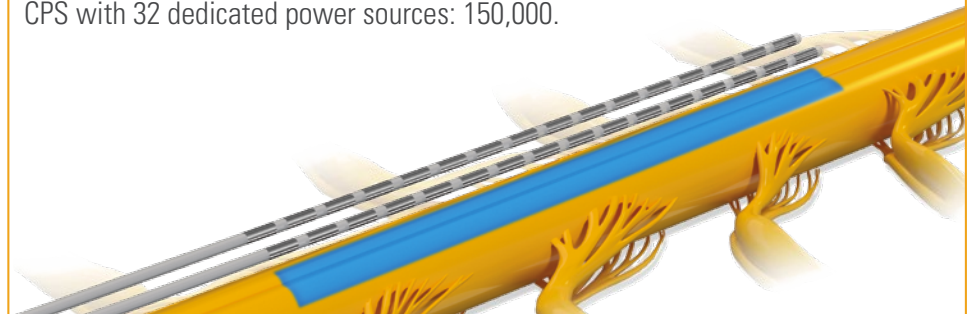
CPS with 16 dedicated power sources: 70,000.



WITH PRECISION SPECTRA: MORE COVERAGE

Two Infinion 16 Leads provide seamless coverage over three vertebral levels.^{2,4}

CPS with 32 dedicated power sources: 150,000.



The Ultimate Trialing System

With two Infinion™ 16 Leads and two 1x16 OR Cables, the Precision Spectra System is designed to give patients the best chance for a successful trial.

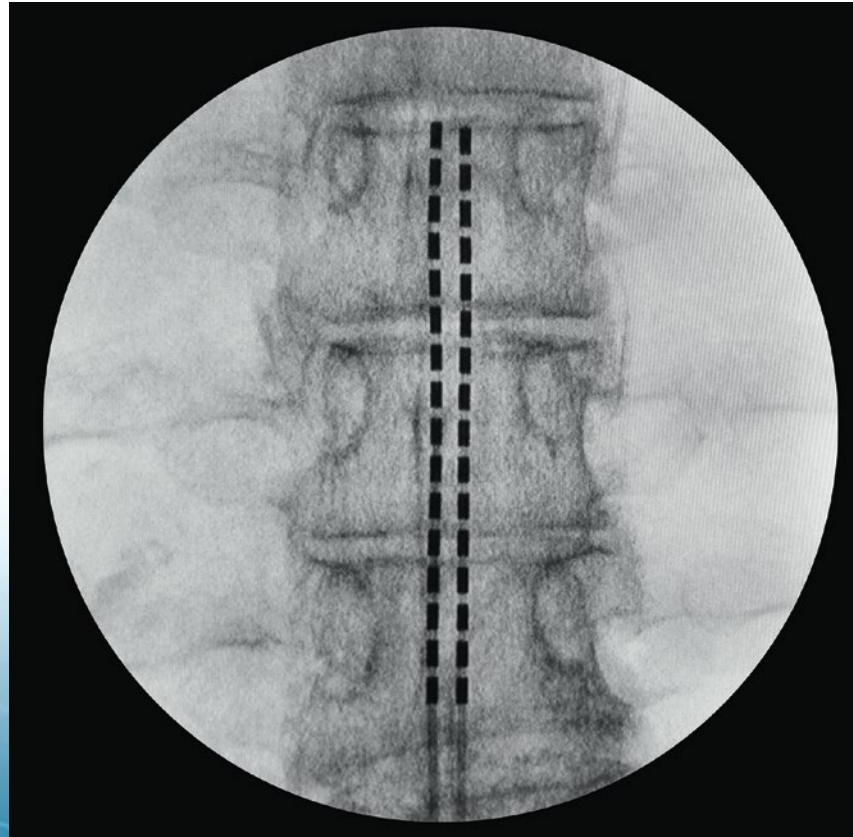
- Twice the coverage of the spinal cord with the same number of needle sticks
- With 2 Infinion Leads, quickly identify the “sweet spot” for permanent lead placement



Trial leads migrate. Precision Spectra™ has you covered.

In a recent study, trial leads were reported to migrate over one vertebral level (an average of 24.3 mm +/- 11.3 mm).⁷ In addition, patient non-compliance may result in trial lead migration.

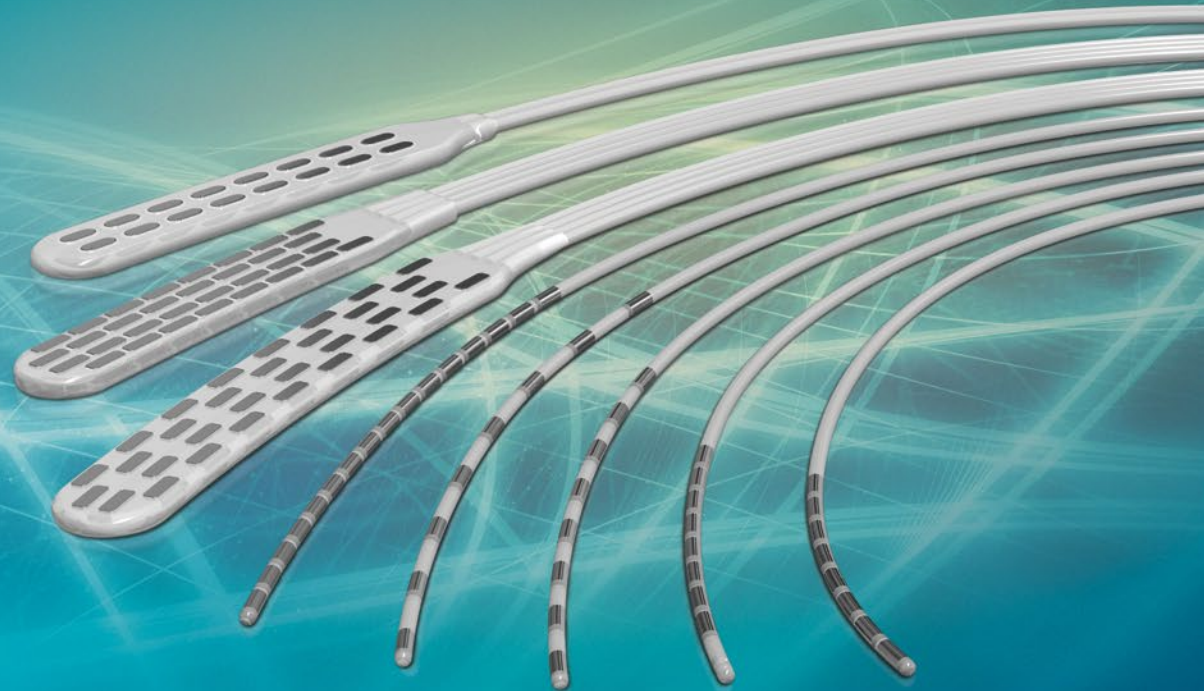
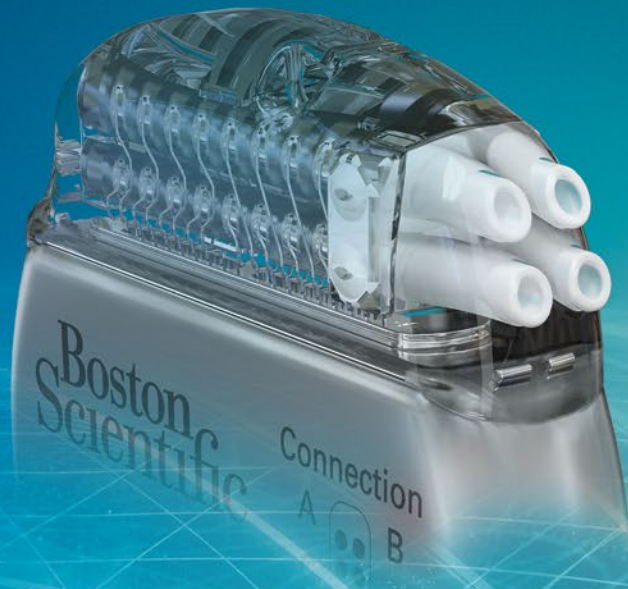
- Seamless coverage of three vertebral levels
- LeadSync™ Technology provides the ability to refocus the stimulation field in the event of relative lead migration



Clinical study results may not necessarily be indicative of clinical performance.

FLEXIBILITY

DESIGNED FOR A NEW LEVEL OF FLEXIBILITY.
FOUR PORTS AND AN UNRIVALED PERCUTANEOUS
LEAD PORTFOLIO FOR UNMATCHED FLEXIBILITY,
NOW AND IN THE FUTURE.



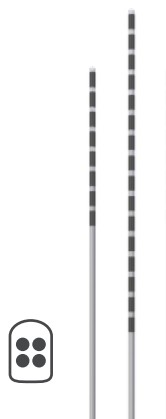
Flexibility for today

The Precision Spectra™ System's four ports plus our broad lead portfolio give you an entirely new level of flexibility. Unprecedented new lead configurations provide more choices designed to manage your patient's unique pain pattern.

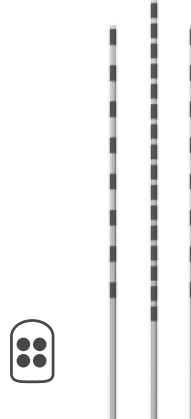
2 Infinion™ 16 Leads



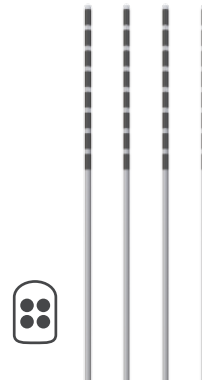
1 Infinion
2 Linear™ ST Leads



1 Infinion
2 Linear 3-4s



4 Linear STs



4 Linear STs



1 Infinion



2 Linear STs



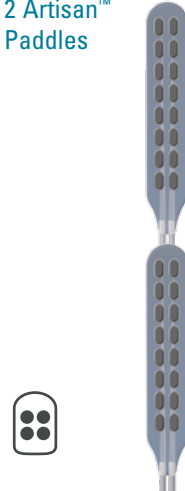
CoverEdge



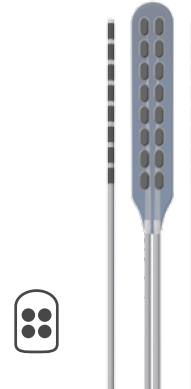
CoverEdge X



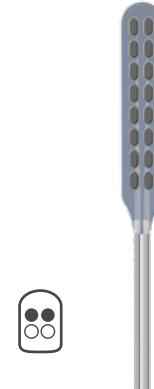
2 Artisan™
Paddles



1 Artisan Paddle
2 Linear STs



1 Artisan Paddle



Flexibility for the future

Prepare for the future with the option of implanting 16 contacts today, while leaving two ports in reserve. If pain patterns change or new areas emerge, you can adapt by implanting more leads for more coverage.

ADVANCED CONTROL

CONTROL STIMULATION IN WAYS
NEVER BEFORE POSSIBLE.

Bionic Navigator™ 3D Programming Software

ILLUMINA 3D™
PROGRAMMING
ALGORITHM

FLUOROSYNC™
INTERFACE

LEADSYNC™
TECHNOLOGY



Precision Spectra™
Remote Control



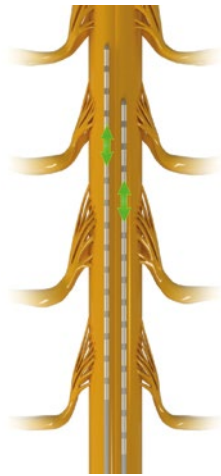
FREELINK™
CORDLESS
TECHNOLOGY

Illumina 3D™ Programming Algorithm

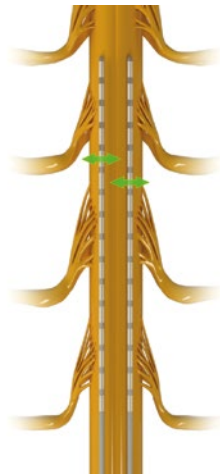
Leads exist in a complex 3-dimensional environment. The Illumina 3D Algorithm is the first and only programming software that takes this into account.

- Incorporates 3-dimensional lead location
- Simple “point and click” targeting
- Designed to focus paresthesia and reduce unwanted stimulation
- Designed to improve pain targeting

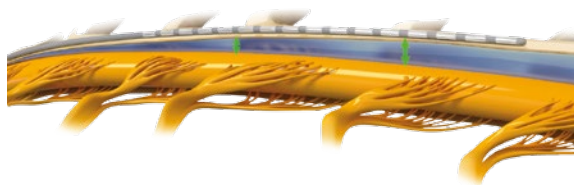
1. Rostrocaudal lead position



2. Medirolateral lead position



3. Dorsoventral lead position: CSF thickness



Point and click targeting

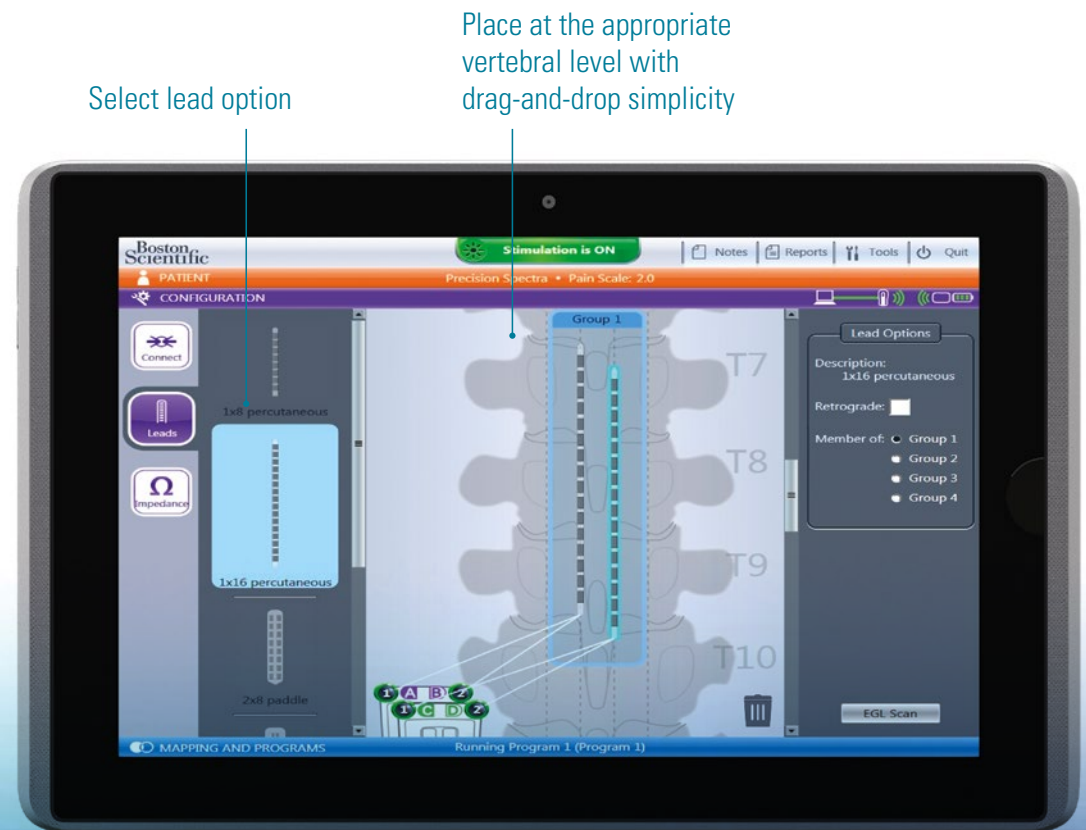
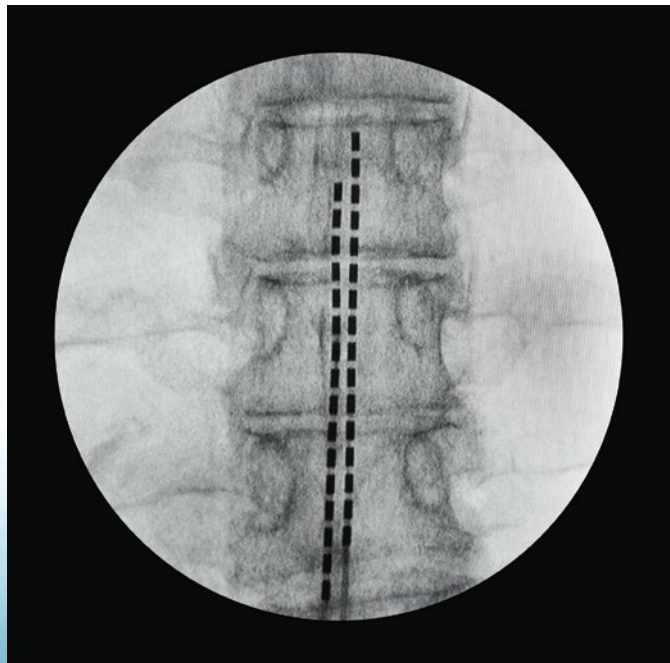
Generates advanced anode/cathode configurations to best target the selected central point of stimulation



FluoroSync™ Interface

Visually intuitive and elegantly simple user interface.

- Select and place leads with drag-and-drop simplicity
- Programming software mirrors fluoro image
- Inputs the 3-dimensional lead location into the Illumina 3D™ Programming Algorithm

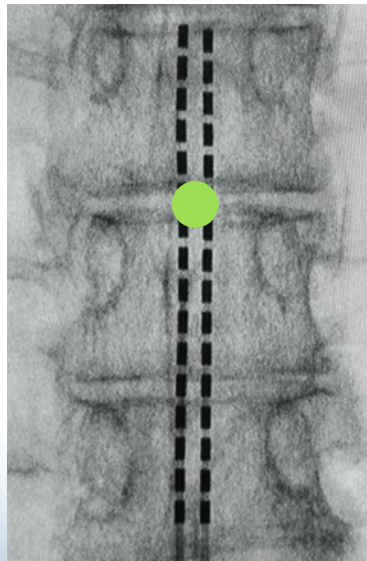


LeadSync™ Technology

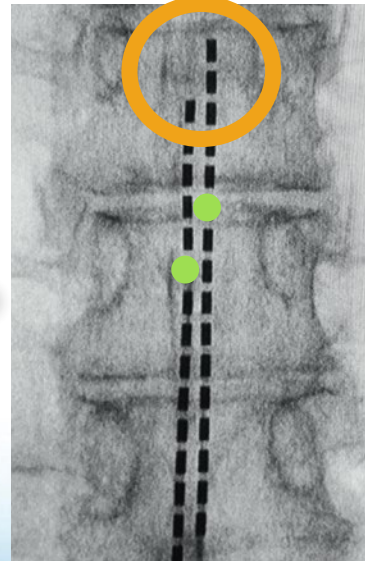
The only programming software to account for lead offset.

- Use programming software to detect relative lead location
- Adjusts for lead offset by synchronizing contacts on parallel leads
- Ability to refocus the stimulation field
- Designed to account for relative lead movement during the trial, after the permanent implant, or during the procedure

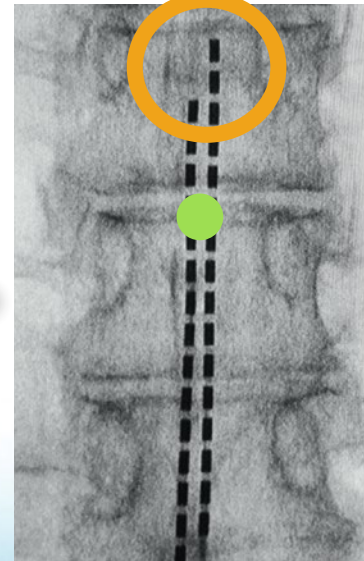
Lead Placement



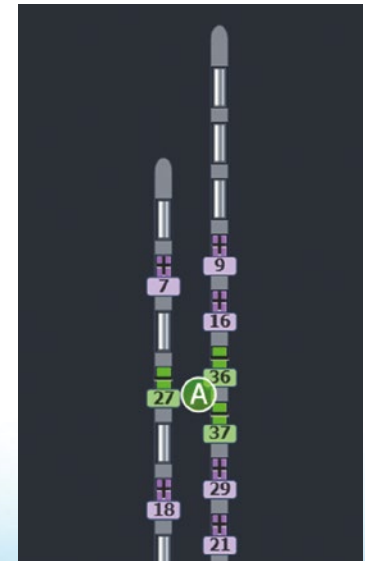
Lead Migration



LeadSync



LeadSync Technology: Ability to refocus the stimulation field



FreeLink™ Technology

Featuring FreeLink Technology, enhanced cordless patient accessories are designed to simplify the patient experience. From functionality to aesthetics, the Precision Spectra™ System is designed to bring the patient experience to a whole new level.

- Cordless Remote Control
- Cordless Charger



SUMMARY

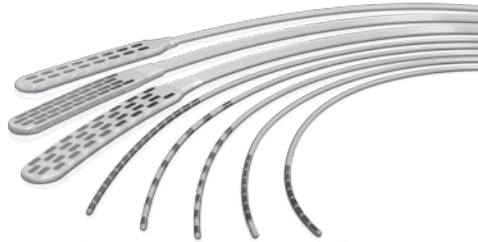
COVERAGE

32 contacts. 32 dedicated power sources. Designed to provide unprecedented coverage.



FLEXIBILITY

Four ports plus an unrivaled lead portfolio designed to cover your patient's pain, both today and in the future.



ADVANCED CONTROL

Next-generation 3D programming algorithm, engineered to provide advanced control for delivering stimulation in ways never before possible.



PRECISION SPECTRA™

Spinal Cord Stimulator System



Precision Spectra Product Information

PRODUCT	ORDER NUMBER
Precision Spectra IPG	M365SC11320
Precision Spectra Patient Trial Kit	M365SC6500320
Precision Spectra Programmer Kit	M365SC553210
Precision Spectra 2x8 OR Cable and Extension	M365SC41080
Precision Spectra 1x16 OR Cable and Extension	M365SC41160
Precision Spectra Port Plugs	M365SC44010

hcp.controlyourpain.com/support_for_physicians/reimbursement.html

REFERENCES

- 1) North RB, et al. Spinal Cord Stimulation for Chronic Intractable Pain: Superiority of “Multi-Channel” Devices. *Pain* 1991; 44:119–30.
- 2) Lee D, Bradley K, Syed ZA, Gillespie E, Esterly D. Improved Stimulation Targeting with a Novel 16-Contact Percutaneous SCS Lead: A Computational Model. Abstracts of the 15th Annual Meeting of the North American Neuromodulation Society (NANS) Meeting, Las Vegas, NV, December 2011.
- 3) Lee D, Gillespie E. Dorsal Column Steerability with Dual Parallel Leads Using Dedicated Power Sources: A Computational Model. Abstract of the 35th Annual Regional Anesthesia Meeting and Workshops (ASRA), Toronto, Canada, April 22-25, 2010.
- 4) Panjabi M, et al. Thoracic Human Vertebrae: Qualitative Three-Dimensional Anatomy. *Spine* 1991;16(8):888-901.
- 5) Lee D, Gillespie E. Incremental Movement of the Central Point of Stimulation Beneath a Spinal Cord Stimulation Lead in a Computational Model. Abstracts of the 13th Annual Meeting of the North American Neuromodulation Society (NANS) Meeting, Las Vegas, NV, December 2009.
- 6) Ranu ER, Gillespie E, Bradley K. The Benefits of Tight Contact Spacing: Computational Model on Avoiding Stimulation Gaps. Presentation at the 14th Annual North American Neuromodulation Society (NANS) Meeting, Las Vegas, NV, December 2-5, 2010.
- 7) Osborne MD, Ghazi SM, Palmer SC, Boone KM, Sletten CD, Nottmeier EW. Spinal Cord Stimulator—Trial Lead Migration Study. *Pain Medicine* 2011;12: 204-208.

Indications for Use. The Precision Spectra™ Spinal Cord Stimulator System (Precision Spectra System) is indicated as an aid in the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome, intractable low back pain, and leg pain. Contraindications, warnings, precautions, side effects. The Precision Spectra System is contraindicated for patients who: are unable to operate the Precision Spectra System, have failed trial stimulation by failing to receive effective pain relief, are poor surgical risks, or are pregnant. Refer to the Instructions for Use provided with the Precision Spectra System or ControlYourPain.com for potential adverse effects, warnings, and precautions prior to using this product. Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician.

Images courtesy of Boston Scientific Corporation.

NM-121404-AC OCT2014 © 2014 Boston Scientific Corporation or its affiliates. All rights reserved.